The U.S. Market for Medical Devices - Opportunities and Challenges for Swiss Companies

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Mark S. Zolno, Katten Muchin Zavis Rosenman

Chicago 2004
The U.S. Market for Medical Devices - Opportunities and Challenges for Swiss Companies

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While this report is intended to provide an overview of this specific market and its opportunities at the time of its edition, each individual manufacturer, exporter or supplier may have to conduct their own analysis to get a better understanding of the possibilities and opportunities available to them. You are encouraged to explore and develop your opportunities based on research and in-depth analysis.

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1. Introduction and Summary

Martin von Walterskirchen, Swiss Business Hub USA, Chicago, IL

1.1. Objectives

The purpose of this report is to help Swiss companies seeking to enter the American market for medical technology. Swiss medical device OEMs, medical component suppliers and subcontractors, as well as machine tool manufacturers will gain an overview of the U.S. health care and medical device market. The study will enlighten Swiss companies about the size of the market along with the potential opportunities and challenges they face when entering the U.S. market.

The study covers important growth segments as well as topics of common interest to medical device manufacturers and marketers. It highlights six major market segments selected in consultation with various experts from the Swiss industry. These sectors include cardiovascular, orthopedics, dental, wound care, minimally invasive surgical devices and techniques, and diagnostics. Information about these market segments includes statistical data related to market size, and expected growth rate, emerging technologies, and major competitors.

1.2. Opportunities

The US market is of strategic importance for the medical sector being the largest and most sophisticated in the world with $71.3 billion in sales for 2002. As a rule of thumb the U.S. market for medical devices and most of its segments represent about half of the world market (the European market representing 25%). This market is expected to grow at a compound annual rate of 8% over the next three years.

Three observations lead to this positive outlook:

- The economy of the United States is expanding and is likely to continue to grow over the next years. Nothing seems to indicate that the U.S. will lose its economic strength or its predominant role in political issues. Most analysts expect GDP to continue to grow at a rate of between 3.5% and 4.3%.

- The U.S. population is aging. Today the group of people aged 65 and over stands at 35 million. These numbers are relevant as the average yearly per capita spending for healthcare increases with age: a man age 30-34 will spend an average of $1,528 for health care whereas a man age 50-54 will spend nearly three times as much ($4,454). In 2020 there will be 55 million Americans age 65 or over and extrapolations expect that this segment of the population will increase by an additional 25% between now and 2075. These trends are not only important for the forecast of needs but also because older people are on average wealthier than younger people: according to the Wall Street Journal the 78 Million Americans that are 50 and above today control 67% of the country’s wealth (please revert to Chapter 2.1, page 8 ).

- The sharp increase in costs of the health care sector (please revert to Chapter 2.2, page 9 ) and the growing demand caused by an aging population exercises great pressure from insurers to health care providers. Health care providers will have to reduce costs among others by increasing productivity. For the innovation driven Swiss industry this represents an important opportunity. Technological advancements that combine improved therapeutic effects (such as better clinical outcome) with lower overall costs (such as shorter hospital stay) will represent...
great opportunities in the market. In addition time of delivery will be an increasingly critical factor of a buyer’s choice in the medical sector.

1.3. **Sales and Marketing**

The marketing costs associated with entering the U.S. market are substantial. Medical technology products often set new standards that impact the industry. This, in turn leads to barriers to entry that may include legal disputes. Companies should complete the following steps before undertaking market entry:

- Companies need to analyze the market (competitive advantage of their product, competitors, pricing, messages their competitors use to penetrate the market, services offered by competitors, development of the market, etc.).
- Companies should make sure that they are prepared for the complex regulatory environment.
- Companies should assess solutions for sales, distribution and marketing of their products and services in the U.S. They need to establish strategies for marketing, including citations, scientific congresses and how to address reimbursement issues (please revert to Chapter 3, page 17). In addition they need to evaluate solutions for sales infrastructure (distributors, strategic alliances, or subsidiaries) and what may best fit their needs. Each scenario bears opportunities and risks that need to be addressed both from a commercial as well as from a legal point of view (please revert to Chapter 10, page 74, Testimonial on page 84, and Chapter 11, page 85).

1.4. **Challenges of the Regulatory Environment**

The complexity of the U.S. legal system needs to be treated with respect. The challenges of the regulatory environment are feasible provided the company is willing to make a careful assessment and plan accordingly.

- For importation into the United States issues related to tariff classification, transfer pricing, and origin marking requirements need to be considered (please revert to Chapter 12, page 93).
- Before market entry products need the approval from the FDA (please revert to Chapter 13, page 99). This approval is granted for products evaluated as safe and effective. It is important to note that CE marks are not recognized in the U.S.
- Product liability and court procedures differ largely from Swiss standards and demand particular attention. As a consequence the Swiss manufacturer needs to fully meet all design standards set by the FDA, make sure that comprehensive quality control is implemented, provide carefully formulated warnings and instructions, follow-up with customers, and file a complete set of all records (please revert to Chapter 14, page 108). In addition issues related to product liability insurance need careful consideration (please revert to Chapter 15, page 118).

1.5. **The SwissMedtech Project**

The Swiss Minister for Economy, Federal Councillor Joseph Deiss, initiated the government’s program to promote innovation and entrepreneurship in June 2003. As he said on this occasion “Innovation is a process that transforms ideas into marketable goods and services”. The project SwissMedtech constitutes part of this program by assisting entrepreneurs in their critical time to access the U.S. market.

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1 *InnoNation Schweiz, Aktionsplan des Eidgenössischen Volkswirtschaftsdepartements für Innovation und Unternehmertum, Juni 2003*
The study “The U. S. Market for Medical Devices – Opportunities and Challenges for Swiss Companies” represents Phase One of the SwissMedtech project. During Phase Two the Swiss Business Hub USA, Osec Business Network Switzerland, and other partners – some of them being co-authors of this report – will assist Swiss companies in their endeavor to enter the American medical technology market. Furthermore, the program will promote the Swiss industry for medical technology, including suppliers and machine builders. For this purpose the brand SwissMedtech was launched.²

1.6. Acknowledgements

It gives me great pleasure to thank the authors of this study: Darren W. Alch (Jenkins & Gilchrist, Houston, TX), Christian Brinkmann (Kessler & Co Inc., Zurich), Richard W. Franklin (Baker & McKenzie, Chicago, IL), David Kouidri (Swiss Business Hub USA, Chicago, IL), Simon Künzler (Kessler Consulting Inc., Zurich), Scot Orgish (Swiss Business Hub USA, Houston, TX), Klaus Peretti (Kessler & Co. Inc Zurich), Daniel A. Wuersch (Wuersch & Gering LLP, New York, NY), and Mark S. Zolno (Katten Muchin Zavis Rosenman, Chicago, IL).

I want to extend special thanks to Andreas Baenziger, MD, Peter Brunner, Swiss Commission for Innovation and Technology (CTI), Claude Bernoulli, and Pierre Hiltpold, Neuchâtel Chamber of Industry and Commerce, Henry Christen, Ernst & Young AG, André Haemmerli, Johnson & Johnson, Le Locle, Claudine Haeni, Swiss Business Hub USA, Chicago, Thérèse Küenzli, Osec, Willi Meier, Swiss Mem, Juerg Schnetzer, FASMED, Anita Soltermann, seco, Frank Ustar, Los Angeles, and Rainer Voelksen, Swissmedic, who provided valuable support to the study.

² Please contact the author (martin@swissbusinesshub.org) or Osec business network Switzerland, Zürich, for additional information on this program.
2. U.S. Health Care industry

By Scot Orgish, Trade Commissioner, Swiss Business Hub, Houston, TX

2.1. Facts and Figures

The U.S. health care equipment and supplies market is the largest in the world which, according to Datamonitor, generated approximately $71.3 billion in sales in 2002. From that amount, 95.5 percent ($68.1 billion) was generated by the medical industry and 4.5 percent ($3.2 billion) was generated by the dental industry. The total health care equipment and supplies market is forecast to increase at a compound annual growth rate of 6.5 percent through 2007 to market value of $97.8 billion. It is estimated that approximately 5,750 companies are working in this market in the U.S. Figure 1 shows the forecast market value and growth rate from 2002-2007.

<table>
<thead>
<tr>
<th>Year</th>
<th>$ Billion</th>
<th>Growth%</th>
</tr>
</thead>
<tbody>
<tr>
<td>2002</td>
<td>71.3</td>
<td>5.3</td>
</tr>
<tr>
<td>2003</td>
<td>74.9</td>
<td>5.1</td>
</tr>
<tr>
<td>2004</td>
<td>79.7</td>
<td>6.4</td>
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<tr>
<td>2005</td>
<td>85.5</td>
<td>7.3</td>
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<tr>
<td>2006</td>
<td>91.8</td>
<td>7.3</td>
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<tr>
<td>2007</td>
<td>97.8</td>
<td>6.6</td>
</tr>
<tr>
<td>CAGR 2002-2007</td>
<td></td>
<td>6.5</td>
</tr>
</tbody>
</table>

Source: Datamonitor Research Report August 1, 2003

Figure 1 U.S. Health Care Equipment & Supplies Market Value Forecast, 2002-2007

Changing demographics will be a driving force in the market as an aging population will significantly contribute to rising health care costs, and increasing demand for medical products and services. Currently, annual per capita health care spending for men age 30-34 is $1,528, however, the amount of per capita spending nearly triples to $4,454 for men age 50-54. It is estimated that every eight seconds another person from the baby boom generation turns 50, and this trend will continue over the next 10 years. This being the case, real per capita spending could increase by 24 percent over current levels by the year 2030.

The over 65 age group currently stands at about 35 million persons. As shown in Figure 2 and below it is forecasted to reach almost 55 million by 2020. In addition, the life expectancy of persons aged 65 is expected to increase by up to 25% by 2075. These demographic trends will ultimately increase demand for medical products, especially in the areas of cardiology, orthopedics, urology, neurology, and diagnostic imaging.

Subsequently, the health care industry is already quite large and is continuing to grow as the demand for more medical devices and treatments continues to grow. Both the number of persons employed in the industry and the number of facilities are increasing every year. In 2002, the number of persons employed in the health care industry was just over 12.65 million which is about 9.3 percent of all employed civilians. Within this amount, physicians offices and clinics employed 1.91 million, dental offices and clinics employed 740 thousand, chiropractic offices and clinics 138

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4 The Medical Device Industry: A Larta White Paper © 2003 www.larta.org

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thousand, hospitals 5.34 million, nursing and personal care facilities 1.94 million, and other health service sites 2.58 million. In looking at the various types of health service facilities, there are 492,124 ambulatory health care service facilities, 6,536 hospitals, and 69,533 nursing and residential care facilities in the U.S. In 2002, the healthcare industry generated revenue of $1.141 trillion. From that amount, hospitals generated $511.1 billion, ambulatory health care services generated $500.3 billion and nursing and residential care facilities generated $129.4 billion.

<table>
<thead>
<tr>
<th>Year</th>
<th>Million</th>
</tr>
</thead>
<tbody>
<tr>
<td>1990</td>
<td>31.2</td>
</tr>
<tr>
<td>2000</td>
<td>35.0</td>
</tr>
<tr>
<td>2010</td>
<td>40.2</td>
</tr>
<tr>
<td>2020</td>
<td>54.6</td>
</tr>
<tr>
<td>2030</td>
<td>71.5</td>
</tr>
<tr>
<td>2040</td>
<td>80.0</td>
</tr>
<tr>
<td>2050</td>
<td>86.7</td>
</tr>
</tbody>
</table>

2.2. The Nations Health Dollar

The U.S. health care industry already accounts for an increasingly large share of the nation’s gross domestic product (GDP), and it is expected to become an even larger portion over the next decade. In 2002, U.S. health expenditures totaled $1.55 trillion, an increase of 9.3 percent over 2001. On a per capita basis, health expenditures averaged $5,440 per person, up $419 from 2001. At the same time, health spending grew 5.7 percentage points faster than the overall economy as measured by growth of the GDP. As a result, the health care share of GDP increased to 14.9 percent in 2002 after nearly a decade in the 13.1 to 13.4 percent range. Figure 4 gives a pictorial overview of where the health expenditure money came from and where it went.

**Where it came from:**

Private payers comprised more than half of national health expenditures in 2002. Private health insurance totaled $479.3 billion, and made up the largest share (36 percent) within the private payers group, while out-of-pocket payments totaled $212.5 billion, and comprised 16 percent of expenditures.

The public sector comprised the remaining 44 percent of health payments in the U.S. The public sector is made up of two primary components: Medicare and Medicaid. Medicare is the national health insurance program which provides coverage to approximately 40 million Americans. Covered individuals include people age 65 or older, as well as some people under age 65 with disabilities, and people with End-Stage Renal Disease. Medicaid is a program that pays for medical assistance for certain individuals and families with low incomes and resources who meet certain eligibility requirements. Medicare spending totaled $259.1 billion (19 percent) while Medicare spending totaled $232.4 billion (17 percent). [http://www.cms.hhs.gov/medicaid/whoiseligible.asp](http://www.cms.hhs.gov/medicaid/whoiseligible.asp).

A third component of the public sector, Other Public, includes government health spending for veterans, military personnel, injured workers and school children and for general public health ac-

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5 2002 Economic Census: Table 1 Advance Summary Statistics for the U.S. 2002 NAICS Basis, U.S. Census Bureau
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activities. This component makes up the remaining 8 percent of health spending by the public sector.6

| Source: Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group. January 8, 2004 |
|---|---|
| Out of Pocket | 16% |
| Medicare | 19% |
| Medicaid | 17% |
| Other Public (1) | 8% |
| Other Private (2) | 4% |
| Private Insurance | 36% |
| Physician & Clinical Services | 22% |
| Prescription Drugs | 10% |
| Nursing Home Care | 7% |
| Program Admin. & Net Cost | 7% |
| Other Spending (3) | 23% |
| Hospital Care | 31% |
| Other Spending (3) | 23% |

Figure 4 The Nations Health Dollar in 2002: The chart on the left shows where it came from - the chart on the right shows where it went

Where it went:

In looking at where the money went, Hospital Care consumed the largest share of expenditures accounting for 31 percent of the health care dollar, and amounting to $486.5 billion in 2002. Physician and Clinical Services consumed 22 percent of the expenditures and totaled $339.5 billion. Prescription Drugs accounted for 10 percent or about $162.4 billion. Nursing Home Costs and Program and Administration Costs each accounted for about 7 percent of total expenditures. The remaining 23 percent of health care expenditures is made up of spending that went to dentist services, other professional services, home health care, durable medical products, over-the-counter medicines and sundries, public health, research and construction.

At a value of about $1.55 trillion, the U.S. healthcare industry accounts for about 38.8 percent share of the estimated $4 trillion global healthcare industry. Figure 5 details national health expenditures by type of product or service from 1998 through 2002. As a whole, national health expenditures experienced a compound annual growth rate of 6.2 percent for the 5-year period.

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- 10 -
## Figure 5 National Health Expenditures ($ Billions plus 5-year compound annual growth rate)

Spending for Hospital Care increased 9.5 percent to $486.5 billion in 2002 making it the fourth consecutive year of accelerated growth, and the first time hospital spending outpaced overall spending since 1991. Recent spending trends reflect growing demands for services, rising compensation and other input costs, and the increased ability of hospitals to negotiate higher prices from private payers.

Spending growth for physician services ($339.5 billion) slowed from 8.6 percent growth in 2001 to 7.7 percent in 2002. Medicare was the primary driver of the deceleration even though it accounted for only 20 percent of the payments to physicians.

Spending growth for prescription drugs slowed slightly, from 15.9 percent in 2001 to 15.3 percent in 2002, but still outpaced growth in all other health services. Growth in private health insurance spending for prescription drugs (16.1 percent) decelerated while growth in out-of-pocket spending (14.4 percent) accelerated in 2002. This was due to the effect of tiered drug formularies which shifted more of the cost to consumers.

Expenditures for free-standing home health care grew by 7.2 percent in 2002. This was the second consecutive year of expansion, and was driven mainly by a rebound in Medicare spending. The recent rapid growth in Medicare was partly due to a change in the interpretation of home-bound that expanded the number of beneficiaries eligible for Medicare services. As a result, Medicare growth increased 17.6 percent in 2001 and 13.3 percent in 2002.7

In 2002, U.S. Personal Healthcare Expenditures totaled $1.34 trillion. From this amount $486.5 billion (36.3 percent) went to Hospital Care and $339.5 billion (25.3 percent) went to Physician and Clinical Services. Likewise, Private Health Insurance accounted for $479.3 billion (35.8 percent) and Medicare accounted for $259.1 billion (19.3 percent) of the Personal Healthcare Expenditures in 2002. Figure 6 and Figure 7 form a two part table which details the amount of expenditures for all types of personal healthcare expenditures in 2002.

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7 Centers for Medicare and Medicaid Services, Highlights – National Health Expenditures, 2002 web site posting: January 8, 2004, 
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### Table 1: Total Hospital Care, Physician & Clinical Services, Dental Services, Other Professional Services, and Home Health Care Expenditures

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Hospital Care</th>
<th>Physician &amp; Clinical Services</th>
<th>Dental Services</th>
<th>Other Professional Services</th>
<th>Home Health Care</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A) Out-of-pocket Payments</strong></td>
<td>212.5</td>
<td>14.7</td>
<td>34.3</td>
<td>30.9</td>
<td>13</td>
<td>6.5</td>
</tr>
<tr>
<td><strong>B) Third-Party Payments</strong></td>
<td>1,127.70</td>
<td>471.8</td>
<td>305.3</td>
<td>39.4</td>
<td>32.8</td>
<td>29.6</td>
</tr>
<tr>
<td>1) Private Health Insurance</td>
<td>479.3</td>
<td>165</td>
<td>166.9</td>
<td>34.8</td>
<td>17.2</td>
<td>6.7</td>
</tr>
<tr>
<td>2) Other Private</td>
<td>56.2</td>
<td>20.3</td>
<td>23.6</td>
<td>0.1</td>
<td>3</td>
<td>1.1</td>
</tr>
<tr>
<td>3) Public</td>
<td>592.2</td>
<td>286.4</td>
<td>114.8</td>
<td>4.5</td>
<td>12.6</td>
<td>21.9</td>
</tr>
<tr>
<td>a) Federal</td>
<td>450.5</td>
<td>229.9</td>
<td>94.7</td>
<td>2.7</td>
<td>8.2</td>
<td>16.2</td>
</tr>
<tr>
<td>i) Medicare</td>
<td>259.1</td>
<td>149.2</td>
<td>68.8</td>
<td>0.1</td>
<td>6.4</td>
<td>11.4</td>
</tr>
<tr>
<td>ii) Medicaid</td>
<td>137</td>
<td>49.8</td>
<td>14.5</td>
<td>2.1</td>
<td>1.3</td>
<td>4.6</td>
</tr>
<tr>
<td>iii) Other (1)</td>
<td>54.3</td>
<td>30.9</td>
<td>11.5</td>
<td>0.5</td>
<td>0.4</td>
<td>0.2</td>
</tr>
<tr>
<td>b) State &amp; Local</td>
<td>141.7</td>
<td>56.5</td>
<td>20.1</td>
<td>1.8</td>
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<td>5.7</td>
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<tr>
<td>i) Medicaid</td>
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<td>ii) Other (1)</td>
<td>46.3</td>
<td>23.2</td>
<td>10</td>
<td>0.2</td>
<td>3.4</td>
<td>1.8</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>1,340.20</td>
<td>486.5</td>
<td>339.5</td>
<td>70.3</td>
<td>45.9</td>
<td>36.1</td>
</tr>
</tbody>
</table>

Source: Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group. January 8, 2004

**Figure 6 Personal Healthcare Expenditures, by Type of Expenditure and Source of Funds, 2002 ($ Billions), Part 1**

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Prescription Drugs</th>
<th>Other Non-durable Medical Pros.</th>
<th>Durable Medical Equip</th>
<th>Nursing Home Care</th>
<th>Other Personal Health Care</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A) Out-of-pocket Payments</strong></td>
<td>212.5</td>
<td>48.6</td>
<td>30.1</td>
<td>8.5</td>
<td>25.9</td>
<td>--</td>
</tr>
<tr>
<td><strong>B) Third-Party Payments</strong></td>
<td>1,127.70</td>
<td>113.8</td>
<td>1.6</td>
<td>10.3</td>
<td>77.3</td>
<td>45.8</td>
</tr>
<tr>
<td>1) Private Health Insurance</td>
<td>479.3</td>
<td>77.6</td>
<td>--</td>
<td>3.5</td>
<td>7.7</td>
<td>--</td>
</tr>
<tr>
<td>2) Other Private</td>
<td>56.2</td>
<td>--</td>
<td>--</td>
<td>--</td>
<td>3.5</td>
<td>4.7</td>
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<tr>
<td>3) Public</td>
<td>592.2</td>
<td>36.2</td>
<td>1.6</td>
<td>6.8</td>
<td>66.1</td>
<td>41.2</td>
</tr>
<tr>
<td>a) Federal</td>
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<td>1.6</td>
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<td>--</td>
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<td>17.8</td>
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<tr>
<td>iii) Other (1)</td>
<td>54.3</td>
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<td>0.7</td>
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</tr>
<tr>
<td>b) State &amp; Local</td>
<td>141.7</td>
<td>15.4</td>
<td>--</td>
<td>0.2</td>
<td>20.5</td>
<td>17.1</td>
</tr>
<tr>
<td>i) Medicaid</td>
<td>95.4</td>
<td>11.9</td>
<td>--</td>
<td>--</td>
<td>20.4</td>
<td>13.3</td>
</tr>
<tr>
<td>ii) Other (1)</td>
<td>46.3</td>
<td>3.4</td>
<td>--</td>
<td>0.2</td>
<td>0.2</td>
<td>3.8</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>1,340.20</td>
<td>162.4</td>
<td>31.7</td>
<td>18.8</td>
<td>103.2</td>
<td>45.8</td>
</tr>
</tbody>
</table>

Source: Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group. January 8, 2004

**Figure 7 Personal Healthcare Expenditures, by Type of Expenditure and Source of Funds, 2002 ($ Billions), Part 2**

Figure 8 and Figure 9 itemize the type of product or service provided and how it was paid. In 2002, National Health Expenditures totaled $1.553 trillion. From this amount we see that Private Funds (Part 1) accounted for $839.6 billion (54.1%) of the total while Public Funds (Part 2) accounted for 713.4 billion (45.9%). Breaking the Private portion down further, we see that $212.5 billion was paid by consumers through out-of-pocket payments while Private Health Insurance companies paid $549.6 billion. In the area of Durable Medical Products, total expenditures were $11.9 billion. However, from that amount, $8.5 billion (71.4%) was paid out-of-pocket by consumers while private health insurance paid only $3.5 billion (29.6%). In the area of Other Non-durable medical products, on the private side, the full balance was paid by the consumer.
### Figure 8 National Health Expenditures, by Source of Funds & Type of Expenditure, 2002 ($ Billions), Public (Part 1)

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Public</th>
<th>State &amp; Local</th>
<th>Federal</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A) Health Services &amp; Supplies</strong></td>
<td>1,496.30</td>
<td>676.6</td>
<td></td>
<td>476.5</td>
</tr>
<tr>
<td>1) Personal Health Care</td>
<td>1,340.20</td>
<td>592.2</td>
<td></td>
<td>450.5</td>
</tr>
<tr>
<td>a) Hospital Care</td>
<td>486.5</td>
<td>286.4</td>
<td></td>
<td>229.9</td>
</tr>
<tr>
<td>b) Professional Services</td>
<td>501.5</td>
<td>173.2</td>
<td></td>
<td>129.7</td>
</tr>
<tr>
<td>i) Physician &amp; Clinical Services</td>
<td>339.5</td>
<td>114.8</td>
<td></td>
<td>94.7</td>
</tr>
<tr>
<td>ii) Other Professional Services</td>
<td>45.9</td>
<td>12.6</td>
<td></td>
<td>8.2</td>
</tr>
<tr>
<td>iii) Dental Services</td>
<td>70.3</td>
<td>4.5</td>
<td></td>
<td>2.7</td>
</tr>
<tr>
<td>iv) Other Personal Health Care</td>
<td>45.8</td>
<td>41.2</td>
<td></td>
<td>24.1</td>
</tr>
<tr>
<td>c) Nursing Home &amp; Home Health</td>
<td>139.3</td>
<td>87.9</td>
<td></td>
<td>61.7</td>
</tr>
<tr>
<td>i) Home Health Care</td>
<td>36.1</td>
<td>21.9</td>
<td></td>
<td>16.2</td>
</tr>
<tr>
<td>ii) Nursing Home Care</td>
<td>103.2</td>
<td>66.1</td>
<td></td>
<td>45.5</td>
</tr>
<tr>
<td>d) Retail Sales of Medical Products</td>
<td>212.9</td>
<td>44.7</td>
<td></td>
<td>29.1</td>
</tr>
<tr>
<td>i) Prescription Drugs</td>
<td>162.4</td>
<td>36.2</td>
<td></td>
<td>20.9</td>
</tr>
<tr>
<td>ii) Other Medical Products</td>
<td>50.5</td>
<td>8.4</td>
<td></td>
<td>8.2</td>
</tr>
<tr>
<td>iii) Durable Medical Equipment</td>
<td>18.8</td>
<td>6.8</td>
<td></td>
<td>8.6</td>
</tr>
<tr>
<td>iv) Other Non-durable Medical Products</td>
<td>31.7</td>
<td>1.6</td>
<td></td>
<td>1.6</td>
</tr>
<tr>
<td>e) Gov’t Admin. &amp; Net Cost of Private Health Insurance</td>
<td>105</td>
<td>33.3</td>
<td></td>
<td>19</td>
</tr>
<tr>
<td>f) Gov’t Public Health Activities</td>
<td>51.2</td>
<td>51.2</td>
<td></td>
<td>7</td>
</tr>
<tr>
<td><strong>B) Investment</strong></td>
<td>56.7</td>
<td>36.8</td>
<td>28.3</td>
<td>8.6</td>
</tr>
<tr>
<td>1) Research (1)</td>
<td>34.3</td>
<td>31.6</td>
<td></td>
<td>27.4</td>
</tr>
<tr>
<td>2) Construction</td>
<td>22.4</td>
<td>5.2</td>
<td></td>
<td>0.8</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>1,553.00</td>
<td>713.4</td>
<td>504.7</td>
<td>208.7</td>
</tr>
</tbody>
</table>

Source: Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group. January 8, 2004

### Figure 9 National Health Expenditures, by Source of Funds & Type of Expenditure, 2002 ($ Billions), Private (Part 2)

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Consumer</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total</td>
<td>Out-of-pocket</td>
<td>Private Insurance</td>
</tr>
<tr>
<td><strong>A) Health Services &amp; Supplies</strong></td>
<td>1,496.30</td>
<td>819.7</td>
<td>212.5</td>
</tr>
<tr>
<td>1) Personal Health Care</td>
<td>1,340.20</td>
<td>748.1</td>
<td>147.1</td>
</tr>
<tr>
<td>a) Hospital Care</td>
<td>486.5</td>
<td>200.1</td>
<td>14</td>
</tr>
<tr>
<td>b) Professional Services</td>
<td>501.5</td>
<td>328.4</td>
<td>78.2</td>
</tr>
<tr>
<td>i) Physician &amp; Clinical Services</td>
<td>339.5</td>
<td>224.7</td>
<td>34.3</td>
</tr>
<tr>
<td>ii) Other Professional Services</td>
<td>45.9</td>
<td>33.2</td>
<td>13</td>
</tr>
<tr>
<td>iii) Dental Services</td>
<td>70.3</td>
<td>65.8</td>
<td>30.9</td>
</tr>
<tr>
<td>iv) Other Personal Health Care</td>
<td>45.8</td>
<td>4.7</td>
<td>--</td>
</tr>
<tr>
<td>c) Nursing Home &amp; Home Health</td>
<td>139.3</td>
<td>51.4</td>
<td>32.4</td>
</tr>
<tr>
<td>i) Home Health Care</td>
<td>36.1</td>
<td>14.3</td>
<td>6.5</td>
</tr>
<tr>
<td>ii) Nursing Home Care</td>
<td>103.2</td>
<td>37.1</td>
<td>25.9</td>
</tr>
<tr>
<td>d) Retail Sales of Medical Products</td>
<td>212.9</td>
<td>168.2</td>
<td>87.2</td>
</tr>
<tr>
<td>i) Prescription Drugs</td>
<td>162.4</td>
<td>126.2</td>
<td>48.6</td>
</tr>
<tr>
<td>ii) Other Medical Products</td>
<td>50.5</td>
<td>42.1</td>
<td>38.6</td>
</tr>
<tr>
<td>iii) Durable Medical Equipment</td>
<td>18.8</td>
<td>11.9</td>
<td>8.5</td>
</tr>
<tr>
<td>iv) Other Non-durable Medical Products</td>
<td>31.7</td>
<td>30.1</td>
<td>30.1</td>
</tr>
<tr>
<td>e) Gov’t Admin. &amp; Net Cost of Private Health Insurance</td>
<td>105</td>
<td>71.7</td>
<td>--</td>
</tr>
<tr>
<td>f) Gov’t Public Health Activities</td>
<td>51.2</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td><strong>B) Investment</strong></td>
<td>56.7</td>
<td>19.8</td>
<td>--</td>
</tr>
<tr>
<td>1) Research (1)</td>
<td>34.3</td>
<td>2.7</td>
<td>--</td>
</tr>
<tr>
<td>2) Construction</td>
<td>22.4</td>
<td>17.1</td>
<td>--</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>1,553.00</td>
<td>839.6</td>
<td>212.5</td>
</tr>
</tbody>
</table>

Source: Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group. January 8, 2004
2.3. U.S. Production & Consumption of Medical Devices & Diagnostic Products

<table>
<thead>
<tr>
<th></th>
<th>Production Billion $</th>
<th>Consumption Billion $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Devices</td>
<td>69</td>
<td>69</td>
</tr>
<tr>
<td>Diagnostic Products</td>
<td>9</td>
<td>6</td>
</tr>
<tr>
<td>Total</td>
<td>78</td>
<td>75</td>
</tr>
</tbody>
</table>

Source: U.S. Department of Commerce

The U.S. is a net exporter of Diagnostic products, but has an even trade balance in the production and consumption of Medical Devices. Figure 10 shows total U.S. production and consumption of medical devices and diagnostic equipment in 2002.

In addition, the U.S. exports about $2 billion more medical products than it imports. Nevertheless, Figure 11 shows at a value of $18.3 billion in 2002, the U.S. imported a substantial amount of medical products from abroad.

2.4. Role of Healthcare Providers

Healthcare providers cover a very broad range of persons and entities providing services in the healthcare sector including general practice physicians, nurses, physical therapists, physicians assistants, surgeons, a multitude of specialty fields, hospitals, hospices, clinics, etc. These persons and organizations are the direct links to the ultimate end-users of medical devices, the patient. In some cases, the patient might have some input regarding medical devices that will be implanted, but for the most part, it is the doctors and healthcare providers that make the decisions about which devices they will recommend or use on patients. Patients generally follow the advice or recommendations given by their physician or healthcare provider. In most cases, when it comes to marketing medical products and devices, the healthcare providers should be considered the end-user. This being the case, marketing efforts should be designed to target the healthcare providers.

2.5. Outsourcing Services to OEMs

There are a number of companies in the U.S. that provide various outsourcing services to Original Equipment Manufacturers (OEMs) of medical devices and products. These outsourcing service providers typically have a particular product area where they specialize, and they are able to provide services all the way from new product design and development, to quick-turn prototyping, to contract manufacturing, to sterilization, assembly and packaging. OEMs that use their services range from small start-up companies to the very largest in the industry.

There are a number of reasons why OEMs choose to outsource some of their product development or production. Some OEMs may choose to outsource because they have an existing product that has just passed the proven-concept stage, but they have no manufacturing facility, or they
U.S. Health Care industry

may need a second source of manufacture for an established product because either demand is exceeding their capacity or they want to free up production capacity for other products. In the case of start-up companies, they may have a product concept, but do not have a manufacturing facility or the machining know-how to produce the device.

Following is a short list of important U.S. companies that provide outsourcing services for OEM medical device manufacturers. The list should not be considered comprehensive as there are numerous companies working in this field.

- **Analogic Corporation** is a leading designer and manufacturer of advanced health and security systems and subsystems sold primarily to OEMs. The company is recognized worldwide for advancing the state of the art in Computed Tomography (CT), Digital Radiography (DR), Ultrasound, Magnetic Resonance Imaging (MRI), Patient Monitoring, Cardiovascular Information Management, and Embedded Multiprocessing. [http://www.analogic.com/](http://www.analogic.com/)

- **CIVCO Medical Instruments** is a key strategic supplier to OEMs such as Philips Medical Systems, General Electric Medical Systems, Siemens Medical Solutions, Toshiba Medical Systems, Aloka Ltd., B-K Medical and SonoSite. Product lines have evolved over the years to include biopsy systems, protective covers, ultrasound supplies, and positioning and stabilization systems. In addition to OEMs, CIVCO’s proprietary products are sold to over 6,500 hospitals and clinics in the U.S. and through distributors worldwide. CIVCO’s engineering team can design products to meet their customers’ specific needs. The company has more than 10 years of experience custom engineering ultrasound accessory products, and can handle any project from concept stage, to prototype, to the finished product. [http://www.civcomedical.com/index](http://www.civcomedical.com/index)

- **Creganna Medical Devices** is a leading global outsourcing partner for medical device OEMs, providing a full device design, development and manufacturing service. Creganna specializes in the area of minimally invasive devices and metal and polymer components and assemblies. [http://www.creganna.com/](http://www.creganna.com/)

- **CSI Medical** offers complete outsourcing solutions to the medical device and pharmaceutical industries, including R&D engineering assistance, manufacturing, packaging, assembly, and distribution. [http://www.csimed.com/](http://www.csimed.com/)

- **MedSource Technologies** provides engineering, product development, manufacturing services, and supply chain management solutions to leading and emerging medical device companies through complete development and design, prototyping, manufacturing, assembly, packaging/sterilization and distribution services of high precision products globally. MedSource is a single integrated company, and serves many of the largest medical device manufacturers in the world. [http://www.medsourcetech.com/content/index.asp](http://www.medsourcetech.com/content/index.asp)

- **NuPak Manufacturing** provides a broad array of design, development, prototypes, testing, injection molding and packaging services for the entrepreneur, inventor, and large medical corporations. [http://www.nupakmedical.com/default.htm](http://www.nupakmedical.com/default.htm)

- **Peak Industries** is a recognized leader in contract manufacturing of complex systems for OEMs. The company offers a full range of manufacturing capabilities, integrated supply-chain solutions, quality management and customer service. Peak is focused on the low-to-medium volume production of complete systems in the medical, biotechnology, commercial, telecommunications, data storage, industrial and semiconductor industries. [http://www.peakind.com/market/medical.aspx](http://www.peakind.com/market/medical.aspx)

- **Plexus Corp.** is an outsourcing service provider within the fast growing Electronic Manufacturing Services (EMS) industry. The company has over twenty years experience in turning product concepts into world-class products. Services include mechanical, electronic and software design, printed circuit board development, prototyping services, new product introduction, material procurement and management, printed circuit board and higher level assembly, test development, in-circuit and functional testing, final system box build, fulfillment and sustaining services. This range of capability provides for the seamless transition of products from one service offering to another, reducing time-to-market and total cost. These products are used in
a variety of industries including medical, networking, data communications, industrial, computer and transportation. Plexus has no proprietary products, but its product realization services have created complex, high-tech products for major OEMs and high-tech start-ups.  
http://www.plexus.com/cgi-bin/r.cgi/index1.html

- Synovis Life Technologies, Inc. is a diversified medical device company that develops, manufactures and markets products for the surgical and interventional treatment of disease. The company's business is conducted in two segments, the surgical business and the interventional business. The surgical business develops, manufactures and markets implantable biomaterial products, devices for microsurgery, and surgical tools, which are all designed to reduce risk and/or facilitate critical surgeries. The interventional business provides design, development, engineering, rapid prototyping, manufacturing, packaging, and delivery services to both small and large medical device OEMs. Specialty products include coils, helices, stylets, guidewires and other complex micro-wire, polymer and machined components used in interventional devices for cardiac rhythm management, neurostimulation and vascular procedures.  
http://www.synovislife.com/

- TriVirix provides services in the design, manufacture and support of electronic and electromechanical medical and life science equipment. The company has experience in the following medical product areas: Patient (Vital Sign) Monitoring, RF Ablation Equipment, Pacemaker Programmers, Cardiac Defibrillation, Cardiac Event Recording, Radioactive Stent delivery, Cancer Detection Equipment, Infant Hearing Screening, Photo Dermal Therapy, Wound Care Management, Renal Dialysis, High Performance Gas Chromatography (HPLC), Arterial Fibrillation Detection, Depth of Anesthesia Monitor, Neonatal Oxygen Delivery, POC Blood Analyzer, and Orthopedic Surgery Targeting Systems.  
http://www.trivirix.com/

- Ventrix Inc. is an FDA registered, ISO certified firm specializing in medical device contract manufacturing and assembly, clean room medical injection molding and the design and fabrication of specialty assembly equipment for medical device manufacturers. The company offers clean room and non-clean room assembly, testing and packaging services for class I, class II and class III medical devices, including sterile and non-sterile products. Assembly process capabilities range from simple products such as tubing sets to ultra-precision electromechanical devices with interface tolerances of one fifth the thickness of a human hair. Personnel are experienced in high volume disposable and low volume reusable device manufacturing.  
http://www.ventrexinc.com/
Reimbursement

By Scot Orgish, Trade Commissioner, Swiss Business Hub, Houston TX

3. Overview

Reimbursement by public and/or private insurance is one of the primary drivers that can affect the successful introduction (or failure) of new medical devices in the U.S. market. Since most patients cannot afford to pay for medical devices and procedures on their own, they rely on insurance to pay about 84 percent of all healthcare expenses. (See figure 1) This being the case, public insurance (through federal and state Medicare and Medicaid programs) as well as a large number of private insurance companies have a major voice in deciding which medical devices and procedures they agree to pay for, and how much they are willing to pay. The public and private sectors operate independently from each other, and each makes its own decisions regarding which devices and procedures it considers eligible for reimbursement. On the public side, The Centers for Medicare and Medicaid takes the leading role in making decisions while on the private side the individual companies conduct their own reviews and make their own decisions.

In order for Swiss medical device manufacturers to successfully introduce new products into the U.S. market, it is important they understand the various major components, entities, and market dynamics that affect the payment and reimbursement for medical products.

3.2. Relationship of Patients, Providers, and Payers

Generally, there are three primary entities that are ultimately involved in the “healthcare transaction”: (1) the patients who receive the healthcare services, (2) the healthcare providers (i.e. doctors, nurses, laboratories, hospitals, etc.) who provide the services, and (3) the insurers (public and private) who pay for the services. In most cases, the patients are required to bear a part of the total cost through deductible and/or co-payment amounts, but insurance usually covers a considerable amount of the overall costs. Nevertheless, the patient is ultimately responsible for all amounts owed to healthcare providers that are not paid by the insurer.

Healthcare providers generally contract with both public and private payers to provide services at a specified maximum amount, and accept payment for the contracted amount as payment in full. Healthcare providers may then bill patients separately for the contractual co-payment and deductible amounts not paid by the insurance provider, but they may not charge patients for any residual amounts above the contractual price. For example, if a doctor charges $5,000 as a standard price to perform a surgery, he may have a discounted contractual price with various public and private payers. If he accepts Medicare reimbursement, he may only receive $3,000 from Medicare if that is the maximum amount of reimbursement Medicare will pay for the specific type of surgery. The doctor must accept that amount as full payment. However, if Medicare allows $3,000 for the surgery and only pays the doctor $2,400, (i.e. 80%), Medicare will inform the doctor the patient is responsible for the additional $600 because of the 20% deductible or co-payment amount. In this case then, the doctor may bill the patient directly (or his supplemental insurance company) for the additional $600. This process would be similar for private insurance except that the negotiated maximum amounts for procedures may vary. Most healthcare providers accept a number of different insurance policies.
3.3. Reimbursement

Reimbursement has become an increasingly important consideration in the development and marketing of medical devices. In its role as the largest single healthcare insurer in the U.S., Medicare has a significant influence on the healthcare market. The Centers for Medicare and Medicaid Services (CMS) formulates national and local coverage policy and sets reimbursement rates for facility and physician providers. In the area of commercial payers, managed care organizations cover approximately 200 million individuals in the U.S., and these payers often follow the lead set by CMS when determining their own coverage and payment guidelines. Regardless of the payer, three basic steps must occur for the product or procedure to be considered reimbursable: (1) payers must consider the product or procedure as a part of a covered set of benefits; (2) a billing code must exist or be established to identify the product or procedure; and (3) payment must be assigned for the code. In general, the complexity and integration of these processes are significant challenges for manufacturers seeking to bring products to market. This being the case, it is important for manufacturers to work with decision makers which include government agencies, specialty medical societies and public and private payers.

Ultimately, in the U.S., approval of a medical device for marketing by the FDA does not guarantee that a third party payer (e.g. Medicare, insurance company, health plan) will provide coverage and reimbursement for that device. Often, payers either perform or contract out for technology assessments to determine the cost-effectiveness of covering a particular device. Since each third party payer has its own process to reach coverage decisions, it is recommended that a medical device manufacturer take up direct contact with those entities that are directly involved in the evaluation and decision process. Listed below are the addresses and phone numbers for the Center for Medicare and Medicaid Services, the National Blue Cross/Blue Shield Technology Evaluation Center, the American Association of Health Plans (which represents many of the private insurers and health plans in the U.S.), and ECRI (an independent, nonprofit health services research agency that performs many technology assessments for the insurance industry).

Mark B. McClellan, MD, PhD  
Administrator  
Centers for Medicare and Medicaid Services  
7500 Security Blvd.  
Baltimore, MD 21244-1850  
Tel:  202-690-6726

Naomi Anderson, PhD  
Executive Director,  
Technology Evaluation Center, and  
Director, Evidence-based Practice Center  
Blue Cross/Blue Shield Association  
225 North Michigan Ave.  
Chicago, IL 60601  
Tel:  312-297-5530

Karen Ignani  
President and CEO  
American Association of Health Plans  
20th Street NW, Suite 600  
Washington, DC 20036-3403  
Tel:  202-778-3200

ECRI  
5200 Butler Pike  
Plymouth Meeting, PA 19462-1298  
Tel:  610-825-6000
3.4. Role of Insurance

Reimbursement for new technology is a major concern for providers, patients, the physician community and medical technology innovators. The process can be complex and reimbursement is affected by things such as the site of service and the type of device used as well as other factors. In addition, clinical trials play a critical role in the development and approval for coverage of new medical technologies.

Medicare and most other insurers typically reimburse physicians based on fee schedules tied to Current Procedural Terminology (CPT) codes. CPT codes are published by the American Medical Association and used to report medical services and procedures performed by or under the direction of physicians.

Medicare reimburses hospitals for outpatient stays (typically stays of less than 24 hours) under Ambulatory Payment Classification groups (APCs). Medicare assigns a procedure to an APC based on the billed CPT code. (Many private insurers require International Classification of Diseases, 9th revision (ICD-9) procedure codes for outpatient payment.)

Many insurers, including Medicare, use a 24-hour length of stay to define inpatient hospital care. A Diagnosis-Related Group (DRG) is a system of classifying patients based on their diagnoses and the procedures performed during their hospital stay. The Centers for Medicare and Medicaid Services (CMS), which runs the Medicare program, uses DRGs to determine how much to pay hospitals for treating Medicare patients who receive inpatient care. Private payers may also pay hospitals using DRG-based systems for providing inpatient services. Each of Medicare’s 500+ DRGs is assigned a single, fixed payment rate. That payment rate reflects the national average cost of caring for patients with similar clinical characteristics who require similar resources (services, supplies, devices, etc.) for their treatment during their hospital stay. However, actual Medicare payments for specific procedures may vary depending on each provider and institution, geographic differences in costs, hospital teaching status, and proportion of low-income patients.

Many procedures are also performed outside of the hospital in free-standing clinics. Payments made to free-standing clinics from private insurers depend on the contract the clinic has with the payer. Medicare payments to free-standing clinics are determined in part, by the licensing status of the clinic. If a free-standing clinic is licensed by Medicare as an Ambulatory Surgical Center (ASC) it is eligible to be reimbursed for select procedures provided in this setting. Not all procedures that Medicare covers in the hospital setting are eligible for payment in ASCs. Medicare has a list of all services (as defined by CPT code), generally non-surgical, that it covers in the ASC setting. These services are classified into nine payment groupings to determine reimbursement.

Currently, private insurance is the expected means of payment in about 57 percent of the cases while Medicare is the expected means of payment in about 20 percent of the cases. Medicaid accounts for about 9 percent of the cases and self-pay about 5½ percent. With an aging population in the U.S., the percentage of cases paid by Medicare can be expected to increase over the next 10 years.

3.5. Primary Types of Private Insurance Coverage

In the U.S., there are several types of private insurance options used to cover individuals and employees enrolled in company sponsored or individual sponsored health insurance plans. Companies that provide health coverage benefits to their employees can either contract with private insurance companies or managed care organizations, or they can self-insure provided that they meet the requirements of the Federal Health Insurance Portability and Accounting...
The U.S. Market for Medical Devices - Opportunities and Challenges for Swiss Companies

Act (HIPAA). The two most common types of private insurance options provided by employers to their employees or purchased by individuals are Health Maintenance Organizations (HMOs) and Preferred Provider Organizations (PPOs).

A Health Maintenance Organization is a healthcare system that assumes or shares both the financial risks and the delivery risks associated with providing comprehensive medical services to a voluntarily enrolled population in a particular geographic area, usually in return for a fixed, prepaid fee. HMOs generally use a managed care approach which integrates both the financing and delivery of health-care within a system that seeks to manage the accessibility, cost, and quality of that care.

Preferred Provider Organizations are a healthcare benefit arrangement designed to supply services at a discounted cost by providing incentives for members to use designated healthcare providers (who contract with the PPO at a discount), but which also provides coverage for services rendered by healthcare providers who are not part of the PPO network.

HMOs are generally a lower cost alternative to employers and individuals than PPOs, but they also have more restrictions in terms of geographic coverage, choice of participating doctors, limitations on using healthcare providers outside the network, the maximum amounts payable for specific procedures and devices, and the types of procedures which are allowed or not allowed.

Following is a list of some of the major private health insurance companies in the U.S. (with links):

Aetna [http://www.aetna.com/index.htm]
Beechstreet [http://www.beechstreet.com/]
Blue Cross Blue Shield [http://www.bluecares.com/]
Cigna [http://www.cigna.com/]
HealthSmart Preferred Care [http://www.healthsmart.net/]
Humana [http://www.humana.com/]
Kaiser Permanente [http://www.kaiserpermanente.org]
PacifiCare Health Systems [http://www.pacificare.com/]
United Healthcare [http://www.uhc.com/]
WellPoint [http://www.wellpoint.com/]

3.6. Medicare and Medicaid

The public insurance sector is made up of two primary components: Medicare and Medicaid. Medicare is the national health insurance program which provides coverage to approximately 40 million Americans. Everyone who pays U.S. Social Security taxes pays a portion to this program, and is thus entitled to benefits. Covered individuals include people age 65 or older, as well as some people under age 65 with disabilities, and people with End-Stage Renal Disease (which is permanent kidney failure requiring dialysis or a kidney transplant). The Centers for Medicare & Medicaid Services (CMS) is the federal agency, which administers the Medicare Program. Medicaid is a program that pays for medical assistance for certain individuals and families with low incomes and limited resources who meet certain eligibility requirements. The program is jointly funded by the federal and state governments to assist
Reimbursement

states in providing long-term medical care assistance to people with low incomes and limited resources.

In order for procedures and medical devices to be reimbursed by the U.S. Federal Government under its Medicare program, the specific services, procedures, or technologies should be listed in the Medicare Coverage Database (http://www.cms.hhs.gov/mcd/indexes.asp). In the absence of a specific non-coverage instruction, and where a medical device has been approved for marketing by the Food and Drug Administration, in many cases, contractor (Physician) discretion may be used to determine whether a procedure performed with a medical device is reasonable and necessary and, therefore, covered.

3.7. Coverage Descriptions

National Coverage Description

A National Coverage Determination (NCD) is one of the two types of Medicare coverage policies. It establishes whether Medicare will cover (or not cover) specific services, procedures, or technologies on a national basis. Medicare contractors are required to follow NCDs. If an NCD does not specifically exclude an indication or circumstance, or if the item or service is not mentioned at all in an NCD or in a Medicare manual, it is up to the Medicare contractor to make the coverage decision. Prior to an NCD taking effect, The Centers for Medicare & Medicaid Services (CMS) must first issue a manual instruction, program memorandum, CMS ruling, or Federal Register Notice giving specific directions to Medicare’s claims-processing contractors. That issuance, which includes an effective date, is the NCD. If appropriate, the Agency must also change billing and claims processing systems and issue related instructions to allow for payment. The NCD will be published in the Medicare Coverage Issues Manual. An NCD becomes effective on the date listed in the transmittal that announces the Coverage Issues Manual revision. A list of the National Coverage Determinations can be found at the following website: http://www.cms.hhs.gov/mcd/index_list.asp?list_type=ncd

NCA Description (National Coverage Analyses)

Numerous documents support the national coverage analyses determination process. They include tracking sheets to inform the public of the issues under consideration and the status of the review, information about and results of the Medicare Coverage Advisory Committee (MCAC) meetings, technology assessments, and the decision memoranda that announce CMS’s intention to issue an NCD. These documents provide the rationale behind the evidence-based NCDs. A list of recently pending and closed NCAs can be found at the following website: http://www.cms.hhs.gov/mcd/index_list.asp?list_type=nca

LMRP Description

Local medical review policy is the second of the two types of Medicare coverage policies. CMS contracts with private insurance companies, known as carriers, intermediaries, and program safeguard contractors, to help process Medicare claims. These “Medicare contractors” review and process claims for services to make sure that payments are made only for services that are covered under Medicare Part A or Part B. If no specific NCD exists, local contractors may make coverage decisions at their own discretion.

Contractors may publish local medical review policies (LMRPs) to provide guidance to the public and medical community within a specified geographic area. These LMRPs explain when an item or service will be covered and how it should be coded. An LMRP may not conflict with an NCD once the NCD is effective. Reviewing Local Medical Review Policies will help in understanding why Medicare claims may be paid or denied. A full description of the
process and criteria used in developing LMRPs can be found at the following web site:  

LCD Description

A "Local Coverage Determination" (LCD), as established by Section 522 of the Benefits Improvement and Protection Act, is a decision by a “Medicare contractor” whether to cover a particular service on an intermediary-wide or carrier-wide basis in accordance with Section 1862(a)(1)(A) of the Social Security Act (i.e., a determination as to whether the service is reasonable and necessary). The difference between LMRPs and LCDs is that LCDs consist only of "reasonable and necessary" information, while LMRPs may also contain category or statutory provisions. The final rule establishing LCDs was published November 11, 2003. Effective December 7, 2003, Medicare contractors will begin issuing LCDs instead of LMRPs. Based on the statutory definition, an LMRP may contain no LCDs at all, or it may contain multiple LCDs. Medicare contractors are in the process of converting all existing LMRPs into LCDs and articles. Until the conversion is complete in October 2005, the term LCD will refer to both (1) Reasonable and necessary provisions of an LMRP and, (2) an LCD that contains only reasonable and necessary language. Any non-reasonable and necessary language a Medicare contractor wishes to communicate to providers must be done through an article.⑨

3.8. Links to other sources of reimbursement information

Local Medical Review Policies
The Gray Sheet*  
FDC Reports*  
GLOBALDeviceReimbursement.com*  
Advanced Medical Technology Association*  
American College of Cardiology (Payer Advocacy/HIPAA)  
NASPE: Washington Advocacy  
CMS: Medicare Learning Network  
* This site may require a subscription or registration to view some information

3.9. Reimbursement Specialist Companies

In order for medical device manufacturers to successfully introduce new medical technology in the U.S., they should have an understanding of three key elements (coding, coverage, and payment), and how these elements relate to reimbursement. It is also important that medical device manufacturers develop long-term strategies for reimbursement as well as implement, monitor, and analyze those strategies.

Coding is a classification system used by insurers and providers to identify diagnoses and describe medical services and products. Codes also serve to track utilization and establish reimbursement rates for facility and professional services. Procedural and diagnosis coding is based on the information contained in the patient's medical record and cannot be coded based on reimbursement levels.

Coverage refers to the terms and conditions under which a payer will or will not provide benefits for a specific treatment. Coverage policies are usually developed for new technologies or procedures.

Reimbursement

Payment refers to the amount of reimbursement provided to the hospital and the physician for services related to the procedure.

Listed below are ten companies that can advise medical device manufacturers about payer trends and industry requirements for specific medical technologies.

- **AlvaMed, LLC**, a Boston-based medical technology consulting firm whose consultants have more than 20 years each of medical technology experience and backgrounds ranging from business strategy, device design, project management and clinical care. AlvaMed consultants understand the needs of offshore medical device companies, and are skilled at identifying market needs, working through reimbursement, regulatory, and clinical issues, and understanding the rapidly changing U.S. healthcare system. [http://www.alvamed.com/](http://www.alvamed.com/)

- **Aventor Reimbursement** is a consulting firm that helps drug, device, and biotech companies commercialize medical technology and build reimbursed markets. Their services cover a number of areas spanning not only the technical requirements of governments and other third-party payers, but also the policy, political, and consumer forces that shape those requirements. In the area of reimbursement they provide services for strategy development, reimbursement support, and policy advocacy and development. [http://www.aventorreimbursement.com/](http://www.aventorreimbursement.com/)

- **BioMedical Strategies (BMS)** offers consulting services in the area of reimbursement at every stage of product development. This includes issues such as whether new or existing medical codes are appropriate, affect regulatory choices in product claims and labeling, and (for devices) whether to prepare 510(k) vs. PMA applications. BMS helps their clients strategically evaluate coding, coverage, and payment issues for their impact on physicians, hospital administrators, and third-party payers. In addition, BMS helps clients understand how product design, clinical needs, regulatory decisions, and marketing plans affect reimbursement levels and timelines to profitability. [http://www.biomedicalstrategies.com/](http://www.biomedicalstrategies.com/)

- **GM Associates** provides consulting expertise on a wide range of health care topics including reimbursement assistance, clinical studies, medical device and wound care product consulting, and marketing and sales support. The company is a nationally recognized leader in strategic reimbursement planning and problem solving. They offer worldwide health care industry clients unique approaches for boosting sales, adding value to products, disseminating ever-changing reimbursement information, and validating the clinical efficacy of new and existing medical technologies. [http://www.gm-associatesinc.com/](http://www.gm-associatesinc.com/)

- **The JGS Group** is a multifaceted reimbursement consulting firm designed to assist clients throughout the world with every aspect of their reimbursement needs from product conception to post market launch. Primary services include Reimbursement Assessments (i.e. comparative market analysis, information gathering; applying for new codes, determining current codes appropriate for new products, assisting clients with bringing new products to the market, etc.), Reimbursement Research, Patient Assistance Programs, Report and Payer Trends, 24-hour Hotline, Development of Billing Guides, Sales Force Training, National Coverage Assistance, and Interviews for Clinical Trials. [http://jgsgroup.com/](http://jgsgroup.com/)

- **JR Associates** provides specialized consulting services in the reimbursement field. The company helps medical practitioners, device manufacturers and other healthcare organizations navigate the complex dynamics of a rapidly changing market. The company combines first-hand clinical experience and extensive knowledge of regulatory requirements to help their clients operate more productively and profitably. They offer products and services in three primary areas: (1) Reinforcement and refinement of product positioning for emerging medical technologies; (2) Coverage, coding and payment process analysis and implementation for healthcare and life science companies; and (3) Coding guides and
schedules that help practitioners simplify and manage billing procedures.  
http://www.1jra.com/

- Medtech Insight provides business information and intelligence on new trends, technologies, and companies in the medical device, diagnostics, and biotech marketplace. The company offers a broad range of products and services for medical technology executives, including: The Medtech Insight Newsletter; Market & Technology Reports; Investment In Innovation (In³) Conferences; Custom Consulting Services; and Practices, Preferences & Projections (Pr³) Custom End-User Surveys.  http://www.medtechinsight.com/

- Princeton Reimbursement Group (PRG) provides expertise on Medicare and third-party payer reimbursement to the medical technology industry. Their services support a broad range of companies, from small start-ups to Fortune 500 corporations. Services include reimbursement assessment, payment analysis and modeling, strategic planning, and healthcare policy analysis.  http://www.prgweb.com/

- Reimbursement Principles offers a fully integrated line of reimbursement support services including reimbursement assessments, clinical trial reimbursement oversight and support, pre-authorization services, hotline support services, and reimbursement strategies, including short and long-range strategic planning, correct coding initiatives, coding applications, third party payer research and educational campaigns, compliance with Medicare regulations and sales force training. The company also offers a fully integrated HIPAA compliance analysis and recommendations program. http://www.reimbursementprinciples.com/

- Strategic Reimbursement Consulting offers consulting services in two primary areas: Market Assessment (1) to determine the appropriate payer market (i.e. Medicare, commercial payers, workers' compensation, etc.) for device or procedure; (2) to determine the optimal site of service (where the procedure will be performed); (3) to research reimbursement landscape for similar technologies; and (4) to conduct payer market research to ensure proper device positioning and payer acceptance. Strategy Development in the areas of coding, coverage, and pricing/payment. This includes (1) identifying appropriate device and procedure billing codes; (2) facilitating product and procedural coding submissions if needed; (3) creating customer support information identifying appropriate product and procedure coding and billing, (4) maximizing Medicare and third-party payer coverage; and (5) identifying expected payment levels for device and procedure at all applicable sites of service, and devising a strategy to support device pricing.  http://www.strategic-reimbursement.com/
4. Cardiovascular

By Scot Orgish, Trade Commissioner, Swiss Business Hub, Houston, TX

4.1. Facts and Figures

Heart disease and stroke are the two most significant areas of cardiovascular disease, and are the first and third leading causes of death in the U.S. (Cancer is the second leading cause). Heart disease and stroke combined accounted for about 38.5 percent of all U.S. deaths in 2001. An estimated 931,000 Americans died from cardiovascular disease in 2001 while about 64.4 million Americans (over one-fifth of the population) live with the disease. (From that amount, approximately 25.3 million [39.3%] are age 65 and older). During that time, about 6.2 million inpatient cardiovascular operations and procedures were performed in the U.S. Cardiovascular disease includes both acute conditions such as myocardial infarction (heart attack), and chronic conditions such as congestive heart failure, atherosclerosis, and hypertension. Although cardiovascular disease may be diagnosed at any age, it occurs most frequently later in life, especially among inactive persons who are also overweight or obese. This being the case, the aging Baby Boom generation in the U.S., which has grown up on and maintained a diet of fast-food, is expected to show a significant increase in the incidence of heart disease over the next ten years. As a result, the economic impact of cardiovascular disease on the U.S. health care system is expected to increase as the population ages. In 2004, the direct economic impact of heart disease and stroke is estimated to be $226.7 billion for health care expenditures.9

<table>
<thead>
<tr>
<th>Type</th>
<th>Millions of Persons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiovascular Disease</td>
<td>64.4</td>
</tr>
<tr>
<td>High Blood Pressure</td>
<td>50.0</td>
</tr>
<tr>
<td>Coronary Heart Disease</td>
<td>13.2</td>
</tr>
<tr>
<td>Myocardial Infarction</td>
<td>7.8</td>
</tr>
<tr>
<td>Angina Pectoris</td>
<td>6.8</td>
</tr>
<tr>
<td>Congestive Heart Failure</td>
<td>5.0</td>
</tr>
<tr>
<td>Stroke</td>
<td>4.8</td>
</tr>
<tr>
<td>Congenital CV Defects</td>
<td>1.0</td>
</tr>
</tbody>
</table>

Source: American Heart Association. Heart Disease and Stroke Statistics — 2004 Update

Figure 12 Prevalence of Cardiovascular Disease, U.S. 2001

Coronary heart disease is the leading cause of death among all types of cardiovascular disease in the U.S. accounting for approximately 460,000 deaths in 2001. Stroke is the second major cause of death among all types of cardiovascular disease in the U.S. accounting for about 163,000 deaths in 2001. Figure 10 gives a pictorial overview of the percentage of deaths resulting from the various types of cardiovascular disease.

The U.S. Market for Medical Devices - Opportunities and Challenges for Swiss Companies

Coronary Heart Disease 55%
Diseases of the Arteries 4%
Other 12%
High Blood Pressure 5%
Congestive Heart Failure 6%
Stroke 18%

Source: American Heart Association. Heart Disease and Stroke Statistics — 2004 Update

**Figure 13 Percentage of Deaths from Cardiovascular Diseases, U.S. 2001 (100% = 931,000)**

There are three health-related behaviors that increase the probability of being afflicted by cardiovascular disease. These include:

- The use of tobacco: Persons who smoke are two times as likely to have a heart attack compared with nonsmokers. Almost one-fifth (190,000) of the deaths resulting from cardiovascular disease are smoking related.

- Lack of physical activity: People who are physically inactive or sedentary have two times the risk for heart disease compared with those who are active. Statistics show that more than half of U.S. adults do not achieve recommended levels of physical activity.

- Poor nutrition: People who are overweight have an increased risk for cardiovascular disease. Statistics show that almost 60 percent of U.S. adults are overweight or obese.

Based on the percentage of the population with these risk factors combined with an aging population, the market for cardiovascular medical devices and treatments is expected to experience significant growth over the next decade.

During the time period from 1979 to 2001, the number of cardiovascular operations and procedures increased 417 percent. Figure 11 shows the number of procedures and the mean cost for each procedure in the U.S. in 2001.

Cardiac catheterization was the most common type of procedure with over 1.2 million performed in 2001 at a mean cost of $16,838 per procedure. Percutaneous Transluminal Coronary Angioplasty was the second most common procedure with 571,000 performed at a mean cost of $28,558. Coronary Artery Bypass Surgery was a close third with 516,000 performed in 2001. Coronary Artery Bypass Surgery is over twice as expensive as Percutaneous Transluminal Coronary Angioplasty at a mean cost of $60,853 per procedure (see Figure 14).

<table>
<thead>
<tr>
<th>Procedure</th>
<th>No. of Procedures</th>
<th>Mean Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiac Catheterization</td>
<td>1,208,000</td>
<td>$16,838</td>
</tr>
<tr>
<td>Coronary Artery Bypass Surgery</td>
<td>516,000</td>
<td>$60,853</td>
</tr>
<tr>
<td>Heart Transplants</td>
<td>2,154</td>
<td>n/a</td>
</tr>
<tr>
<td>Percutaneous Transluminal Coronary</td>
<td>571,000</td>
<td>$28,558</td>
</tr>
</tbody>
</table>

Source: American Heart Association. Heart Disease and Stroke Statistics — 2004 Update

**Figure 14 Medical Procedures and Costs, 2001**

- 26 -
In 2004, the direct cost of cardiovascular disease is estimated at $226.7 billion for health care expenditures. (For comparison, in 2003 the estimated direct cost of treating all cancers was $64 billion or about 28 percent). U.S. expenditures for the treatment of patients with coronary heart disease is estimated at $66.3 million of which hospital costs make up about 55.8 percent of the costs. Likewise, the direct costs for treating congestive heart failure is estimated at $23.7 million of which hospital costs account for up 57.4 percent. Although stroke is the second leading cause of death among cardiovascular diseases (i.e. coronary heart disease 54%, stroke, 18%), expenditures for stroke appear to make up a disproportionate amount of the total cost figure (relative to coronary heart disease). The data show the total direct costs for stroke is about one half of the direct costs for coronary heart disease. (i.e. $33.0 vs. $66.3 billion) However, the more logical proportion would be one third the cost. Looking further, we can see that persons who suffer a stroke require proportionally more nursing home care than persons treated for coronary heart disease or congestive heart failure. Likewise, stroke victims require a disproportionate amount of home health care as well.

Figure 15 shows the estimated direct costs of cardiovascular disease and stroke in the U.S. in 2004.

<table>
<thead>
<tr>
<th>Direct Costs</th>
<th>Heart Disease*</th>
<th>Coronary Heart Disease</th>
<th>Stroke</th>
<th>Hypertensive Disease</th>
<th>Congestive Heart Failure</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital</td>
<td>72.0</td>
<td>37.0</td>
<td>13.7</td>
<td>5.5</td>
<td>13.6</td>
<td>101.7</td>
</tr>
<tr>
<td>Nursing Home</td>
<td>18.5</td>
<td>9.7</td>
<td>12.8</td>
<td>3.8</td>
<td>3.5</td>
<td>38.1</td>
</tr>
<tr>
<td>Physicians/Other Professionals</td>
<td>17.1</td>
<td>9.6</td>
<td>2.7</td>
<td>9.6</td>
<td>1.8</td>
<td>33.4</td>
</tr>
<tr>
<td>Drugs/Other Medical Durables</td>
<td>18.3</td>
<td>8.5</td>
<td>1.1</td>
<td>21.0</td>
<td>2.7</td>
<td>43.3</td>
</tr>
<tr>
<td>Home Health Care</td>
<td>4.6</td>
<td>1.4</td>
<td>2.7</td>
<td>1.5</td>
<td>2.1</td>
<td>10.3</td>
</tr>
<tr>
<td>Total Expenditures</td>
<td>130.6</td>
<td>66.3</td>
<td>33.0</td>
<td>41.5</td>
<td>23.7</td>
<td>226.7</td>
</tr>
</tbody>
</table>

Source: American Heart Association. Heart Disease and Stroke Statistics — 20 04 Updat0e

Figure 15 Estimated Direct Costs of Cardiovascular Disease and Stroke, U.S. 2004 (US$ Billion)

* This category includes coronary heart disease, congestive heart failure, part of hypertensive disease, cardiac dysrhythmias, rheumatic heart disease, cardiomyopathy, pulmonary heart disease, and other ill-defined heart diseases.

Interventional Cardiology Devices Market

According to Frost & Sullivan, the U.S. Interventional Cardiology Devices market was valued at $7.5 billion in 1999 and is forecast to grow to a value of $13.7 billion in 2005. It is interesting to note that the growth rate is accelerating in the three year period from 2002 to 2005 with a compound annual growth rate of 14.1 percent compared with a CAGR of 7.1 percent for the three year period 1999-2002. As pointed out earlier in this chapter, the aging U.S. population combined with the number of persons with health risk factors for heart disease should continue to fuel the growth in the interventional cardiology devices market over the next decade.

There are three primary device segments which make up most of the sales and are driving the growth in the interventional cardiology devices market. These segments include stents, pacemakers, and implantable defibrillators. In addition, there are also a number of other important segments as well. In 2002, the Rapid Exchange Stents market was valued at $1.0 billion and it is expected to grow at a rate of 46.6 percent per year to a market value of $3.2 billion in 2005. In the area of pacemakers, double chamber rate responsive pacemakers is the most important segment. This segment was valued at $1.1 billion in 2002 and is forecast to grow at a rate of 9.7 percent per year to market value of $1.45 billion in 2005. The third primary device segment is implantable defibrillators. This segment was valued at $1.95 billion in 2002 and it is expected to grow 15.4 percent per year to a value of $3.0 billion in 2005. Other segments that are expected to experience above average growth include the Left Ventricular Assist Devices (LVAD) market and the AAA Stem Grafts market. The LVAD market was valued at $95 million in 2002 and is expected to grow at an annual rate of 16.4 percent to a value of $150 million in 2005. (Information about several new LVAD devices in development...
can be found later in this chapter under Emerging Technologies.) Finally, the AAA Stem Grafts segment was valued at $180 million in 2002 and is expected to grow at an annual rate of 30.5 percent per year to a market value of $400 million in 2005. Figure 16 gives an overview of the various product segments that make up the interventional cardiology devices market.

<table>
<thead>
<tr>
<th>Segment</th>
<th>1999</th>
<th>2000</th>
<th>2001</th>
<th>2002</th>
<th>2005</th>
<th>CAGR (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rapid Exchange Stents</td>
<td>647</td>
<td>825</td>
<td>915</td>
<td>1,015</td>
<td>3,200</td>
<td>46.6</td>
</tr>
<tr>
<td>Over the Wire Stents</td>
<td>737</td>
<td>545</td>
<td>425</td>
<td>325</td>
<td>200</td>
<td>-14.9</td>
</tr>
<tr>
<td>Over the Wire Balloons</td>
<td>237</td>
<td>203</td>
<td>175</td>
<td>150</td>
<td>100</td>
<td>-12.6</td>
</tr>
<tr>
<td>RX Balloons</td>
<td>230</td>
<td>234</td>
<td>239</td>
<td>242</td>
<td>250</td>
<td>1.1</td>
</tr>
<tr>
<td>FW Balloons</td>
<td>7</td>
<td>6</td>
<td>5</td>
<td>3</td>
<td>2</td>
<td>-15.7</td>
</tr>
<tr>
<td>Perfusion Balloons</td>
<td>23</td>
<td>20</td>
<td>18</td>
<td>16</td>
<td>15</td>
<td>-2.1</td>
</tr>
<tr>
<td>Guiding Catheters</td>
<td>73</td>
<td>72</td>
<td>71</td>
<td>70</td>
<td>65</td>
<td>-2.4</td>
</tr>
<tr>
<td>Guidewires</td>
<td>104</td>
<td>103</td>
<td>102</td>
<td>100</td>
<td>95</td>
<td>-1.7</td>
</tr>
<tr>
<td>Other Accessories</td>
<td>39</td>
<td>39</td>
<td>38</td>
<td>36</td>
<td>30</td>
<td>-5.9</td>
</tr>
<tr>
<td>Interventional Atherectomy</td>
<td>75</td>
<td>75</td>
<td>74</td>
<td>70</td>
<td>70</td>
<td>-1.8</td>
</tr>
<tr>
<td>Interventional Thrombectomy</td>
<td>24</td>
<td>24</td>
<td>23</td>
<td>21</td>
<td>21</td>
<td>-3</td>
</tr>
<tr>
<td>Myocardial Revascularization Products</td>
<td>60</td>
<td>36</td>
<td>22</td>
<td>18</td>
<td>8</td>
<td>-23.7</td>
</tr>
<tr>
<td>Angiography Catheters</td>
<td>132</td>
<td>135</td>
<td>137</td>
<td>138</td>
<td>140</td>
<td>0.5</td>
</tr>
<tr>
<td>Inducer Sheaths</td>
<td>30</td>
<td>31</td>
<td>32</td>
<td>33</td>
<td>35</td>
<td>2</td>
</tr>
<tr>
<td>Angiography Guidewires</td>
<td>24</td>
<td>25</td>
<td>25</td>
<td>26</td>
<td>26</td>
<td>1.3</td>
</tr>
<tr>
<td>Mechanical Heart Valves</td>
<td>208</td>
<td>219</td>
<td>227</td>
<td>245</td>
<td>275</td>
<td>3.9</td>
</tr>
<tr>
<td>Tissue Heart Valves</td>
<td>168</td>
<td>183</td>
<td>202</td>
<td>230</td>
<td>250</td>
<td>2.8</td>
</tr>
<tr>
<td>Angioplasty Ring</td>
<td>16</td>
<td>17</td>
<td>17</td>
<td>18</td>
<td>19</td>
<td>1.8</td>
</tr>
<tr>
<td>Surgical Equipment &amp; Tools</td>
<td>392</td>
<td>419</td>
<td>446</td>
<td>472</td>
<td>600</td>
<td>8.3</td>
</tr>
<tr>
<td>Bypass &amp; Disposables</td>
<td>357</td>
<td>364</td>
<td>371</td>
<td>381</td>
<td>400</td>
<td>1.6</td>
</tr>
<tr>
<td>Mini CABG &amp; HV</td>
<td>26</td>
<td>26</td>
<td>27</td>
<td>27</td>
<td>30</td>
<td>3.6</td>
</tr>
<tr>
<td>Single Chamber Pacemakers</td>
<td>24</td>
<td>20</td>
<td>16</td>
<td>12</td>
<td>8</td>
<td>-12.6</td>
</tr>
<tr>
<td>Single Chamber Rate Responsive</td>
<td>303</td>
<td>321</td>
<td>339</td>
<td>354</td>
<td>400</td>
<td>4.2</td>
</tr>
<tr>
<td>Double Chamber Pacemakers</td>
<td>65</td>
<td>48</td>
<td>36</td>
<td>32</td>
<td>25</td>
<td>-7.9</td>
</tr>
<tr>
<td>Double Chamber Rate Responsive</td>
<td>871</td>
<td>949</td>
<td>1,034</td>
<td>1,098</td>
<td>1,450</td>
<td>9.7</td>
</tr>
<tr>
<td>Pacemaker Leads</td>
<td>255</td>
<td>272</td>
<td>284</td>
<td>296</td>
<td>315</td>
<td>2.1</td>
</tr>
<tr>
<td>Implantable Defibrillators</td>
<td>1,213</td>
<td>1,468</td>
<td>1,762</td>
<td>1,950</td>
<td>3,000</td>
<td>15.4</td>
</tr>
<tr>
<td>Defibrillator Leads</td>
<td>288</td>
<td>346</td>
<td>415</td>
<td>478</td>
<td>750</td>
<td>16.2</td>
</tr>
<tr>
<td>External Defibrillators</td>
<td>303</td>
<td>333</td>
<td>366</td>
<td>399</td>
<td>550</td>
<td>11.3</td>
</tr>
<tr>
<td>IntraAortic Balloon Pumps</td>
<td>105</td>
<td>110</td>
<td>116</td>
<td>118</td>
<td>125</td>
<td>1.9</td>
</tr>
<tr>
<td>External Monitoring</td>
<td>210</td>
<td>221</td>
<td>232</td>
<td>240</td>
<td>250</td>
<td>1.4</td>
</tr>
<tr>
<td>Left Ventrical Assist Devices</td>
<td>26</td>
<td>43</td>
<td>74</td>
<td>95</td>
<td>150</td>
<td>16.4</td>
</tr>
<tr>
<td>Peripheral Vascular Stents</td>
<td>220</td>
<td>249</td>
<td>285</td>
<td>325</td>
<td>446</td>
<td>1.3</td>
</tr>
<tr>
<td>AAA Stem Grafts</td>
<td>20</td>
<td>125</td>
<td>142</td>
<td>180</td>
<td>400</td>
<td>30.5</td>
</tr>
<tr>
<td>Total Cardiac Market</td>
<td>7,512</td>
<td>8,106</td>
<td>8,694</td>
<td>9,218</td>
<td>13,700</td>
<td>14.1</td>
</tr>
</tbody>
</table>

Source: Frost & Sullivan, U.S. Medical Device Market Outlook, March 1, 2003

Figure 16 U.S. Cardiovascular Segmentation and Forecasts, 1999-2005. US$ Million, except CAGR. Note: All figures are rounded; the base year is 2002

### 4.2. Major Players & Market Share Estimates

The pacemaker market is dominated by three major players, Medtronic, St. Jude Medical and Guidant. Due to the high R&D costs in this market, the barriers to entry are quite high. Medtronic is the market leader with 50 percent market share. St. Jude Medical is number two with 25 percent share, and Guidant is a close third with 22 percent share.

<table>
<thead>
<tr>
<th>Player</th>
<th>Share</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medtronic</td>
<td>50%</td>
</tr>
<tr>
<td>St. Jude Medical</td>
<td>25%</td>
</tr>
<tr>
<td>Guidant</td>
<td>22%</td>
</tr>
<tr>
<td>Other</td>
<td>3%</td>
</tr>
</tbody>
</table>

Source: Electronic Business, July 2002 as cited in Market Share Reporter, 2004

Figure 17 Pacemaker Market Shares, 2001 (Percent of $1.7 billion)

Likewise, in the Implantable Cardiac Defibrillator (ICD) market, the same three companies dominate the market. Medtronic is the market leader with about 50 percent market share. In
this market, Guidant is the number two company with 37 percent market share while St. Jude Medical is a distant third with 11 percent share.

<table>
<thead>
<tr>
<th>Company</th>
<th>Market Share</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medtronic</td>
<td>50%</td>
</tr>
<tr>
<td>Guidant</td>
<td>37%</td>
</tr>
<tr>
<td>St. Jude Medical</td>
<td>11%</td>
</tr>
<tr>
<td>Others</td>
<td>2%</td>
</tr>
</tbody>
</table>

Source: Electronic Business, July 2002 as cited in Market Share Reporter, 2004

Figure 18 Implantable Cardiac Defibrillator (ICD) Market Shares, 2001 (Percent of $1.5 billion)

In the stent market, Guidant is the market leader with 43 percent market share followed closely by Johnson & Johnson with a 36 percent market share. Medtronic is a distant third with 13 percent share. Boston Scientific, the fourth ranked company is expected to gain considerable market share with the recent introduction and market acceptance of its TAXUS™ drug eluting stent. In July 2004, Boston Scientific voluntarily recalled 85,000 Taxus stents and 11,000 bare-metal stents after 3 patients died and 43 others were injured during implementation surgery. The problem leading to the recall stems from a failure of the deployment balloon to deflate forcing surgeons to perform emergency bypass surgery to remove it. As a result, several leading hospitals have suspended use of Boston Scientific stents. The company has modified its manufacturing process to correct the problem, but only time will tell how convinced hospitals are that the problem has truly been fixed.

<table>
<thead>
<tr>
<th>Company</th>
<th>Market Share</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guidant</td>
<td>43%</td>
</tr>
<tr>
<td>Johnson &amp; Johnson</td>
<td>36%</td>
</tr>
<tr>
<td>Medtronic</td>
<td>13%</td>
</tr>
<tr>
<td>Boston Scientific</td>
<td>7%</td>
</tr>
</tbody>
</table>


Figure 19 Stent Market Shares, 2001

4.3. Emerging Technologies

Boston Scientific is developing the company’s cardiovascular business by investing its R&D efforts in the following technologies: balloon catheters, guide catheters, guidewires, grafts, stents, intravascular ultrasound, and diagnostic devices. The following nine products are listed in their interactive 2002 and 2003 annual reports as future product growth areas for the company.

Carotid Wallstent® Monorail™ Endoprosthesis

The Carotid Wallstent® Monorail™ device is a self-expanding stent which is mounted on a rapid exchange deployment system. The device is designed to keep the carotid arteries open and improve blood flow to the brain. The device was the first carotid stent to receive a CE Mark, and is the leader in the European market. It is currently in clinical trials in the U.S.

Cutting Balloon Ultra²™ Microsurgical Dilatation Catheter

Boston Scientific’s current Cutting Balloon™ device technology has captured 15 percent of the U.S. balloon market, and they are now awaiting FDA approval of its successor, the Cutting Balloon Ultra²™ device. The new device combines the company’s Maverick™ balloon catheter technology with their Bioslide™ coating and enhancements to the balloon and microsurgical blades. These improvements are designed to provide clinicians with greater deliverability and trackability to a resistant lesion.
FilterWire EX™ and FilterWire EZ™ Embolic Protection Systems

The FilterWire EX™ is a low profile embolic filter mounted on a rapid exchange deployment system. The device is designed for coronary and carotid stent interventions to capture embolic debris which may be released when the blood vessel is enlarged. The device acts as a net to catch the debris and prevent a possible heart attack or stroke. The FilterWire EX product is currently pending approval in the U.S., and when launched is expected to be the first filter-based embolic protection system in the U.S.

Greenfield® RP Vena Cava Filter

The Greenfield® Vena Cava Filter is a cone-shaped permanent implant designed to prevent pulmonary embolism (PE) by capturing and dissolving an embolized clot. (Every year, about 200,000 people in the U.S. die from PE). This condition is a result of blood clots that form in the legs (known as deep vein thrombosis) that travel up through the heart and lodge in the lungs. The Greenfield filter design already has 30 years of proven clinical performance, and is recognized by doctors as the top medical standard in patient protection. The Greenfield RP Vena Cava Filter is currently in final development, and will reduce the size of the delivery system while maintaining long-term clinical efficacy. In the U.S., where most filters are used, all currently available designs are for permanent implantation. However, a second filter development effort now under investigation is designed to offer the possibility of being removed. This technological advancement will widen the range of patients who could benefit from the life-saving protection of a Vena Cava Filter.

Liberté™ Stent System

The Liberté,™ Stent System is a next-generation stent which is a follow up to the TAXUS™ paclitaxel-eluting coronary stent. The Liberté stent features a thinner strut design to provide improved deliverability and greater vessel conformability. The design is expected to improve patient outcomes in some of the more difficult clinical cases. Once approved, this new technology will be available in both a bare metal stent system and a paclitaxel-eluting stent system.

Matrix™ Detachable Coils

The Matrix™ Detachable Coil platform is a next-generation aneurysm therapy that builds on the established Guglielmi Detachable Coil (GDC®) technology. The current GDC product consists of platinum coils that are inserted through the femoral artery, advanced into the brain, and coiled into an aneurysm to prevent it from rupturing. The Matrix Detachable Coil device is made of platinum and a bioabsorbable co-polymer, and is designed to treat recurring aneurysms or aneurysms that are more likely to recur. Once inserted, the co-polymer reabsorbs and promotes healing of the aneurysm. The Matrix Detachable Coil has received clearance from the FDA for endovascular treatment of cerebral aneurysms and was granted the CE Mark in Europe. This technology is being introduced into selected worldwide markets in conjunction with physician training programs. In the U.S., it is estimated that nearly 18 million people will develop a brain aneurysm during their lifetimes.

Neuroform™ Microdelivery Stent System (MSS)

The Neuroform™ MSS is an ultra-thin, self-expanding nitinol stent used in the treatment of brain aneurysms in the approximately 25 percent of patients who cannot be treated with coils alone. The device is the first micro-catheter delivered neurovascular stent which is specifically designed to bridge the opening of “wide neck” aneurysms to keep coils in place once they are inserted. The Neuroform stent gained FDA approval as a Humanitarian Use Device (HUD) in 2002, and is currently available in Europe and other international markets.
Sentinol™ SE Nitinol Stent System

The Sentinol™ Self-Expanding Nitinol stent is expected to be the only large-diameter nitinol stent available in the market. Once approved by the FDA, the Sentinol stent will have a biliary indication to treat malignant neoplasm. (In the self-expanding stent market, 60 percent of the devices are stents made of nitinol, a metal alloy that allows for more precise placement.)

Symbiot™ Covered Stent System

The Symbiot Covered Stent System (CSS) is specifically designed for use in treating saphenous vein graft (SVG) disease. The design of the Symbiot CSS addresses the two major limitations of treating SVG disease: (1) the risk of plaque embolization during the procedure, and (2) poor long-term outcomes. From the approximately 600,000 coronary artery bypass graft surgeries performed worldwide annually, about 250,000 patients develop SVG when saphenous veins are taken from the leg and used as grafts in coronary artery bypass surgery. The Symbiot CSS features a self-expanding nitinol stent encased in a thin porous ePTFE polymer membrane. The ePTFE cover and self-expanding deployment are intended to work together to reduce plaque embolization during the stenting procedure and provide a long-term patient benefit by reducing restenosis. The Symbiot product is available in Europe and other international markets and is currently in U.S. clinical trials.

Other Emerging Technologies

Anastomotic Assist Device For Multiple-Vessel Heart Bypass Surgery

Novare Surgical Systems Inc., announced in February 2004 it received clearance from the FDA to market its Enclose® II Cardiac Anastomosis Assist Device. The device is used by surgeons to attach a bypass vessel to the aorta during on-pump and off-pump (or beating-heart) coronary artery bypass graft surgery. The improved device incorporates a 40 percent lower profile for trouble-free handling in the surgical field, 20 percent larger suture area in a hexagonal shape for easier vessel attachment, and remote actuation by the surgeon.

Contegra® Pulmonary Valved Conduit

In November 2003, Medtronic Heart Valves received FDA humanitarian device approval for their Contegra® Pulmonary Valved Conduit, a bioprosthetic heart valve made from a segment of cow (bovine) jugular vein. (The device is a prosthesis made from biological material). It is treated with preservatives to keep it durable, flexible, and sterilized for human implantation. The vein contains a venous valve with three leaflets (trileaflet) that open to allow the forward flow of blood and close to prevent the backward flow of blood. At the time of implantation, the surgeon removes the patient’s defective pulmonary valve and artery and replaces them with the valved conduit. The Contegra Pulmonary Valved Conduit functions like the patient’s natural pulmonary valve. Three leaflets flap open to permit blood flow from the right ventricle into the pulmonary artery and then to the lungs. In conjunction with the three other heart valves (tricuspid, aortic, and mitral), this device controls the direction of blood flow through the chambers of the heart. The conduit portion of the device allows for the replacement of part of the patient’s own pulmonary artery, as needed.

daVinci™ Surgical System

The daVinci system was developed by Intuitive Surgical, Inc. in 1995, and it was approved by the FDA in May 2001. The daVinci System is the first intuitive laparoscopic robot currently available. It provides surgeons and patients two main advantages: (1) it has the benefits of a minimally invasive procedure, and (2) it gives surgeons the ability to see what they are working with as clearly as if they were performing open surgery. Radical prostatectomies are its most common application, but it is also cleared for use in general laparoscopic surgery, thorascopic surgery and thorascopically assisted cardiotomy procedures. The system is cur-
currently in clinical trials for additional applications within cardiac surgery, including coronary artery bypass.

**Genetic Research Discoveries**

The Cardiovascular Research Center (CVRC) at Massachusetts General Hospital has made several ground-breaking discoveries which include: (1) cloning of the first vertebrate cell death genes, and (2) performance of the first large-scale genetic screen in a vertebrate (the zebrafish). From these screens, it is then possible to identify genes critical to cardiac pacemaking, rhythm, and contractile function, genes needed for the pattern assembly of a normal heart, as well as a new methylase gene responsible for altering DNA structure during a person’s lifetime.

**Heartsbreath Test**

In February 2004, Menssana Research Inc. received FDA humanitarian device approval for their *Heartsbreath* test, a breath test that is used along with a traditional heart (endomyocardial) biopsy on patients who have received a heart transplant within the past year. This test measures possible organ rejection in heart transplant patients. The Heartsbreath test works by measuring the amount of methylated alkanes (natural chemicals found in the breath and air) in a patient’s breath. The patient breathes into a plastic mouth piece that is attached to a breath collecting device. The device subtracts the amount of methylated alkanes in a patient's breath from the amount of methylated alkanes in the room air. The value generated by the device is then compared to the results of a biopsy performed during the previous month to measure the probability of the implanted heart being rejected.

**Implantable Pulse Generator**

In January 2004, Guidant Corp. received FDA approval for its CONTAK® RENEWAL™ TR system, an implantable pulse generator (IPG) that delivers cardiac resynchronization therapy (CRT). The CRT portion of this device uses small electrical pulses to coordinate the heartbeat and improve blood pumping ability in certain patients with moderate to severe heart failure. The system consists of an IPG that is made up of a battery and electronic circuitry connected to three independent leads (insulated wires). The IPG is usually implanted below the collarbone, just beneath the skin. The leads are placed in three different areas: one in an upper heart chamber (the right atrium), a second in a lower heart chamber (the right ventricle), and a third in a vein that overlies the left ventricle. The CRT portion of the device coordinates the beating of the left and right ventricles so that they work together more effectively to pump blood throughout the body.

**Implantable Replacement Heart**

Abiomed Inc. is currently developing the AbioCor™ Implantable Replacement Heart, a totally implantable, battery-powered heart replacement device intended for patients with irreparably damaged hearts who are at risk of death due to acute myocardial infarction, chronic ischemic disease or some form of end-stage congestive heart failure, but whose vital organs otherwise remain viable. The AbioCor is in an advanced stage of development and the company is devoting significant resources to help ensure that the AbioCor is the first replacement heart to reach the market. (The AbioCor has not been approved for commercial distribution, and is not yet available for use or sale outside of the initial clinical trial.)

The company also offers a bridge-to-recovery device called the BVS® 5000 cardiac support system. The device provides a patient's failing heart with full circulatory assistance while allowing the heart to rest, heal and recover its function. The BVS 5000 has been approved by the FDA for the treatment of all patients with potentially reversible heart failure. It is now the most widely used advanced cardiac assist system in the world. It is installed in hundreds of leading medical centers worldwide. The BVS 5000 is most frequently used with patients
Cardiovascular

whose hearts do not immediately recover their function following heart surgery.
http://www.abiomed.com/

Left Ventricular Assist Device

The Columbia Weill Cornell Heart Institute is developing a left ventricular assist device (LVAD) which is a mechanical pump that enhances the function of the left ventricle. The device consists of an electric pump, an electronic controller, and a power supply. The pump, which is about the size of a person’s palm, is implanted in the abdominal cavity. The pump is connected to the heart at two points. The blood is diverted from the left ventricle into the pump and then propelled into the aorta, where it can help a weakened heart circulate blood until a donor organ becomes available. There are also indications from recent U.S. clinical research that the device may also be useful as long-term therapy for heart failure, rather than a temporary bridge to transplantation. Researchers have found that patients with the implanted device had more than a 50 percent chance of surviving a year, compared with a 25 percent survival rate for patients who took drugs and were medically monitored. This breakthrough therapeutic option could benefit up to 100,000 people who are terminally ill with end-stage heart failure for which transplant is not possible.10

Left Ventricular Assist System

Thoratec Corporation announced on May 3, 2004 it received FDA approval to expand its Phase I feasibility trial for the HeartMate(R) II left ventricular assist system (LVAS). The HeartMate II is a next generation heart assist device designed to provide long-term cardiac support for patients with end-stage heart failure. The HeartMate II is an implantable LVAD consisting of a rotary blood pump designed to provide long-term support. It weighs approximately 12 ounces, making it significantly smaller than currently approved devices. The device has only one moving part, is designed to operate more simply and quietly than other approved devices, and has a much longer functional life. The company hopes to use the data from this initial trial for approval of an expanded trial that will also study use of the device for Destination Therapy.

MYOLIFT Heart Retractor and FLEXSITE Heart Stabilizer

Cardiovations, a division of Ethicon, a Johnson & Johnson company, announced in March 2003 the introduction of the MYOLIFT Heart Retractor, and the FLEXSITE Heart Stabilizer, instruments that help position the heart and stabilize the coronary artery during beating heart cardiac surgery. The devices can be used together to expose coronary vessels and permit precise placement of stabilization "feet" to hold the coronary artery in place, allowing cardiac surgeons to bypass the blocked artery without resorting to the traditional method of stopping the heart and employing the heart/lung machine.

VAD Child Heart Pump

MicroMed Technology, Inc. announced in March 2004 that it received FDA Humanitarian Device Exemption (HDE) approval to provide transplant centers with the DeBakey VAD Child heart pump. The device is designed to improve blood flow for children aged 5 to 16 who are awaiting a heart transplant. The DeBakey VAD Child utilizes the technology of the implanted adult pump and further miniaturizes it for use in children. This is the first VAD approved by the FDA for use in children. The miniaturized heart pump is designed to provide increased blood flow (up to 10L/min) from the left ventricle of the heart throughout the body for patients in end stage heart failure.

Vascular Grafts

LifeCell Corp. is developing acellular vascular grafts as a potential alternative to autografted (from the patient) blood vessels in peripheral vascular and coronary bypass procedures. Currently, physicians often treat severe coronary artery disease by surgically bypassing blocked arteries using blood vessel grafts obtained from another part of the patient's body. Their harvest often causes patients considerable donor-site morbidity and pain. In addition, patients undergoing repeat bypass procedures or individuals whose vessels are significantly diseased often have no appropriate blood vessels available for this use. The use of LifeCell vascular grafts may eliminate many of these problems and offer significant benefits in terms of improved function, reduced patient morbidity, improved convenience, and decreased cost. (Coronary artery disease affects approximately 12 million people in the U.S.)

Thermo Imaging and Ultrasound for Stent Placement and the Detection of Heart Blockages

Two other emerging technologies that are in very early stage research in the cardiovascular area include research into the imaging of temperatures in blood vessels to help determine where to place stents, and the use of ultrasound to detect heart blockages. The temperature of the blood vessel at the specific location increases as the blood vessels become clogged. This new technology will help doctors quickly identify the exact location where to put a stent.

4.4. Major Competitors in the Cardiovascular Market

- **Arrow International, Inc.** is a publicly traded company that develops, manufactures and markets cardiac care products that are used for the diagnosis and treatment of patients with heart and vascular disease. Arrow has a line of disposable critical care catheterization products which are used primarily to access the central vascular system for administration of fluids, drugs and blood products. These products are also used for patient diagnosis, monitoring, and pain management. Arrow is a leading supplier of central vascular access catheterization products worldwide. [http://www.arrowintl.com/](http://www.arrowintl.com/)

- **Boston Scientific** is a leading worldwide developer, manufacturer and marketer of medical devices. The company offers a broad range of innovative products, technologies and services across six medical specialties including Interventional Cardiology, Electrophysiology, Endoscopy, Oncology, Urology, and Neurovascular. The company’s interventional cardiology business is a leading developer of medical technologies used to diagnose and treat cardiovascular disease and other cardiovascular disorders. (The company’s interventional cardiology products are used in approximately one million procedures annually). Boston Scientific is also a leading developer of medical technologies used in cardiac electrophysiology, a field that focuses on the heart's electrical system. The company also manufactures devices for the diagnosis and treatment of cardiac conditions called arrhythmias (abnormal heartbeats). Boston Scientific employs approximately 15,000 persons and had revenue of $3.5 billion in 2003. [http://www.bsci.com](http://www.bsci.com)

- **Cordis Corporation**, a subsidiary of Johnson & Johnson, is a global leader in developing and marketing devices for circulatory disease management. The company’s product line includes stents, balloons and catheters which are used in treating cardiovascular disease and related conditions. Products are marketed by clinical application through four main divisions: (1) Cordis Cardiology for coronary applications; (2) Cordis Endovascular for all peripheral applications; (3) Cordis Neurovascular for neurological applications; and (4) Biosense Webster for electrophysiology and medical sensor technology in endocardial procedures. Cordis is a world leading developer and manufacturer of breakthrough products for interventional medicine, minimally invasive computer-based imaging, and electrophysiology. Worldwide sales for Cordis totaled $2.7 billion in 2003 and increased 65 percent over 2002. (U.S. sales of this subsidiary are not broken out separately in the J&J
consolidated financial statements.) The primary driver of this sales growth for 2003 was the CYPHER® Sirolimus-eluting Stent that was approved in the U.S. by the FDA in April 2003. This device is used for the treatment of coronary artery disease, and has been implanted in approximately half a million patients worldwide. www.cordis.com

- **Ethicon, Inc.**, a subsidiary of Johnson & Johnson, is a worldwide developer, manufacturer and marketer of products used in cardiovascular surgery. The company’s CARDIOVATIONS® division features minimally-invasive surgical devices that help restore and improve cardiac health. Worldwide sales for Ethicon totaled $2.6 billion in 2003 and increased 6 percent over 2002. Headquartered in Somerville, New Jersey, ETHICON is currently doing business in 52 countries, and employs approximately 11,000 persons worldwide. www.ethiconinc.com

- **Guidant Corp.** is a world leader in the design and development of cardiovascular medical products. The company was incorporated in 1994, and since has grown to $3.7 billion in revenue and more than 12,000 employees. In 2003, 40 percent of the company’s revenue came from implantable defibrillator systems, 18 percent from pacemaker systems, 11 percent from U.S. end-user coronary stent systems, 25 percent from other coronary stent systems and angioplasty, and 6 percent from cardiac surgery, biliary, peripheral and cardiovascular systems. The company generated 68 percent of its revenue in the U.S. while 20 percent came from Europe, 9 percent from Japan and 3 percent from all other countries. www.guidant.com

- **Medtronic** is a world leading medical technology company with a focus on treating patients with chronic disease. Primary products in the cardiovascular area include medical devices and technology to treat bradycardia, tachyarrhythmia, heart failure, atrial fibrillation, coronary vascular disease, endovascular disease, peripheral vascular disease, and heart valve disease. In 2003, net sales increased by $1.254 billion or 19.6 percent to reach $7.665 billion. The increase in net sales was driven by growth in their Cardiac Rhythm Management (CRM), Ear, Nose, and Throat (ENT), Spinal, and Surgical Navigation Technology (SNT) operating segments. CRM net sales increased 23 percent over 2002 to total $3.631. CRM growth was driven by new product introductions, continued strong growth in existing products, growth in the emerging heart failure market, and the acceleration in growth of the tachyarrhythmia market, resulting in a 47 percent increase in net sales of implantable defibrillators and a 10 percent increase in net sales of pacing systems. Consolidated U.S. sales for all product segments totaled $4.449 billion. The company employs 30,000 persons worldwide. www.medtronic.com

- **St. Jude Medical, Inc.** develops, manufactures and distributes cardiovascular medical devices for the global cardiac rhythm management (CRM), cardiac surgery (CS) and cardiology and vascular access (C/VA) therapy areas. The company's principal CRM products are bradycardia pacemaker systems, tachycardia implantable cardioverter defibrillator systems and electrophysiology catheters. Its principal CS products are mechanical and tissue heart valves, and valve repair products. The line of C/VA products include vascular closure devices, angiography catheters, guidewires and hemostasis introducers. The principal geographic markets for St. Jude Medical's products are the United States, Europe and Japan. The company also sells its products in Canada, Latin America, Australia, New Zealand and the Asia-Pacific region. www.sjm.com

- **Thoratec Corporation** is engaged in the research, development, manufacturing and marketing of medical devices for circulatory support and vascular graft applications. The company’s Thoratec® VAD System is the only ventricular assist device that is approved for use both as a bridge to transplant and for recovery from open-heart surgery. The company is also a leader in the research, development and manufacture of implantable left ventricular assist systems (LVAS). Thoratec also supplies whole-blood coagulation testing equipment and related disposables, as well as single-use skin-incision devices through its wholly-owned subsidiary, International Technidyne Corporation (ITC). www.thermocardio.com
• **WorldHeart Corporation** is a global provider of implantable heart-assist devices that deliver pulsatile blood flow for temporary and long-term support. WorldHeart’s Novacor® LVAS is well established in the marketplace, and has approval for use throughout the world. The Novacor® LVAS is the first successful Bridge-to-Transplant device, and is the first and only left ventricular assist device to meet the multi-year Device Readiness Test Protocol of the U.S. National Institute of Health, and the first to surpass six years of support in a single patient. Company revenues for the first quarter of 2004 were $3.5 million on shipment of 51 Novacor® LVAS implant kits. The company maintains headquarter operations in Ottawa, Canada and Oakland, California. [www.worldheart.com](http://www.worldheart.com)
5. Orthopedics

By David Kouidri, Swiss Trade Commissioner for the Midwest

5.1. Facts and Figures

Behind cardiovascular, orthopedics is the second most important sector in the U.S. medical implant markets accounting for 24% of the U.S. medical device industry and is projected to experience a growth rate of 7 - 9%. Orthopedic devices are used for the repair and replacement of skeletal problems and include products such as artificial body parts, joint replacement, products used for repairing broken bones (splints, pins, screws, and plates), devices for spinal column repair, and arthroscopic equipment for vision and camera applications.

![Figure 20 The Importance of Orthopedics in the Projected U.S. Medical Device Market 2005](source.png)

According to Standard and Poors, the global orthopedic market in 2002 was $13 billion, and the US accounted for approximately 60% of total sales, or $7.6 Billion. In 2004 that figure increased by 44%, or 22 % per annum to a figure of $10.9 billion. The most dominant products within the orthopedic sector are devices that are implanted for reconstruction in hip, knee, and spine. These are the areas that continue to experience the most growth at a rate over 20%.

<table>
<thead>
<tr>
<th>Category</th>
<th>2002</th>
<th>2004</th>
<th>2004 Share</th>
<th>Avg. Annual Growth (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reconstructive Devices</td>
<td>3,085</td>
<td>4,620</td>
<td>42</td>
<td>25</td>
</tr>
<tr>
<td>Spinal Products</td>
<td>1,425</td>
<td>2,210</td>
<td>20</td>
<td>27</td>
</tr>
<tr>
<td>Fixation</td>
<td>990</td>
<td>1,555</td>
<td>14</td>
<td>29</td>
</tr>
<tr>
<td>Arthroscopy</td>
<td>700</td>
<td>830</td>
<td>8</td>
<td>19</td>
</tr>
<tr>
<td>Softgoods and bracing</td>
<td>485</td>
<td>545</td>
<td>5</td>
<td>12</td>
</tr>
<tr>
<td>O.R. Supplies</td>
<td>285</td>
<td>315</td>
<td>3</td>
<td>11</td>
</tr>
<tr>
<td>Powered Surgical Equipment</td>
<td>195</td>
<td>215</td>
<td>2</td>
<td>10</td>
</tr>
<tr>
<td>Bone Cements and Accessories</td>
<td>170</td>
<td>205</td>
<td>2</td>
<td>21</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>7,600</td>
<td>10,940</td>
<td>100%</td>
<td>22</td>
</tr>
</tbody>
</table>

*Source: Standard & Poors Medical Device Survey 2003*

*Figure 21 2002 and 2004 Musculoskeletal Products Market in Million US$*
As with many fields in the medical device sector, the aging population will have a direct effect on the demand of orthopedic products and services. The higher demand is also beginning to affect prices as the cost for knee and hip replacement has gone up by 90% over the last decade. Over 65% of the orthopedic hip replacements in the U.S. are done on patients 65 years or older and 75% of knee replacements are to patients 65 and older. It is interesting to note that doctors are reporting an increase in procedures on individuals in their 40's and 50's. This trend used to be discouraged as the life span of an implant, which averaged 10 - 15 years, required such individuals to go through two or even three replacements throughout their life. This trend is obviously gaining demand as the implant life span increases.

**Figure 22 Orthopedic Market Segmentation 2002**

The orthopedic market is predominantly driven by the reconstructive surgery segment which makes up 41% of the orthopedic market, followed by Spinal (15%), and trauma (13%). Reconstructive joint implants are to remain the largest segment in the field as the increased elderly population demand more procedures. It is estimated that joint replacements, spinal hardware, external and internal fixation and arthroscopy products make up 75% of the market.

**Figure 23 Orthopaedic Implant Market Share 2001**

The predominant characteristics of the orthopedic market are twofold: 1) close relationships between surgeons and orthopedic manufacturers and 2) the importance of research and development. The relationship between orthopedic doctors and orthopedic companies is very intense and includes sales discussions, as well as research and design issues. Due to the small amount of large suppliers of orthopedic devices, there is a very competitive environment to gain access and loyalty from the orthopedic surgeon. In the field of orthopedics, on average, companies allocate 33% of their budgets to market and sell to doctors, compared to 27%.
in the consumable market. It is this relationship that helps drive the acceptance of new technologies. New technologies are an important driver of the industry with 10% of budgets going back into product development, compared to 6% in other medical fields. It must also be said new technologies are looked at favorably by doctors and are not price sensitive.

Source: Center for Medicaid and Medicare

**Figure 24 Budgetary allocation of Medical Device Companies (%)**

![Pie chart showing budget allocation]

**Hip and Knee Replacements Market**

Hip and Knee implants are the main reconstructive procedure in the orthopedic sector. In 2001 the segments together represented 60.2% of the total implant market of $3.4 billion. The most common cause of hip and knee replacements is osteoarthritis, or degenerative joint disease, the wear and tear of joints. Around 21 million Americans have osteoarthritis and by 2020 this number is estimated to jump to 30 million as the common age of this disease is 45. As the U.S. population grows older, so will the cases of osteoarthritis. In 2002, surgeons performed approximately 266,000 knee replacements and 160,000 artificial hip implants.

Source: Standard & Poor's Healthcare Industry Report

**Figure 25 Estimated Market Share of Top Hip Implant makers 2003**

The average cost of a hip or knee replacement procedure is $20,000 - 35,000 and has a good success rate. The average age for a hip replacement patient is 66. The average life span for a hip replacement is 10 - 15 years whereas a knee replacement can last up to 20 years.
Spinal Implants

According to Standard and Poors, the spinal market represents $2.4 billion and is experiencing a growth rate of more than 20% annually. It is estimated that there are over 10,000 spinal cord injuries per year of which 50% of which are due to car and motorcycle injuries and 20% are due to sports or violent acts. All together it is estimated that there are over 1.1 million spinal cord operations performed in the U.S. each year both to treat injuries and also to correct degenerative conditions including post injury conditions. Most common spinal procedures involve fusion, where unstable vertebrae are fused in order to stop painful motion. Products that are involved with this procedure include plates, screws, rods, spinal cages, and bone dowels.

Arthroscopic Knee Surgery

One of the more popular treatments for people with osteoarthritis is the minimally invasive procedure known as Arthroscopic surgery. However, it has recently come to the attention of scientists and medical experts that this procedure may not be as effective as previously thought. A recent study cited in the New England Journal of Medicine in July 2002, showed that the surgery was no more effective than those who received a placebo. One in three patients claimed improvement whether they had the surgery or not, casting definite doubt on the effectiveness of the procedure that usually costs $5,000 and is performed on 200,000 Americans annually.
Other Orthopedic Procedures

The National Center for Health Statistics (NCHS) has suggested that around 59 million Americans suffer from at least one foot problem each year. Based on an interview of 46,476 U.S. households, the NCHS estimates the following causes of foot problems with the numbers of Americans concerned:

- Infections: 11.26 Million
- Toenail problems: 11.26 million
- Corns or calluses: 11.17 million
- Injuries: 5.59 million
- Flat Feet/Fallen Arches: 4.62 million
- Bunions: 4.37 million
- Arthritis: 3.9 Million
- Toe/Joint deformity: 2.52 million

The Academy of Orthopedic Surgeons reports that 43.1 million Americans have foot problems and 36% view their problem as serious and requiring medical attention. The level of problems increases from 70 to 100% on those 50 years or older.

Over 3 Million Americans suffer from Plantar Facilitis a condition affecting the tendon like connector between the heel and toes. It is suggested that over 7 million have the symptom but decide not to seek attention. It predominantly affects women ages 40 - 50. However, as more Americans take on activities such as running, it is projected that more individuals will seek attention. About 5% of all cases require surgery.

Hospital Orthopedics

A 2002 survey by Merritt, Hawkins & Associates found that orthopedic doctors each generate an average of $1.86 million annually of inpatient and outpatient income for a hospital, ranking

**Figure 28 Orthopedic Trauma Market Share**

A 2002 survey by Merritt, Hawkins & Associates found that orthopedic doctors each generate an average of $1.86 million annually of inpatient and outpatient income for a hospital, ranking
fifth among 20 specialties. Orthopedics have historically been among a hospital's most lucrative services. Emerging technologies and competition, however, are posing a challenge for hospitals to maintain this lucrative business. Advances in medical techniques and devices have pushed many procedures to outpatient settings, reducing the need for hospital orthopedics. In addition, increasing device costs and stagnant reimbursements are making many procedures less profitable.

Top Hospital Orthopedic Centers (Source: U.S. News & World Report, August 4, 2003)

- Mayo Clinic (Rochester, Minnesota)
- Hospital for Special Surgery (New York, New York)
- Massachusetts General Hospital (Boston, Massachusetts)
- Johns Hopkins Hospital (Baltimore, Maryland)
- Cleveland Clinic
- Duke University Medical Center (Durham, North Carolina)
- UCLA Medical Center (Los Angeles, California)
- University of Iowa Hospitals and Clinics (Iowa City)
- Harborview Medical Center (Seattle, Washington)
- University of Michigan Medical Center (Ann Arbor)
- Rush-Presbyterian-St. Luke's Medical Center (Chicago)
- Stanford Hospital and Clinics (Stanford, California)
- University of Pittsburgh Medical Center
- Brigham and Women's Hospital (Boston, Massachusetts)
- Barnes-Jewish Hospital (St. Louis, Missouri)
- Parkland Memorial Hospital (Dallas, Texas)
- University of California (San Francisco Medical Center)
- New York-Presbyterian Hospital
- Thomas Jefferson University Hospital (Philadelphia, Pennsylvania)
- Northwestern Memorial Hospital (Chicago) Major Competitors

5.2. Major Competitors

![Figure 29 Market Share of Reconstructive Industry 2001](Source: Annual 2001 Menu, Biomet)
The U.S. orthopedic market has been going through a period of consolidation. As shown in Figure 29 today there are 5 major players in the field of orthopedics, namely, Stryker, Zimmer, Smith & Nephew, DePuy (J & J), and Biomet.

- **Biomet, Inc.** Headquartered in Warsaw, Indiana, Biomet was incorporated in November of 1977. As a leader in the field of musculoskeletal repair, Biomet was one of the first companies to promote the use of titanium alloy for its orthopedic implants thanks to its high biocompatibility, strength, durability and elasticity. Titanium alloy is now the material of choice for orthopedic implants. Biomet also introduced the use of plasma spray, or titanium porous coating that encourages bone growth onto the implant. Other developments include hip stems with a tapered design to reduce stress on the femur. Biomet had sales of approximately $1.4 billion with over 50 facilities, including 18 manufacturing facilities, and a combined sales force of approximately 2,100 sales representatives. ([www.biomet.com](http://www.biomet.com))

- **DePuy Orthopedics**: Headquartered in Warsaw, Indiana and founded in 1895, DePuy is the oldest manufacturer of orthopedic implants in the United States. DePuy is credited as an innovator in the development of the total hip replacement procedure, a major contribution to what the orthopedic market has become today. DePuy is a subsidiary of Johnson and Johnson. ([www.depuy.com](http://www.depuy.com))

- **Smith and Nephew** is a designer, manufacturer and marketer of joint replacement systems for knees, hips and shoulders as well as trauma products to help repair broken bones. In addition, Smith & Nephew provides medical devices for pain management in joints. Smith and Nephew advocates service as a major part of their business. Specifically, they are known for their nail systems to repair broken bones allowing for quicker and less invasive procedures. Other developments include the Exogen Bone Healing System, an ultrasound therapy that accelerates healing in bone fractures. Smith & Nephew employs over 7,000 people in 32 countries and had sales of $1.8 billion in 2003. ([http://www.smith-nephew.com/what/orthopaedics.jsp](http://www.smith-nephew.com/what/orthopaedics.jsp))

- **Stryker Orthopedics** Headquartered in Kalamazoo, Michigan, Stryker is one of the largest manufacturers and marketers of hip, knee, upper extremity, trauma and spinal systems, as well as bone cement and bone substitutes. Stryker Orthopedics is part of the $3.6 billion, 15,000 employee strong Stryker Corporation ([http://www1.stryker.com/jointreplacements](http://www1.stryker.com/jointreplacements))

- **Wright Medical Technology / Cremascoli** Headquartered in Arlington, Tennessee, WMT designs, manufactures, and markets orthopedic medical devices, and biologics. Products include large hip and knee implants, implants for hand, elbow, shoulder, foot and ankle; and both synthetic and tissue-based bone graft substitute materials. Wright has been around for over 50 years and employs over 750 employees. Targeted sales for 2004 are $300 million. ([www.wmt.com](http://www.wmt.com))

- **Zimmer Holdings** Headquartered in Warsaw, Indiana, Zimmer is one of the leaders in orthopedic products supplying over 8,000 products in the field. In 2003, Zimmer acquired Centerpulse, the Swiss manufacturer of orthopedic products and has retained a large research and development facility in Switzerland. Zimmer employs over 6,500 people in 70 countries and has sales of $1.9 billion in 2003. ([www.zimmer.com](http://www.zimmer.com))

### 5.3. Emerging Technologies

It is clear that in the field of orthopedic implants, new technologies are being developed that will dramatically change the field including the elimination of certain procedures, the reduction of length of stay of the patient, life span on implants and many others.
One of the driving forces in the field of orthopedics is the life span of the implants that are used. Due to the aging U.S. population and the demand by the individual for a more active lifestyle in the older age bracket, the demand on implant procedures has increased among a younger generation, such as 45 – 50 year olds. Therefore the need for longer lasting implants has become a major area of research and new technology development. Technology developments are in the area of implants themselves, bonding materials, as well as alternative therapy.

**Ceramic Implants**

In February 2003 the FDA approved two newly designed hip implants made of durable ceramic. Stryker and Wright Medical are the two companies that make the ceramic implants which consist of a ceramic ball that fits into a ceramic lined socket. The traditional joint replacement implant is made out of a metal ball fitted into a plastic socket. The metal ball and plastic socket are known to rub against each other producing a fine dust that degenerates the natural bone that is attached to the implant. It is for this reason that surgeons have been hesitant to perform hip replacements on patients 40 – 50 years old, making it necessary to perform hip replacement twice or even three times due to implant life of 10 – 15 years. The new ceramic implants introduced by Stryker and Wright, have proven to last up to 5 years longer than the traditional implants opening up the market to the younger generation.

**Shockwave Treatment**

HealthTronics Surgical Services (Ossatron) and Dornier MedTech (Epos Ultra) have won FDA approval for shock-wave treatment machines for plantar fasciitis. The new treatments and the use of shock waves to break up scar tissue to help increase blood flow and ultimately repair have been available in the U.S. since 2000. However, in a recent article in the Journal of the American Medical Association, an Australian research group has questioned the effectiveness of such therapies, stating that placebo therapy and the shock wave procedure had the same results. The treatment typically runs $3,000 to $5,000.

**Knee Navigation System**

Through a collaboration between Stryker divisions, a new tool was invented that helps doctors plot the landmarks and bone structures in the knee to plot out the impending surgery. Trackers will then assist the surgeon and his instruments making sure that placement of such instruments and movements are appropriate. The benefit is accuracy of cuts, placement of implants, and the reduction of soft tissue.

**Minimally Invasive Surgery**

Minimally invasive surgery is becoming a popular surgical procedure due to the less traumatic nature as well as the accompanying benefits including less pain and faster recovery of the patient. Reduced blood loss during the operation as well as a reduction of the patients stay in the hospital, are other benefits stemming from minimally invasive surgery. Areas of minimally invasive surgery include the knee, ankle, and other joints and applications on the spine are becoming more prevalent. Chapter 4 will address this field in greater detail.

**Laparoscopic Joint Replacement**

Laparoscopy is a term given to a group of operations that are performed with the aid of a camera. The technique has been used for major procedures such as abdominal illness and other diagnostic purposes. However, now laparoscopy is finding application in the orthopedic field offering diagnostic capability and assistance during minimally invasive surgery.
Gene-based bone regeneration methods

Human bone has the unique ability to repair itself also known as regeneration. The most common example is the natural repair of a bone fracture. There is however, regeneration applications that could include the development of applications for bone regeneration for orthopedic therapy including bone loss and skeletal defects. Research underway suggests that some applications could one day offer the ability to regulate bone regeneration as a therapeutic tool.

Nanotechnology

The new field of nanotechnology (the science of particles as small as an atom) has produced new applications in the medical field. The invention of “nanotubes” that assemble themselves using the same DNA could be an exciting new process for new implants and other artificial joints. Research has also shown that nanotube coated titanium implants attach to bone cells better than conventional materials.
6. Minimally Invasive Surgical Techniques

By Scot Orgish, Trade Commissioner, Swiss Business Hub, Houston, TX

6.1. Facts and Figures

The U.S. Market for Minimally Invasive Surgical (MIS) Devices and Equipment was estimated at $3.6 billion in 2002, and is forecast to grow at an average annual rate of 6.2 percent to a market value of $4.88 billion in 2007. MIS devices are leading the way in the Cardiothoracic segment accounting for $1.87 billion of market value in 2002. This segment will power the growth of the MIS device and equipment market as it increases an estimated 7.8 percent per year through 2007 to a forecast market value of $2.7 billion. This represents a market value growth of just under $1 billion over the 5 year period. Big growth is also expected in the MIS Orthopedic products segment which was estimated at $649 million in 2002. This segment is forecast to grow at an average annual rate of 8.0 percent to $953 million in 2007, an increase of $300 million over the 5-year period. A third segment that will experience above average growth is the MIS Vascular devices segment, which was valued at $70 million in 2002. This segment is expected to increase 6.7 percent per year through 2007 to a market value of $97 million. The MIS Plastic Surgery devices market is expected to more than double in size to $28 million by 2007.

<table>
<thead>
<tr>
<th>Type of Surgery</th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>2002-2007 (AAGR)</th>
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<tbody>
<tr>
<td>Gastrointestinal</td>
<td>687.7</td>
<td>695.3</td>
<td>702.9</td>
<td>710.6</td>
<td>718.5</td>
<td>727.0</td>
<td>1.1%</td>
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<tr>
<td>Gynecological</td>
<td>176.8</td>
<td>178.6</td>
<td>180.4</td>
<td>182.2</td>
<td>184.0</td>
<td>186.0</td>
<td>1.0%</td>
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<tr>
<td>Urological</td>
<td>114.0</td>
<td>115.8</td>
<td>117.7</td>
<td>119.6</td>
<td>121.5</td>
<td>123.3</td>
<td>1.6%</td>
</tr>
<tr>
<td>Plastic</td>
<td>12.6</td>
<td>14.8</td>
<td>17.3</td>
<td>20.3</td>
<td>23.9</td>
<td>28.0</td>
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<tr>
<td>Thoracic</td>
<td>43.2</td>
<td>43.5</td>
<td>43.9</td>
<td>44.2</td>
<td>44.6</td>
<td>45.0</td>
<td>0.8%</td>
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<td>Cardiothoracic</td>
<td>1,867.0</td>
<td>2,012.6</td>
<td>2,169.6</td>
<td>2,338.8</td>
<td>2,521.3</td>
<td>2,723.0</td>
<td>7.8%</td>
</tr>
<tr>
<td>Vascular</td>
<td>70.0</td>
<td>74.7</td>
<td>79.7</td>
<td>85.0</td>
<td>90.7</td>
<td>97.0</td>
<td>6.7%</td>
</tr>
<tr>
<td>Orthopedic</td>
<td>648.7</td>
<td>700.6</td>
<td>756.6</td>
<td>817.2</td>
<td>882.5</td>
<td>953.0</td>
<td>8.0%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>3,620.0</td>
<td>3,835.9</td>
<td>4,068.1</td>
<td>4,318.0</td>
<td>4,586.9</td>
<td>4,882.3</td>
<td>6.2%</td>
</tr>
</tbody>
</table>

Source: Business Communications Co. (BCC, Inc)

Figure 30 U.S. Market for Minimally Invasive Surgical Devices and Equipment Sales by Application ($ Millions Except AAGR)

There is a broad array of inpatient and outpatient procedures that make use of minimally invasive surgical techniques. Today, as many as 70 percent of all high-volume surgeries performed in the U.S. are done using laparoscopic techniques, and the trend is expected to continue in the future. Minimally invasive surgery is surgery performed without making a major incision or opening. This results in less trauma for the patient, and provides significant overall cost savings because of shorter hospitalization times and reduced therapy requirements. Other benefits of minimally invasive surgery include less pain, less need for post-surgical pain medication, less scarring, and reduced probability of complications related to the incision. Therefore, the definition of minimally invasive surgery is based on either (1) the operative procedure: small incisions, or (2) the outcome: reduced surgical complications or cost. However, it is important to note that minimally invasive surgery does not mean minor surgery. Some minimally invasive procedures, (such as coronary artery bypass surgery), are still major opera-
tions requiring a hospital stay. In minimally invasive surgery, a miniature camera is inserted into the body through a small incision where it transmits images back to a video monitor. The physician is then able to diagnose, and if necessary, treat a variety of conditions.

The most commonly performed minimally invasive abdominal procedure is gallbladder removal. Other abdominal conditions that may be treated laparoscopically include acute or chronic cholecystitis, choledolithiasis, choledocholithiasis, and obstructive jaundice due to gallstones or malignancy.

There are also a number of procedures on the upper Gastrointestinal (GI) tract that are now being performed laparoscopically. The most common is fundoplication to treat gastroesophageal reflux disease (GERD). Also, gastrectomy for benign gastric tumors (leiomyoma), cardiomyotomy for achalasia and esophageal resection can all be completed laparoscopically.

On the lower GI tract, laparoscopic colon resection for benign disease results in a decreased length of recovery for most patients. In addition, colostomy, repair of rectal prolapse and appendectomy can be completed to the patient’s advantage using laparoscopic methods as well as procedures for diverticulitis; inflammatory bowel disease; and bowel obstruction. Laparoscopic resection as a treatment for colorectal cancer is being studied actively.

Several organs or systems in the retroperitoneum can be treated laparoscopically. Benign, hormone-producing tumors of the adrenal gland can almost always be removed laparoscopically, with a clear decrease in the recovery time for the patient. Additionally, nephrectomy can be done through laparoscopic means, including nephrectomy from living donors for renal transplantation. Many patients with spinal or intervertebral disk disease can be treated surgically using the laparoscopic approach. These conditions include: Benign cortical adenomas of the adrenal glands; pheochromocytoma; herniated disk disease of the lumbar spine; and benign diseases of the kidney requiring nephrectomy.

Laparoscopic techniques can be used to remove the spleen for most patients with benign hematologic disease of the spleen. In some cases, the laparoscopic approach can be used for staging or therapeutic procedures in patients with malignancy. Laparoscopic splenectomy may be used to treat: idiopathic thrombocytopenic purpura (ITP); hereditary hemolytic anemia, such as spherocytosis; AIDS-related thrombocytopenia; splenic abscess; some lymphomas or hematologic malignancies.

Hemias that may be repaired laparoscopically include: hiatal hernia, inguinal hernia, ventral hernia, femoral hernia, and incisional hernia.

Other minimally invasive procedures are available for: lung cancer; coronary artery bypass and cardiac valvular surgeries; cryosurgery to treat prostate and kidney cancers; breast biopsy; surgical correction of spinal disorders; lung volume reduction surgery for emphysema; fibroid disease of the uterus; endometriosis; alternative treatments for post-menopausal women; and surgical techniques for pediatric and adolescent gynecology. 

Less-invasive treatment options for cardiovascular disease include the use of balloon angioplasty catheters and stent systems, embolic protection devices, cutting balloons, ultrasounds and imaging systems. These devices are used in a range of procedures including coronary angioplasty and stenting. Thoracoscopic procedures are used when the chest wall is accessed to perform biopsies of thoracic masses, spinal disectomy and fusion for scoliosis.

In the area of orthopedic surgery, Small Incision Total Knee Replacement (TKR) is a new, less invasive surgical technique that enables patients to recover faster, regain more mobility and experience less pain. In a recent study of over 100 Small Incision TKR surgeries, the new pro-

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11 Minimally Invasive Surgery at Allegheny General Hospital, website http://www.allhealth.edu/mis/serv/index.html
procedure has shown that patients recover far faster and regain excellent range of motion in four to six weeks compared to over three months with traditional TKR surgery.

<table>
<thead>
<tr>
<th>Patient</th>
<th>Less Scarring</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Shorter recovery times</td>
</tr>
<tr>
<td></td>
<td>Faster return to normal activities</td>
</tr>
<tr>
<td></td>
<td>Additional surgical options</td>
</tr>
<tr>
<td>Surgeons</td>
<td>Better clinical outcomes</td>
</tr>
<tr>
<td></td>
<td>Lower medical risks (improved quality)</td>
</tr>
<tr>
<td></td>
<td>Differentiation of services</td>
</tr>
<tr>
<td>Hospitals</td>
<td>Reduced costs via reduced lengths of stay</td>
</tr>
<tr>
<td></td>
<td>Improved clinical outcomes (quality)</td>
</tr>
<tr>
<td></td>
<td>Leverage for improved reimbursement</td>
</tr>
<tr>
<td></td>
<td>Differentiation</td>
</tr>
<tr>
<td></td>
<td>Growth potential</td>
</tr>
<tr>
<td>Insurers</td>
<td>Lower medical costs</td>
</tr>
<tr>
<td></td>
<td>Improved clinical care</td>
</tr>
<tr>
<td></td>
<td>Lower disability costs</td>
</tr>
<tr>
<td>Health Care Plans</td>
<td>Reduced total health care costs to employers</td>
</tr>
<tr>
<td></td>
<td>Improved clinical care</td>
</tr>
<tr>
<td></td>
<td>Competitive differentiation</td>
</tr>
<tr>
<td></td>
<td>Measurable quality improvements</td>
</tr>
<tr>
<td></td>
<td>Member satisfaction</td>
</tr>
</tbody>
</table>

*Figure 31 Benefits of Using Minimally Invasive Surgical Techniques*

6.2. Major Competitors

- **Acueity Inc.** is a private company located in Palo Alto, CA. The company develops, produces and markets medical products for physicians diagnosing and treating breast cancer in its early stages. Their patented Acuity micro-endoscopy system allows physicians to perform minimally-invasive procedures that may reduce the number and severity of conventional invasive surgeries in the future. [http://www.acueity.com/](http://www.acueity.com/)

- **American Cystoscope Makers, Inc. (ACMI)** is the largest producer of medical endoscopes and video systems for minimally invasive surgery. Products are supplied through 115 dealers in 72 countries. Formed in 1908, the company has been focused on the development and production of top quality endoscopy instrumentation for the medical industry. [http://www.acmicorp.com](http://www.acmicorp.com)

- **ArthroCare Corporation** seeks to become the global leader in soft tissue surgical technology. The company develops, manufactures and markets products based on a technology, called Coblation® technology. Coblation technology is a platform technology applicable across a broad range of soft tissue surgical procedures. Their patented Coblation process allows surgeons to operate with a high degree of precision and accuracy with minimal damage to surrounding tissue. ArthroCare's initial success has been in the field of arthroscopy. The company has also commercialized products based on the Coblation process for the spinal surgery, neurosurgery, cosmetic surgery, ear, nose and throat (ENT), and general and gynecology surgery markets. ArthroCare's long term strategy includes commercializing the benefits of Coblation technology in a range of other soft tissue markets. [http://www.arthrocare.com/](http://www.arthrocare.com/)

- **Boston Scientific** is a worldwide developer, manufacturer and marketer of medical devices with approximately 15,000 employees and revenue of $3.5 billion in 2003. The company is investing in less-invasive therapeutic technologies that could be introduced into the lungs through the mouth and throat, using a bronchoscope, to help treat patients
with pulmonary disorders. (A bronchoscope is a flexible tube used for visualizing and passing devices into the lungs.) In addition, the company is studying the use of drug-eluting stents in patients with multi-vessel coronary disease as an alternative to surgical intervention. The company is also developing less-invasive endovascular stent-graft technology that allows a physician to deliver a device through a small puncture in the groin, eliminating the need for surgical incisions. http://www.bsci.com

- **Clarus Medical** was founded in 2000, and has quickly become a world leader in endoscopic, minimally-invasive products for the treatment of spinal pain including back and neck pain, sciatica, herniated discs and other spinal disorders. Surgeons use endoscopes to see into the spine while they operate with lasers and specially designed instruments. http://www.clarus-medical.com/

- **Computer Motion Inc. (CMI)** is the global leader in pioneering and developing robotic systems for minimally invasive surgery. CMI was founded in 1989, and now has over 1500 robotic systems in use worldwide. CMI products are in use in 900 hospitals by over 3000 surgeons in 32 countries. More than 300,000 surgical procedures have been performed with their assistance. CMI is a publicly traded company with 225 employees worldwide. The company maintains a strong international presence, with offices and distributor relationships in Europe, Asia, South America, and the Middle East as well as North America. CMI merged with Intuitive Surgical in June 2003. http://www.computermotion.com/

- **Ethicon Endo-Surgery, Inc.** is a subsidiary of Johnson & Johnson. The company develops and markets a broad range of advanced surgical instruments for both less invasive and traditional surgery, as well as a line of safety catheters for vascular access. Worldwide sales for Ethicon-Endo totaled $2.6 billion in 2003. http://www.ethiconendo.com/

- **Gyrus Medical, Inc.** is a fast growth medical technology company focused on the management of tissue using less traumatic techniques during both open and endoscopic surgical procedures. Gyrus sells and markets its products through both direct channels and through distribution and licensing agreements with multinational healthcare companies. Their direct sales and marketing activities are focused on two market segments: (1) surgery on the lower abdomen including gynecological, urological and colorectal surgery; and (2) head and neck surgery including ear nose and throat (ENT), plastic, facial and reconstructive surgery. http://www.gyrusgroup.com/medical/

- **Integrated Surgical Systems, Inc.** designs, manufactures, sells and services image-directed, computer-controlled robotic products for use in orthopedic and neurosurgical procedures. The company’s ROBODOC® is a computer-controlled surgical robot equipped with specialized drill bits and other hardware for preparing bones for prosthetic implants. The robot drills cavities for hip implants, removes bone cement for revision surgeries, and planes surfaces on the femur and tibia for knee implants. The action of the robotic arm, equipped with the high-speed drill, is generally less traumatic than manual preparation techniques. http://www.robodoc.com/

- **Linvatec Corp.**, is a subsidiary of Conmed Corp., and is a leading arthroscopy/power surgical instrument equipment manufacturer in the U.S. The company is also a top market share leader globally. Linvatec is developing cutting edge technology for a growing range of least-invasive and orthopedic surgery procedures. Orthopedic surgeons use Linvatec arthroscopic instruments for diagnostic purposes, for minor surgeries and complex reconstructions of knees, shoulders and small joints such as the wrist and ankle. Linvatec's Hall® Surgical line of power surgical instruments are used for— oral/maxillofacial, otolaryngology, hand surgery, podiatry, thoracic surgery, and neurosurgery. Additionally, many procedures are supported by a variety of endoscopic and fiber optic products also made at Linvatec. Imaging instruments, including cameras, video monitors and VCRs, are manufactured at the Linvatec Imaging Systems division, located in Santa Barbara, California. http://www.conmed.com/
- Medtronic Xomed is a leading company in least invasive Functional Endoscopic Sinus Surgery (FESS) procedures. The company is also a leading developer, manufacturer, and marketer of other surgical products for use by Ear, Nose and Throat (ENT) specialists. The company markets over 6,500 microsurgical products worldwide. Their medical devices are designed for surgical procedures in the three major ENT subspecialties of Head & Neck, Sinus & Rhinology, and Otology. The company's core ENT products include powered tissue-removal systems and other microendoscopy instruments, nerve monitoring systems, disposable fluid-control products, implantable devices, and an image-guided surgery system. [http://www.xomed.com/]

- Mentice Medical Simulation is a leading supplier of virtual reality (VR) based applications within the field of medicine, with a focus on the area of minimally invasive surgery. Mentice established a new standard of VR-based training simulators for minimally invasive surgery when they introduced Procedicus VA (Virtual Arthroscopy) for shoulder surgery in 1999. The company now has a complete line of products in the areas of endovascular and cardiovascular intervention, laparoscopy and arthroscopy. [http://www.mentice.com/]

- Pilling Surgical is a leading manufacturer of handheld surgical instruments used in both open and minimally invasive procedures. The company offers both specialty instrumentation used in Cardiovascular, ENT, laparoscopic and orthopedic procedures, as well as a broad range of general instrumentation. [http://www.pillingsurgical.com/]

- Karl Storz is a global company that manufactures a wide range of reusable instruments and devices for many areas of minimally invasive surgery. In the area of cardiac surgery, the product range includes instruments for the endoscopic removal of the great saphenous vein, the thoracoscopic resection of the internal thoracic artery as well as a universal, modular retractor system for all conventional open heart interventions. For vascular surgery, the company offers a broad array of special instruments for laparoscopic, laparoscopy-assisted and hand-assisted abdominal aorta surgery as well as various instrument sets for the endoscopic treatment of perforating veins. The company also offers a wide range of MIS products for Maxillo-Facial and Oral surgery, ENT, Plastic Surgery, Thorax surgery, Gynecology, Urology, Proctology, and Arthroscopy. [http://www.karlstorz.com]

- Smith & Nephew was founded in 1856, and is a leader in each of their three specialist markets: Endoscopy, Orthopedics, and Advanced Wound Management. S&N currently operates in 32 countries, employs over 7,000 people and generates annual sales of £1.2 billion. Smith & Nephew Endoscopy focuses on repairing and healing the human body through minimally invasive techniques. [http://www.smith-nephew.com/]

- Stryker Corporation is a leader in the worldwide orthopedic market and is one of the world's largest medical device companies. Stryker offers an extensive selection of products including joint replacements (hip joint and total knee), spine and micro implant systems, endoscopic products, orthobiologics, trauma, powered surgical instruments, surgical navigation systems, as well as patient handling and emergency medical equipment. The company had net sales of $3.6 billion in 2003. [http://www.stryker.com/]

- United States Surgical is a unit of Tyco Healthcare Group LP. The company is a leading manufacturer of advanced surgical devices and wound closure products. In addition, the company also offers a line of instrumentation for minimally invasive surgery. The Auto Suture Division has a complete line of surgical products and instrumentation that surgeons utilize for laparoscopic, endoscopic and traditional open surgical procedures, and lymphatic mapping. The company is a market leader as its products are being used in an expanding range of new surgical specialties including Laparoscopic Colon, Laparoscopic Gastric Bypass, Laparoscopic Hernia, and Urology procedures as well as Minimally Invasive Gynecology, and Solid Organ Removal procedures. [http://www.ussurg.com/]

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6.3. Emerging technologies

**Carotid Artery Stent**

Johnson & Johnson is expected to receive FDA approval by late 2004 for its *Precise* stent which is designed to open clogged neck arteries. The *Precise* stent is positioned to be the first of its kind to receive FDA approval. Use of the *Precise* stent is expected to be a less invasive procedure than the current procedure called an endarterectomy, which accounts for about 140,000 surgeries a year.

**daVinci™ Surgical System**

The da Vinci System is the first “intuitive” laparoscopic robot currently available. The system was developed by Intuitive Surgical, Inc. in 1995, and it received FDA approval in May 2001. The robotic system offers surgeons and patients two major advantages: (1) it has the benefits of a minimally invasive procedure, and (2) it gives surgeons the ability to see what they are working with as clearly as if they were performing open surgery. Radical prostatectomies are its most common application, but it is also cleared for use in general laparoscopic surgery, thorascopic surgery and thorascopically assisted cardiotomy procedures. The system is currently in clinical trials for additional applications within cardiac surgery, including coronary artery bypass.

**Endoscopic Full-Thickness Plicator**

NDO Surgical, Inc. has developed an endoscopic, full-thickness plication device for the treatment of gastroesophageal reflux disease (GERD). The Plicator system consists of a reusable Plicator instrument, a single use cartridge containing a suture-based implant, and a specially designed endoscopic tissue retractor which is designed to provide a long-term solution to GERD through a simple outpatient procedure. No surgical incisions are required for the procedure because the system is passed transorally. The device uses direct endoscopic visualization throughout the procedure. The Plicator secures and fixates tissue at the gastroesophageal junction to restore the natural anti-reflux barrier. (The market for GERD treatment exceeds $9.3 billion each year in the U.S. with more than 15 million Americans suffering from daily heartburn).

**Enteryx Polymer Injection Therapy**

Boston Scientific has developed a new polymer injection therapy called Enteryx for the treatment of gastroesophageal reflux disease (GERD). Enteryx is an injectable endoscopic therapy that is designed to treat the symptoms of the disease which is lower esophageal sphincter (LES) dysfunction. Enteryx is designed to enhance the gastroesophageal reflux barrier by modifying the LES. Enteryx is the first endoscopic therapy for GERD to be evaluated by the FDA as part of the Pre-Market Approval (PMA) process. In April 2003, Boston Scientific announced it had received approval from the FDA to market the Enteryx technology for the treatment of symptoms of GERD in patients responding to and requiring daily pharmacological therapy with proton pump inhibitors (PPI).

**High Intensity Focused Ultrasound**

Boston Scientific Corp. is seeking to develop vascular sealing technologies which are used to close arterial puncture sites. The technology called High Intensity Focused Ultrasound (HIFU), is completely non-invasive, and is being developed to close the puncture site by delivering heat. HIFU is an energy form that precisely focuses sound waves in a method that can be compared to the way a magnifying glass focuses light. Sound waves are concentrated on the puncture site where it rapidly coagulates the surrounding tissue, closes the puncture site, and stops the bleeding in a few minutes. Separately, the technology is also being developed by
the National Space Biomedical Research Institute and funding from the U.S. Department of Defense.

**Indigo Optima laser system**

The Indigo Optima laser system is manufactured by Ethicon Endo-Surgery Inc., a subsidiary of Johnson & Johnson. The system is one of the most advanced benign prostatic hyperplasia (BPH) or enlarged prostate treatment options available. The system is comprised of a diode laser and diffusing fiber optics which permits office-based, minimally invasive treatment of BPH. The system uses a thermotherapy process known as interstitial laser coagulation. The Indigo Optima laser system offers a permanent solution to patients who would otherwise need to take medications for the rest of their lives.

**Intra-Coronary Radiation**

A group of cardiologists at the Columbia Weill Cornell Heart Institute have recently developed a procedure that uses a safe source of radiation to help prevent artery reclogging. In the one-third of patients who undergo angioplasty, the dilated segment of the artery renarrows within six months after the procedure. (This reclogging of arteries after angioplasty is also known as restenosis). This revolutionary technique, called intra-coronary radiation, uses beta radiation, in solution form, which is inserted into the repaired heart vessels through a special balloon. After ten minutes, once irradiation is completed, the balloon containing the radioactive source is removed from the body.

**Laprotek System**

The Laprotek System, manufactured by endoVia Medical, is a computer assisted surgical unit which is comprised of two components. The Laprotek console is a mobile surgical workstation that can be placed anywhere in the operating room. It enables the surgeon to operate the instrument interface from a comfortable sitting position. Surgeons then control the second component, the Laprotek Surgical Arms, while sitting at the console. The Laprotek System is targeted towards large community hospitals and teaching institutions to help them attract new patients who are seeking minimally invasive therapies.

**Progressive Scan Autoclavable Camera**

In March 2004 Smith & Nephew's Endoscopy division announced the launch of a new camera system, which includes the medical device industry's first progressive scan autoclavable camera for use in endoscopic surgery. The Progressive Scan technology offers a significantly higher level of performance in its display images. (i.e. similar to the quality of images displayed by high definition televisions in the consumer electronics industry). While traditional interlaced video uses two separate visual fields, progressive scan camera systems read and display images in one pass, or as one single frame. This technology offers several advantages over conventional camera systems including: (1) improvement in fine detail resolution; (2) elimination of flicker, especially with low-motion and static images; and (3) reduction in fast motion artifacts, resulting in a smoother image. The system offers a wide range of autoclave and non-autoclave options such as interlaced-compatible cameras and control units for use in arthroscopic, laparoscopic, cystoscopic and other endoscopic procedures.

**Robotic Surgery**

There are 12 institutions in the U.S. involved in ongoing FDA clinical trials to investigate the use and effectiveness of robotics in cardiac surgery. By using robotics, surgeons may be able to offer their patients a safe, less invasive means of coronary bypass surgery. Robotic bypass surgery leaves the patient with only a tiny scar, and provides a much faster and less painful recovery time compared to traditional bypass surgery. The first patient in the U.S. to receive robotically-assisted coronary artery bypass surgery was treated at the Columbia Weill Cornell Heart Institute. This historic operation follows the successes of more than 40 robotic cardiac
operations including internal mammary artery harvests, mitral valve repairs, and the first robotically-assisted atrial septal defect repair in the U.S.

**TRIVEX System for Varicose Vein Removal**

Smith & Nephew's Endoscopy division announced the launch of their next generation TRIVEX™ System for the minimally invasive removal of varicose veins in March 2004. The new all-in-one system now includes a precision-controlled surgical pump which provides consistent delivery of an anesthetic solution, and better visualization for accurate targeting and removal of diseased veins. The original TRIVEX System, which was introduced in 2000, revolutionized varicose vein removal. The minimally invasive TRIVEX procedure uses a technique called transilluminated powered phlebectomy. Transillumination is a unique feature which is similar to placing a flashlight under the skin. The illumination enables a surgeon to see, accurately target and remove varicose veins, then visually confirm the extraction.
7. Diagnostics

By Scot Orgish, Trade Commissioner, Swiss Business Hub, Houston, TX

7.1. Facts and Figures

The worldwide diagnostic market was valued at approximately $20.3 billion in 2002. From that amount, the U.S. accounted for two-thirds of the world market with $13.55 billion in sales in 2002, making it the world's largest single market for diagnostic testing equipment. The U.S. diagnostics market is expected to grow at an average rate of 6.9 percent per year from 2002 through 2007 to an estimated market value of $18.91 billion. The expected growth is due to favorable reimbursement policies for clinical lab testing, an increasing demand for point-of-care testing, and an aging population whose demographic trends demand increased diagnostic testing.

<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Laboratory Instruments</td>
<td>$5.68</td>
<td>$6.04</td>
<td>$6.43</td>
<td>$6.84</td>
<td>$7.28</td>
<td>$7.76</td>
<td>6.4%</td>
</tr>
<tr>
<td>Point-of-care instruments</td>
<td>$4.20</td>
<td>$4.54</td>
<td>$4.91</td>
<td>$5.31</td>
<td>$5.74</td>
<td>$6.20</td>
<td>8.1%</td>
</tr>
<tr>
<td>Medical diagnostic kits</td>
<td>$3.67</td>
<td>$3.90</td>
<td>$4.14</td>
<td>$4.40</td>
<td>$4.67</td>
<td>$4.95</td>
<td>6.2%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$13.55</strong></td>
<td><strong>$14.48</strong></td>
<td><strong>$15.48</strong></td>
<td><strong>$16.54</strong></td>
<td><strong>$17.68</strong></td>
<td><strong>$18.91</strong></td>
<td><strong>6.9%</strong></td>
</tr>
</tbody>
</table>

Source: BBC Inc.

Figure 32 The U.S. Clinical Diagnostic Testing Market Including Reagents and Consumables, 2002-2007

Technological advances in the market have brought forth an increase in point-of-care (POC) testing that is as accurate as testing performed in central laboratories. This being the case, POC instruments are expected to experience an above average growth rate of 8.1 percent per year through 2007. U.S. sales of POC equipment totaled $4.2 billion in 2002, and the segment is forecast to grow by $2 billion to $6.2 billion by 2007. A major factor for this growth is POC equipment offers immediate, bedside assays resulting in better and faster patient care. In addition to offering instruments that perform new analyses, manufacturers are providing integrated systems, wider testing capacities in a single instrument, and integrated workstations.

A 1999 survey by Enterprise Analysis Corp. of 510 hospitals ranging in size from 100 to 600+ beds showed that 69 percent of the hospitals surveyed had two or more types of POC instruments and 48 percent had three types or more. Figure 33 shows the number of point of care instrument types in each hospital.

Looking further into the types of POC instruments carried by hospitals, 99 percent had blood glucose monitors, 69 percent had coagulation monitors, 38 percent had blood gas and electrolyte monitors, 24 percent had hematology instruments, 17 percent had chemistry instruments, 5 percent had urine chemistry instruments, 3 percent had cholesterol instruments and only 1 percent had cardiac instruments.

Within the diagnostic equipment market, there are a number of important testing types. These include: Clinical Chemistry, Immunoassay, Hematology and Hemostasis, Microbiology, Urinalysis, Blood Banking, Glucose Monitoring, and Molecular Diagnostics. Large medical de-

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vice companies dominate all these markets. It is expected that growth in the diagnostic equipment market will come from testing being shifted from the central laboratory to the point-of-care. In fact, the U.S. Clinical Chemistry market is expected to decrease from a market value of $1.77 billion in 2002 to $1.54 billion in 2007 (a decrease of $230 million) while the point-of-care market is expected to increase by $2 billion (from $4.2 billion to $6.2 billion) during the same period. Overall, the diagnostic equipment market is very competitive, and could be affected by new drug therapies under development that may not require the intense monitoring of a patient’s assays, and by new competitors that might enter the market offering equipment with broader test menus.

![Figure 33 Number of Point of Care Instrument Types per Hospital](source: Enterprise Analysis Corp.)

<table>
<thead>
<tr>
<th>Instrument Category</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Glucose Monitors</td>
<td>99%</td>
</tr>
<tr>
<td>Coagulation</td>
<td>69%</td>
</tr>
<tr>
<td>Blood Gases/ Electrolytes</td>
<td>38%</td>
</tr>
<tr>
<td>Hematology</td>
<td>24%</td>
</tr>
<tr>
<td>Chemistry</td>
<td>17%</td>
</tr>
<tr>
<td>Urine Chemistry</td>
<td>5%</td>
</tr>
<tr>
<td>Cholesterol</td>
<td>3%</td>
</tr>
<tr>
<td>Cardiac</td>
<td>1%</td>
</tr>
</tbody>
</table>

![Figure 34 Percentage of Hospitals with POC Instruments by Category](source: Enterprise Analysis Corp.)

The U.S. glucose monitoring market, which includes both diabetes self-monitoring and professional point-of-care (POC) devices, totaled $2 billion in 2002. Within that total, sales of blood glucose testing strips led the industry with sales of $1.6 billion. Non- and minimally-invasive glucose testing systems, the smallest and most recent market entrant, had sales of $3.5 million. Other important segments include lancets and lancing devices, POC glycated hemoglobin testing products, and urine glucose/metabolite monitoring strips.

Overall, the U.S. glucose monitoring industry is forecast to reach sales of $3 billion in 2008, and will experience an annual growth rate of 7.2 percent from 2003 to 2008. The growth is being driven by the number of persons afflicted with diabetes. In 2002, there were an estimated 13 million Americans diagnosed with diabetes and that number is expected to climb to 14.5 million in 2008. In addition, many more persons will remain undiagnosed, meaning the actual number of afflicted persons will be much higher than 14.5 million. Likewise, market growth will likely be driven from increased overall awareness that regular monitoring can greatly decrease the serious and even fatal consequences of uncontrolled blood glucose levels in patients.

The outlook for the period 2003-2008 is that blood glucose testing strips will continue to dominate the market, with sales growing to nearly $2.4 billion in 2008. Non- and minimally-invasive
meters will grow the fastest at an estimated rate of 81.9% annually (to about $127 million), and will account for an estimated 15 percent of all blood glucose meter sales in 2008. Traditional blood glucose meters are expected to remain the "meters of choice" in the near term because of the high price and limited availability of alternative site testing meters (those that test blood taken from relatively pain-free areas of the body, such as the thumb, forearm, thigh, etc.). Glucose meters with easy to load test strip cassettes will broaden the market appeal for this segment. Also, less painful products such as ultra fine lancets will appeal to patients to continue using more traditional testing methods.13

7.2. Major Competitors

Today, the top 10 diagnostics manufacturers represent about 80% of industry sales. Listed below are the most important industry players. (Not all the companies compete in every market segment). In the infectious disease market, key competitors include Abbott Diagnostics, Beckman Coulter, Biomérieux, Dade Behring, Roche Diagnostics, and Trinity Biotech. In the market for Hemostasis Reagents, key competitors include Dade Behring, Instrumentation Laboratories, Diagnostica Stago, and Biomérieux. In the market for Hemostasis Instrumentation, key competitors include Instrumentation Laboratories, Diagnostica Stago, and Sysmex. In the Clinical Chemistry market, key competitors include Roche Diagnostics, Ortho-Clinical Diagnostics, Dade Behring, Beckman Coulter, Abbott Diagnostics, and Bayer Diagnostics. Four companies dominate the glucose-monitoring market. These companies include: Roche Diagnostics, LifeScan, a Johnson & Johnson company, (each with about one-third of the market) and Bayer AG and Abbott Laboratories (each with about one-sixth of the market).

Market shares of the major competitors vary by specific market segment (i.e. Clinical Chemistry, Immunoanalysis, Hematology, etc.) Figure 35 shows the company market shares for the Clinical Chemistry Market.

<table>
<thead>
<tr>
<th>Company</th>
<th>% Share</th>
</tr>
</thead>
<tbody>
<tr>
<td>Roche Diagnostics</td>
<td>22</td>
</tr>
<tr>
<td>Ortho-Clinical Diagnostics</td>
<td>21</td>
</tr>
<tr>
<td>Dade Behring</td>
<td>18</td>
</tr>
<tr>
<td>Beckman Coulter</td>
<td>15</td>
</tr>
<tr>
<td>Abbott Diagnostics</td>
<td>7</td>
</tr>
<tr>
<td>Bayer</td>
<td>6</td>
</tr>
<tr>
<td>Other</td>
<td>11</td>
</tr>
<tr>
<td>Total</td>
<td>100</td>
</tr>
</tbody>
</table>

*Includes instruments, reagents, and other supplies

Source: BCC, Inc.

Figure 35 U.S. Clinical Chemistry Market, Company Market Shares, 2002

Listed below are the major competitors in the U.S. diagnostic equipment market.

- **Abbott Diagnostics** is a division of Abbott Laboratories, a global health care company that is doing business in over 130 countries. Abbott’s primary businesses are pharmaceuticals, nutritional, and medical products which include diagnostics and cardiovascular devices. The company employs 70,000 persons and had net sales of $19.7 billion in 2003. The Diagnostics Division manufactures and markets diagnostic systems and tests for

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blood banks, hospitals, consumers, commercial laboratories and alternate care testing sites on a worldwide basis.  http://www.abbottdiagnostics.com/

- **Bayer Diagnostics** is one of the largest diagnostic businesses in the world. The company does business in more than 100 countries, and offers a wide range of laboratory, self-testing, molecular testing and near patient (critical care and point-of-care) diagnostics systems which are focused on the areas of cardiovascular and kidney disease, oncology, virology, women's health and diabetes. The company employs about 7,000 persons worldwide and had 2002 sales of $1.9 billion. Bayer Diagnostics’ global headquarters in the U.S. operates as part of Bayer HealthCare LLC a member of the worldwide Bayer HealthCare group. Bayer HealthCare is a sub group of Bayer AG of Germany with annual sales exceeding 10 billion Euro.  http://www.bayerdiag.com/

- **Beckman Coulter, Inc.** is a leading manufacturer of instrument systems and complementary products used in the automation of laboratory processes. The company’s product line includes centrifuges, blood analyzers, and diagnostic rapid-test kits. Annual sales for the company totaled $2.2 billion in 2003. Beckman Coulter has offices in 130 countries worldwide.  http://www.beckman.com

- **Becton Dickinson (BD)** manufactures and sells a broad range of diagnostic products, devices, laboratory equipment and medical supplies. The company serves healthcare institutions, life science researchers, clinical laboratories, industry and the general public. BD Diagnostics offers system solutions for collecting, identifying and transporting specimens, and advanced instrumentation for analyzing specimens. The company also offers services to help with their customers’ process flow, supply chain management, and training and education.  http://www.bd.com/

- **BioMérieux** is a major player in the field of in-vitro infectious disease diagnostics. The company designs, develops, manufactures and markets reagents and automated instruments for medical analyses. (Other product applications include product quality control in the agri-food, cosmetics and pharmaceutical industries). The company had sales of 944 million Euros in 2002, and ranks as the eighth largest biological diagnostics company worldwide. Over 82 percent of its activity takes place on an international level. The company employs 5,450 people worldwide and has 14 production sites located in France, the Netherlands, the United Kingdom, Italy, the United States, Brazil, Japan and Australia.  http://www.biomerieux.com

- **Dade Behring** ranks as the sixth largest diagnostics company in the world, and is the largest company dedicated solely to clinical diagnostics. The company has four core product lines: Chemistry/Immunochemistry, Hemostasis, Microbiology, and Infectious Disease Diagnostics. Dade Behring has operations in 43 countries, employs approximately 6,500 people and serves more than 24,000 customers worldwide. The company had $1.3 billion in sales in 2002.  http://www.dadebehring.com/

- **Diagnostica Stago, Inc.** is the U.S. subsidiary of the French parent company by the same name. The company is a leading global supplier, and offers a complete system of coagulation instruments and optimized reagent kits for research as well as for routine analysis.  http://www.stago-us.com/

- **Instrumentation Laboratory (IL)** is headquartered in Spain, and is a leading company in the markets of clinical diagnostic systems for blood gas/electrolytes analysis, hemostasis and clinical chemistry. IL’s medical technology is used in hundreds of hospitals and laboratories around the world. The company’s North American headquarters are based in Lexington, MA.  http://www.ilww.com/

- **IRIS International, Inc.** is a leader in in-vitro diagnostic urinalysis systems, digital imaging software development, sample collection, sample processing and small bench top centrifuges and supplies for chemistry, coagulation, cytology, hematology, and urinalysis for the clinical and veterinary markets. The company operates through its Iris Diagnostics divi-
The U.S. Market for Medical Devices - Opportunities and Challenges for Swiss Companies

The U.S. Market for Medical Devices - Oppor

International Technidyne Corporation (ITC) is a wholly owned subsidiary of Thoratec Corp., and is a worldwide leader in the development, manufacture, and marketing of point of care hemostasis management products for use in hospitals, physician's offices, and the home. The company's major product lines are: Hemochron POC coagulation system, IRMA POC blood gas/electrolyte and chemistry system, ProTime coagulation monitoring system, Hemoglobin Pro system and Tenderfoot, tenderlett and surgicutt incision products. ITC instruments and disposables are used in areas requiring point-of-care or near patient monitoring including cardiac surgery and interventional procedures, critical care and alternate site areas, as well as clinics, physician offices, and patient self-testing. The parent company had gross sales of $149.9 million in 2003. http://www.itcmed.com

Ortho-Clinical Diagnostics, Inc., a subsidiary of Johnson & Johnson, provides professional diagnostic products to hospital laboratories, commercial clinical laboratories and blood donor centers. Its products include reagents used in blood transfusions and blood screening; reagents and instrument systems for clinical chemistry; and RhoGAM®, an injectable drug used to prevent hemolytic disease of the newborn. http://www.orthoclinical.com/

Roche Diagnostics is a division of F. Hoffmann-La Roche Ltd, Basel, Switzerland, and is the world's leading provider of diagnostic systems. The company offers a broad range of diagnostic products which are sold to key research and production locations in more than 50 countries. Products include early detection, targeted screening, evaluation and monitoring of disease. Roche Diagnostics employs a total of 16,500 people worldwide. The North American division employs over 2,500 people, and is one of five global centers for Roche Diagnostics. The company's Indianapolis site in the U.S. is a key manufacturing site for Roche's blood glucose monitoring strips, and is responsible for the marketing, sales, service and distribution of all Roche Diagnostics' products sold within North America. http://www.roche-diagnostics.com/

Sysmex America, Inc. is the U.S. headquarters for SYSMEX CORPORATION (Japan), a leading international manufacturer of diagnostic systems for medical laboratories worldwide. Sysmex is involved in the development of clinical laboratory testing devices, reagents and software for hematology, hemostasis, immuno-chemistry, particle counting and urinalysis as well as in the development of information systems. http://www.sysmex.com/

Trinity Biotech is a leading global supplier of diagnostic reagents and instrumentation to the world diagnostic market. The company manufactures and markets over 500 individual products, and competes in four significant sections of the world market: Infectious Diseases, Hemostasis, Clinical Chemistry and Point-of-Care Diagnostics. The company is headquartered in Dublin, Ireland and employs over 550 people worldwide. With revenues of over $50 million in 2002 and profit after tax in excess of $5 million, Trinity is a significant player in the diagnostic marketplace. http://www.trinitybiotech.com/

7.3. Emerging Technologies

ADeptas Cell Separators and Cell Counters

aDEPtas, Inc. is using Dielectrophoresis technologies to enable new powerful analysis and diagnostic products in the medical and life-sciences areas. aDEPtas uses its DEP-based
technologies to manipulate cells and other particles directly in their sampling medium for detection, sorting, isolation, trapping and analysis. Either as stand-alone applications, or as integrated front-end for PCR, micro-arrays or micro-fluidics devices, aDEPtas’ technology offers new alternatives to current analysis methods and procedures at a fraction of the cost. In late 2004, the company is expected to introduce its Cell Separator which the company feels will replace centrifuges for separating out cells in laboratory research and analysis. In mid-2005, the company expects to introduce its DEP Counter technology which will enable cell viability testing and apoptosis monitoring in tissue culture labs and cell production facilities. The DEP Counter line provides an enhanced alternative to Coulter Counters which is one of the most common pieces of equipment used in tens of thousands of life sciences labs and hospitals. The DEP counter has the advantage of a higher cell counting discrimination method. In 2006, the company plans to introduce its Electrosmear technology which will be targeted toward medical pathology labs. The device will be used to look for cancer cells and biological agents such as malaria, anthrax, etc.

**Blood Glucose Meter**

BD Medical, Diabetes Care/Medtronic Minimed/Nova Biomedical have jointly developed the Paradigm Link blood glucose meter. The Paradigm Link blood glucose meter is the world’s first untethered wireless glucose meter that provides bi-directional communication between a glucose meter and insulin pump.

**CellSearch™ Epithelial Cell Kit/ CellSpotter™ Analyzer**

Veridex LLC, a subsidiary of Johnson & Johnson, in January 2004 received FDA clearance to market its CellSearch™ Epithelial Cell Kit/ CellSpotter™ Analyzer. The device is used on breast cancer patients to help determine the effectiveness of their cancer treatment. The presence of Circulating Tumor Cells (CTC) in the blood is associated with decreased survival in patients for spreading (metastatic) breast cancer. The device helps a medical professional find CTCs in a blood sample.

**Guardian™ Continuous Glucose Monitoring System**

Medtronic Minimed is currently developing the Guardian™ Continuous Glucose Monitoring System which is a continuous glucose monitoring system designed to sound an alarm when the patient’s blood-sugar level is out of the target range. A sensor that is inserted just under the skin records glucose levels using fluid from the layer of fat between the skin and muscle (called “interstitial fluid”). The sensor is designed to be worn up to three days. The system’s transmitter receives blood glucose readings from the sensor. It then relays this information to a monitor using radio waves. The transmitter can be worn discreetly under clothing and is not implanted into the body. The monitor which is about the size of a large pager, can be worn or carried anywhere as long as it is within 6 feet (1.8 meters) of the transmitter. This device is expected to be on the market by the end of 2004.

**Immuno-magnetic Selection**

Immunicon has developed a revolutionary diagnostic platform based on immuno-magnetic selection and fluorescence characterization of rare cells in blood. The company’s principal focus is cell-based and molecular diagnostic products in the field of cancer. The technology is broadly applicable to other fields of diagnostics, drug development and life science research. Immunicon scientists have developed breakthrough technologies for isolating and quantifying cancer cells of epithelial origin in a sample of blood from the patient. The company’s Cell-Tracks AutoPrep system is used with immunomagnetic reagents that capture target cells and labeling reagents that differentiate them. The first application is based on isolation and characterization of rare circulating tumor cells. Veridex, LLC, a Johnson & Johnson company, will market exclusively any cellular diagnostic products developed in the cancer field. Immunicon
plans to develop additional commercial strategic alliances for products outside of cancer markets.

**Retinal Imaging System**

Joslin Diabetes Center has invented a Retinal Imaging System designed for Improved Retinal Imaging, Eye Imaging in Diabetic Patients, and Eye Imaging in Geriatric Populations. The system offers tangible advantages over existing ophthalmoscopes and retinal imaging systems for non-mydriatic imaging of the retina. Its specific advantage is in providing an improved imaging capability and retinal image quality for patients with small pupil dilation, less than 3.8 mm or even less than 2.5 mm, for which existing systems do not work particularly well. Individuals with diabetes, as well as many older patients, have such small pupil dilation. Joslin Diabetes Center is seeking a licensee for the manufacture and sale of this device, under a worldwide, exclusive license.

**VersaTrek Automated Microbial Detection System**

Trek Diagnostic Systems recently won a 2004 Medical Design Excellence Award for its VersaTrek automated microbial detection system. The VersaTrek automated microbial detection system is a clinical laboratory instrument that combines blood culture, sterile body fluid culturing, mycobacterial detection, and mycobacterium tuberculosis susceptibility testing in a single platform.

**Wireless Blood-sugar Monitor**

Abbott Laboratories has developed the Freestyle Navigator, a device for continuous monitoring of blood-sugar levels of diabetics. The device consists of a small paper thin probe that constantly takes blood-sugar readings from the fluid under the skin, and transmits the data wirelessly to a reader which is the size of a pager. The user then, receives a new blood-sugar reading every 60 seconds. (One probe lasts three days). An arrow also indicates whether blood-sugar is rising, holding steady, or falling, and how quickly. The device is being reviewed by the FDA as an alternative to the current “finger-stick tests”, and could be on the market in mid to late 2005.

### 7.4. Other Growth Areas in Diagnostics

The main focus of this chapter has been on the *In-vitro* area of the diagnostics market. *In-vitro* testing analyzes samples (i.e. blood, urine, tissue, etc.) at a single point in time. (Similar to a still photograph). However, the truly revolutionary market in diagnostics in the future will be in the area of Molecular Imaging and Diagnostics. This is classified as the *In-vivo* (in body) area of the diagnostics market. This new area of diagnostics provides a *movie like* view of the patient’s data for use in diagnosing and treating disease. This is the largest growth segment in diagnostics of the future with an estimated market value of $5-8 billion.

Molecular Imaging (MI) is a diagnostic imaging procedure which utilizes a Positron Emission Tomography (PET) medical camera. MI combines new molecular agents with traditional imaging tools to capture pictures of specific molecular pathways in the body, particularly those that are key targets in disease processes. MI has the potential to detect, diagnose and treat disease *in-vivo*, and at the same time show how well a particular treatment is working. The field of molecular imaging has become possible through recent advances in molecular and cell biology techniques, new methods of combinatorial drug design, high throughput testing, and the emergence of novel imaging techniques and probes. While emphasis today is on highly sensitive nuclear medicine techniques, scientists expect all imaging modalities will soon be affected by molecular imaging. There is already active molecular imaging work using MRI, ultrasound, CT (computed tomography) and optical imaging. While imaging today focuses on anatomy
and morphology, imaging modalities will soon be required to image the anatomy, its morphology and the molecular processes involved.

Molecular imaging allows radiologists and doctors to generate information beyond what is directly available from captured images. Software packages created for molecular imaging systems can provide Computer Assisted Diagnostic (CAD) information used by physicians to interpret images and generate prognostic information. For example, CAD application in molecular imaging has the potential to suggest how quickly a cancer is growing by determining how rapidly cancer cells are proliferating and how many are (or are not) dying. Once this assessment is made, physicians can compile an evidence-based database to determine how best to treat patients with cancers growing at specific rates.\(^\text{14}\)

Leading molecular imaging and diagnostics companies in the North American market include GE, Philips, and Siemens.

**General Electric (GE) Healthcare**

GE Healthcare is a $14 billion unit of General Electric Company which is headquartered in the United Kingdom. Worldwide, GE Healthcare employs more than 42,500 people in more than 100 countries. Product areas include digital x-ray, ultrasound, nuclear medicine, positron emission tomography, computed tomography, magnetic resonance imaging, surgical navigation and interventional imaging systems, and clinical IT. [http://www.gehealthcare.com/](http://www.gehealthcare.com/)

**Philips Medical Systems**

Philips Medical Systems has approximately 22,000 employees with sales and service operations in 63 countries and distribution in 100 countries. The company is a leading supplier of diagnostic imaging equipment, information technology and related healthcare services. Product areas include general x-ray, ultrasound, nuclear medicine, computed tomography, magnetic resonance imaging, cardiac and monitoring systems, clinical IT, and radiation therapy planning. Philips Medical Systems is also a leader in the molecular imaging arena. The company is developing next-generation PET as well as single photon emission computed tomography (SPECT) systems that meet the unique requirements of molecular imaging.  

**Siemens Medical Solutions**

Siemens Medical Solutions is one of the largest suppliers of healthcare equipment in the world. The company offers innovative products, services and complete solutions, ranging from imaging systems for diagnosis and therapy equipment for treatment, to electromedicine and hearing instruments, to IT solutions that optimize workflow and increase efficiency in hospitals, clinics and doctors' offices. Product areas include fluoroscopy, angiography, ultrasound, nuclear medicine, computed tomography, magnetic resonance imaging, patient monitoring systems, clinical IT, and mammography.  
[http://www.siemensmedical.com](http://www.siemensmedical.com)

**Opportunities for Swiss Companies**

Opportunities for Swiss companies in the molecular imaging and diagnostics field are good for companies engaged in micro-fluidic technologies, micro-electronic memory systems, nanotechnology, and producers of contrast enhancing agents and markers.

8. Wound Care and Wound Management

By Scot Orgish

8.1. Facts and Figures

The U.S. wound care products market was valued at $4.82 billion in 2003, and is forecast to grow to $6.77 billion in 2010. This represents an average annual growth rate of about 4.8 percent. There are four primary categories within the wound care products market. These four categories include: (1) Biological skin and dressings, (2) Moist wound healing products, (3) Wound management products, and (4) Wound closure products.

The Biological skin and dressings category was valued at $69.38 million in 2003, and is forecast to grow about 5.8 percent per year through 2010 to a value of $105.8 million. In this product category, collagen products is the largest segment with a market value of $43.3 million in 2003. This segment is forecast to grow 5.2 percent per year to a value of $62.75 million in 2010. The product segment of Artificial and cultured skin is expected to experience above average growth for the category growing 8.9 percent per year from $12.8 million in 2003 to $25.17 million in 2010.

The Moist wound healing products category was valued at $312.31 million in 2003, and is forecast to grow about 6.6 percent per year to a value of $497.21 million in 2010. In this product category, hydrocolloids is the largest product segment with a market value of $101.33 million in 2003. This segment is forecast to experience below average growth (for the category) and will grow about 4.2 percent per year to a value of $136.74 million in 2010. The product segment of Alginates is expected to experience above average annual growth of 9.4 percent increasing from a market value of $53.45 million in 2003 to $102.67 million in 2010. The product segment of Hydrogels is also expected to experience above average growth for the category. The segment is forecast to grow about 9.3 percent per year from $63.24 million in 2003 to $118.12 million in 2010.

The Wound management products category was valued at $2.12 billion in 2003, and is forecast to grow about 3.0 percent per year to a value of $2.61 billion in 2010. The wound management products category is made up of four product segments: (1) adhesive bandages, (2) cleansing products, (3) debriding products, and (4) gauzes. All four segments relative to the overall U.S. wound care products market are forecast to experience below average growth for the market as a whole. This moderate growth forecast indicates a mature market with products considered more as commodity items where price is an important factor in selling the product.

The Wound closure products category was valued at $2.27 billion in 2003, and is forecast to grow about 6.1 percent per year to a value of $3.5 billion in 2010. Non-absorbable sutures is the largest product segment in this category with a value of $865.25 million in 2003. This segment is forecast to experience below average growth for the category, and will grow 4.6 percent per year to a value of $1.2 billion in 2010. Absorbable sutures is the second largest segment in the wound closure category. It was valued at $698.29 million in 2003. This segment is expected to experience above average growth for the category, and will grow about 7.0 percent per year to a market value of $1.14 billion in 2010. The surgical sealant segment is forecast to experience the fastest growth of all the segments in the U.S. wound care products market.
The surgical sealant segment will grow about 12.9 percent per year from a value of $142.19 million in 2003 to $337.99 in 2010. Figure 36 and Figure 37 give the actual and forecast market values of each of the product segments of the U.S. wound care products market from 2001 through 2010.

<table>
<thead>
<tr>
<th>Product Segment</th>
<th>2001</th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
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</thead>
<tbody>
<tr>
<td>Biological skin &amp; dressings</td>
<td>63.92</td>
<td>66.44</td>
<td>69.38</td>
<td>72.91</td>
<td>77.09</td>
</tr>
<tr>
<td>Artificial &amp; cultured skin</td>
<td>11.69</td>
<td>12.17</td>
<td>12.80</td>
<td>13.63</td>
<td>14.82</td>
</tr>
<tr>
<td>Collagen products</td>
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<td>41.45</td>
<td>43.30</td>
<td>45.48</td>
<td>47.92</td>
</tr>
<tr>
<td>Non-collagen products</td>
<td>8.29</td>
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<td>8.99</td>
<td>9.41</td>
<td>9.86</td>
</tr>
<tr>
<td>Impregnated dressings &amp; adhesives</td>
<td>4.11</td>
<td>4.20</td>
<td>4.29</td>
<td>4.39</td>
<td>4.49</td>
</tr>
<tr>
<td>Moist wound healing products</td>
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<td>295.44</td>
<td>312.31</td>
<td>331.16</td>
<td>352.34</td>
</tr>
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<td>Alginites</td>
<td>45.67</td>
<td>49.29</td>
<td>53.45</td>
<td>58.19</td>
<td>63.70</td>
</tr>
<tr>
<td>Films</td>
<td>45.06</td>
<td>45.83</td>
<td>46.79</td>
<td>47.97</td>
<td>49.31</td>
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<td>Foams</td>
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<td>47.50</td>
<td>50.75</td>
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<td>101.33</td>
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<td>109.50</td>
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<td>2,119.01</td>
<td>2,182.78</td>
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<td>552.40</td>
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<td>Cleansing products</td>
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<td>707.52</td>
<td>729.81</td>
<td>753.67</td>
<td>778.99</td>
</tr>
<tr>
<td>Debridging products</td>
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<td>117.73</td>
<td>121.07</td>
<td>124.74</td>
<td>128.74</td>
</tr>
<tr>
<td>Gauzes</td>
<td>677.99</td>
<td>696.91</td>
<td>715.73</td>
<td>733.91</td>
<td>751.89</td>
</tr>
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<td>Wound closure products</td>
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<td>2,273.69</td>
<td>2,397.56</td>
<td>2,535.31</td>
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<td>Internal staplers</td>
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</tr>
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<td>65.18</td>
<td>67.80</td>
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<td>Surgical/Ligature clips</td>
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<td>46.01</td>
<td>47.52</td>
<td>49.22</td>
<td>51.16</td>
</tr>
<tr>
<td>Vascular clips</td>
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<td>73.60</td>
<td>75.76</td>
<td>78.20</td>
<td>80.93</td>
</tr>
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<td>Absorbable sutures</td>
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<td>658.45</td>
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<td>742.63</td>
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<td>Non-absorbable sutures</td>
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<td>900.98</td>
<td>939.99</td>
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<td>126.88</td>
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<td>179.84</td>
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<tr>
<td>Tape closures</td>
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<td>30.97</td>
<td>31.98</td>
<td>33.08</td>
</tr>
<tr>
<td>Other types of dressings</td>
<td>47.81</td>
<td>48.87</td>
<td>49.97</td>
<td>51.13</td>
<td>52.39</td>
</tr>
</tbody>
</table>

Source: Global Industry Analysts, "Wound Care Products", Feb. 1, 2004

Figure 36 U.S. Wound Care Products: Annual Demand by segment, 2001-2005 (In Million $)

<table>
<thead>
<tr>
<th>Product Segment</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
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</thead>
<tbody>
<tr>
<td>Biological skin &amp; dressings</td>
<td>81.79</td>
<td>87.04</td>
<td>92.84</td>
<td>99.07</td>
<td>105.79</td>
</tr>
<tr>
<td>Artificial &amp; cultured skin</td>
<td>16.33</td>
<td>18.15</td>
<td>20.22</td>
<td>22.55</td>
<td>25.17</td>
</tr>
<tr>
<td>Collagen products</td>
<td>50.52</td>
<td>53.30</td>
<td>56.32</td>
<td>59.47</td>
<td>62.75</td>
</tr>
<tr>
<td>Non-collagen products</td>
<td>10.34</td>
<td>10.87</td>
<td>11.44</td>
<td>12.05</td>
<td>12.71</td>
</tr>
<tr>
<td>Impregnated dressings &amp; adhesives</td>
<td>4.60</td>
<td>4.72</td>
<td>4.86</td>
<td>5.00</td>
<td>5.16</td>
</tr>
<tr>
<td>Moist wound healing products</td>
<td>375.98</td>
<td>402.23</td>
<td>431.28</td>
<td>462.99</td>
<td>497.21</td>
</tr>
<tr>
<td>Alginites</td>
<td>69.96</td>
<td>77.10</td>
<td>85.06</td>
<td>93.64</td>
<td>102.67</td>
</tr>
<tr>
<td>Films</td>
<td>50.91</td>
<td>52.68</td>
<td>54.66</td>
<td>56.77</td>
<td>59.00</td>
</tr>
<tr>
<td>Foams</td>
<td>58.59</td>
<td>63.13</td>
<td>68.19</td>
<td>74.02</td>
<td>80.68</td>
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<tr>
<td>Hydrocolloids</td>
<td>114.08</td>
<td>119.03</td>
<td>124.54</td>
<td>130.46</td>
<td>136.74</td>
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<tr>
<td>Hydrogels</td>
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<td>90.29</td>
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<td>Adhesive bandages</td>
<td>607.73</td>
<td>626.75</td>
<td>646.05</td>
<td>666.21</td>
<td>687.53</td>
</tr>
<tr>
<td>Cleansing products</td>
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<td>831.41</td>
<td>859.26</td>
<td>888.22</td>
<td>917.89</td>
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<tr>
<td>Debridging products</td>
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<td>136.91</td>
<td>141.09</td>
<td>145.49</td>
<td>150.06</td>
</tr>
<tr>
<td>Gauzes</td>
<td>770.76</td>
<td>790.49</td>
<td>811.20</td>
<td>832.13</td>
<td>853.77</td>
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<tr>
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<td>Internal staplers</td>
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<td>495.54</td>
<td>529.67</td>
</tr>
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<td>90.11</td>
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<td>Surgical/Ligature clips</td>
<td>53.31</td>
<td>55.69</td>
<td>58.28</td>
<td>61.10</td>
<td>64.18</td>
</tr>
<tr>
<td>Vascular clips</td>
<td>83.99</td>
<td>87.36</td>
<td>91.11</td>
<td>95.28</td>
<td>99.90</td>
</tr>
<tr>
<td>Absorbable sutures</td>
<td>846.98</td>
<td>908.64</td>
<td>977.33</td>
<td>1,053.66</td>
<td>1,139.00</td>
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<td>Non-absorbable sutures</td>
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<td>260.60</td>
<td>296.40</td>
<td>337.99</td>
</tr>
<tr>
<td>Tape closures</td>
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<td>35.60</td>
<td>37.02</td>
<td>38.60</td>
<td>40.32</td>
</tr>
<tr>
<td>Other types of dressings</td>
<td>53.74</td>
<td>55.28</td>
<td>56.91</td>
<td>58.58</td>
<td>60.35</td>
</tr>
</tbody>
</table>

Source: Global Industry Analysts, "Wound Care Products", Feb. 1, 2004

Figure 37 U.S. Wound Care Products: Annual Demand by segment, 2006-2010 (in $ Million)
8.2. **Major Competitors**

Figure 38 shows the leading companies in the Worldwide Wound Management market in 2001. Percentage of market share by revenues:

<table>
<thead>
<tr>
<th>Company</th>
<th>Market Share</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smith &amp; Nephew</td>
<td>22.1%</td>
</tr>
<tr>
<td>Johnson &amp; Johnson</td>
<td>17.0%</td>
</tr>
<tr>
<td>Convatec</td>
<td>13.2%</td>
</tr>
<tr>
<td>3M</td>
<td>12.9%</td>
</tr>
<tr>
<td>Others</td>
<td>34.8%</td>
</tr>
<tr>
<td>Total</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

*Source: Global Industry Analysts: Global Strategic Reports, February 1, 2004*

Figure 38 Market leaders in Wound Management 2001

Although Smith & Nephew, Johnson & Johnson, Convatec and 3M have major market shares in the world wound care market, there are several other important competitors as well as some newly emerging companies in the U.S. market.

- **AcryMed** is a rapidly growing biomaterials and medical device company based in Portland, Oregon. The company specializes in the development and manufacture of advanced tissue repair products. Their technology base has great potential for the development of products which combine wound dressing attributes together with healing agents for use in a wide range of applications for both acute and chronic wounds. [http://www.acrymed.com/]

- **Bard Medical Division of C. R. Bard Inc.** is a market leader in urological drainage systems. In addition to urology, the company also offers a broad range of skin and wound care products and wound drainage products to treat 2nd degree burns and blisters, arterial ulcers, dehisced surgical wounds, denuded areas, diabetic foot ulcers, stage II, III and IV pressure ulcers, radiation reactions, skin graft donor site, skin tears and venous stasis ulcers. [http://www.bardmedical.com/]

- **Carrington Laboratories** has conducted over 25 years and $75 million in basic and clinical research to develop a line of products from Aloe vera L. The company’s product line includes more than 90 products for the treatment of wounds, radiation, and diabetic related skin burns, irritations and abrasions. [http://www.carringtonlabs.com/]

- **ConMed Corp.** is a major medical technology company specializing in instruments, implants and video equipment for arthroscopic sports medicine, and powered surgical instruments, such as drills and saws, for orthopedic, ENT, neurosurgery and other surgical specialties. In addition, the company has a line of wound care products called ClearSite which are saline-based hydrogel dressings. The company had sales of $497 million in 2003, employs about 2,500 and distributes its products worldwide from eleven manufacturing locations. [http://www.conmed.com/]

- **ConvaTec** is a subsidiary of Bristol-Myers Squibb Company. The company manufactures and markets products and services for advanced wound care, skin care, and ostomy care. The company’s wound care brands include DuoDERM® hydrocolloid dressings, AQUACEL® Hydrofiber dressings, KALTOSTAT® alginate dressings, CombiDERM® and CarboFlex® dressings. The newest wound care brands are Versiva®, an advanced wound dressing that combines three proven technologies, and AQUACEL®Ag, a unique antimicrobial wound dressing for acute and chronic wounds. [http://www.convatec.com/]

- **Ethicon, Inc.** is a subsidiary of Johnson & Johnson, and is a global leader in the development and marketing of products for surgery in the area of wound care and wound management. The company’s product line features devices that facilitate precise wound clo-
Wound Care and Wound Management

sure and tissue repair. Key brands include TIELLE Hydropolymer Adhesive Dressing; FIBRACOL Collagen Wound dressings for the management of pressure ulcers, diabetic foot ulcers and venous leg ulcers; and PREVACARE, a line of skin care products for the care of damaged or compromised skin. Other traditional wound care products include sponges, bandages, dressings, transparent films and tapes. The company also offers INTEGRA Dermal Regeneration Template for the regeneration of the dermis in burn care. http://www.ethiconinc.com/

- **Johnson & Johnson Wound Management** is a subsidiary of Johnson & Johnson, and is a sister company to Ethicon. J&J Wound Management offers a complete line of innovative products for hemostasis, tissue regeneration and advanced wound care. http://www.jnj.com/product/categories/Wound_Care.htm

- **Kendall**, a subsidiary of Tyco Healthcare, manufactures and markets a broad range of wound care, needles and syringes, vascular therapy, urological care, incontinence care, sharps disposal, and nursing care products. These products are distributed and used in a variety of clinical settings including hospitals, rehabilitation centers, long-term care facilities and homes throughout the world. Market leading brands include KERLIX® antimicrobial dressings, CURITY®, MONOJECT®, KANGAROO®, and ARGYLE®. http://www.kendalhq.com/

- **Smith & Nephew** (S&N) was founded in 1856 and is a leader in three specific markets: advanced wound management, endoscopy, and orthopedics. The parent company is based in London, England. S&N operates in 32 countries, employs over 7,000 people, and generates annual sales of £1.2 billion. The company is the world leader in advanced wound management, and has an extensive product range to treat: pressure ulcers, leg ulcers, diabetic foot ulcers, burns, scars, surgical wounds, and IV fixation. Products range from hydrocellular foam dressings to bio-engineered temporary skin substitutes for burns. The company has the largest wound management sales force in the world, and provides nurses and clinicians with a full range of education programs. http://wound.smith-nephew.com/us/Home.asp. S&N also has available a sample reimbursement manual covering wound care that can be found at: http://wound.smith-nephew.com/us/Standard.asp?NodeId=2395

- **3M** is a leading global supplier of single-use medical supplies including tapes, dressings, surgical drapes, masks, electrodes and other products used by health care providers. 3M also has specific expertise in infection prevention and skin and wound care, and offers products, services and solutions for professionals in hospitals and alternate care settings. Key brands in wound care include: 3M™ Micropore™ tape, 3M™ DuraPrep™ skin prep, and 3M™ Tegaderm™ dressings. Other medical products include: 3M™Avagard™ Hand Antiseptic, 3M™ Littmann ® Stethoscopes, 3M™ Steri-Drape ™ surgical drapes, 3M™ Red Dot™ electrodes, and 3M™ Attest™ sterilization indicators. http://www.3m.com/US/healthcare/index.jhtml

8.3. Emerging technologies

**ACTISORB Silver 220 dressing**

Johnson & Johnson Wound Care announced in March 2003 the introduction of ACTISORB Silver 220 Antimicrobial Binding Dressing, a primary wound dressing in the U.S. that combines broad-spectrum antimicrobial action, bacterial toxin management and odor control. The product has been proven effective in vitro against more than 150 clinically relevant wound pathogens, including antibiotic resistant strains such as Staphylococcus aureus and Vancomycin-
resistant Enterococcus. In addition, clinical studies of more than 12,400 chronic wounds indicate the dressing is both safe and effective.

Antimicrobial Silver Dressing

AcryMed's antimicrobial silver dressing, SilvaSorb(r), won the Frost & Sullivan 2004 Wound Care Product of the Year Award. AcryMed's SilvaSorb is a superior single-use wound dressing that combines antimicrobial silver together with absorbent polyacrylate matrix moisture management material to treat wounds, promote wound healing and prevent infection. SilvaSorb uses the proprietary properties of the company's patented biopolymer Microlattice(r) technology, which regulates wound moisture levels to maintain an optimal healing environment. The dressing simultaneously controls the release of ionic silver, which is triggered by contact with moisture. Microlattice makes it possible for SilvaSorb to provide moisture when needed or absorb up to five times its weight in excess wound exudate. The dressing prevents infection for up to seven days.

Contreet Foam

Coloplast of Denmark has recently developed a new antibacterial foam product called Contreet Foam which belongs to a new generation of dressings based on hydroactivated silver technology. The use of silver fights bacteria growth because the bacteria are unable to develop resistance against silver, which they may do against antibiotics. The antibacterial activity of the foam has been tested by the company in a model simulating bacteria multiplying in chronic wounds. The results of the tests show both greater antibacterial activity, and a longer duration of activity than the majority of other anti-bacterial dressings because the product kills bacteria both in the wound bed and in the exudate absorbed by the dressing. The antibacterial effect of Contreet Foam is considered superior because of the sustained and effective release of the silver. Silver is only released when in contact with wound exudate (hydroactivation), and lasts for up to seven days. In addition, Contreet Foam is active against all microorganisms. The product is used for treatment of burns, leg ulcers, diabetic foot ulcers, pressure sores, postoperative wounds, and donor sites.

Dermagraft® Skin Substitute

In July 2003, the FDA granted Humanitarian Device Approval for Smith & Nephew's Dermagraft®, a dermal (skin) substitute that is made from living human cells known as fibroblasts. These cells are placed on a dissolvable mesh material. Over time, the cells grow and form a skin substitute and the mesh is absorbed. The dressing covers and protects wounds while supporting healing. Dermagraft is used on the wounds of patients with dystrophic epidermolysis bullosa (DEB). Patients with this disease have fragile skin that is susceptible to multiple blistering lesions because their skin lacks certain proteins that normally hold the layers of skin together.

IPM Wound Gel

L.A.M. Pharmaceutical Corporation has recently received FDA approval to sell its IPM Wound Gel™, a next generation wound healing product. The gel is designed to deliver high concentrations of the hyaluronic acid (HA) derivative sodium hyaluronate to the ulcer bed thus providing an optimal environment for wound healing to occur. (HA is a major molecule located between skin cells and in the dermis below the skin). High concentrations of HA, particularly in fetal wounds have long been noted to be associated with rapid healing and little scarring. Although HA's healing qualities have been well known and documented, the pharmacological challenge has been to deliver high concentrations of HA directly to the ulcer bed. L.A.M.'s proprietary Ionic Polymer Matrix™ technology makes it possible. The product is intended for

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use on diabetic, venous stasis, pressure, leg and foot ulcers, debrided wounds, minor lacerations, cuts and abrasions.

TISSUPOR Wound Pads

TISSUPOR of Switzerland has recently developed a wound pad technology to treat a wide range of poorly healing chronic wounds resulting from various causes (except burns). The company received CE approval for the product in December 2001, and efforts are being made to attain FDA approval for the U.S. The wound pads feature a novel, 3D stitched material with specific pore structure which promotes the in-growing of cells and capillaries and thus the formation of granulation tissue. The TISSUPOR wound pads follow the principles of moist wound treatment and can be used for wounds with varying degrees of exudate. The product can also be combined with other wound treatment applications such as vacuum assisted closer (VAC), plastic, muscle, and graft. TISSUPOR offers the benefit of lower treatment costs by reducing the frequency the dressings need to be changed to 3 to 7 days. (www.tissupor.ch)

Thymosin Beta 4

RegeneRx Biopharmaceuticals, Inc. announced in October 2003 that it has successfully completed a Phase 1 clinical trial with its lead therapy, Thymosin beta 4 (Tß4), a novel wound-healing drug. Tß4 is a naturally occurring 43-amino acid peptide that is vital for the repair and remodeling of injured tissues. It exhibits anti-inflammatory properties, is nontoxic, active systemically and topically, and can be produced synthetically at low cost. Unlike other prospective wound treatments, it is not a growth factor. Tß4 is present in virtually all human cells. Its gene is up-regulated following tissue injury and during the remodeling and differentiation of cells, and is found in highest concentrations in blood platelets, the first cells to enter wounds. Unlike other wound repair treatments, such as growth factors, Tß4 promotes endothelial and keratinocyte cell migration, down-regulates a number of inflammatory cytokines and chemokines, promotes angiogenesis, and has a very low molecular weight that allows it to diffuse relatively long distances through tissues. It also has the unique ability to regulate the cell-building protein actin -- a vital cytoskeletal component. The Company is developing Tß4 under an exclusive worldwide license from the National Institute of Health (NIH).

Vacuum Assisted Closure ® (V.A.C.®) Therapy

Kinetic Concepts, Inc. is a global corporation that develops and markets a broad range of healthcare products. The company has recently received the American Podiatric Medical Association’s (APMA) seal of approval for its Vacuum Assisted Closure ® (V.A.C.® ) Therapy. Clinical studies have shown that V.A.C.® Therapy™ encourages high quality and efficient patient care by promoting wound healing, and reducing the threat of increased morbidity associated with unhealed wounds. The V.A.C.® assists granulation tissue and helps uniformly draw wounds closed by applying controlled, localized negative pressure. It also helps to remove infectious materials and provides a closed, moist wound healing environment. The therapy is intended to promote healing in many types of wounds such as diabetic ulcers and pressure ulcers, as well as flaps and grafts.

VICRYL Plus Antibacterial Suture

Ethicon, Inc., a Johnson & Johnson company, announced in December 2002 that it received U.S. FDA clearance to market its VICRYL Plus Antibacterial Suture. The product is the first and only suture which features an antibacterial agent designed to reduce bacterial colonization on the suture. The agent is known to be effective against staphylococcus aureus, staphylococcus epidermitis and methicillin resistant strains of staphylococcus, the leading surgical site bacteria. VICRYL Plus is the first coated suture for wound closure that has been introduced. It begins to work as soon as it comes into contact with the patient by creating an Active Zone around the suture. The product is intended to help decrease the rising number of infections acquired in hospitals and surgical sites.

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9.

Dental

By David Kouidri, Trade Commissioner, Chicago, IL

9.1. Facts and Figures

The dental equipment and supplies market is one of the smaller sectors of the US medical equipment industry. However, it is a sector that is expected to grow as baby boomers address their oral hygiene as well as those of their children. The dental supply and equipment market in the U.S. was $14.265 billion in 2003. The total professional segment of the industry, or the products used by dentists, make up $10.24 billion, or 72% of the total market. It is this segment that we will focus on in this chapter.

The professional dental supply and equipment market is understandably broken down into two sectors; 1) supplies sector, which includes amalgams, drill bits, tooth cement, etc, and 2) the equipment sector, such as furniture, drills, lighting systems, and others. The supply sector makes up the majority of the professional dental market with a size of $9.3 billion in 2003. This sector is experiencing a growth rate of 8% per year and is anticipated to hit a market size of $13 billion by 2008 according to Freedonia Research.

Repair and restorative supplies remain the major source of revenue within the market accounting for 55% of the total professional dental market. It is projected this sector will continue to experience healthy growth rates of 7% through 2008. New materials and advancements in chair-side productivity will be the main drivers for this increase.

Although quite small in terms of overall implication within the dental industry, clearly the most dramatic trend is in the field of cosmetic dentistry. Between 2003 and 2008, the demand for cosmetic services will increase by 88% and is forecast to explode by 2013 increasing by 312% from levels seen in 2003.

Generally, the dental market continues to go through an adjustment as the focus of service is on prevention rather than restoration. The American Dental Association has reported a de-
crease in metal amalgams (fillings) of -51.7%, a reduction of plastic restorations by -5.7% and 41.2% less extractions. However, periodic oral exams increased by 12.1% as increased demand for preventive dental care and insurance covers more preventive treatment. As noted in the following table, diagnostics and preventive services for patients will increase 17% from 2003 - 2008 whereas repair and restorative services will increase by 13%.

Interestingly, as noted in Figure 39, preventative supplies only account for 2 - 3% of sales within the professional market however preventive procedures demanded by patients account for over 67% of the total in 2003 (see Figure 40), whereas restorative services amounted to 28% of the activity but 60% of sales of dental product.

<table>
<thead>
<tr>
<th>Year</th>
<th>Dental Procedures</th>
<th>Diagnostic &amp; Preventative</th>
<th>Repair and Restorative</th>
<th>Cosmetic</th>
<th>Other</th>
<th>Procedures/visit</th>
<th>Dental visits</th>
</tr>
</thead>
<tbody>
<tr>
<td>1993</td>
<td>1070</td>
<td>711</td>
<td>325</td>
<td>3</td>
<td>31</td>
<td>2.0</td>
<td>530</td>
</tr>
<tr>
<td>1998</td>
<td>1240</td>
<td>824</td>
<td>379</td>
<td>4</td>
<td>33</td>
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<td>575</td>
</tr>
<tr>
<td>2003</td>
<td>1430</td>
<td>962</td>
<td>425</td>
<td>8</td>
<td>35</td>
<td>2.3</td>
<td>620</td>
</tr>
<tr>
<td>2008</td>
<td>1655</td>
<td>1123</td>
<td>480</td>
<td>15</td>
<td>37</td>
<td>2.5</td>
<td>660</td>
</tr>
<tr>
<td>2013</td>
<td>1910</td>
<td>1306</td>
<td>540</td>
<td>25</td>
<td>39</td>
<td>2.7</td>
<td>700</td>
</tr>
</tbody>
</table>

**Figure 40 Dental Patient Activity & Procedures in Millions**

The single most important reason that brings patients to dentists is insurance coverage. Dental insurance coverage for Americans is clearly on the rise. Back in 1970 just 6 million Americans were covered by dental insurance whereas today, over 160 million Americans are covered. The National Health Center for Statistics states that people with dental insurance are twice as likely to visit a dentist versus those who do not have coverage (2.6 visits per year versus 1.7), highlighting once again the preventive nature of the industry.

An additional dynamic affecting the dental industry is the decrease in the amount of dentists. According to the US Department of Health and Human Services (DHHS) there are 170,000 dentists located in the US compared to 275,000 in Europe and 85,000 in Japan. But the trend in the US suggests that by 2020 there will be less dentists per 100,000 inhabitants despite the increase in demand for dental services (see table below). Therefore, it is foreseen that a "squeeze" on the dental providers will take place in the near future putting pressure on the dentists as well as the manufacturers requiring more efficient and productivity-enhancing products.

With this in mind and in combination with Figure 39, productivity is clearly on the increase as we see procedures per dentist visit on the rise. In 1993 there was an average of 2 procedures per visit with a projected increase by 2013 to 2.7.

**Dental Implants**

The dental implant market is estimated to be more than $1 billion globally and over $400 million in the United States. Growth in the industry is expected to be 10 to 15 percent annually. Over 700,000 implant procedures took place in the U.S. in 2003, compared to over 1.3 million in Europe.

A dental implant is a small metal post that substitutes the natural root and is inserted into the jawbone. The post is then used as a stable base for an artificial tooth. Titanium is the material of choice for implants.

There are a number of benefits stemming from implants including stability and, more importantly, aesthetics. Research shows that for healthy patients, implants have a 90 – 98 percent success rate and usually last the life of the patient. As the older population increases over the
next ten years, and their desire to have aesthetically acceptable solutions, implants will gain market penetration. Some hurdles to overcome include accelerated healing times and more refined implant designs. Additionally, the marketing of implants, its success, and increased simplicity of treatment should help growth in the field.

![Figure 41 U.S. Dentists per 100,000 Inhabitants 1990 and 2020](source: Center for Medicare and Medicaid)

Today a small percentage of general practitioners place implants. In the US, only nine percent of all general practitioners carry out the treatment, while in Italy, around 50 percent place implants. Educating the general practitioner in the US will be an important step for the market. Here is where the opportunity lies.

In a recent study done by Stan Goff with the Dental Product Report 91% of the responding dentists stated that they do not perform implant procedures. Of those, 96% said they do not intend to place implants in the next 12 months. However, 80% of responding dentists stated that the number of inquiries from patients regarding implants has increased in the last two years.

The Dental Lab Market

Dental laboratories produce dental consumables for dentists and their patients. Products include ceramic replacement teeth, crowns, bridges, and porcelain inlays among others. Dental labs are responsible for 10–15 percent of the total dental market, or $1.5 to 2.0 billion of total revenue. The dental laboratory business is segmented and geographically focused with approximately 12,000 labs in North America compared to 43,000 in Europe. Usually dental labs service dentists in their region and rarely market themselves outside of a geographical region. The laboratories depend on the dentist to supply the ultimate consumer, or patient, and are evaluated by delivery time and quality of the outcome.

Materials

One of the most prevalent and costly consumables in the dental industry is material that is used for tooth restoration. The table below explains the percentage of dentists who responded positively to using certain restorative techniques. Traditionally, dentists and dental labs who perform restoration procedures use metal (such as gold), ceramic, or porcelain-fused-to-metal (PFM). Although PFM products and metal restoration dominates the market, metal-free products are on the rise. The use of metal-free bridges doubled from 2002 to 2003 going from 16% to 31% of respondents confirming use of the technique. In addition, metal-free crowns have also been experiencing an increase in usage from 60% in 2002 to 73% in 2003. Interestingly, the decision process for choosing the material and technique provides great indicators as to how dentists make their decisions. Clearly, past experience is a key driver for the decision to perform certain techniques in dentistry. Therefore, education and marketing can be crucial in changing dentists procedures.

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**Figure 42 Choices of Restoration Made by Dentists**

Dental Hand Pieces

Another substantial sector of the U.S. dental market is the hand piece that dentists use for drilling and other similar applications. A recent survey suggests that more than half of the general practitioners have at least 10 functioning hand pieces which calculates to a $125 Million market. The survey suggested that maintenance was the main concern with the performance of the hand piece and 60% of the time service was provided by the dealer and/or the manufacturer.

**Figure 43 Reasons for Buying a Hand Piece**

Other market characteristics of the dental market worth mentioning include the importance of wholesalers and delivery times. The most common means for dentists to purchase dental equipment and consumables is through wholesalers such as Darby Spencer Mead, and Keystone Industries. Other manufacturers like Patterson Dental and Henry Schein, complement their manufactured products with items that they have agreed to distribute on behalf of the manufacturer. This is to answer the dentists request for a one-stop-shop. In addition to the one-stop-shop desires of the dentist, they are also requesting fast delivery. Similar to many other industries, the end user, in this case the dentist, does not want to retain a large inventory and therefore follows a strategy of Just in Time, making delivery time crucial.

### 9.2. Major Competitors

Major consolidation is taking place in the U.S. dental industry. Presently there is a handful of major players manufacturing and supplying the dental market. Wholesalers play a major role in the industry, so much so that the major manufacturers are also taking on the role of wholesalers within the market, becoming the desired one-stop-shop for the dentist.

- Established in 1899, **Dentsply** is one of the largest dental manufacturing and supply company in the world with 22 facilities globally, supplying 100 countries. Dentsply supplies all aspects of the professional dental market including materials, consumables, capi-
The U.S. Market for Medical Devices - Opportunities and Challenges for Swiss Companies

tal equipment as well as supplies for dental labs. Dentsply sales in 2003 were $445 million.  (www.dentsply.com)

- **Henry Schein** Dental Group is a major distributor and wholesaler of dental equipment. Henry Schein claims to own 30% of the US and Canadian dental market. They also claim to serve 75% of the 170,000 U.S. dental practices as well as 75% of the 12,000 dental labs. Henry Schein has 80 equipment sales and service centers, to serve the dental market including the US government (Army). Henry Schein has 900 field sales consultants and over 200 telesales representatives carrying 70,000 products. In 2003 Henry Schein (dental, medical and veterinary) had sales of $3.3 billion and 7,900 employees.  (www.henryschein.com)

- **ITI Straumann** is leader in the field of dental implants and tissue regeneration. Headquartered in Switzerland, Straumann has a brand new research facility in Boston and a training facility in southern California. In 2003 Straumann had 900 employees and sales of CHF 344 million.  (www.straumann.com)

- German/U.S. owned **KaVo** is a manufacturer of straight and contra-angle hand pieces and turbines, dental equipment and treatment units, care materials and systems. KaVo is also a leading manufacturer of new technology products, including lasers, caries detector, and dental laboratory equipment. In 2003 KaVo had sales of Euro 370 million and 3,300 employees.  (www.kavo.com)

- **Nobel Biocare**: Headquartered in Switzerland, this Swedish company is a leader in aesthetic dental solutions. Nobel Biocare has production facilities in Sweden and the USA and a sales organization in 28 countries. In 2003 Nobel Biocare had 1,400 employees and net sales of approximately $434 million.  (www.nobelbiocare.com)

- **Patterson Dental Supply** is one of the largest dental equipment distributors, offering a complete range of dental consumables, clinical and laboratory equipment, and value-added services to dentists, dental laboratories, institutions and other healthcare providers. Patterson Dental Supply has the largest direct sales force in the industry, with 1,300 sales reps and specialists serving the United States and Canada and amounting $1.6 billion in revenue in 2003.  (www.pattersondental.com)

- **Sybron Dental Specialties** is a manufacturer of high technology dental and infection prevention products in the dental restorative, orthodontic, and endodontic market. Sybron is also the owner of Kerr Dental, a manufacturer of dental products as well as dental laboratory products. In 2003 Sybron had 4,200 employees and sales of $526 million.  (www.sybron.com)

- **Young Innovations**: One of the faster growing dental product companies in the US, Young Innovations manufactures dental supplies, consumables, and equipment such as x-ray machines, pastes, gloves, and much more. Based in Earth City, Missouri, Young had sales of $76 million in 2003 and 294 employees.  (www.yndt.com)

### 9.3. New Technologies

The dental supply and equipment industry continues to readjust and emphasize prevention. Other dynamics such as the reduction of dentists per capita, and the increase of procedures per visit are demanding more productivity. The purchasing process by dentists has also been identified as a changing paradigm. Baird Equity suggests that dentists are no longer interested in just replacing dental equipment any longer. They are now more interested in replacing the equipment with a new and improved model. Therefore, the demand for new and better technologies is even greater. One of the key drivers for such demands is the necessity and
desire of the dentist to become more efficient and profitable. Cited examples include digital x-ray machines, software, and other tools that offer more productive processes.

**Cosmetic Dentistry Gaining Ground**

As mentioned before, a major trend within the dental industry is the importance of preventive care rather than the previous "drill and fill" strategy. Cosmetic services and procedures are a profitable business experiencing an annual growth rate of 8 - 10%, according to Baird Equity Research. Although cosmetic dentistry is not covered by health insurance, it remains and will continue to be a popular service especially considering the growing population. All-ceramic materials are improving the aesthetics of replacements and, thanks to CAD/CAM capabilities, are moving the production of such replacements away from the traditional labs to chair-side operations or directly to industrial partners.

**Computer Aided Design Technology**

Computer based technology has been developed to offer the dentist the ability to design and manufacture ceramic restorations during a single patient visit. Through computer aided design the dentist has an efficient and productive tool that elevates the need for impressions, temporaries and the outsourcing to costly dental laboratories.

**Micro Dentistry: Air Abrasion**

Air Abrasion is a gentle spray of an air and powder mix that removes decay and prepares the tooth for restoration. It has often been referred to as "no needle, no drill" dentistry. Often a numbing shot is not necessary when Air Abrasion is used because the procedure is virtually painless. It allows for very small cavity preparations and removes only a minimal amount of healthy tooth surface. Air Abrasion is not ideal for large cavities or cavities filled with silver-mercury fillings. The powder-mix includes silicate and has ADA and FDA approval.

**New X-ray Systems**

A new x-ray technique, called digital radiography positions an electronic sensor in the examining area. The system then takes an electronic image and stores it in a computer. It is almost immediately viewable in the computer and can be enhanced with color and other enhancement tools. In addition to the fast processing and enhancement tools, digital radiography significantly reduces the radiation exposure to the patient.

**Laser**

The fear of high cost has prohibited the large scale penetration of laser technology in the dental office; however, lasers could be the drill of the future. As applications and approved procedures for lasers increases, dentist will begin to see a benefit in the relatively large investment (at least compared to a standard drill). Now lasers are approved for up to 20 dental procedures for both soft and hard tissue applications. It will just be a matter of gaining the attention of dentists and convincing them of the benefits. One of the clearest benefits is the positive response from patients who experience no numbing and practically no pain after the procedure.
10. Marketing Tools and Distribution Channels

David Kouidri, Trade Commissioner, Chicago, IL and Scot Orgish, Trade Commissioner, Houston, TX

The marketing costs associated with entering into the U.S. medical device sector can be substantial as is the time necessary, but once overcome the opportunities can be great. This chapter will discuss some of the most relevant marketing dynamics of the medical device industry. We will look at the purchasing process and marketing tools that are standard (in some cases required) to help the decision maker decide on new product. The chapter will also address the question of how to access the individuals who make the purchasing decision, such as marketing platforms, which will help to gain a foothold in the U.S. market.

10.1. Defining Distribution Channels

Understanding specifics of distribution channels, for the purpose of marketing, that affect a company’s industry can be a vital step. It is critical to understand how to access potential customers when plotting out market entry strategy. It can also be important to evaluate how the competition constructs distribution channels, with the intention to identify industry standards, comparative advantages, and areas of opportunity.

Many elements contribute to defining the distribution channels of the industry. First and foremost is defining the purchasing process and identifying the decision makers that are involved. Understanding the vehicles of communication that are most commonly used by companies to inform potential customers will also contribute to the defining of distribution channels. In the medical field, scientific citations, presentations at conferences as well as traditional advertising play an important role in communicating to potential and current customers.

An additional definition is the level of customer service and the resulting customer relations expected by a potential customer. This is particularly relevant in many of the highly competitive segments within the medical field and has a direct implication on the level of presence a company needs to consider.

Clearly, all these dynamics and definitions have specific answers and criteria according to the market segment and the product being supplied.

10.2. Market Segmentation

The medical device industry continues to be supplied by a large number of industries and sectors, including materials, machine tools, electronics and much more. Most of these suppliers however are targeting similar markets such as hospitals, physicians, and other healthcare providers. Therefore, the medical device sector can be segmented into two categories, namely medical technology products, and conventional hospital supply products.

Medical Technology Products

Products, that address a new need and create new standards and procedures in the medical field, including surgery, are considered medical technology products. Examples include the
implantable cardiac defibrillator (ICD), new orthopedic implants, and drug coated stents. As these new products create new standards, they also demand higher prices and higher margins. Usually the decision to use medical technology products lies in the hands of the medical doctor.

Market entry of new medical technology products can be extremely time consuming and expensive due to the need of clinical trials, evaluations and a proactive sales process. This poses a challenge to the small and medium sized firms that may not have the resources, both financially and human resources, to see the complete process through. Therefore, strategies that include partnerships and technology licensing should be included as one of the many options when considering entering into the US market (See Chapter 11 Daniel Wuersch).

Conventional Hospital Supply Products

Conventional hospital supply products are products that can be considered commodities where bulk purchases are made usually by a hospital procurement officer. Conventional products include bandages, syringes, and similar products. As stated, this is a high volume, bulk purchase type transaction where low margins are the norm and long term contracts are the key to profitable business. There has been, however, recent debate on such long term contracts as the industry is now debating whether or not these contracts hinder competition and create unfair monopolies. It is argued that long term contracts discourage other firms to invest in new developments within that sector simply because they do not have the monetary incentive and revenue. In the US today, conventional hospital products can provide a good revenue stream that helps fund the development of new higher technology products.

10.3. The Decision Makers

Healthcare providers cover a very broad range of persons and entities providing services in the healthcare sector including general practice physicians, nurses, physical therapists, physicians assistants, surgeons, a multitude of specialty fields, hospitals, hospices, clinics, etc. These persons and organizations are the direct links to the ultimate end-users of medical devices, the patient. In some cases the patient might have some input regarding medical devices that will be implanted, but for the most part, it is the doctors and health providers that make the decisions about which devices they will recommend or use on patients. Patients generally follow the advice or recommendations given by their physician or healthcare provider. In most cases, when it comes to marketing medical products and devices, the healthcare providers should be considered the end-user. This being the case, marketing efforts should be designed to target the healthcare providers.

Doctors continue to play a vital role in the purchasing of medical technology products. There are, however, processes where the influence of doctors are secondary to the health insurance companies (see Reimbursement). It has become common that health insurance companies get the last say regarding certain devices and procedures, due to whether or not the insurance company will reimburse the patient. Nonetheless, it is clear that doctors remain on the front line when it comes to recommending procedures and products to patients. Doctors continue to be instrumental in evaluating and recommending new techniques.

Procurement officers at hospitals are important decision makers especially when discussing the purchase of conventional hospital products. Procurement officers also purchase some medical technology products. Purchases by these officers can be done either directly or more commonly, via a Group Purchasing Organization.
Key factors for medical device purchase consideration

- Price of the medical device (i.e. direct cost comparison to similar devices)
- Benefits to the patient relative to other commercially available devices or procedures (i.e. size/weight, reduced risk of infection, reduced complications, improved patient quality of life, improved safety, increased survival rate)
- Time needed for surgery (i.e. reduced surgical time, fewer surgical staff)
- What is the service life of the device? (i.e. does the device last longer than other products)
- Ease of installation or procedure (i.e. is the new device easier to use or install compared with other available devices)

10.4. Purchasing Process

There are two primary channels whereby doctors, hospitals and healthcare providers purchase medical products: (1) Direct Purchasing, and (2) through Group Purchasing Organizations.

Direct Purchasing

Some large hospitals and healthcare providers do their own purchasing directly. The purchasing process varies by hospital or healthcare facility and by state as each organization has its own procurement guidelines and is governed by state statute as well as the institution’s own policies. Some large institutions are likely to have a procurement department which is responsible for the procurement of supplies, materials, equipment and services for the hospital. A trend in the industry is for hospitals to have their common stock inventories online with suppliers in an effort to maintain just-in-time inventory levels. Distributors are primarily used to maintain and distribute common stock and frequently used goods. Hospital departments in need of such items are often required to purchase them through their responsible department. Vendors may be discouraged or even forbidden to attempt to "back door" sell "stock" items to individual departments.

For services and items that are not considered common stock or frequently used goods, a "Request for Proposal/Quotation" or "Invitation to Bid" will most likely be issued. A sample procurement policy at a major hospital in the U.S. can be found at the following link: M.D. Anderson Cancer Center, Houston, TX [http://www.mdanderson.org/departments/procurement/]

Group Purchasing Organizations

Smaller healthcare providers that do not have the buying power of some of the larger institutions usually choose to do their purchasing through Group Purchasing Organizations (GPOs). GPOs are able to negotiate deep-discounted deals with suppliers and distributors, and provide collective buying power for their healthcare provider members. It is estimated that GPOs save their members an average of 10.4 percent on supply costs. This includes price savings on goods purchased through GPOs, patronage dividends received from GPOs, and labor costs avoided by using GPOs. In addition, a recent survey by the American Hospital Association of hospital executives shows that ninety percent indicate they purchase between 60 percent and 90 percent of their products on GPO contracts. Smaller hospitals tend to purchase 20 percent more supplies through a GPO than a larger hospital system because of the cost savings, while larger hospital systems sometimes can negotiate on their own for better pricing using the GPO price as a base. It is expected that the use of GPOs will continue to be strong in the future.
Almost two thirds of hospitals surveyed indicated they plan to increase purchases through GPO contracts. Listed below are the names and websites of several major GPOs.

- **Amerinet** headquartered in St. Louis, MO, was founded in 1986, and is one of the country’s largest group purchasing organizations with members throughout the U.S. The company operates through its three shareholders: Amerinet Central, Intermountain Health Care, and Vector. Amerinet currently serves more than 19,000 member facilities including hospitals, surgery centers, managed care organizations, closed pharmacies and integrated delivery networks and surpassed $6 billion in sales in 2003. ([www.amerinet-gpo.com/](http://www.amerinet-gpo.com/))

- **Broadlane** based in San Francisco, operates Broadlink, a private exchange of 841 acute care facilities and 3,395 sub acute care facilities which purchase $3.6 billion in supplies annually. ([www.broadlane.com/](http://www.broadlane.com/))

- **Consorta, Inc.** based in Chicago, IL, is a leading healthcare resource management and group purchasing organization, whose shareholders are faith based or non profit health systems. The Consorta membership encompasses over 400 acute care facilities, representing 55,944 beds, and more than 1700 non-acute care sites. Consorta had planned purchase levels of 3.0 $ Billion in 2003. ([www.consorta.com/](http://www.consorta.com/))

- **HealthTrust Purchasing Group (HPG)** was established in May, 1999, and is based in Nashville, TN. The company’s main focus is to provide superior and cost efficient services to both their patients and their members. HPG supplies 900 facilities, including not-for-profit and for-profit acute care hospitals, ambulatory surgery centers, alternate care sites, and physician offices. HPG maintains a purchasing volume of $5.0 Billion. ([www.healthtrustpg.com/](http://www.healthtrustpg.com/))

- **MedAssets HSCA**, headquartered in St. Louis, MO, is the largest independent group purchasing organization in the country, serving more than 16,000 healthcare providers. ([www.hsca.com/](http://www.hsca.com/))

- **Novation/VHA/UHC** in Irving TX, was established Jan. 1, 1998, when VHA Inc. and the University HealthSystem Consortium, two national health care alliances, consolidated their supply-contracting functions. Novation acts as the supply company for members, associates and affiliates of both alliances, to help them manage and reduce supply costs. The GPO serves health care organizations of all sizes, ranging from many of the nation's best-known and most prestigious health care systems to small, rural hospitals throughout the country. Novation represents the purchasing interests of more than 2,300 health care organizations that account for almost 90,000 of the nation's staffed beds. Through its affiliation with VHA and UHC, Novation represents approximately $29 billion in annual purchasing potential and $19.6 billion in annual purchases. ([www.novationco.com/](http://www.novationco.com/))

- **Premier** is a leading healthcare alliance which is collectively owned by more than 200 independent hospitals and healthcare systems in the U.S. Premier’s owners include some of the nation’s largest and best-known not-for-profit hospital and healthcare systems and referral centers as well as strong community hospitals, generally mirroring the composition of the hospital/health system industry in the U.S. Together, they operate or are affiliated with nearly 1,500 hospitals and other healthcare sites. [http://www.premierinc.com/frames/index.jsp](http://www.premierinc.com/frames/index.jsp)

### 10.5. Road Map for Market Entry

A road map to market is a useful tool that helps plot out the steps necessary to take when approaching the new market. It will also help to understand what needs to be done and at what

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sequence. In this case we focus on the segment involving the engagement of doctors or other decision makers in the buying process. It is here that the distribution channels and marketing takes front stage. Engaging the medical doctor/purchaser can be broken down into 4 steps; standard/product comparison; opinion leader evaluations; promotion of evaluation result; and finally sales and distribution.

![Figure 44 Roadmap for Market entry into the US Medical Device Industry](image)

The road map should begin with the comparison of products, especially those in the market today that set the standard.

From a marketing perspective, a new standard-setting product that has an impact on the industry may face substantial barriers to entry, including legal disputes. Other competitive forces may also try to prevent entry such aggressive marketing messages from competitors. However, if a new product creates new and successful standards, it can almost become a necessity that the field adapts and begins using the new standards. This is partly due to the risk doctors face if they do not adapt to new technologies and procedures for the benefit of the patient (malpractice law suits). Nonetheless, the setting of new standards and comparative advantages can have an extremely important implication on marketing and market entry strategy.

In the U.S. clinical trials are the most common tool used to prove that new medical devices, technologies, and procedures are useful and, most importantly, safe. Clinical trials are usually performed by a third party evaluator or opinion leader, and commonly cited in relevant literature promoting the usefulness and safety of the development. It is important, therefore to understand the relevance of the opinion leader within the U.S. medical device industry and the process.

### 10.6. Importance of Opinion Leaders

Opinion leaders are the leading voices within the medical device field and play an important role as evaluators of medical devices. Opinion leaders can be doctors, medical professors, scientists, and others that are recognized within the industry as legitimate and respected investigators. The higher the recognition of the opinion leader within the field is, the more valuable the opinion. A favorable opinion from one of these leaders can be helpful, and most commonly crucial, to convince a user (be it a doctor, scientist, a medical device producer) to change suppliers and go with a new standard. A positive opinion from a respected individual can be a major marketing tool.

Access to opinion leaders can be very challenging due to numerous elements, including limited time, cost associated with an evaluation, and established ties between doctors and medical device manufacturers.
10.7.  Clinical Trials

The most common evaluation of a device or technology in the medical field is known as a clinical trial. With many medical products, going through a clinical trial is required for regulatory approval (see also Chapter 13 Darren Alch). The extent and expense of a clinical trial varies by product as does the legal regulations of such trials. However, for the purpose of marketing, a clinical trial can be a critical testimonial, or reference.

Clinical trials are done by three types of groups a) Academic institutions b) private medical research facility; c) or a combination of both. Cost of the trial can be covered by numerous organizations, including a federal agency, a hospital, and/or the medical device manufacturer. The evaluation is agreed to by a lead professor/doctor (opinion leader) and is usually implemented by a team of researchers and doctors. Oversight of such trials is done by committee made up of leaders within the field.

What is important, however, for marketing purposes is that clinical trials, if successful, provide the main marketing tools establishing testimony, product benefit and other marketing content. This information must be captured, properly presented and cited, a critical marketing step.

Although many suppliers may not need clinical trials, understanding that the industry relies heavily on them as a marketing tool is important. Proof of concept/product is a necessary sales tool within the medical device industry.

U.S. Agent for Sponsorship of Clinical Trials

If a Swiss medical device manufacturer wishes to conduct a clinical trial in the U.S. to obtain FDA approval to market the device, they must find a U.S. partner to act as their agent to request an Investigational Device Exemption (IDE) to conduct the clinical trial. A foreign company cannot sponsor an IDE, therefore, they must have a U.S. agent who acts as the sponsor. The regulations regarding the promotion of IDE’s are as follows:

Sponsors, investigators, or any person acting for or on behalf of a sponsor or investigator cannot: (1) Promote or test market an investigational device, until after the FDA has approved the device for commercial distribution; (2) Commercialize an investigational device by charging the subjects or investigators a higher price than that necessary to recover costs of manufacture, research, development, and handling; (3) Unduly prolong an investigation; (i.e. If data developed by the investigation indicate that pre-market approval (PMA) cannot be justified, the sponsor must promptly terminate the investigation.); or (4) Represent that an investigational device is safe or effective. However, the sponsor may advertise for research subjects to solicit their participation in a study. Appropriate advertising methods include but are not necessarily limited to: newspaper, radio, TV, bulletin boards, posters, and flyers that are intended for prospective subjects. No claims should be made, either explicitly or implicitly, that the device is safe or effective for the purposes under investigation, or that the test article is known to be equivalent or superior to any other device.

Solicitation of Candidates For Clinical Trial Use

In order for medical device manufacturers to find suitable candidates to use in Clinical trials, it is necessary that they be allowed to advertise to attract persons for the study group. Since the medical devices are not yet approved for commercial distribution, they are classified as Restricted Medical Devices. A draft guidance proposal for consumer-directed advertising was issued on 10 February 2004. At the time of this report, the guidance document was distributed for comment purposes only. Listed below are the non-binding recommendations.

The Federal Food, Drug, and Cosmetic Act (the Act) requires that manufacturers, packers, and distributors who advertise restricted devices distributed or offered for sale in any State include in all advertisements certain information about the advertised device’s uses and risks.
Specifically, the Act requires such advertisements to contain "a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications".

The purpose of this guidance is to describe an approach that the FDA believes can fulfill the requirement of the brief statement in connection with consumer-directed broadcast advertisements for restricted devices. The approach presumes that such advertisements:

Are not false or misleading in any respect. This would include communicating that the advertised device is restricted to sale, distribution, or use only upon authorization of a licensed practitioner or upon other conditions established by FDA in regulations or in an approval order.

Present information about effectiveness and information about risk in a balanced manner.

Include a thorough major statement conveying all of the device's most important warnings, precautions, side effects, and contraindications in consumer-friendly language.

Communicate all information relevant to the device's indication (including a brief statement of the intended use(s) of the device and any limitations to use) in consumer-friendly language.

The full draft can be found at http://www.fda.gov/cdrh/comp/guidance/1513.html

10.8. Citations

One of the more common vehicles used by medical device companies to introduce and market product capabilities to the U.S. market is through citations, or articles, within relevant magazines or publications. Medical publications are an important communication channel for publishing results of trials as well as new technologies. For a listing of medical publications see Annex II on page 128.

The field of scientific and medical publications can be depicted in a pyramid-like structure (Figure 45). At the top are the general science magazines such as Nature (www.nature.com), or Scientific American (www.sciam.com), that publish major scientific breakthroughs from many fields of science including medicine and have a large subscription base. Only substantial breakthroughs in medicine find their way into these general science publications. However, these are not the publications of choice that the "decision makers" read in order to find new technologies and developments in their field.

Figure 45 Pyramid Structure of Science Publications
The second level is defined by general medical publications such as the *New England Journal of Medicine* (www.nejm.org), and the *Journal of the American Medical Association* (www.ama-assn.org). These publications highlight major developments, including new product evaluations, in all fields of medicine.

The next level of publications are those that address the sub sectors of the medical field, such as the *Journal of Cardiology*, a magazine that highlights issues in the field of cardiology. It is in this arena, where specialized decision makers, including doctors, gain specific information regarding developments within their fields. These publications are usually run by the relevant academy, or overseer of the field (American Academy of Cardiology). For conventional hospital products there are also specific publications for GPO's as well. In certain areas there can be further levels of specialization.

Understanding where, in the supply chain, the customer gets their information can be critical. In addition, due to the broad industry involvement in the medical field, appropriate publications may be found outside of the medical field, such as the machine tooling industry and the publication of choice by the medical device engineers.

Scientific conferences are also good venues to present papers and findings. In the United States conferences have a competitive process for the presentation of papers. Usually a "call for papers" is announced well before the conference. Submitted papers are then reviewed by committee who chooses the presenters.

Obtaining a citation is not guaranteed, of course, nor is coverage of a press release. Each publication as well as field studies have their own standards and procedures. Clearly, the significance of the finding, or product development, is a major determinant of whether a publication publishes or cites the finding. In addition, some publications work as private businesses and therefore offer citation coverage if a company is interested in advertising. Nonetheless, citations and press coverage are important marketing tools for the medical industry.

### 10.9. Marketing Platforms

Many industries in the U.S. are overseen, organized and collected via gathering points of the main players of the industry and field. This "association", or community of interest is also known as a platform and carries a great amount of importance in the medical field. There can be two types of platforms, namely the medical academy and the industry association. Both entities can be host to trade shows and conferences, where their members can exchange ideas, learn new techniques from one another, network, collect industry information, and promote products and services. These platforms are extremely important for the medical device industry as they act as the introduction point of new technologies and products. These platforms can also decide on new standards within the relevant industry. Therefore, understanding where all the main players meet to create this "community of interest" becomes very valuable when looking for opinion leaders, doctors, partners, sales channels and information.

For companies looking at the U.S. medical device market it can be useful to map out the relevant industry, including all decision makers such as doctors, medical scientists and engineers. In addition, insurance reimbursement (see chapter 2) is a major driver of accepted medical devices. Therefore identifying and using platforms that foster the communication with doctors, scientists, insurers, and other decision makers is important.

The main platform for all medical doctors is the American Medical Association (www.ama-assn.org), a not-for-profit association that plays the role of advocacy (lobby) and advancement of the healthcare field in general. Under the AMA are the specialty academies of medical fields such as the American Academy of Orthopedic Surgeons (www.aaos.org). To be a member, or fellow of the academy you must be an orthopedic surgeon and abide by certain...
admission criteria as well as ongoing evaluations. A full list of all medical academies is on page 134.

The manufacturers of medical devices have also come together to create communities of interest. For example, the Advanced Medical Technology Association (www.advamed.org) advocates the access for patients to new medical technologies, as well as reimbursement issues and much more. A list of such associations is found in Annex II on page 128.

For the suppliers to distinctive medical device industries and OEMs, focused platforms can also be very useful venues to generate relevant contacts and business leads.

10.10. Level of Presence

It becomes clear that many of the market demands have direct ramifications on the level of presence a Swiss supplier to the medical device industry may need. Understanding the level of involvement in the clinical trial and citation process as well as the level of service, customer relations and standard sales process will help define the presence. Obviously, the larger the presence the more expensive the undertaking. However, the awareness of the competitive nature and the level of investment of the competition can explain the environment.

It can be challenging for the smaller manufacturers to go up against the powerful sales forces and scale advantages of the larger device manufacturers when competing for contracts with large hospital supply purchasing collectives and individual clinics and physician offices. It can also be difficult to win big contracts away from larger suppliers who have not only invested time and money into the facility itself but also into the purchaser, via all-expense paid conferences, training, etc. The reality of the U.S. medical market is that the relationship between medical device manufacturers and the purchasers, including doctors and purchasing officers, is one of the most important competitive elements.
Figure 47 Spectrum of Business Presence
A major vehicle for strong customer service is the presence of an aggressive sales and service team which remains very close to the doctors, engineers and other purchasers in the field. The "closeness" of customer service was so strong that the federal government recently stepped in to limit the customer service techniques and training by suppliers that bordered on questionable ethics, as all-expense-paid training courses, among others, were becoming the norm in the industry.

Regarding new products, the relationship between the doctor and the sales/customer service representative can be a vital communication channel. Additionally, as hospitals move more towards a Just-In-Time inventory system themselves, delivery times become more and more important. All these indicators point to committed, eager, and proactive customer relations.

10.11. Average Margins

According to an analysis of the healthcare components of the S & P, medical device companies enjoyed an average net margin of 14% in 2003, a number above average. This is a decrease from 2002 where margins were on average 14.5% however, remains above the healthcare industry average of 8%. It is anticipated that margins will hit 15% during 2004 due to new technologies and benefits from off shore manufacturing in Puerto Rico, Ireland, and Costa Rica.
Many entrepreneurial companies with successful technologies, products or services did not assess alternative solutions for a market entry prior to signing long term distribution agreements with a representative in the US. In some cases such agreements gave the U.S. representative control of their regulatory assets and on occasion, products and services were introduced to the market in absence of the manufacturer's brand name.

Agreements of this nature bear disadvantages for the manufacturer. Their lengthy duration locks the manufacturer into a long term commitment that does not allow for the possibility to exit in the event of unforeseen market challenges or a dissatisfactory partnership.

Due to the challenging U.S. legal culture, as well as other reasons, Swiss companies may decide to refrain from establishing a wholly owned U.S. subsidiary. However, in my opinion, such a subsidiary is the key to success in the world's biggest medical device market.

From my point of view and based on experience, a successful start-up in the U.S. Med-Tech business requires the following considerations:

- People with expertise and superior knowledge of the US market
- Control of the regulatory assets (e.g. FDA approvals, import licenses)
- Clear definition of responsibilities between manufacturer and distributor
- Contract containing parameter of mutual expectations in view of performance (e.g. pricing structure in accordance with market performance, exchange rate criteria, sales figures, etc.)
- Clear guidelines in the application of the brand name
- Contract featuring detailed exit clause
- Tax and transfer policies when marketing is the responsibility of a wholly-owned subsidiary.
- Clear reporting structure and contractual statutes for personnel hired by the subsidiary.

Dr. med. Andreas Baenziger
COO and Member of the Board HealthTronics Inc.

Figure 48: Testimonial: The U.S.A. - A Feasible Challenge
11. Marketing Agreements, Strategic Partnerships and Licensing

By Daniel A. Wuersch, Wuersch & Gering LLP

11.1. Legal Issues related to Marketing in the United States

When a Swiss medical technology company considers marketing its products or services in the United States, it should not only research the market opportunities and risks from a commercial point of view, but also from a legal point of view. In addition to the regulatory requirements discussed in Chapter 13, and the laws governing intellectual property rights discussed in 11.6 below, the impact of a number of federal and state laws (e.g., contracts, torts, and health care laws) on the planned marketing activities and their tax implications should be understood before beginning active marketing in the United States.

With the advent of the Internet, companies who have reason to believe that their products or services may reach customers in the United States should consider these issues even if they do not plan to actively market their products or services in the United States. To avoid any surprises, these companies should consult with legal counsel as to the developing law governing online contracts and adapt the limitations of warranties and liabilities in their general terms and conditions to meet the stringent requirements of U.S. law (see 11.2 below).

Swiss medical technology companies should approach the complexity of the U.S. legal system with sufficient respect. However, with careful planning, risks and the impact of government regulation can be reduced to a manageable level in most cases.

Like Switzerland, the United States constitution established a federal system in which the 50 states (and the District of Columbia) maintain considerable autonomy. Certain areas of the law fall both within the scope of authority of the federal and the state governments, including income tax laws, unfair trade laws, anti-trust laws, and trademark law. Other areas are exclusively governed by federal law (e.g. patent law) or state law (e.g., contracts and general tort law). Thus, no less than 52 legal systems can govern the marketing of medical products or services in the United States, each with a multitude of potentially applicable statutes, regulations, and court decisions.

11.2. Marketing Arrangements

Swiss companies can either actively market their products in the United States on their own or through intermediaries, including agents, distributors or resellers. These intermediaries can either be independent third parties or related parties, such as joint ventures or subsidiaries. Agents are independent contractors who solicit sales of products or services of a domestic or foreign company for a commission, typically calculated as a percentage of gross sales. Distributors and resellers purchase goods or services from a manufacturer or service provider and resell them at a mark-up to other distributors, wholesalers or retail customers. If the
“product” consists of intellectual property rights (e.g., software), a master licensee assumes the role of a distributor vis-à-vis its sub-licensees.

It is not uncommon for the arrangement between a manufacturer or service provider and its intermediaries to encompass several legally significant relationships. E.g., a distribution agreement can include elements of an agency relationship for certain products or services, a license to use intellectual property, and an agreement to provide services for the manufacturer or service provider (e.g., training customers, or after-sales servicing).

11.3. Marketing through a U.S. Subsidiary or Branch

In the course of its activities in the United States, a Swiss medical technology company may determine that it would be beneficial to establish a physical presence in the United States to more effectively market its products, for regulatory reasons or to ensure the quality of customer training or servicing.

For Swiss companies, a subsidiary in the form of a corporation, rather than a branch (or a subsidiary in the form of a transparent entity for tax purposes), typically is the desirable form for a physical presence in the United States. Otherwise, the Swiss parent company may directly become subject to taxation in the United States. Prior to forming a U.S. subsidiary and structuring its relationship with the Swiss parent, the impact of the rules of international taxation contained in the Internal Revenue Code of 1986 (including the transfer pricing regime pursuant to Section 482) and the Swiss-U.S. Income Tax Treaty of October 2, 199617 should be understood.

11.4. General Contract Issues

Contract Law in the United States

The law on contracts is state law. Except for Louisiana, all states and the District of Columbia follow the English common law tradition, in which case law (court decisions), rather than statutes traditionally determined the law. Despite its roots in the English common law, the case law is often supplemented (but not replaced) by statutes (e.g., New York General Obligations Law of April 23, 1963 (“GOL”); California Commercial Code, effective as of January 1, 1965; Chapter 106 of the General Laws of Massachusetts). An important statute, which has been adopted by all states (with certain exceptions and modifications) is the Uniform Commercial Code (UCC), a uniform statute drafted by the National Conference of Commissioners on Uniform State Laws in partnership with the American Law Institute (see www.nccusl.org). In its Article 2 (which was not adopted by Louisiana), the UCC establishes the rules applicable to contracts for the sale of goods. The United States is also a party to several treaties that can apply to a contract between a Swiss and a U.S company (e.g. the Vienna Convention on the International Sale of Goods of 1980).

The conflict of laws rules of the states determines which state law applies to a contract between residents of different states (or foreign countries). These rules generally permit the parties to a contract to select the law that shall govern their relationship. In the absence of a choice of law by the parties, courts will decide which law has the “most significant relationship” with the contract in question.

The parties may also choose the courts or arbitration forums that have jurisdiction over any disputes arising in connection with their contract. Otherwise, the jurisdiction of the various
state courts is determined by the so called “long-arm” statutes of the states and by the jurisdictional provisions of the Rules of Civil Procedure for the federal courts. According to these rules, the federal courts have jurisdiction in contract disputes between a U.S. and a foreign company if the amount in dispute exceeds $70,000. Alternative dispute resolution (such as arbitration or mediation) is often used to resolve contract disputes. Arbitration rules that are well established include those of the American Arbitration Association (AAA) and, for international contracts, the rules of the International Chamber of Commerce (ICC).

Because there is no uniform statutory law that regulates all aspects of contract law and contracts are interpreted strictly based on the language in a written agreement (parole evidence rule), American contracts tend to be longer and more comprehensive than their European counterparts. Despite the understandable desire to keep contracts “short and simple,” a Swiss medical technology company that enters into a contract with a U.S. business partner should be aware of the risks that can result from an incomprehensive contract.

Contractual Risk Allocation

Most commercial risks can be freely allocated to either party in an agreement. However, there are limitations. For example, common law does not permit a party to deny responsibility for willful misconduct or gross negligence. In addition, while limitations for statutory or tort liability can be limited vis-à-vis a contract party, these limitations are not effective vis-à-vis third parties (e.g. liability for defective products, infringement of intellectual property rights).

Implied Covenants and Warranties

A contract party may not only be liable for commitments and representations expressly made in a contract, but also for implied covenants and warranties. For example, UCC Art. 2 provides that in every contract for the sale of goods there is an implied warranty that title to the goods is transferred to the buyer. In a contract for the sale of goods by a merchant, implied warranties of merchantability and fitness for a particular purpose are deemed to be given, except where these warranties are conspicuously disclaimed with language prescribed in UCC Art. 2.

Regulatory Issues

To avoid inadvertent violations of regulatory rules and regulations (e.g., FDA rules), appropriate conditions to the performance of a contract (e.g., filing a 510k pre-market notification with the FDA) and covenants to comply with these rules (e.g., observing cGMP) may be required. In some instances, regulatory authorities prescribe specific obligations that must be imposed on a contract party.

11.5. Exploring and Evaluating Market Opportunities

Confidentiality Agreements

For a manufacturer of a medical device, a developer of software with applications in medical technology or a provider of services to the health care industry, entering into a confidentiality agreement with a potential business partner in the United States is an absolute must before any serious discussions are held on a future cooperation. Otherwise, the potential partner is not restricted from publishing this information or from using the confidential information for its own purposes. To ensure the enforceability of a confidentiality agreement, the information covered must be described as precisely as possible and may not include non-confidential information. Because damages resulting from the violation of a confidentiality agreement are
difficult to prove, confidentiality agreements should specify that injunctive relief is available to remedy any violation of the agreement.

Under U.S. rules of civil or criminal procedure and certain laws and regulations, confidential information may, however, be required to be disclosed to third parties or governmental authorities. In order to avoid a violation of a confidentiality agreement, confidentiality agreements typically permit the disclosure of confidential information in these circumstances.

Consulting Agreements

During the evaluation and market development phase, it may become necessary to engage consultants in the United States. Consultants typically perform services for a time-based flat fee, a performance based compensation or a combination of the foregoing. Generally, the terms of these agreements should permit an easy termination of the relationship and clear milestones that define the expected results. Consultants should be bound by a confidentiality agreement (which can either be part of the consulting agreement or a stand-alone agreement), and the consulting agreement should specify that any work product created by the consultant belongs to the client (see below). Depending on the circumstances, an exclusivity and possibly a non-compete clause may be appropriate elements of a consulting agreement.

Development Agreements

A Swiss manufacturer may enter into a development agreement with a U.S. engineering firm if a medical device requires modifications for the U.S. market. Conversely, a U.S. marketing company may enter into a development agreement with a Swiss manufacturer or service provider who has unique know-how or expertise in a specific area. In a development agreement, the scope and purpose of the project, the instructions to be observed, as well as any modifications of these instructions need to be clearly and conclusively described. An important area to be addressed is the ownership of intellectual property used to develop the work product and any improvements thereto (see 11.6 below). A developer has a legitimate interest in maintaining control over its know-how. The principal on the other hand must make certain that it can freely use the work product in the desired manner without any interference from the developer or third parties. Other aspects that the parties should consider are similar to those encountered in consulting agreements.

The developer's liability for defects of the work product and damages arising out of its use should be limited to those for which the developer can reasonably be held responsible. Because the developer runs the risk of being held liable for damages beyond its control and the principal could become responsible for failures of the developer, the parties should make certain that these risks are allocated fairly in the agreement. Although neither the developer nor the principal can escape liability to third parties completely, a carefully drafted contract can substantially reduce the risk that either party becomes responsible for mistakes of the other.

11.6. Marketing and Licensing of Products and Know-how in the United States

Product Sale and Delivery Agreements

Agreements for the sale or delivery of products to U.S. customers are generally governed by UCC Art. 2. Therefore, limitations of implied warranties must follow the UCC Art. 2 rules mentioned in 11.2 above. The licensing of software is not governed by UCC Art. 2. However, it is good practice to follow the UCC format for limitations of warranties and liability in these contracts as well (in particular vis-à-vis end users).

UCC Art. 2 also contains a special rule for "battles of the forms," i.e., situations where the general terms of a seller and those of a buyer contradict each other. Under the common law
“mirror image” rule, a valid contract can only be formed if offer and acceptance are identical (i.e. the mirror image of each other). Under the UCC rule, an acceptance which contains terms that are different from those contained in the offer can lead to a valid contract if the new terms do not materially alter the offer and the offer did not expressly limit the acceptance to the terms of the offer. To avoid being bound by unexpected terms, general terms and conditions should contain such a limitation. Swiss medical technology companies should also be aware that large U.S. companies typically require strict adherence to their terms of purchase or sales.

Outbound Service Agreements

The issues that arise in outbound service agreements, i.e., agreements in which a Swiss company agrees to provide services to a U.S. principal, are similar to those discussed for consulting and development agreements under 11.5 above, including in particular the allocation of liability risks in particular. Because there is no strict liability for errors that occur in providing services, a limitation of liability to a negligence standard with which a Swiss service provider feels comfortable (e.g., gross negligence) can be an effective tool to limit its liability.

Agency Agreements

As briefly described 11.2 above, an agent is retained to solicit offers from U.S. buyers (or licensees) in consideration for a commission. The amount and type of commission varies greatly, depending on the product, the expected volume, exclusivity and other factors. When structuring agency agreements, it is important to create incentives for the agent to maximize the sales for the principal. This can be achieved through a tiered commission structure based on sales volume and penalties for the agent’s failure to reach a minimum level of sales (e.g., loss of exclusivity for a particular territory, reduced commissions, etc.).

Because the agency relationship may not be clear to a customer (or the general public), the agreement should clearly define the role of the agent and specify that the agent is not authorized to commit the principal or make unauthorized representations on its behalf. Otherwise, the principal could become liable for unauthorized promises or warranties made by the agent to third parties. The agent, on the other hand, risks that it will likely be attacked first if problems with a product result in liability claims in the United States. Agents therefore have a legitimate interest in limiting their liability to acts for which they can reasonably be held responsible and in securing the support of the principal in defending such claims (including indemnification for costs and damages).

Distribution Agreements

The issues arising in connection with distribution agreements are in many respects similar to those discussed with respect to the agent. As in an agency agreement, a distribution agreement should contain restrictions on the representations and warranties that a distributor is authorized to make vis-à-vis its customers. The distributor, on the other hand, will have similar liability concerns to those of an agent.

However, distribution agreements can create additional issues under applicable intellectual property law and the federal anti-trust laws. Because a distributor will use the intellectual property rights of a Swiss manufacturer (including its trade marks and patent rights), the issues discussed below should be considered when structuring the relationship with a U.S. distributor. Antitrust concerns include prohibited price fixing, and exclusion of third parties from competition.

Licensing Agreements

The licensing of intellectual property and know-how is not only an effective tool to market medical technology in the United States, but also an element of many of the other types of agreements discussed in this chapter.
**Patent Licenses**

Pursuant to the federal Patent Law, the owner of a U.S. patent has the right to exclude others from making, using, selling and offering the technology or invention claimed in the patent for up to 20 years. The owner of a valid U.S. patent can license any or all of these rights to a third party within a specified territory and for a specified time period. Because the patent has a limited life, a patent license cannot extend beyond the life of the patent. A patent license may also not restrict the licensee from challenging the validity of the patent. A patent license may need to address the ownership of future inventions based on the patents (improvements). Without an agreement to the contrary, improvements are owned by the licensor. Thus, any modification of this rule must be specified in the license agreement.

**Copyright Licenses**

Under the 1976 federal Copyright Act, the author of any “original” work automatically becomes the owner of the copyright without any need to register the copyright in the United States. Areas in which copyrightable work may be created by or for a medical technology company include software programs, marketing brochures and Website design. Like a patent, a copyright can be licensed to third parties for the duration of the copyright (which usually lasts for decades). To be effective under U.S. law, any transfer or license of rights in a copyright must be in writing. If copyrightable work is created by an independent contractor (consultant, developer, etc.), the copyright in this work does not automatically belong to the principal, but may need to be contractually licensed or assigned to the principal.

**Licensing of Trademarks and Service Marks**

Under the federal Lanham Act, trademarks (used to distinguish goods) or service marks (used to distinguish services) can be registered in the U.S. Patent and Trademark Office. Through registration, the owner of the mark is permitted to use the ® symbol in connection with the registered mark. Use of the ® symbol without a valid registration is prohibited in the United States (instead the “TM” symbol may be used with unregistered marks). A trademark registration is *prima facie* evidence of the exclusive ownership of a mark.

However, both under the Lanham Act and under state law, rights in trademarks or service marks are created through the simple use of a mark in commerce.

A trademark or service mark license is similar in nature to a patent license. However, there are crucial differences. Unlike a patent, a trade or service mark does not *per se* have a limited life. However, the owner of a trade or service mark can lose its right (or the value of its mark) if it permits the use of the mark by unauthorized persons or in a manner that diminishes the value of the mark. Therefore, a license agreement must permit the licensor to monitor the quality of the goods and/or services that the licensee sells under the licensor’s mark, and the licensor must in fact exercise its control rights. The licensor can also lose the protection of its mark if the license does not provide that all goodwill created in the mark by the licensee inures to the benefit of the licensor.

**Licensing of Know How and Trade Secrets**

The issues that must be addressed in licenses of know-how or trade secrets are similar to those discussed with respect to confidentiality agreements under 11.5. It is important to remember that the protected “property” may not be publicly available and needs to be carefully defined in the license agreement. Because the confidential information is revealed to the licensee for the purpose of a commercial activity, the transfer of the know-how or trade secrets, the scope of authorized users, the duty to maintain the information confidential, and the return of the confidential information at the end of the license term should be clearly regulated in the agreement. A know-how license does not need to have a time limitation. However, the publication of confidential information or the loss of its value may make a know-how license unenforceable.
11.7. Cooperation with U.S. Companies

Manufacturing and OEM Agreements

In a (toll) manufacturing agreement, a company outsources the manufacturing of a product to a third-party manufacturer. Because the principal makes valuable intellectual property and know-how available to the toll manufacturer, toll manufacturing agreements raise many of the issues discussed under 11.5 and 11.6 above. In addition, maintaining the quality of the manufactured products, adherence to manufacturing guidelines, timely delivery (and payment) and regulatory requirements and a fair allocation of liability rights are primary concerns that need to be addressed in these agreements. Product liability can become a tricky issue in toll manufacturing agreements. The allocation of the liability risk for manufacturing and design defects should follow the law that has developed in this area. However, this can result in a joint liability to third parties of both the principal and the manufacturer in certain cases.

An original equipment manufacturer (OEM) agreement permits a company to sell a product made by a third party manufacturer under the company’s own brand name. The intellectual property clearly stays with the manufacturer, but the OEM reseller may negotiate for (limited) exclusive marketing rights. Other concerns that OEM resellers have are similar to those of the principal in a toll manufacturing agreement. With respect to product liability, the ultimate responsibility for design and manufacturing defects should be allocated to the manufacturer in all cases (unless the product has been modified according to instructions of the OEM reseller). Despite a contractual allocation of this risk, the OEM reseller’s exposure remains significant. Not only can it be held responsible for marketing the defective product, but any problems could tarnish its brand name.

Supply Agreements

In a supply agreement, the customer is primarily concerned with securing the timely supply of raw material or product components at the desired quality and the allocation of liability to the supplier for damages resulting from defective or inadequate material supplied. The supplier, on the other hand, is interested in being excused from performing its obligations in the event it becomes unable or commercially unreasonable to adhere to the terms of the contract and in limiting its liability for the use of the supplied material or components to the maximum extent possible.

Support and Inbound Service Agreements

The issues arising in support and inbound service agreements (e.g., agreements for the provision of maintenance services on a Swiss manufacturer’s products in the United States) have mostly been covered under Consulting Agreements in chapter 11.5 and from a different perspective in 11.6 (Outbound Service Agreements). Adherence to maintenance and repair guidelines, training in handling equipment and products and compliance with regulatory requirements should be regulated in detail in these types of agreements. The concerns of a U.S. service provider with respect to possible claims by U.S. customers of the foreign principal can be similar to those of an agent, distributor or licensee.

Joint Ventures

Joint ventures can be formed for purposes of developing, manufacturing, or marketing products or services. Contrary to the agreements discussed so far, the common denominator of all types of joint ventures is the achievement of a common purpose by two or more parties through a joint decision making process. Joint ventures can be mere contractual arrangements among parties or take the form of legal entities operated for the common purpose of the joint venture. The decision making process, supervision and monitoring of the joint venture’s activities, ownership and protection of intellectual property and the rights and obligations of the parties in the event of a break-up or sale of the joint venture (or interests therein) are key is-
sues that should be addressed in a joint venture arrangement. Because unincorporated joint ventures are generally treated as partnerships for tax purposes, Swiss companies should consider that, absent a proper structure, their participation could subject them to U.S. taxation (see 11.3 above).

11.8. Acquisition or Disposition of U.S. Companies or Assets

As part of its strategy to enter (or expand in) the U.S. market, a Swiss medical technology company may consider acquiring a U.S. company or its assets (such as intellectual property rights or research or production facilities). A Swiss company that is already present in the United States may dispose of a U.S. subsidiary or assets, or its shareholders may decide to sell the company to a U.S. purchaser. These agreements are typically extensively negotiated by the parties and their respective counsel. In addition, complex rules of U.S. corporate and securities law may need to be considered. Therefore, a comprehensive discussion of the plethora of issues that arise in the context of these transactions would go beyond the scope of this chapter. Nevertheless, the following key considerations apply generally to these types of transactions:

- Prior to entering into serious discussions about an acquisition or disposition of a company or assets, a mutual confidentiality agreement, possibly coupled with a right of exclusivity for a certain period of time should be signed. This not only protects the know-how and trade secrets of the parties, but avoids the untimely publication of a potential transaction. However, Swiss companies need to be aware of the fact that U.S. public companies may be compelled by U.S. securities law to disclose a proposed transaction (see also 11.5).

- Prior to completion of any acquisition of a company or investment assets, the buyer should conduct a thorough due diligence of the acquisition target from a business, technical, legal and financial standpoint (see also Klaus Peretti’s contribution under 15.4). Responding to a due diligence request can lead to disruption of the seller’s operations and uncertainties among its employees. To minimize the impact on the seller’s business, careful planning of the due diligence process by the buyer and the seller is required.

- The U.S. taxation of stock or asset acquisitions/dispositions is very complex and involves many issues both on the federal and state level. Depending on the structure of the transaction, the tax effects on the buyer and seller can differ widely.

- If U.S. securities (such as shares or notes) are issued to a Swiss company, these securities will likely be subject to resale restrictions under the federal securities laws that can limit the public resale of these securities for years.

- As in all other agreements discussed in this chapter, the parties should assume that their recourse for a breach of the agreement against each other is limited to the remedies set forth in the contract. Therefore, any issues that are considered essential should be conclusively addressed in the acquisition or disposition agreement.
12. Importing Into the United States

By Mark S. Zolno, Partner, Katten Muchin Zavis Rosenman

12.1. Overview

This chapter informs Swiss medical device companies of some of the most important customs laws and regulations which apply to the importation of items into the United States and provide some specific examples of how these laws apply to medical devices.

The principal federal agency charged with the enforcement of these laws is the Bureau of Customs and Border Protection ("CBP"), which is part of the Department of Homeland Security. CBP is a revenue collection and law enforcement agency with the power to stop products at the border and to assess civil and criminal penalties. CBP is also charged with enforcing the laws of many other agencies, such as the Food and Drug Administration ("FDA"), as they relate to admissibility of imported merchandise. For purposes of this chapter, the agency will be referred to as "Customs" since it is the Customs function of the agency, rather than the border protection aspect, that is of primary concern for import and trade compliance.

Customs assesses duties based on the value of the shipment and how the imported item is described in the Harmonized Tariff Schedule of the United States ("HTSUS"). The applicable duty rate under the appropriate description is multiplied by the "appraised value" of the item to calculate the amount of customs duties owed.

12.2. Introduction to U.S. Customs and Border Protection

In light of the terrorist attacks against the United States on September 11, 2001, the priority mission of Customs is to prevent terrorists and terrorist weapons from entering the United States. With the recent concern directed toward tightening the border, the agency is newly focused on any possible security weaknesses in the supply chain. Therefore, the original import compliance mission of Customs has been combined with the new, broader scope of the Department of Homeland Security to ensure a secure trade environment in which imported products are in compliance with all U.S. laws and regulations.

In 2002, Customs launched "C-TPAT," the Customs-Trade Partnership Against Terrorism, a joint government-business initiative to strengthen importers' supply chains and increase border security against terrorist activities. There are certain benefits afforded importers who join this voluntary program, such as reduced inspections, assignment of an account manager, eligibility for account-based processes, and improved security along supply chains.

Importers must apply to participate in C-TPAT. The application process includes the execution of a Memorandum of Understanding ("MOU") with Customs, as well as completion of a supply chain security questionnaire.
12.3. The Entry Process

Articles are considered imported when they arrive from a foreign country into the “customs territory” of the United States, which is the fifty states, the District of Columbia and Puerto Rico. The process for obtaining legal clearance from Customs is called the “entry” process. Physically, products or components are imported into the United States when the carrier arrives at the port of importation with the intent to unlade them, at which time duties begin to accrue.

The most critical party for Customs purposes is the “importer of record” because it is the purchaser and owner of the articles at the time of importation or has an appropriate financial interest in the imported articles. An importer of record normally retains a customs broker as its agent to prepare and file the required entry documentation with Customs. An importer of record is responsible for payment of all customs duties and fees as well as for the accurate filing and complete documentation of the entry, even when a licensed customs broker accomplishes the filing. An importer is also required to provide supplemental information to the agency in the event that information declared at the time of entry is subsequently determined to be incorrect or has otherwise been subsequently amended.

The fact that Customs releases a shipment or assesses a particular amount of duty without questioning the information filed by an importer or customs broker does not mean that Customs has accepted the information as correct. In fact, Customs reviews only a small percentage of the entry information and inspects only a small percentage of imported shipments before releasing the items to the importer of record or the importer’s agent. Most problems are uncovered post-entry via formal inquiries issued by Customs or during a Customs audit, which may occur up to five years after the date of entry.

Customs has established specific rules on the content of a commercial invoice. A commercial invoice shall be prepared for each shipment and shall not represent more than one shipment. Invoices must include complete and accurate information in the English language, or be accompanied by an English translation.

12.4. Tariff Classification

All products imported into the customs territory of the United States are subject to customs duties, or exempt from them, depending on how they are classified within the Harmonized Tariff Schedule of the United States (“HTSUS”) in effect at the time the product is imported into the United States. The HTSUS provides specific rules and guidelines for classifying all imported items. The tariff classification of a product or component establishes the rate of duty which applies to that imported item. An importer must exercise reasonable care when classifying imported articles.

As most products are not described by name in the HTSUS, the process of tariff classification is often complex. HTSUS provisions may be described by use, composition, or other characteristics. Often a product or component is described in more than one heading. An ad valorem rate, which is the type of duty rate most often applied, is a percentage of value of the item, such as five percent (5%) ad valorem. Incorrect tariff classifications can cost an importer many thousands of dollars in duties and penalties.

The duty rate of most medical devices is zero or free. However, Customs may classify such devices, or components of such devices, in a different, dutiable tariff provision. An example is an imported blood oxygenation monofilament used in open heart surgery. Instead of classifying it as a part of a medical device, “duty free,” Customs classified it as an article of textiles, with an 8 percent rate of duty. Conversely, kidney dialysis equipment was classified by Customs as “electro-medical apparatus,” dutiable at 5 percent. Upon review by the courts, how-
ever, it was determined that such devices were duty-free under the tariff provision for "articles for the physically handicapped." Solution administration ("IV") sets were determined to be classified under the duty-free tariff subheading for "other medical apparatus," and not "plastic hose, pipe or tubing," dutiable at 5 percent.

Customs makes its final decision as to the dutiable status of merchandise when the entry is "liquidated" after the entry documents have been filed. The importer may disagree with the dutiable status after the entry has been liquidated. Any challenge against the assessment of duty upon liquidation of an entry must be made by filing a protest with Customs within 90 days after liquidation.

The customs regulations provide a method in which an importer, exporter, or other interested party can determine, prior to importation, the tariff classification of a particular medical product or component. This system is known as the binding rulings program and a ruling issued under the program must be adhered to by all Customs officials at every port of entry. Normally, Customs issues such rulings within 30 days after receipt of the ruling request. By using this method, a party can know for certain what the duty rate will be for a product and be able to factor that amount into its costs analysis, rather than be subject to an unanticipated increase in duties, which can be imposed by Customs for more than a year after the article is imported.

12.5. Valuation of Imported Merchandise

The amount of duty an importer pays to Customs on an imported product is calculated by multiplying the rate of duty applicable to that product (as ascertained by the article’s tariff classification) by the customs (or “appraised”) value of the product. The importer must determine the customs value for each product according to U.S. value law, which is based on an international agreement that forms part of the World Trade Organization ("WTO"), formerly the General Agreement on Tariffs and Trade ("GATT"). There are five methods for valuing imported merchandise under Customs law, and the most common method used is the transaction value method. The five methods are:

- Transaction Value
- Transaction Value of Identical Merchandise and Similar Merchandise
- Deductive Value
- Computed Value
- Value if Other Values Cannot be Determined or Used (Fallback Method)

The valuation methods must be applied in the order listed. For example, if merchandise cannot be appraised based on the transaction value method (e.g., consignment shipments where there is no sale), then the transaction value of identical or similar merchandise will be applied, if appropriate, to establish the value. The majority of shipments are appraised using the transaction value method.

The transaction value of imported merchandise is the price actually paid or payable for the merchandise when sold for exportation to the United States. The “price paid or payable” includes all payments made by the buyer to the seller (or for the benefit of the seller). Normally, the transaction value of the imported merchandise is based on the price shown on the commercial invoice issued by the exporter. However, certain additions and exclusions to that price may have to be made to arrive at the proper “customs value” of an imported product.

If not already included in the invoice price, the value of the following items must be added to the invoice price to arrive at the customs value of an imported product:
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- Foreign packing costs. These costs consist of the cost incurred for all containers and coverings (and for the labor and materials) used in packing the imported merchandise ready for export. Accordingly, if an importer pays a third party for packaging, the price paid to the third party must be declared to Customs (in addition to the value shown on the commercial invoice for the goods).

- Commissions. All commissions (other than those for bona fide buying agents) incurred with respect to the imported merchandise constitute part of the transaction value. A buying commission means a commission paid to an agent who is controlled by the importer. Buying or selling commission charges, regardless whether ultimately determined to be dutiable, should be separately identified on the commercial invoice accompanying the shipment.

- Assists. If the following items are supplied free of charge or at a reduced cost to the foreign manufacturer for use in connection with producing merchandise which is later imported into the United States, their value must be included in the customs value of the imported article:
  - Materials, components, parts and similar items incorporated into the merchandise, e.g., plastic resin supplied to the foreign manufacturer at a reduced cost and used to manufacture a plastic handle for a surgical instrument.
  - Tools, dies, molds and similar item used in the production of the imported merchandise, e.g., molds used to forge surgical scissors.
  - Merchandise consumed in the production of the imported merchandise.
  - Engineering, development, artwork, design work, plans and sketches produced other than in the U.S. and which are necessary for the production of the imported merchandise.

- Royalties or license fees that the importer is required to pay as a condition of sale. Whether a royalty is dutiable will be decided on a case-by-case basis and will require careful analysis of the facts and applicable legal precedent.

- Proceeds, accruing to the seller, of any subsequent resale, disposal, or use of the imported merchandise. Any proceeds resulting from the subsequent resale, disposal, or use of the imported merchandise that accrue, directly or indirectly, to the foreign seller must be reported to Customs. Such proceeds may include license fees or royalties not paid "as a condition of sale" of the imported merchandise but nonetheless remitted to the foreign seller, or may be the result of profit-sharing with the foreign seller.

Customs may refuse to value an imported product using the “transaction value of the imported merchandise” (transfer price) method if the buyer and seller are related (i.e., family members or own more than 5 percent of the stock of the other company, or are jointly controlled, such “sister” companies) and Customs believes that the relationship has influenced the price so that the transfer price is artificially low or high. Factors which Customs will review in a related-party transaction include whether the price was a negotiated price, whether the price is consistent with normal pricing practices in the industry, and whether the price is adequate to cover all of the related supplier’s costs plus a reasonable industry profit.

Alternatively, an importer can demonstrate to Customs that the transaction value is acceptable in a related-party situation by showing that the transaction value closely approximates a test value, which is usually either (1) the transaction value of identical or similar merchandise sold to unrelated parties, or (2) the computed value of identical or substantially similar merchandise imported at about the same time.
12.6. Country of Origin Marking

Customs law requires that, at the time of importation, every article of foreign origin or its container must be marked with its country of origin. The country of origin marking must be:

- Legible (*i.e.*, not hard to read).
- Indelible (*i.e.*, must not fade or smear).
- Permanent (*i.e.*, will not fall off unless deliberately removed).
- Conspicuous (*i.e.*, easy to find).
- In English.

The purpose of these requirements is to let the ultimate purchaser in the United States know the foreign origin of the goods. The “ultimate purchaser” for whom the marking laws are designed to protect is generally the last person in the U.S. who receives the product in its imported form. Therefore, the identity of the ultimate purchaser depends on the circumstances of the importation and how an imported product is distributed. The ultimate purchaser may be an intermediate manufacturer in the U.S. or a retail consumer.

The foreign “country of origin” is the (single) nation of manufacture, production or growth of the product. If the product is manufactured in more than one country, its country of origin is the place where it last underwent a “substantial transformation.” “Substantial transformation” has been defined as a manufacture or assembly operation that results in a new article with a different name, character, or use.

Marking varies depending on the product to be marked. Most imported products are marked using labels, hangtags, or stickers. However, as noted above, the marking of the item must be permanent enough to reach the ultimate purchaser.

A country of origin marking on an imported product cannot contain words or information which may potentially mislead the ultimate purchaser into believing that a product is of U.S. origin when, according to Customs law, it is considered of foreign origin. Accordingly, customs law requires that whenever a product label or its container contains words such as “United States,” “American,” “U.S.A.,” the name of a city in the United States, or even a U.S. address, then the words “Made in” or “Product of” plus the foreign country of origin should appear in close proximity and comparable size and type to the U.S. address, such as on the same side of the box. This situation arises frequently where the name and address of the U.S. distributor is shown on the packaging of the imported product.

If Customs determines that an article is not legally marked, the article is not allowed entry into the United States. If there is a discrepancy with the marking of a product, a Notice to Redeliver and/or Mark will be issued within 30-days of release of the article.

Failure to redeliver improperly marked products when required by Customs may subject the importer to penalties pursuant to the terms of its customs bond in the amount of the declared value of the shipment. Customs may also assess marking duties of ten (10) percent of the appraised value of the improperly marked items upon liquidation of the entry. It is imperative to respond promptly to any Customs’ Notice to Mark and/or Redeliver and correct or otherwise remedy any country of origin deficiencies.

Some specific examples of issues pertaining to the marking of medical devices include:

**Surgical Instruments** – Although, at one time, the country-of-origin was the place where the device underwent its last “substantial transformation,” for the last several years, due to a court decision, the country-of-origin of the surgical instrument’s steel forging governs the origin of the finished instrument.
Dental Implants – When a local Customs official at the Port of Boston insisted that the country-of-origin had to be etched in titanium dental implants imported from Sweden, the importer appealed to Customs Headquarters. Headquarters ruled, based upon the importer’s attorney’s argument that such marking would be impracticable and cause potential infections in the patient’s mouth, due to food particles accumulating in the etched portions of the implants, that a country-of-origin marking exemption would be afforded the dental implants and that only their containers need specify “Sweden” as the country-of-origin.

Medical Kits – Kits consisting of various components (e.g., scissors, gown, gauze, cotton, etc.) used in surgery or other medical procedures must have the foreign country-of-origin of each of its components listed on the outer container of the kit in order to inform the “ultimate consumer in the United States” (typically a hospital or physician) of the origin of each component in the kit.
13. FDA Related Issues

By Darren W. Alch, Jenkens & Gilchrist

The Food and Drug Administration’s (FDA) international role grows as the world becomes a “global economy.” As the world leader in drug and medical device regulatory science, FDA commits enormous resources to information exchange, technical cooperation, scientific collaboration, and regulatory harmonization. Yet, given this dedication of resources and efforts, the U.S. medical device market remains limited to those foreign device manufacturers who have complied with the same FDA regulatory requirements as U.S. manufacturers.

Swiss device manufacturers are no different. Although global harmonization efforts continue down a path of regulatory uniformity among nations, several constants remain the same: the FDA does not have the authority to delegate its public safety mandate to another government, nations have, by and large, been unwilling to dramatically alter existing regulatory infrastructure, and the U.S. remains the single largest medical device market.  

FDA operates its international role on a set of five basic principles:

- Harmonization activity should further FDA’s mission to protect the public’s health by insuring that medical devices are safe and effective and that medical device products are not adulterated and are labeled truthfully and informatively.
- The harmonization activities should be consistent with U.S. government policies and procedures and should promote the United States’ interests with foreign governments.
- FDA’s involvement in international standard setting activities should be open to public scrutiny.
- FDA should accept, where legally permissible, the equivalent standards, compliance activities, and enforcement programs of other countries.
- Scientific and regulatory information and knowledge should be exchanged with foreign government officials, to the extent possible within legal constraints, to expedite the approval of medical devices and protect public health.

A unique aspect of FDA’s international program for medical devices is that the agency has an explicit international mandate. By the time the Safe Medical Devices Act of 1990 (SMDA) was enacted, the global interests of the U.S. medical device industry were quite evident. While international considerations played no significant role in the congressional deliberations leading to the enactment of earlier U.S. medical device laws, such considerations were important in 1990.

The SMDA added a new Section 803 to the federal Food, Drug and Cosmetic Act (FDCA):

SEC 803(a) There is established in the Department of Health and Human Services an Office of International Relations.

(b) In carrying out the functions of the office under subsection (a), the Secretary may enter into agreements with foreign countries to facilitate commerce and devices between the United States and such countries consistent with the requirements of this Act. In such agreements, the Secretary shall encourage the mutual recognition of –

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18 The U.S. market is nearly double that of the European Union market, by almost any objective measure.
(1) good manufacturing regulations promulgated under § 520(f); and

(2) other regulations and testing protocols as the Secretary determines to be appropriate.

As is evident, the FDA’s international authority includes authority to enter into agreements with other foreign regulatory agencies.

Further evidence of FDA’s increased focus on international harmonization can be found in the FDA’s active participation with the Global Harmonization Task Force (GHTF). An international forum focused on medical device regulation, the GHTF has embarked on several activities that move the participating countries closer to harmonization, and even mutual recognition, of regulatory processes. Formed in 1992, the GHTF is comprised of government and industry representatives from North America, Europe, Asia, and Australia, as well as observers from other countries. Both the FDA and Swissmedic are active participants in GHTF.

The GHTF consists of a main task force (which meets once a year) and Study Groups that concentrate on a particular aspect of medical device regulation and meet three or four times a year. The GHTF meeting includes reports from each Study Group as to the status of pending projects, presentations of delegates from member and observer nations about important developments in their medical device regulatory systems, assignments to leadership positions in the GHTF and its Study Groups, and any new work that should be taken on by the GHTF and its groups.

The original concept behind the formation of the GHTF was to bring together experienced regulators and industry members on a regular basis in order to discuss ways in which medical device regulatory practices within their jurisdictions could be harmonized. Today the objective of the GHTF remains the same: to encourage convergence at the global level, harmonization of regulatory systems for medical devices in order to facilitate trade while preserving the right of participating members to address the protection of public health by regulatory means considered to be most suitable.

The GHTF’s initial focus was primarily on quality systems harmonization. Ultimately, the GHTF celebrated its first major achievement: the harmonization of quality system requirements in the United States, Canada, Japan, and the EU, as well as the development of a guidance document on the application of these requirements.

Most recently, a Memorandum of Understanding (MOU) between the FDA and Swissmedic was agreed to. Effective in September, 2003, the MOU further enhances and strengthens communication and existing public health promotion and protection activities related to medical devices. Long on scope and short on detail, the MOU clarifies an intent between the countries to develop specific procedures for the exchange of regulatory and public health information. The types of information that may be shared include: (i) drafts of pending laws, regulations, and guidance documents; (ii) post marketing data and information impacting public health; (iii) information on quality defects or product recalls; (iv) information contained in or related to marketing or investigational applications; (v) inspection reports and product sample test results; (vi) information on facilities registered in each country; and (vii) information related to import refusals for safety reasons.

It is important to note that although the MOU facilitates the exchange of information regarding medical devices between the U.S. and Switzerland, the MOU in no way eases market entry requirements for Swiss medical device manufacturers in the United States. The MOU is geared toward patient and consumer safety, as well as cooperation in the exchange of data.
13.1. Standards Authority

Three principal laws govern the FDA’s international device standards activities. First, FDCA contains detailed provisions for device standards, which have been part of the law since the medical device amendments of 1976, and which were greatly simplified in 1990 with the passage of the SMDA. In streamlining the procedures for mandatory performance standards for devices, the United States Congress ensured, in several ways, that FDA would consider international impacts. For example FDA is required, to the extent practicable, to consult with nationally and internationally recognized standard-setting entities.

The Food and Drug Administration Modernization Act of 1997 (FDAMA) created a new section of the FDCA that gives manufacturers explicit authority to use FDA recognized standards to meet requirements. This section 514(c) directs FDA to recognize national and international standards by publication in the Federal Register, and allows manufacturers – if they elect to conform to any of these standards – to submit a Declaration of Conformity to FDA. It further mandates that FDA will accept a manufacturer’s Declaration of Conformity to an FDA recognized standard to meet a requirement under the FDCA to which the standard is applicable.

Other laws governing FDA’s international device standards activities include the Trade Agreements Act, the general U.S. statute that implements the World Trade Organization (WTO) agreement on technical barriers to trade, instructs federal agencies to use international standards, as appropriate, as the basis for technical regulations.

Finally, the National Technology Transfer and Advancement Act, enacted in 1996 requires federal agencies to use voluntary consensus standards in their activities.

13.2. Swiss Imports

Despite efforts at harmonization and the recent MOU, Swiss medical device manufacturers can only gain entry to U.S. markets through the regulatory process required of all U.S. device manufacturers. That is, U.S. law applies identical substantive requirements to domestically-produced and Swiss-imported medical devices. Given FDA’s public safety mandate, U.S. consumers must be protected from the same health risks, regardless of the geographical source of the devices. Furthermore, to comply with the General Agreement on Tariffs and Trade (GATT), a country’s laws must be no less favorable to imports than to domestic products.

Like U.S. companies, Swiss medical device processors who wish to export devices to the United States must follow good manufacturing practices (GMPs), shall be permitted to register their establishments, and are required to list their devices with the FDA.

A good starting point for foreign medical device processors and manufacturers who wish to export devices to the United States is the Division of Small Manufacturers, International and Consumer Assistance (DSMICA). DSMICA was mandated by the 1976 Medical Device Amendments to provide technical and regulatory assistance to small and foreign manufacturers in order to help them comply with the FDCA. The SMDA of 1990 and the FDAMA of 1997 also expanded DSMICA’s role in providing regulatory assistance. Within DSMICA, the international affairs staff identifies and supports global harmonization activities, educates foreign governments on the U.S. medical device regulatory process, and directs U.S. firms to sources of information on foreign requirements for medical devices.
13.3. U.S. Market Approval

As stated, from a regulatory perspective there is no distinction between a Swiss made medical device and a U.S. made device. That is, medical device manufacturers (domestic and foreign) generally must obtain clearance of a 510(k) pre-market notification or approval of a pre-market approval application (PMA) for any device they intend to market in the U.S., unless the device is exempt from such requirements.

The 510(k) process requires a demonstration of substantial equivalence. By contrast, the PMA process requires a showing that a device is reasonably safe and effective. Although the show of substantial equivalence is a far less burdensome regulatory requirement, the 510(k) process is only available to persons and companies who wish to market a Class I, Class II, and a limited number of Class III devices intended for human use in the United States. Those wishing to market most Class III devices, as well as implantable devices, must obtain pre-market approval from the FDA through the PMA application process. Figure 49 summarizes the major distinctions between 510(k) notices and PMAs.

<table>
<thead>
<tr>
<th></th>
<th>510(k)</th>
<th>PMA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Devices Subject to Requirements</td>
<td>Few Class I, most Class II, and some Class III pre-amendment devices.</td>
<td>All Class III post-amendment devices and some Class III pre-amendment devices.</td>
</tr>
<tr>
<td>Clinical Data Requirements</td>
<td>Most are not supported by clinical data.</td>
<td>Clinical studies usually required to support submission.</td>
</tr>
<tr>
<td>Evidence of Safety and Efficacy Required</td>
<td>Information and data to support “substantial equivalence” to a predicate device.</td>
<td>Clinical data and/or scientific evidence supporting “safety and efficacy” claims.</td>
</tr>
<tr>
<td>Marketing Barriers</td>
<td>Low barrier to competitors.</td>
<td>High barrier to competitors.</td>
</tr>
<tr>
<td>Average FDA Review Time</td>
<td>Approx. 75 days [traditional 510(k)].</td>
<td>411 Days.</td>
</tr>
<tr>
<td>Regulations on Device Changes</td>
<td>Must file new 510(k) if change could “significantly affect” the safety or efficacy of the device.</td>
<td>Must file a new PMA or other filing depending on the nature of the change.</td>
</tr>
<tr>
<td>Advisory Panel Review</td>
<td>No APR for almost all 5610(k) devices.</td>
<td>APR for some, but not all PMAs.</td>
</tr>
</tbody>
</table>

Figure 49 510(k) vs. PMA

13.4. GMPs and Inspections

FDA GMPs were revised in 1996 and published in 1997. The revisions dealt largely with (1) replacing quality assurance program requirements with quality system requirements that include design, purchasing, and servicing controls; (2) clarifying record-keeping requirements for device failure and complaint investigations; (3) clarifying requirements for qualifying, verifying, and validating processes and specification changes; and (4) clarifying requirements for evaluating quality data and correcting quality problems. In addition, the regulation is intended to better harmonize FDA’s GMP requirements for devices with the specifications for quality systems contained in ISO 9001 and other applicable international standards.20

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19 A detailed description of the 510(k) process is outside the scope of this submission.

20 The ISO 9000 series of QA standards ranges from basic quality control to very significant design and production systems. ISO 9001 is the most comprehensive because it covers design, production, servicing and corrective/preventive activities. The FDA GMP requirements are slightly more extensive because they include extensive coverage of labeling, and complaint handling.
Although the subject of ongoing extensive debate, manufacturers of device components, and third-party servicers, are still not covered by the new QS/GMP regulations. These operations are considered to be “vendor” operations, which are considered to be the responsibility of the finished product manufacturer under 21 C.F.R. § 820.50. Under the QS/GMP regulations, medical device manufacturers, foreign and domestic, are expected to control their products from “cradle to grave” meaning from design stage through post-market surveillance. Manufacturing processes, such as sterilization, are required to be implemented under appropriate controls.

Swiss manufacturers, like U.S. manufacturers, are subject to quality system inspections. FDA’s inspecional strategy is called the Quality System Inspections Technique (QSIT). QSIT is based on a “top-down” inspection (21 C.F.R. Part 820) of a manufacturer’s quality system, using the seven subsystems of the QS/GMP regulation. The seven subsystems are: Management Controls, Design Controls, Corrective and Preventive Actions (CAPA), Production and Process Controls, Facilities and Equipment Controls, Materials Controls, and Documents/Records/Change Controls.

Clearly the FDA has the authority to enter into agreements with other foreign agencies in order to enhance consumer protection with respect to the products it regulates. The agency has explicit authority to enter into “arrangements” with other foreign agencies whose manufacturers export medical devices to the United States, and the agency is required to assure that these arrangements provide for the FDA to conduct inspections, “from time to time,” of the foreign firm. The FDA’s agreements with other foreign agencies bear a variety of labels, MOU, Memorandum of Cooperation, and exchange of letters. In the United States, what is important is not the label or form of an agreement, but rather its substance. All FDA international cooperative agreements, other than the most innocuous exchanges of letters, are cleared with the State Department under its Circular 175 clearance process, which enables that department to fulfill a congressional reporting obligation under the Case-Zablocki Act.

Section 201 of FDAMA amends section 704 of the FDCA by authorizing FDA to establish a voluntary third party inspection program applicable to foreign manufacturers of Class II or Class III medical devices who meet certain eligibility criteria. Under this new Inspection by Accredited Persons Program (AP Program), such manufacturers may elect to have third parties that have been accredited by FDA conduct some of their inspections instead of FDA.

The AP Program is open to Swiss device establishments that are required to register with FDA under section 510(i) of the FDCA, provided such establishments otherwise meet the program’s eligibility criteria. Based on requirements found in Section 704(g) of the act, you must satisfy the following criteria in order to be eligible to participate in the program:

1. You manufacture class II or class III medical devices;
2. You market at least one of the devices in the United States;
3. You market or intend to market at least one of the devices in one or more foreign countries and one or both of the following two conditions are met:
   a. One of the foreign countries certifies, accredits, or otherwise recognizes the AP you have selected as a person authorized to conduct inspections of device establishments, or

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21 Component manufacturers and contracting firms that are contract sterilizers, design contractors, or finished device manufacturers, are subject to the QS/GMP regulations.

22 As discussed previously, an MOU between FDA and SwissMedic was finalized in September, 2003. The MOU provides the basis for closer cooperation between FDA and SwissMedic as well as facilitating exchange of information regarding medical devices. The information to be exchanged includes data regarding negative side effects, recalls and quality defects, applications, and inspection reports.
(b) Your firm submits a statement that the law of a country where you market or intend to market your devices recognizes an inspection by the FDA or by the AP. (Sec. 704(g)(6)(A)(iii)(I), (II) of the act);

(4) Your most recent inspection performed by FDA, or by an AP under this program, was classified by FDA as either “No Action Indicated (NAI)” or “Voluntary Action Indicated (VAI)”;

and

(5) You submit a notice to FDA requesting clearance (approval) to use an AP, identify the AP you selected, and FDA agrees to the use of the selected AP.

In order to provide FDA with a listing of establishments and entities that are subject to inspection, Section 510 of the FDCA requires that all establishments engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of medical devices intended for human use and commercial distribution in the United States register their establishments with the FDA. FDA Form 2891 is used to register an establishment. This process provides FDA with the location of medical device manufacturing facilities and importers. An establishment includes any place of business under one management at one physical location at which a device is manufactured, assembled, or otherwise processed for commercial distribution.

Swiss establishments that manufacture, prepare, propagate, compound, or process a device that is imported, or offered for import, into the U.S. must register their establishments on FDA Form 2891. This includes contract manufacturers and contract sterilizers.

Section 510 of the FDCA also requires both domestic and foreign manufacturers to list their devices with FDA if the devices are in commercial distribution in the United States. Devices are listed by their classification name on FDA Form 2892.

Known as Medical Device Listing, this process is a means of keeping FDA advised of the generic category of devices an establishment is marketing. Each generic category is represented by a separate classification regulation found in 21 C.F.R. Parts 862-892. Any owner/operator of an establishment not exempt who is engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of a medical device intended for commercial distribution or marketing in the U.S. is required to list its device on FDA Form 2892 within 30 days of entering the device into commercial distribution in the United States. Swiss manufacturers must list their devices prior to importing into the U.S. Although contract manufacturers, contract sterilizers, and initial importers located in the U.S. are required to register establishments, these establishments need not list devices on FDA Form 2892.

Since February, 2002, all Swiss establishments (and other foreign countries) must also notify FDA of the name, address, and phone number of their United States Agent. The U.S. agent must either reside in the U.S. or maintain a place of business in the U.S. The U.S. agent cannot use a post office box as an address.

Neither registration nor listing constitutes FDA clearance or approval for marketing or commercial distribution in the U.S. Unless the device is exempt, a pre-market notification 510(k) or a pre-market approval application is required before commercial distribution is allowed. Registration of a device establishment or submission of device listing does not in any way denote approval of the establishment or its products by FDA.

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23 See Figure 51: FDA – Form Initial Registration of Device Establishment.

24 See Figure 52: FDA – Form Device Listing.
13.5. Conclusions

Although efforts at harmonization have focused on regulatory redundancy among nations, the results have been slow to ease the burden on device manufacturers wishing to access the U.S. market. In fact, the U.S. market remains available only to those devices that have secured the necessary approvals from the FDA.

Some post-approval requirements have been made more accessible, such as inspections under the AP Program, whereby manufacturers may elect to have third parties that have been accredited by FDA conduct some of their inspections instead of FDA.

Ultimately, however, Swiss companies wishing to access the U.S. market must comply with FDA regulations. There is no mechanism for reliance on Swiss regulatory requirements as a substitute for FDA requirements.

Figure 50 FDA Regulatory Flow Chart
**Figure 51: FDA – Form Initial Registration of Device Establishment**

<table>
<thead>
<tr>
<th>SECTION A</th>
<th>SECTION B</th>
<th>SECTION C</th>
<th>SECTION D</th>
<th>SECTION E</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. ESTABLISHMENT BUSINESS NAME</td>
<td>12. OWNER/OPERATOR BUSINESS NAME</td>
<td>21. OFFICIAL CORRESPONDENT (Name of Individual)</td>
<td>32. OTHER BUSINESS TRADING NAMES</td>
<td>33. SIGNATURE OF OFFICIAL CORRESPONDENT</td>
</tr>
<tr>
<td>3. RECORD DATE</td>
<td>13. OWNER/OPERATOR NUMBER</td>
<td>22. BUSINESS NAME</td>
<td>(Enter any other name which the establishment in field #2 uses. Do not list Registered trademarks or names of private label distributors. This is usually any name such as a brand name which is not the firm name.)</td>
<td>54. TITLE</td>
</tr>
<tr>
<td>(Mo.)</td>
<td>14. NUMBER AND STREET</td>
<td>23. NUMBER AND STREET</td>
<td>SEQ</td>
<td>SEQ</td>
</tr>
<tr>
<td>01</td>
<td>15. CITY</td>
<td>24. CITY</td>
<td>BUSINESS NAME</td>
<td>BUSINESS NAME</td>
</tr>
<tr>
<td>01</td>
<td>16. STATE</td>
<td>25. STATE</td>
<td>SO1</td>
<td>SO3</td>
</tr>
<tr>
<td>AL</td>
<td>17. ZIP/POSTAL CODE</td>
<td>26. ZIP/POSTAL CODE</td>
<td>SO2</td>
<td>SO4</td>
</tr>
<tr>
<td>AL</td>
<td></td>
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</tbody>
</table>

- 106 -
Figure 52  FDA – Form Device Listing
Swiss manufacturers selling or distributing medical devices in the United States should exercise particular care because United States product liability law and court procedures are, in numerous important respects, different from the law and procedures in Switzerland. In virtually every respect, these differences are favorable to the plaintiff and enhance the plaintiff’s likelihood for a substantial recovery.

Moreover, United States product liability law is complicated by the following two factors. First, U.S. product liability law is almost entirely the law of the 50 individual states. Although the product liability laws of the 50 states have many similarities, there are some material differences. This means that there may be differences in otherwise identical product liability litigation if the applicable law is, for example, the law of New York rather than the law of California. Second, U.S. product liability law is predominately judge-made common law and not legislative law. This means that the body of U.S. product liability law generally is not to be found in codified laws passed by legislatures. Instead, product liability law results primarily from the development of the law by judicial decisions. This raises a degree of uncertainty, as the law needs to be derived from an analysis of the applicable judicial decisions rather than through reference to a code. Moreover, the common law, by its nature, is in constant evolution and is always subject to alteration by subsequent judicial decisions.

Bearing these uncertainties in mind, the discussion below will include the following topics: (1) the legal basis for U.S. product liability law focusing on the doctrine of strict liability in tort; (2) the damages that may be awarded in a U.S. product liability suit; (3) the procedural aspects of a U.S. product liability suit, particularly as they are distinctive from Swiss litigation procedures; (4) product liability exposure through mergers and acquisitions; and (5) methods and practices that can reduce U.S. product liability risks.

14.1. The Legal Basis for U.S. Product Liability

The vast majority of the states of the United States have adopted the doctrine of strict product liability in tort. Although there are some material variations among the states, the following will summarize the general principles:

The General Rule

The general rule for strict product liability in tort for medical devices is as follows:

A manufacturer of a medical device who sells or otherwise distributes a defective medical device is subject to liability for harm to persons caused by the defect.

Definition of Defect

In order for there to be product liability, the medical device product has to be “defective”. A medical device can be defective in any of the following three ways:
Manufacturing Defect

A manufacturing defect includes any flaw or deficiency arising at any stage of the manufacturing process and may result from improper production, assembly, packaging or transportation of the medical device.

Design Defect

Even if properly manufactured, a product may be defective if it is designed in such a way that it is not reasonably safe. A medical device is not reasonably safe due to a design defect if the foreseeable risks of harm posed by the medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the medical device for any class of patients.

With regard to unavoidably unsafe products, most courts will not find liability provided that the product was properly prepared and marketed, and a proper warning was given. Some courts engage in a “risk-utility test” under which a key factor may be the availability of a feasible safer alternative design.

Warning/Instructions Defect

Even if the medical device is completely free from both manufacturing and design defects, it still may be defective if it is not reasonably safe due to inadequate instructions or warnings. This is the case if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to: (i) prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings; or (ii) the patient when the manufacturer knows or has reason to known that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions warnings. With regard to category (i), the “learned intermediary rule” generally provides that a manufacturer of a prescription medical device does not have a legal duty to warn the patient of potential hazards of a product, but that the manufacturer’s duty is limited to providing adequate warnings to the physician or other health-care provider.

Defenses

The available defenses to a product liability claim involving a medical device are quite limited. Significantly, contributory or comparative negligence generally is not a defense. The following defenses may be available:

FDA Preemption

In 1976, Congress enacted the Medical Device Amendments (the “MDA”) to the Food, Drug & Cosmetic Act (the “FDCA”). The MDA included the following preemption clause:

“No State or political subdivision of a State may establish or continue an effect with respect to a device intended for human use any requirement – (1) which is different from, or in addition to any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.”

The jurisprudence up to 1996 largely held that this clause preempted most state law claims against manufacturers of medical devices. This meant that there were no state law product liability claims available with respect to products that were approved by the FDA and conformed with FDA regulation. However, in 1996, the Supreme Court decided Medtronic v. Lohr, 518 U.S. 470 (1996), which has resulted in a confusing and inconsistent subsequent jurisprudence. Based on Medtronic, the lower courts virtually unanimously have found that there is no express preemption of state product liability litigation concerning medical devices.
that received FDA approval through the “substantial equivalence” process. This is very significant, since this is the method of approval used for many medical devices. There is a split of opinion among the lower courts as to the extent to which express preemption is an available defense with respect to products that are subject to the FDA’s pre-market approval process, with the majority of the case favoring exemption. There also is a split of opinion regarding whether there is federal preemption of claims arising from medical devices approved pursuant to the FDA’s investigational device exemption regulators, with the majority of the cases again favoring exemption. Finally, a minority of the lower courts have read Medtronic to abolish all express preemption of state product liability claims.

State of the Art

Some states allow the defendants to escape liability if they can demonstrate that the product meets the state of the art at the time the product was released into the marketplace. Generally, “state of the art” means the technological or scientific knowledge existing as of the relevant point in time.

Assumption of Risk

The defense of assumption of risk applies when the person injured used the product voluntarily and unreasonably exposed himself to the risk posed by the product with knowledge of the danger.

Misuse

The defense of misuse applies when an unforeseeable, abnormal use of a product causes the injury.

Alterations/Modifications

The defense of alteration or modification arises when there has been a substantial change in the condition of the product after it has been sold.

Statute of Limitations/Statute of Repose

The time period under which suit must be brought and other issues relating to the application of the statute of limitations and/or statute of repose generally are determined by the law of the state in which the suit is brought. The period for the statute of limitations, depending on the state involved, generally is between 2 and 5 years. However, this time period generally only begins to run when the plaintiff is injured or discovers his injury.

In order to prevent unfair results, a number of states have enacted an additional defense called the statute of repose. Unlike the statute of limitations, a statute of repose generally starts running on the date of manufacture, delivery or sale of the product. The time period generally is rather long, between 8 and 12 years.

14.2. Damages

There are certain significant distinctions in the availability of compensatory and punitive damages to a United States product liability plaintiff:

Compensatory Damages

Product liability plaintiffs in the United States, like product liability plaintiffs in Switzerland, can recover compensatory damages for economic damages such as medical costs, lost wages and property damage, as well as for non-economic damages such as pain and suffering and emotional distress.
The principal difference with regard to compensatory damages is quantitative rather than qualitative. In general, a United States plaintiff has the potential to recover a much larger amount of compensatory damages. In cases involving serious physical injury, recoveries of compensatory damages ranging from hundreds of thousands to millions of dollars are not at all uncommon. The rationale for such relatively large recoveries is often attributed to the jury system and to the absence in the United States of a highly developed social network, which would provide universal protection from certain risks for which compensatory damages otherwise provide compensation.

**Punitive Damages**

Punitive damages are damages intended to punish the wrongdoer, not to compensate the injured party. They are generally awarded in the United States only when the wrongdoer intends to cause harm or engages in acts that the wrongdoer knows or should know are very likely to cause harm. Although the risk of punitive damages may not be great, the possibility that they may be awarded in United States product liability litigation is a material distinction for Swiss medical device manufacturers entering the United States market.

### 14.3. Procedural Aspect of a U.S. Product Liability

The procedural differences between a United States and a Swiss product liability suit are probably even more striking than the substantive distinctions. Seven of the principal procedural distinctions are discussed below:

**Jurisdiction**

The jurisdiction of the United States courts over a Swiss manufacturer of medical devices is not dependent upon the manufacturer having consented to jurisdiction or having a place of business in the United States. Substantially all of the states of the United States have enacted so-called long-arm statutes, which can provide very broad grounds for jurisdiction over a Swiss manufacturer. Jurisdiction may be based on a Swiss manufacturer's activities, however limited, in connection with the sale or distribution of its medical devices causing injury to a United States party. Courts typically find that these actions constitute the transaction of business or the commission of a tortuous act within a state of the United States.

**Pleadings and Service of Process**

**Pleadings**

Pleadings under United States procedure tend to be short and concise and need only provide the parties with notice of the claim or defenses. United States pleadings will not contain references to the evidence that may prove the pleading’s allegations. A complaint must only include a description of the parties, a statement justifying the court’s subject matter jurisdiction, a brief description of the plaintiff's claim and a request for relief. The exact amount in dispute generally does not have to be stated; it is usually sufficient to state that the amount of the claim exceeds the minimum amount required in order to establish the court’s jurisdiction. Similarly, a defendant’s answer need only provide a short response to each allegation in the complaint, indicating whether the allegation is admitted or denied, or whether the manufacturer lacks sufficient information to answer the allegation, together with any affirmative defenses that the defendant may wish to raise.

**Service of Process**

A Swiss medical device manufacturer has no obligation to defend against the complaint until a copy of the summons and complaint has been properly served upon the manufacturer. If the Swiss manufacturer has a branch or other agent in the United States, the summons and com-
plaint generally can be served upon the branch or the agent. If the Swiss manufacturer does not have a branch or other agent in the United States, the summons and complaint must be served upon the foreign manufacturer in the foreign jurisdiction where it is located. Under Volkswagenwerk AG v. Schlunk, 486 U.S. (1988), such service must be made under the Hague Service Convention. The Hague Service Convention is an international treaty to which the United States and approximately 35 other countries, including Switzerland, are signatories. Under the Hague Service Convention, the principal method of service requires the United States plaintiff to send the summons and complaint, together with a short form and a translation of the pleadings into the language of the recipient, to the cantonal Central Authority designated by Switzerland, which then serves the pleadings in accordance with its own procedures.

Class Actions

A class action is a case brought by one or more representative plaintiffs on behalf of a larger group of similarly situated plaintiffs. It is a procedural device under which either one or a few plaintiffs may represent the claims of a much larger class of allegedly injured parties. Successful product liability class actions have been brought against medical device manufacturers on behalf of the entire class of persons who allege they have been injured as a result of allegedly defective medical devices. The particular danger in class actions is that the total amount of the claim may be so enormous that the defendant manufacturer may be threatened with bankruptcy.

When a class action claim is filed, the court requires that the class action plaintiff give notice to all members of the potential class by the best available method. In a relatively small case, the notice may require a letter to be posted to each potential class member. In a large case, the notice may take the form of a newspaper advertisement. The class members have the right to “opt out”, or not participate in, the class action. Class members who “opt out” will not benefit from any settlement or judgment in favor of the class. On the other hand, they will not be barred by an adverse judgment against the class and they are free to file their own individual actions, independent of the class action against the defendant.

The court is required to hold a hearing as soon as possible to determine whether the class action should be maintained. At this hearing, the court will address questions such as: (i) whether the class is so numerous that individual suits are impractical; (ii) whether there are questions of law or fact common to the class; (iii) whether the claims or the representative parties are typical of the claims of the class; and (iv) whether the representative parties and their lawyers will adequately protect the interests of the class.

If a court decides after this hearing that a class action is proper, the case proceeds much like any other civil action, but it cannot be settled or compromised without notice to the class members and approval from the court.

Discovery

Pretrial discovery is one of the hallmarks of the United States procedural system. As little or no discovery is available in Switzerland, this is one of the major differences between the United States and the Swiss procedural systems. The purpose of discovery is to assure that the parties to the litigation have available to them in advance of trial all the evidence relating to the claims and defenses in the case. This is to assist the parties in preparation for trial, to prevent the presentation of any surprise evidence at trial and to aid the parties in reaching a possible settlement before trial. The available discovery procedures include the following:

Mandatory Discovery Procedures

For actions proceeding in federal court, a 1993 amendment to the Federal Rules of Civil Procedure obligates the parties to make certain initial disclosures prior to conducting any other discovery in the litigation. These initial disclosures include: (i) the names and addresses of
witnesses, both favorable and unfavorable; (ii) copies or descriptions of relevant documents, both favorable and unfavorable; (iii) a computation of damages; and (iv) copies of any insurance policy which may be applicable to claims in the litigation.

Actions filed in state court may or may not have mandatory disclosure requirements, depending on the particular jurisdiction.

**Other Discovery Procedures**

In addition to mandatory discovery, the principal discovery procedures that are available to the parties in both federal and state courts include:

- **Written interrogatories** are questions prepared by one party which the other party has to answer under oath. Although some of the information otherwise obtainable by written interrogatories should be disclosed pursuant to the mandatory discovery disclosures, this provides a method for the parties to obtain additional information, particularly regarding the identities of witnesses, the types and location of documents and details regarding the opposing party’s claims to the extent they are not disclosed in the pleadings.

- Through **document production requests**, a party may request that the opposing party produce documents that may lead to discovery of evidence relevant to the claims and defenses in the litigation. Although some of the documents should be disclosed pursuant to the mandatory discovery disclosures, document production requests give the parties an opportunity to seek additional relevant documents.

- Each party is allowed to take the deposition of potential witnesses. **Depositions** are a form of testimony, but they are not taken in a courtroom, and no judge is present. Instead, they are taken in the lawyer’s office, with the lawyers for both sides present, along with a court reporter who records the testimony. The party taking the deposition is allowed to ask the witness any question that may lead to relevant evidence, and the witness is required to answer under oath. The only basis for refusing to answer a question is if the question would intrude upon a privilege, such as the attorney-client privilege which protects communications between an attorney and the attorney’s client. Due to the lack of direct control by the judge, depositions may be quite detailed, lengthy and expensive.

**Hague Evidence Convention**

The Hague Evidence Convention is an international treaty signed by both the United States and Switzerland. The Hague Evidence Convention provides specific methods by which United States litigants can obtain evidence under the supervision of a foreign court from parties residing abroad. Some foreign parties have raised the Hague Evidence Convention as a defense to United States discovery procedures by arguing that all discovery taken from the foreign party should be taken pursuant to the procedures of the Convention. However, the United States Supreme Court in *Société Nationale Industrielle Aerospatiale v. U.S. District Court*, 482 U.S. 522 (1987), held that the Hague Evidence Convention is neither the mandatory nor the preferred method for taking evidence from foreign litigants. Instead, it is only an optional method for taking discovery from foreign litigants and its use is to be determined by courts on a case-by-case basis. After the *Aerospatiale* decision, in deciding whether the use of the Hague Evidence Convention should be required, United States courts have looked to factors such as: (a) how burdensome the discovery is; (b) the sovereign interests of the countries involved; and (c) the likelihood that resort to the Hague Evidence Convention procedures will prove effective. In a few cases, foreign parties have been successful in convincing United States courts to require use of the Hague Evidence Convention to the exclusion of ordinary discovery rules; however, in most cases they have not. Accordingly, it is probable that a Swiss manufacturer involved in United States product liability litigation will be fully exposed to the usual United States discovery procedures.
Sanctions for Non-Compliance

In the event that any disputes arise regarding discovery, they are brought to the judge’s attention by a motion from the parties. After reviewing the parties’ positions, the judge will either grant or deny the requested discovery. If a party refuses to comply with the judge’s order, severe sanctions may be imposed, including the entry of a default judgment against the non-complying party.

Potential Impact on a Swiss Medical Device Manufacturer

The potential impact of U.S. discovery upon a Swiss medical device manufacturer cannot be overemphasized. A Swiss manufacturer involved in United States product liability litigation may find itself required to produce its documents relating to the research and development, design, manufacture, testing and marketing of its medical devices, and to present for depositions its management, research, engineering, manufacturing and marketing employees who may possess knowledge that may lead to relevant evidence supporting the plaintiff’s claims or the manufacturer’s defenses. Claims that documents have been lost or destroyed are ill-received and may lead the judge to instruct the jury to infer that the missing documents contained information adverse to the manufacturer. Not only can United States discovery cause liability risks to a Swiss manufacturer that it may not experience in Switzerland, but the process of answering interrogatories, producing documents and presenting witnesses for depositions can be quite time-consuming and expensive.

Use of Experts

Expert witnesses are used with great frequency in United States product liability cases involving medical devices. The plaintiff in most cases must have an expert to testify that the medical device was defective in its manufacture, design or safety warnings, and in turn, the defendant will present an expert to rebut the plaintiff’s expert’s testimony. In addition, expert witnesses may be used at trial on any other issue in which expert scientific, technical or other specialized knowledge will assist the jury. For example, experts often are used to establish damages by proving the economic effect of an injury.

In many foreign jurisdictions, experts are designated by the court and their fees and expenses are assessed as a court cost. The use of experts in the United States is distinctive because experts almost never are designated by the court but instead are selected and paid by the parties. Thus, an expert witness is more a part of the party’s litigation team than an impartial witness. Often there will be conflicting evidence between two opposing expert witnesses, and it will be the jury’s or the judge’s task to decide which expert to believe.

Certain United States Supreme Court decisions have placed some limitations upon the use of experts in federal court. In Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993), the United States Supreme Court directed the trial judges to make a preliminary assessment as to whether an expert’s reasoning or methodology is scientifically valid and can be properly applied to the facts at issue. The Supreme Court stated that many considerations will bear on the inquiry, including whether the theory or technique in question has been tested, whether it has been subject to peer review and publication, what its error rate is and whether it has attracted wide spread acceptance within the scientific community. In Kumho Tire Co. v. Carmichael, 526 U.S. 137 (1999), the Supreme Court further held that the general principles of Daubert apply to all expert testimony, including the testimony of non-scientific experts. These decisions have had a significant effect in limiting the submission of expert reports based upon unsubstantiated conclusions.

Trial By Jury

Under United States procedure, plaintiffs in product liability claims are entitled to a trial by jury, and they almost always exercise this right. Product liability claims that go to trial therefore almost always are decided by a jury of six or twelve lay people. From the point of view of a
Swiss medical devices manufacturer, this provides an element of risk different in character from the risk to which it is accustomed in Switzerland.

Attorneys’ Fees and Costs

Swiss medical device manufacturers are accustomed to a system where the losing party in litigation reimburses the winning party’s attorneys’ fees, where contingency fees are impermissible and where costs are sufficiently high to act as a deterrent to the filing of litigation. The United States procedural system takes a different approach on all these points:

Reimbursement of Attorneys’ Fees

Under the general American rule, the parties generally always bear their own attorneys’ fees, irrespective of whether they win or lose the case. There are no mandatory fee schedules in the United States, and attorneys’ fees generally are determined on the basis of hourly rates, or, as discussed below, on a contingency basis.

Contingency Fees

In a United States product liability case, it is almost a certainty that the plaintiff is represented by an attorney on the basis of a contingency fee, which is legally and ethically permissible in the United States. Under a typical contingency arrangement, the plaintiff’s attorney will receive between 20 and 40 percent of the amount recovered by a verdict or a settlement.

Costs

Although a winning party in United States litigation generally has a right to recover court costs from the losing party, court costs in a United States proceeding generally are nominal, not determined on the basis of the amount in controversy and do not act as a deterrent to the filing of litigation.

14.4. Product Liability Exposure Through Mergers/Consolidations and Acquisitions

A Swiss medical device manufacturer may seek to increase its business in the United States by acquiring an existing U.S. corporation. In so doing, the Swiss medical device manufacturer may become exposed to product liability claims resulting from medical devices that the U.S. company has sold either before or after the acquisition. The following will discuss such exposure as it may result from mergers/consolidations and from acquisitions.

Mergers/Consolidations

A merger is a transaction in which two or more constituent companies combine to form a single new entity with one of the constituent companies becoming the surviving company and carrying on the business. A consolidation is similar, except that a new company is formed to carry on the combined business.

In the case of either a merger or a consolidation, the surviving or new company is fully liable for all product liability claims asserted against any of the constituent entities arising either before or after the merger or consolidation. In other words, a Swiss medical device manufacturing company that is a party to a merger or consolidation will find its assets fully exposed to product liability claims that have been, or will be, asserted against the U.S. companies that were constituents of the transaction.
Acquisitions

The two forms of acquisitions, stock acquisitions and asset acquisitions, can yield quite different results regarding product liability risks, and they are discussed separately hereunder:

Stock Acquisitions

In a stock acquisition, the Swiss medical device manufacturer acquires the issued stock of the U.S. company. As long as the U.S. company continues to operate as an independent subsidiary, the Swiss manufacturer would not have direct liability for product liability claims that might be asserted against the U.S. company. However, there are exceptions to this general rule. One exception is the doctrine of piercing the corporate veil. The U.S. courts may permit product liability claimants to pierce the corporate veil of a U.S. subsidiary and impose liability on the Swiss parent, provided that there is proof that (i) the Swiss parent unreasonably dominated and controlled the business and operations of the U.S. subsidiary and (ii) such domination and control led to fraud or an unjust result.

Asset Acquisitions

In an asset acquisition, the Swiss medical device manufacturer acquires the assets of a U.S. company. The transaction can be structured so that only assets are transferred, and liabilities, including product liability claims in particular, are excluded from the acquisition. As a general matter, the Swiss manufacturer would not be responsible for product liability claims resulting from the operations of the U.S. company prior to the transaction.

However, the U.S. courts recognize four exceptions to this general rule. These exceptions occur where: (i) there has been an express or implied agreement that the purchaser will assume the seller’s liabilities; (ii) the transaction is a de facto merger of the purchaser and the seller; (iii) the purchaser is a “mere continuation” of the seller; or (iv) the seller transferred its assets with actual fraudulent intent to avoid, hinder or delay its creditors.

Summary

Two important points emerge from the foregoing for Swiss medical device manufacturers who are contemplating a merger/consolidation with, or an acquisition of, a U.S. company. First, the Swiss manufacturer should conduct very careful due diligence to determine the extent to which product liability claims have been or may be asserted against the U.S. company. Second, Swiss manufacturers should seek expert legal advice regarding structuring the transaction so as to minimize the likelihood that its assets will become subject to product liability claims resulting from the U.S. company’s operations.

14.5. Reducing the Risk of Product Liability

Any Swiss medical device manufacturer selling its products into the United States should institute programs in order to reduce its U.S. product liability risks. The program should include the following:

State of the Art Design

All medical devices sold in the United States should fully meet all design standards set by the FDA as well as by trade associations, professional societies and technical organizations and other standard setting groups. In addition, Swiss medical device manufacturers should strive for their product designs to meet the highest state of the art prevailing in the industry.
Quality Control

Careful attention should be given to every phase of manufacturing medical devices including materials and component selection, assembly, testing and inspection and packaging, storage and handling. Comprehensive and effective quality control of manufacturing standards is absolutely essential.

Warnings and Instructions

Warnings and instructions must be formulated and provided for health-care providers and, if the health-care providers will not be in a position to reduce the risks of harm, for patients as well. Warnings and instructions must take into account all foreseeable risks of harm resulting from both use and misuse of the medical device. They must be clear and intelligible and appropriately prepared for understanding by either medical providers or patients. Moreover, as relevant information is obtained, warnings and instructions need to be updated and systems need to be in place to provide such information to existing users of the medical devices.

Monitoring and Follow-up with Customers

Lines of communication should be open with both medical care providers and patients. This will facilitate prompt notice of any possible defects in the medical device and additional instructions or warnings or a recall of the product, if necessary.

Preservation of Records

Careful records must be kept in order to document that all standards are met with regard to the design and manufacturer of medical devices. Of particular importance are documented standard operating procedures that evidence that regulatory requirements and appropriate manufacturing processes have been followed, that provide for critical functions such as adverse event reporting and that demonstrate meaningful employee training and quality assurance. This is particularly important in light of the obligation in U.S. discovery proceedings to provide records to the plaintiff.

Insurance

Insurance plays a significant role in protecting medical device manufacturers against United States product liability risks. The insurance carrier providing product liability coverage, subject to the terms and limitations of the insurance policy, will indemnify the manufacturer against payments that must be made as a result of a judgment (although a punitive damages award generally will be excluded from coverage) or as a result of a settlement. Moreover, the insurance carrier will generally provide a defense to product liability litigation and will assume the costs of the attorneys representing the medical device manufacturer and the expert witnesses testifying on the manufacturer’s behalf.

Any Swiss manufacturer selling or otherwise distributing a product in the United States market should obtain insurance coverage sufficient in amount and scope to cover its United States product liability risks. Particular care should be taken to ensure that their insurance is sufficient because non-United States general liability policies often exclude United States product liability risks from their coverage.
15. Risk and Insurance Aspects of Product Liability

By Klaus Peretti and Christian Brinkmann, Kessler & Co Inc., and Simon Künzler, Kessler Consulting Inc.

15.1. Enterprise Risk Management to reduce Uncertainty

Management of threats has become at least as important as managing investment opportunities in most companies. The collapse of the new economy, corporate governance failures, terrorist attacks and a series of costly natural disasters are high profile events which have focused senior management’s attention on risk mitigation. However, enterprise value is most often not destroyed through these kinds of spectacular events, but rather through more mundane but common organizational risks. Such ‘ordinary’ risks are manifold and are of strategic, operational and financial nature (see Figure 53).

Entering the U.S. market with an expansion project gives ample opportunity to discuss not only opportunities but to understand and manage considerable downside risks potential which may impede growth, jeopardize a project, or in a worst case, even threaten the company. The basis for successful decisions is full knowledge and understanding of the company’s risk landscape. The same applies for expansion projects. Management must be aware of the various optimistic, realistic and pessimistic scenarios of possible outcomes before undertaking a project.

How can this be achieved?

It is recommended to go through a thorough risk assessment process by identifying and evaluating risks and, subsequently, by managing and carefully monitoring the identified key risks. External consultants such as Kessler Risk Consulting have a Best-Practice Risk Management methodology which can be aligned to companies of all sizes. Surveys indicate that companies with an implemented modern risk management process in terms of an enterprise-wide risk approach are better placed to run a sustainable, successful business including launching of flourishing expansion projects. It provides companies with an important competitive advantage.
15.2. **Product Liability Insurance Issues**

One of the major threats and risks addressed in a thorough risk assessment for a company in the med-tech sector most probably will be product liability. In the following section we would like to discuss some background aspects such as claims scenarios as well as reasons why to buy insurance, furthermore give some insight into what solutions are achievable and how to obtain them.

The med-tech company entering the U.S. market is entering an economic and legal environment, where, for the second consecutive year, the tort system has experienced double-digit increases in costs, far outpacing trends of the past decade. U.S. tort costs have grown by more than 13% in 2003, on the heels of an over 14% increase in 2001 which is well in excess of overall economic growth.

Medical device manufacturers are exposed to product liability claims in many ways, be it a faulty product, medical malpractice of a surgeon or doctor, or adverse reactions of patients.

Due to this constellation, proof of liability may not always be conclusive, i.e. the final cause of and corresponding liability for bodily injury cannot be determined in each and every case.

The law suits mentioned below give an overview of past losses due to faulty medical devices which have occurred in the USA and Canada:

- **1979 -1990’s:** Heart valve manufacturer entered into a settlement agreement to resolve claims by creating a settlement class of 55’000 recipients of the product together with their spouses. Strut fracture has been experienced in just under 1 % of the products and has allegedly led to anxiety amongst those with valves still functioning. Estimates as to the ultimate net loss vary from $300m to over $500m.

- **1970’s -1980’s:** Canada: Breast implant manufacturer settled with nearly 2’000 Canadian breast-implant recipients for over CND 20m as compensation for their alleged injuries.

- **1960’s -1990’s:** U.S. manufacturers of silicone breast implants announced proposal to set up $ 4.25bn fund over a 30-year period to settle claims. Thousands of lawsuits alleged implants cause diseases of the immune system etc. Manufacturers continue to deny implants being unsafe. Proposed settlement collapsed after bankruptcy of principal manufacturer and was replaced by a settlement worth approximately $2bn by remaining major producers. Total expenditure to date and remaining exposure estimated at $10bn by one of the defendants in 2001. Main manufacturer in 1998 offered $3.2bn to settle and had incurred $500m in legal costs. Another manufacturer estimates $4bn before insurance.

- **1970’s -1980’s:** $ 30m settlement approved by federal judge in Texas to compensate patients who have received implants in the jaw joint. As many as 3000 plaintiffs will receive between $ 1’500 and $ 100’000. Many implants break up into microscopic fragments and cause erosion of the jaw bone creating painful complications. Implant manufacturer is bankrupt and limited funds/insurance that were available are nowhere near adequate to compensate the injured.

- **1980’s -1990’s:** Settlement worth $ 112m announced between one of the principal manufactures of orthopedic bone screws used in spinal surgery. Settlement is hoped to resolve claims against defendant who was facing thousands of suits.

- **1980’s:** U.S. court approved a $ 21m class action settlement resolving 3’000 personal injury claims arising from the use of allegedly defective pacemakers.

- **1990’s:** U.S. manufacturer is faced with an alleged product liability / personal injury claim due to a contraceptive implant. Class certification denied, several individual cases are expected to go to trial from early 1997. Settlement for approx. $ 100m estimated.
2000: U.S. manufacturer of hip replacement units and knee implants involved in class action. Final settlement over $700m. Insurance was not sufficient to cover entire settlement.

2001: U.S. healthcare/medical device company announced $100m – $150m charge resulting from recall costs and liability associated with 51 deaths in the U.S. and Europe allegedly involving a contaminant in its filters used in kidney dialysis.

As one can easily gather from the data above it is evident that no company is safe from getting involved in a litigation and/or being confronted with a product liability claim. From a holistic risk management perspective there are 4 important steps to manage the risk:

- Avoid certain risk, e.g. not to sell a specific product in certain markets
- Reduce the risk of getting involved in a product liability claim, e.g. extend clinical testing prior to launching the product into the market or improve safety rules
- Transfer the risk to a third party, e.g. to an insurance company
- Bear the costs of claims through own funds, e.g. set off against reserves in the balance sheet.

Under the pretext that avoiding and reducing is not always possible, residual risk is always inherent to manufacturing and selling products. It is therefore necessary to look at the total costs of risk one will have to bear doing business.

One may want to protect one’s balance sheet by not bearing excessive risks related to product liability. Thus, it is most recommendable to take out insurance coverage against product liability claims, especially if doing business in North American Territories. Product liability insurance does not only cover indemnities for bodily injury and property damage due to faulty products but in addition supports the company in providing defense against unjustified claims for compensation.

Bearing protection against potential product liability claims makes the risk quantifiable to a certain extent: Insurance protection subject to a premium. Whereas, if one does not take out insurance coverage against product liability, one has to build up large reserves in the balance sheet in order to set off-set potential future claims. Unless an internal legal department is maintained, additional fees for external legal defense will be incurred.

The aim of a modern Risk Management is to reduce the total cost of risk consisting of net premiums (i.e. after deduction of loss/profit sharing agreements), deductibles and uninsured losses (i.e. costs incurred one cannot collect from a third party), expenditures for risk prevention and loss reduction (e.g. reviewing the production process and the supply chain management) and administrative costs (e.g. Risk Management and legal costs).

The health care industry as such, consisting of health care equipment and supplies, health care providers and services, pharmaceuticals and biotechnology as well as medical devices experienced the highest increase in their total cost of risk between 2002 and 2003. As a percentage of revenue the health care industry has one of the highest total cost of risk of any industry.
The principles of risk financing as per the chart below provide a tool to determine the level of costs/risk the company is able to retain depending on the financial situation (balance sheet/profit and loss account). A balanced Risk Management approach helps to achieve company objectives. We need to aim at a higher, justifiable economic measure. Such a modern Risk Management approach begins with Risk Analysis, which identifies the possible dangers and assesses them in terms of possible interference with company goals/objectives.

Priority is given to the relatively rare events, which in the event the situation arises, could lead to huge financial loss and impair profit and liquidity objectives (Catastrophe Principle).

To facilitate the discussion of the principles, the elements shown have the following dimensions for Risk Categories and Loss Exposure per Claim:

- High: A possible loss would lead to an extraordinary decline in company results and force a drastic change in objectives.
- Medium: A possible loss would interfere with company results and could cause changes in objectives.
- Low: A possible loss is not crucial and can be paid out of the available resources.

Categories for Loss Frequency:

- High: Frequent, i.e. once a month
- Medium: Probable, i.e. once a year
- Low: Improbable, i.e. once in 5 years

A probable Insurance Strategy may be derived as follows: Self-retention of minor losses, either by foregoing insurance or by way of deductible; Insurance of medium-sized losses according to a cost/benefit analysis; Transferring of possible high losses to the insurance market; Conscious avoidance of activities with catastrophic risks which are either uninsurable or only insurable at excessive cost.

What can be insured, what is the scope of coverage of a product’s liability insurance?

If third party individuals (= individuals not employed by the company) are injured or killed and/or suffer physical damage to property due to a faulty product produced / manufactured/sold by the company, the company will invariably be confronted with a claim for compensation. This so called product liability exposure can be insured to a large extent via a Comprehensive Liability Insurance which includes product liability coverage for claims based on civil proceedings. Criminal proceedings as such cannot be fully insured, however, a limited amount can be made available for legal defense cost where the criminal proceedings are in
combination with civil proceedings. If the claim is covered, the insurer will be in charge of handling the claims and the subsequent settlement.

The core element of a product liability policy or the trigger of the coverage is the consequential loss due to a faulty product causing damage to third parties. Costs for the pure rectification of a product failure as such, is considered an entrepreneurial or business risk and as a rule cannot be insured (=fulfillment of contract). However, a variety of additional extensions provide limited coverage in this area. It is of utmost importance to have an understanding of the difference between legal liability / duty to compensate for damages and the insurance coverage provided by product liability insurance as shown below.

![Diagram of a Comprehensive Liability Policy](image)

**Figure 55 Elements of a Comprehensive Liability Policy**

A comprehensive liability policy covers the following elements of risk emanating from:

- Premises of the company, e.g. a visitor slips or falls whilst on the premises, resulting in a broken leg. The company might get sued on grounds that it did not comply with safety rules or failed to post warning signs.
- Operations, e.g. due an explosion of a boiler where a person is injured.
- Products, e.g. an implant shows a failure in design or is defective and must therefore be replaced and a patient needs to undergo additional surgery.

In Europe it is customary to have aforementioned exposures insured under one single policy (comprehensive liability insurance covering premises, operations and products completed). In other hemispheres, mainly overseas (in the USA amongst others) two separate policies, one for premises and operations and one for product liability are more common.

Specific elements of coverage include definition of bodily injury, product recall, contractual liability, hold harmless/back to back agreements, vendors endorsements etc. These need to be carefully reviewed and agreed upon subject to the company’s exposures.

Foremost in the med-tech industry it is of utmost importance to assess and review the definition of “bodily injury” of an existing policy. In the absence of such specific bodily injury definition the policy may not offer adequate coverage in cases where faulty implants require further surgery and must be replaced by a sound product.

Coverage for Products Recall (1st and 3rd party) should be arranged as well. If the company enters contractual agreements with 3rd parties extending beyond legal liability (e.g. extended warranty periods, hold harmless agreements, etc.) it is vital that the policy contains a section covering these exposures too.

Before a product may be launched it will have to undergo intensive testing in accordance with regulations and as requested by authorities (e.g. FDA approval, CE-mark etc.). Product Liability insurance starts on the day the product is approved and allowed to be sold. Prior to that
stage, i.e. during the phase of clinical testing, a so-called clinical trials coverage must be con-
cluded to protect against claims incurring during or after testing.

Coverage for conducting clinical trials can either be included under the general liability policy
or can be arranged for the duration of a specific trial separately. Another possibility is to ar-
range coverage under an open policy. In various countries in which testing is conducted, lo-
cally admitted policies meeting local regulations are compulsory (e.g. Germany, France etc.).

The summary below comprises a non exhaustive overview. Exclusions vary by type of busi-
ness and are subject to insurer’s surveys/acceptance/non-acceptance and may read as fol-
lo.

- Own damages, pure fulfillment of contracts, business/entrepreneurial risk, damages to prop-
erty directly worked upon, restrictions for property in care custody and control (CCC), restric-
tions to pure financial loss apply (partially insurable via extended coverages), intentional and
criminal acts, restrictions apply to contractually assumed liabilities going beyond legal liability,
compulsory insurance (e.g. motor, aviation, ships).

- Last but not least, a variety of specific products are normally excluded: asbestos, chlorinated
hydrocarbons, tobacco, HIV/AIDS, restrictions to silicon implants, products of human origin,
DES, SMON, contraceptives etc.

Punitive and exemplary damages can be awarded by U.S. courts in addition to the regular
indemnification for a product liability claim. The intention of punitive & exemplary damages is
to punish the manufacturer for fraudulent and highly risky products or behavior. Thus, from an
ethical and moral stand point one would not expect punitive and exemplary damages to be
insurable. Nevertheless, this exposure may, under certain circumstances, be insurable de-
pending on the state of the insurance market (soft vs hard market) and subject to restrictions
in various U.S. states. In some states it is permissible to insure P&C, in others it is strictly for-
bidden. A few examples on how the coverage can be arranged are:

- Punitive Wrap up Bermuda. A separate off-shore policy will be issued contingent on the
general/product liability insurance placed elsewhere.
- Remain silent solution, i.e. the Swiss liability policy does not exclude P&S damages.
- Cover via side letter. Coverage is stipulated in a separate addendum to the policy. Having
a separate document may be advantageous. Especially in the event that a court requires
the defendant to reveal the entire policy. In this case, one might want to refrain from show-
ing the side letter.

Once a claim for compensation is filed against the company, it must be passed on to the liabil-
ity insurer without delay, who in turn then investigates whether the claim falls within the scope
of the insurance policy. If coverage is provided, the insurance carrier has, as a general rule
the following responsibilities:

- Ascertain whether the company is legally liable.
- Indemnify the justified claim, (where the company is legally liable and must indemnify the
claimant(s)).
- Reject unjustified claims if the company is not liable (provide legal defense).

In practice insurers and brokers work hand in hand with the insured during litigation and/or
claims settlement. If there is no coverage under the policy, the company will have to bear the
costs arising out of the settlement unless funded elsewhere.

In order to obtain insurance offers from the market the broker will prepare a submission paper
containing all necessary underwriting information, i.e. all the relevant details and exposure
related facts which will enable the insurer to quote a premium. Some carriers use and request specific questionnaires to be filled out by clients prior to quoting. Depending on the individual exposure and the complexity of the business, insurance carriers might want to additionally review certain exposures directly with a so-called risk engineering survey. Clients’ transparency towards insurance markets has become of utmost importance. Sufficient time must be allowed for the entire process from submission to quotations and offers. The set-up of a global product liability insurance program may easily take 2 to 3 months.

Depending on how the U.S. market is entered, principally 3 options are available:

- Review or extension of the existing Swiss products liability policy to cover U.S. exports, if there is no legal entity established in the U.S.
- Arranging coverage for U.S. sales via a 3rd party vendor/vendors endorsement (no legal entity in the U.S.)
- The set-up of a global products liability policy/program if one has already or intends to establish or acquire a legal entity in the U.S.

Alternatives (Alternative Risk Transfer/ART such as Finite or Pooling solutions) may be considered as well, depending on the size of the company and can be combined with an international liability program. See also the discussion of an industry-wide solution in sub-section 3 below.

A variety of insurance markets are available in Switzerland, UK, United States and off-shore in Bermuda. Not all of the carriers are prepared to write product liability insurance for med-tech companies.

Criteria for the selection of an Insurer are financial strength/security rating (A.M. Best, S&P), coverage availability, quality of service and experience/claims handling ability, premium.

Determining the correct and adequate limit is not an easy task as one will never know the ultimate exposure. Nonetheless, the class action law suit which Sulzer Medica was involved in has clearly shown that an adequate limit is vital. Thus, it is recommended to consider increasing deductibles instead of reducing or buying low limits.

The average primary limit (all industries) for public and product liability insurance in the USA was $ 2m in 2003. Deductibles varied between $ 37’000 (companies with turnover up to $ 200m) and $ 2.8m (companies with turnover in excess of $ 10bn). Average premium per $ 1’000 in turnover was $ 0.55 bearing in mind that companies with turnovers below $ 200m paid approx. $ 6 per $ 1’000 in turnover which is significantly more than the average.

The average excess limits worldwide (all industries) were $ 71m in 2003. The non-US average limit was $ 47m, while the U.S. average was $ 87m.

Chemical and pharmaceutical companies followed by healthcare and medical device companies purchased the highest limits on average.

The average cost per $ 1m of excess coverage worldwide was $ 11’629, virtually identical to the price in the U.S. The U.S. healthcare industry paid the most on average for insurance coverage.

In the U.S., the “peak probability award” for wrongful death has increased almost threefold in the past 10 years and is now in excess of $ 4m per life. Highest Indemnity Award for a single bodily injury was $ 124m in the U.S., whereas $ 10.8m in Switzerland with lowest of $ 600’000 in Portugal.

In 2002, average limits in the U.S. ranged from $ 39m (government) to $ 214m (chemicals pharmaceuticals). In 2003, the range is $ 30m (healthcare) to $ 190m (chemicals & pharmaceuticals).
For the vast majority of companies, available insurance capacity is sufficient to meet their excess needs, albeit at prices substantially higher than in prior years due to a hard market. After reaching a high of $2bn in 2000, total excess capacity dropped to $1.6bn in 2002—a decline of 20%. While total capacity stabilized over the past years, in many cases, insurers remain cautious about committing all their risk capital to certain buyers, e.g., those in highly exposed industry segments such as chemical/pharmaceuticals followed by medical device manufacturers.

For benchmark details see the charts below and MARSH, Limits of Liability Report 2003 ("How much is enough?").

<table>
<thead>
<tr>
<th>Annual Revenues</th>
<th>Minimum Limits</th>
<th>Maximum Limits</th>
<th>Average Limits</th>
<th>Average Price per $ Million in $</th>
<th>Average Cost per $1,000 Revenue in $</th>
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</thead>
<tbody>
<tr>
<td>0-200</td>
<td>3</td>
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<td>4.39</td>
</tr>
<tr>
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<td>640</td>
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<td>120</td>
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<td>2.3</td>
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<td>1'300</td>
<td>547</td>
<td>11'165</td>
<td>0.65</td>
</tr>
<tr>
<td>10'000 +</td>
<td>11</td>
<td>1,200</td>
<td>561</td>
<td>34'867</td>
<td>0.65</td>
</tr>
</tbody>
</table>

**Figure 56 Chemical / Pharmaceuticals (All Values in $ Million)**

<table>
<thead>
<tr>
<th>Annual Revenues</th>
<th>Minimum Limits</th>
<th>Maximum Limits</th>
<th>Average Limits</th>
<th>Average Price per $ Million in $</th>
<th>Average Cost per US$1,000 Revenue in $</th>
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<tr>
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<td>37'627</td>
<td>3.22</td>
</tr>
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<td>120</td>
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<td>32'155</td>
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</tr>
<tr>
<td>10'000 +</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
</tr>
</tbody>
</table>

**Figure 57 Healthcare (All Values in $ Million; *= No data available)**

It must be noted that at least for the next two years premiums are expected to increase. A softening of the market as encountered in the area of property insurance is not foreseeable in respect of product liability insurance at the moment.

### 15.3. Pooling – An Innovative Risk Bearing Approach for Product Liability

Product liability is one of the most important risk factors to consider for med-tech companies. Obtaining sufficient insurance coverage at reasonable cost may prove to be difficult. Premium levels can be exorbitant and, in individual cases, insurance coverage for med-tech companies may not even be available due to tough underwriting conditions. A med-tech company may end up with the obligation to self-insure in part or in its entirety.

High premium levels and limited availability of insurance coverage are general issues of the med-tech market and not limited to a few individual med-tech companies. Thus, an innovative approach with a new insurance concept uniquely tailored to the med-tech industry’s needs may be the solution. Med-Tech Pool Insurance Ltd. is one concept (see figure below for illustration). Individual med-tech companies would become shareholders of "Med Tech Pool Insurance Ltd", a captive pooling company. The med-tech companies' financial participation would serve as an incentive to good performance and tight monitoring of claims situations.
Following underwriting regulations said insurance company would assume individual product liability risks of the members in part or in entirety and, in turn, reinsure itself in the global insurance and reinsurance markets. This strategy allows for best possible conditions, while limiting the risk exposure.

The most suitable structure of the pooling company would be a direct insurance company with its headquarters in Switzerland or in Liechtenstein\(^1\). The company would issue the insurance policies for the individual med-tech companies. This approach requires adequate capitalization and expertise from the start. Tasks such as accounting, underwriting, management and legal issues could be outsourced to enterprises specialized in those fields. Cooperation with a renowned international insurance company would be imminent for the issuance of policies in the U.S. and elsewhere. Additionally, this company could assume limited underwriting and claim handling in international business relations. From a cost/benefit point of view this approach could only be justified if the pooling company could generate the volume needed to be self-sufficient. If this were not attainable, re-insurance pooling with fronting insurance companies acting as primary policy issuers who ensure the subsequent transfer of the insurance business to the reinsurance captive company could be another avenue. With this solution it would be the fronting companies' privilege to determine guidelines and conditions in conducting the business and, individual med-tech companies would have to agree to secured collateral to protect the fronting companies' credit risk exposure.

The concept of a direct insurance company is preferable. Issues such as finance/accounting, legal, taxes and management would have to be looked at carefully. A set of clear guidelines would have to be established to define the parameter of each individual shareholder's responsibilities in major product liability claim filings. The strategic value of this business model for individual med-tech companies should not be underestimated. The formation of Med-tech Pool Insurance Ltd. with the individual med-tech companies as shareholders turns the insurance issue from a business expense into a strategic investment vehicle. A carefully prepared feasibility study conducted by a risk and insurance consultant with the necessary expertise would lay the basis for decision-making through the boards of those med-tech companies who would participate in such a solution.

\(^1\) An insurance treaty between Switzerland and Liechtenstein allows a Liechtenstein based company to operate in Switzerland with proper licensing.
15.4. Risk and Insurance Aspects related to Mergers & Acquisitions (M&A)

Acquisition of a US company, or participation in an existing venture with a majority stake are ways to enter the US market. The assessment and understanding of the risks involved are critical aspects in a business plan and demand due diligence. Risk management procedures should be an integral part of an enterprise's management (see description under sub-section 1).

Cultural differences resulting in occasional misunderstandings are foreseeable despite the widespread use of the English language. It is, therefore, highly recommended to seek the support of your risk and insurance advisor and allow sufficient time when addressing complex issues. Your advisor should work closely with the investor's acquisition team and also be involved in field work (visits at the target's location). Good communication among all team members is imminent to ensure that legal, tax, accounting, human resources, health, safety and environmental matters are addressed and dealt with. A risk profile for the target should include relationships among a group of companies and with suppliers and customers. It is not uncommon that an investor's new business plan may change substantially and require adjustments to the original risk profile. An accurate risk profile is needed to identify any potential exposures in the reporting of quality control, client satisfaction and human resources aspects (accidents, absenteeism). This may help to quantify unfunded or under-funded liabilities in a target's financial projections.

Professional risk and insurance advisory service should include the provisions for insurance programs with required implementation and the calculation of associated costs. Experience shows that M&As do not solely consist of operational integration but quite often require increase in insurance protection and a new marketing concept. Separate insurance coverage becomes an issue in cases where the target was able to benefit from the parent company's insurance protection.

Due diligence will discuss compatibility of the investor's actual risk management policy with the target's actual standing. Priorities in risk management should be addressed immediately. They can include upgrading of health, safety and environmental protection as well as the allocation of human resources as to comply with local laws and regulations. Additional investment needs and costs associated with aforementioned issues may call for a new set of financial projections and thus, influence the purchase price.

Recent developments in the insurance market allow for transfer of risks that otherwise, would have the potential to be deal breakers. Insurance can provide security and limit risks related to warranties or indemnities, environmental exposures or potential litigation liabilities. Reputable risk and insurance advisors have the expertise to structure insurance contracts to protect the seller or buyer. Risk exposure and insurance needs should be addressed at an early stage of the negotiation process and a contract established in tandem with the sales and purchase agreement. Such procedure will ensure that the buyer's and the seller's expectations will be met and, thus, increase the success of such endeavors.
16. Annexes

16.1. Annex I: Links to Data Sources

American Heart Association: http://www.americanheart.org/
BCC Inc.: http://www.buscom.com/
Centers for Medicare and Medicaid: http://www.cms.hhs.gov/
DataMonitor: http://www.datamonitor.com/
Enterprise Analysis Corp: http://www.eacorp.com/
Freedonia Group: http://www.freedoniagroup.com/
Frost & Sullivan: http://www.frost.com/
Global Industry Analysts: http://www.globind.com/
Larta: http://www.larta.org/
National Center for Health Statistics: http://www.cdc.gov/nchs/
U.S. Census Bureau: http://www.census.gov/

16.2. Annex II: Trade Associations, Trade Shows, and Publications

By Scot Orgish

Trade Associations

The Advanced Medical Technology Association (AdvaMed) is the largest medical technology association in the world. The association represents more than 1,100 innovators and manufacturers of medical devices, diagnostic products and medical information systems. Their members manufacture 90 percent of the $75 billion of health care technology purchased annually in the U.S. and more than 50 percent of the $175 billion purchased around the world annually. http://www.himanet.com/

The Health Industry Distributors Association (HIDA) is the international trade association representing medical products distributors. Since 1902, HIDA has provided leadership in the healthcare distribution industry. From education programs and benchmarking studies to business tools and resources, HIDA ensures that members have the business and industry information they need to perform profitably in today’s complex healthcare supply chain. www.hida.org
The Independent Medical Distributors Association (IMDA) is an association of specialty medical products sales and marketing organizations. Their main focus is to bring truly innovative technologies to health care providers. The association offers a membership directory listing 100 independent specialty medical product distributors covering the entire U.S. www.imda.org

The Medical Marketing Association (MMA), with over 1,200 members nationwide, is a nonprofit organization comprised of marketing professionals from the pharmaceutical, device, and diagnostic industries. In addition to its annual conference, which includes educational seminars and its IN-AWE Awards for outstanding marketing in all media, MMA conducts Executive Education programs in conjunction with the Kellogg School of Management at Northwestern University and the Anderson Graduate School of Management at UCLA, as well as local seminars and networking events across the country. www.mmanet.org

The Medical Device Manufacturers Association (MDMA) is a national trade association based in Washington, D.C. which represents independent manufacturers of medical devices, diagnostic products and health care information systems. MDMA seeks to improve the quality of patient care by encouraging the development of new medical technology and fostering the availability of beneficial innovative products. www.medicaldevices.org

The Alliance for Cardiovascular Professionals (ACVP) has a membership of over 3000 professionals involved in all levels of cardiovascular service (administration, management, nursing and technology), and involved in all specialties (invasive, noninvasive, echo, cardiopulmonary). The organization seeks to meet the needs of all cardiovascular and pulmonary providers, promulgate standards, and promote recognition of the cardiovascular profession. www.acp-online.org

Founded in 1985, the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR) is dedicated to the professional development of its members, through information, networking, and educational opportunities. Central to the mission is the improvement in the quality of life for patients and their families. Their mission is to reduce morbidity, mortality, and disability from cardiovascular and pulmonary diseases through education, prevention, rehabilitation, research, and aggressive disease management. www.aacvpr.org

The American College of Cardiology (ACC) was chartered and incorporated as a teaching institution in 1949, and established its headquarters, called Heart House, in Bethesda, Maryland in 1977. The mission of the ACC is to advocate for quality cardiovascular care—through education, research promotion, development and application of standards and guidelines—and to influence health care policy. www.acc.org

The American Heart Association (AHA) is a national voluntary health agency whose mission is to reduce disability and death from cardiovascular diseases and stroke. AHA is divided physically into the National Center (located in Dallas, TX) and 12 affiliate offices that cover the United States. Millions of volunteers and donors support their efforts every year. www.americanheart.org

The American Dental Association (ADA) is the professional association of dentists committed to the public's oral health, ethics, science and professional advancement. The ADA leads a unified profession through initiatives in advocacy, education, research and the development of standards. The ADA was established in 1859 and has over 147,000 members today. www.ada.org

The American College of Healthcare Executives (ACHE) is an international professional society of 30,000 healthcare executives who lead the nation's hospitals, healthcare systems, and other healthcare organizations. ACHE is known for its prestigious credentialing and educational programs and its annual Congress on Healthcare Management, which draws more than 4,000 participants each year. ACHE is also known for its journal, the Journal of Health-
The U.S. Market for Medical Devices - Opportunities and Challenges for Swiss Companies

care Management, and magazine, Healthcare Executive, as well as ground-breaking research and career development and public policy programs. ACHE’s publishing division, Health Administration Press, is one of the largest publishers of books and journals on all aspects of health services management in addition to textbooks for use in college and university courses. Through such efforts, ACHE works toward its goal of being the premier professional society for healthcare leaders by providing exceptional value to its members. www.ache.org

The American Hospital Association (AHA) is the national organization that represents and serves all types of hospitals, health care networks, and their patients and communities. Close to 5,000 hospitals, health care systems, networks, other providers of care and 37,000 individual members come together to form the AHA. Through their representation and advocacy activities, AHA ensures that members' perspectives and needs are heard and addressed in national health policy development, legislative and regulatory debates, and judicial matters. Their advocacy efforts include the legislative and executive branches and include the legislative and regulatory arenas. Founded in 1898, the AHA provides education for health care leaders and is a source of information on health care issues and trends. www.aha.org

The American Academy of Orthopaedic Surgeons (AAOS) provides education and practice management services for orthopedic surgeons and allied health professionals. The Academy also serves as an advocate for improved patient care and informs the public about the science of orthopedics. Founded at Northwestern University as a not-for-profit organization in 1933, the Academy has grown from a small organization serving less than 500 members to the world's largest medical association of musculoskeletal specialists. The Academy now serves about 24,000 members internationally. Members of the Academy, called fellows, are orthopedists concerned with the diagnosis, care, and treatment of musculoskeletal disorders. The orthopedist's scope of practice includes disorders of the body's bones, joints, ligaments, muscles, and tendons. Fellows have completed four years of medical school and at least five years of an approved "residency" in orthopedics. In addition, they must pass a comprehensive oral and written examination, be certified by the American Board of Orthopedic Surgery, and submit to stringent membership review processes prior to admittance to the Academy. www.aaos.org

Founded in 1887, The American Orthopaedic Association (AOA) is the oldest and most distinguished orthopedic association in the world. At the core of the AOA lie the solid and consistent ideals of its mission: To identify, develop, engage and recognize leadership to further the art and science of orthopedics. The AOA is dedicated to developing future leaders to serve the specialty in communities, orthopedic organizations, businesses and civic endeavors. AOA's development and support of advanced courses on leadership allow members to hone their leadership abilities. www.aoassn.org

Founded in 1847, the American Medical Association (AMA) is the leading advocate for physicians and their patients, always working to improve America's healthcare system. From tobacco to adolescent health, from AIDS to Medicare, the AMA speaks out on issues important to patients and the nation's health. AMA policy on such issues is decided through its democratic policy making process, in the AMA House of Delegates, which meets twice a year. The House is comprised of physician delegates representing every state; nearly 100 national medical specialty societies; federal service agencies, including the Surgeon General of the United States; and six sections representing hospital and clinic staffs, resident physicians, medical students, young physicians, medical schools and international medical graduates. www.ama-assn.org

The American Association for Thoracic Surgery (AATS) was founded in 1917 by representatives from the specialties of Anatomy, Physiology, Pathology, Internal Medicine, Surgery, Roentgenology, Broncho and Esophagoscopy and Anesthesia, to foster the evolution of an interest in surgery of the Thorax. Since that date, the AATS has continually encouraged and stimulated education and investigation into the areas of intrathoracic physiology, pathology and therapy. Originally created by a group of twenty of the last century's earliest pioneers in
the field of thoracic surgery, the AATS has now grown to an international organization of 1143 members which consist of the world’s foremost cardiothoracic surgeons representing 34 countries throughout the world. www.aats.org

The American Academy of Wound Management (AAWM) is a voluntary, not-for-profit organization established for the purpose of credentialing multi-disciplinary practitioners in the field of wound management. The AAWM is dedicated to the multidisciplinary team approach in promoting the science of prevention, care, and treatment of acute and chronic wounds. The primary function is to establish and monitor a national certification process, recognize competency, promote education and research, and elevate the standard of care across the continuum of wound management. www.aawm.org

Major Trade Shows and Conferences

MED + Surg Conference and Expo
Sponsored by the Health Industry Distributors Association
7-9 October, 2004
Navy Pier
Chicago, IL

American Heart Association Scientific Sessions 2004
7-10 November, 2004
New Orleans, LA
Website: http://www.scientificsessions.org

Medical Design & Manufacturing, Minneapolis
20-21 October, 2004
Minneapolis, MN
Website: http://www.devicelink.com/expo/minn03/

Medtrade 2004
26-28 October, 2004
Orlando, FL
Website: http://www.medtrade.com

American Dental Association Annual Session
1-3 October, 2004
Orlando, FL
Website: http://www.ada.org/prof/events/session/index.asp

Recent Shows
American Academy of Orthopaedic Surgeons 71st Annual Meeting
March 10 - 14, 2004 ·
San Francisco, CA
Website: http://www.aaos.org/wordhtml/anmt2004/exhibits.htm

American College of Cardiology
7-10 March, 2004
New Orleans, LA
Website: http://www.acc.org/2004ann_meeting/home/home.htm

Major Industry Publications

HIDA 2004 Membership Directory and Buyers Guide A who’s who directory of the medical products supply chain. The Membership Directory & Buyer’s Guide includes a full listing of HIDA distributor members, HIDA Educational Foundation Associates, and additional manufac-
The U.S. Market for Medical Devices - Opportunities and Challenges for Swiss Companies


**Medical Device & Diagnostic Industry** serves manufacturers of finished medical devices, manufacturers of in vitro diagnostics, manufacturers of pharmaceuticals, and manufacturing service providers, including contract manufacturing, packaging, sterilization, R&D, testing and design. Also served are manufacturing consultants, government/academic personnel and others allied to the field. [http://www.devicelink.com/mddi/index.html](http://www.devicelink.com/mddi/index.html)

**Medical Product Manufacturing News** is a product tabloid magazine that provides information on the new products and services available to medical device manufacturers. The publication is published ten times per year, and is read by design engineering, manufacturing, and specifying personnel who need accurate, up-to-date information on materials, components, equipment, and services. [http://www.devicelink.com/mpmn/index.html](http://www.devicelink.com/mpmn/index.html)

**Cardiovascular Reviews & Reports** features editorial content in which the current state-of-the-art in cardiovascular medicine is presented. Special emphasis is given to the practical application of cardiovascular therapy by primary care physicians and the critical analysis of new clinical issues. Features include New & Interesting From the Literature, New Therapy Update, Society of Geriatric Cardiology, and Noninvasive Cardiology. [http://www.lejacq.com/journals.cfm](http://www.lejacq.com/journals.cfm)

**American Medical News** is the newspaper for America's physicians. Published since 1958, it is one of the most widely read publications in the United States on news affecting the medical profession. From Medicare and managed care to public health and practice management, no other source covers the same range of current events affecting medical practice. [http://www.ama-assn.org/amednews/index.htm](http://www.ama-assn.org/amednews/index.htm)

**The Journal of Bone and Joint Surgery** is received and read by the largest number of orthopaedic physicians worldwide. Orthopaedic surgeons look at more issues of JBJS, more thoroughly, than any other publication in the field. JBJS is also used more as a reference source than any other orthopaedic publication. [http://www.ejbjs.org/misc/public/advinfo.shtml](http://www.ejbjs.org/misc/public/advinfo.shtml)

**Diagnostic & Invasive Cardiology** is the widest-reaching provider of new product information, technology and device information, trends, performance and related connectivity solutions in the diagnostic and interventional cardiology markets. DAIC's 29,000+ readers include clinicians, technologists and department chiefs/supervisors in cardiology, echo lab, cath lab and electrophysiology departments plus hospital administration, information technologists, integrated healthcare delivery networks and group purchasing organizations. [http://www.dicardiology.net/](http://www.dicardiology.net/)

**Orthopedic Technology Review (OTR)** provides the missing link between the orthopedic practitioner and health care administrator operating within today’s managed care environment. This publication is intended as a forum for discussion of the common economic issues that they both face, especially those related to the development, diffusion, acquisition and utilization of medical technologies. OTR covers the economics of technology acquisition, tackles productivity issues, describes the best medical practices and provides information that is currently unavailable in this marketplace. [http://www.orthopedictechreview.com/](http://www.orthopedictechreview.com/)

**Surgical Products** is a premier source for news of technological advances in the operating room. It is read by the most important surgical professionals, including surgeons, O.R. supervisors, related department heads and O.R. purchasing/materials management. [http://www.reedbusiness.com/index.asp?layout=theListProfile&theListID=645&groupId=66&industryid=66](http://www.reedbusiness.com/index.asp?layout=theListProfile&theListID=645&groupId=66&industryid=66)

**The Journal of the American Academy of Orthopaedic Surgeons** is the official journal of the American Academy of Orthopaedic Surgeons. [http://www5.aaos.org/jaaos/about.cfm](http://www5.aaos.org/jaaos/about.cfm)
For over 25 years, ORTHOPEDICS has been the preferred choice of orthopedic surgeons for clinically relevant information. A monthly, peer-reviewed journal, ORTHOPEDICS offers clinically valuable, original articles covering all aspects of adult and pediatric orthopedic surgery and treatment. [http://www.orthobluejournal.com/about.asp](http://www.orthobluejournal.com/about.asp)

**The American Journal of Cardiology** ® is an independent journal designed for cardiovascular disease specialists and internists with a subspecialty in cardiology throughout the world. **AJC** is an independent, scientific, peer-reviewed journal of original articles that focus on the practical, clinical approach to the diagnosis and treatment of cardiovascular disease. **AJC** has one of the fastest acceptance to publication times in Cardiology. Features report on systemic hypertension, methodology, drugs, pacing, arrhythmia, preventive cardiology, congestive heart failure, valvular heart disease, congenital heart disease, and cardiomyopathy. Also included are case reports, brief reports, editorials, readers’ comments, and symposia. [http://www.elsevier.com/wps/find/journaldescription.cws_home/525048/description#description](http://www.elsevier.com/wps/find/journaldescription.cws_home/525048/description#description)

**Medical Electronics Manufacturing** is for engineering and design professionals who work in the medical electronics device industry. The annual Designers Guide issue published in the fall provides articles on a full range of design and engineering issues, including electromagnetic compatibility, reliability, testing, regulatory requirements, new technologies, and component selection. The Buyers Guide issue published each spring serves as a complete guide to product sourcing, listing suppliers of electronic components, systems, packaging and hardware, instrumentation and power sources, production equipment, and testing services and equipment, as well as contract design and manufacturing firms. [http://www.devicelink.com/mem/index.html](http://www.devicelink.com/mem/index.html)

**Dental Products Report** is the premier product publication serving the North American dental market. Dental Products Report is circulated to more than 151,000 qualified recipients (practicing dentists and others), and is published 12 times a year by Advanstar Dental Communications. The tabloid newspaper focuses on new products introduced to the dental profession. [http://www.dentalproducts.net/publications/dpr.html](http://www.dentalproducts.net/publications/dpr.html)

**The Journal of Thoracic and Cardiovascular Surgery** presents original, exclusive articles on conditions of the chest, heart, lungs, and great vessels where surgical intervention is indicated. An official publication of The American Association for Thoracic Surgery and The Western Thoracic Surgical Association, the journal focuses on techniques and developments in cardiac surgery, pacemaker insertion/removal, lung and esophageal surgeries, heart and lung transplantation, and other procedures. The Journal ranks in the top 3.4% of the 5,684 scientific journals most frequently cited (Science Citation Index). [www.aats.org](http://www.aats.org)

**The Journal of Wound Care** provides expertise, practical advice and in-depth research on every aspect of wound care. Archive material is available from 1999, thereby giving you access to the most up-to-date practice, research and review articles in the discipline of wound management and tissue viability. [http://www.aawm.org/publications.html](http://www.aawm.org/publications.html)
### 16.3. Annex III - List of Medical Academies, Societies, and other platforms

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<thead>
<tr>
<th>Medical Academy</th>
<th>Website</th>
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<tr>
<td>American Academy of Allergy Asthma &amp; Immunology</td>
<td><a href="http://www.aaaai.org">www.aaaai.org</a></td>
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<tr>
<td>American Academy of Child &amp; Adolescent Psychiatry</td>
<td><a href="http://www.aacap.org">www.aacap.org</a></td>
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<tr>
<td>American Academy of Cosmetic Surgery</td>
<td><a href="http://www.cosmeticsurgery.org">www.cosmeticsurgery.org</a></td>
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<td>American Academy of Dermatology</td>
<td><a href="http://www.aad.org">www.aad.org</a></td>
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<td>American Academy of Family Physicians</td>
<td><a href="http://www.aafp.org">www.aafp.org</a></td>
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<td>American Academy of Hospice &amp; Palliative Medicine</td>
<td><a href="http://www.aahpm.org">www.aahpm.org</a></td>
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<td>American Academy of Insurance Medicine</td>
<td><a href="http://www.aaimedicine.org">www.aaimedicine.org</a></td>
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<tr>
<td>American Academy of Neurology</td>
<td><a href="http://www.aan.com">www.aan.com</a></td>
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<td>American Academy of Ophthalmology</td>
<td><a href="http://www.aao.org">www.aao.org</a></td>
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<td>American Academy of Orthopaedic Surgeons</td>
<td><a href="http://www.aaos.org">www.aaos.org</a></td>
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<td>American Academy of Otolaryngic Allergy</td>
<td><a href="http://www.aaoaf.org">www.aaoaf.org</a></td>
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<td>American Academy of Otolaryngology - Head and Neck Surgery</td>
<td><a href="http://www.entnet.org">www.entnet.org</a></td>
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<td>American Academy of Pain Medicine</td>
<td><a href="http://www.painmed.org">www.painmed.org</a></td>
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<td>American Academy of Pediatrics</td>
<td><a href="http://www.aap.org">www.aap.org</a></td>
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<td>American Academy of Pharmaceutical Physicians</td>
<td><a href="http://www.aapp.org">www.aapp.org</a></td>
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<td>American Academy of Physical Medicine &amp; Rehabilitation</td>
<td><a href="http://www.aapmr.org">www.aapmr.org</a></td>
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<tr>
<td>American Academy of Psychiatry &amp; the Law</td>
<td><a href="http://www.emory.edu/AAPL/">www.emory.edu/AAPL/</a></td>
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<tr>
<td>American Academy of Sleep Medicine</td>
<td><a href="http://www.aasmnet.org">www.aasmnet.org</a></td>
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<td>American Association for Hand Surgery</td>
<td><a href="http://www.handssurgery.org">www.handssurgery.org</a></td>
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<td>American Association for Thoracic Surgery</td>
<td><a href="http://www.aats.org">www.aats.org</a></td>
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<td>American Association for Vascular Surgery</td>
<td><a href="http://aavs.vascularweb.org">http://aavs.vascularweb.org</a></td>
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<td>American Association of Clinical Endocrinologists</td>
<td><a href="http://www.aace.com">www.aace.com</a></td>
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<td>American Association of Clinical Urologists</td>
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<td>American Association of Electrodiagnostic Medicine</td>
<td><a href="http://www.aaem.net">www.aaem.net</a></td>
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<td>American Association of Gynecological Laparoscopists</td>
<td><a href="http://www.aagl.com">www.aagl.com</a></td>
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<td>American Association of Hip &amp; Knee Surgeons</td>
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<td>American Association of Neurological Surgeons</td>
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<td>American Association of Plastic Surgeons</td>
<td><a href="http://www.aaps1921.org">www.aaps1921.org</a></td>
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<td>American Association of Public Health Physicians</td>
<td><a href="http://www.aaphp.org">www.aaphp.org</a></td>
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<td>American Clinical Neurophysiology Society</td>
<td><a href="http://www.acns.org">www.acns.org</a></td>
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<td>American College of Allergy, Asthma, &amp; Immunology</td>
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<td>American College of Cardiology</td>
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<td>American College of Pharmacology</td>
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<td>American College of Physical Medicine &amp; Rehabilitation</td>
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<td>American College of Sleep Medicine</td>
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<td>American College of Vascular Surgery</td>
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<td>American College of Chest Physicians:</td>
<td>American Institute of Ultrasound in Medicine:</td>
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<td><a href="http://www.chestnet.org">www.chestnet.org</a></td>
<td><a href="http://www.aium.org">www.aium.org</a></td>
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<tr>
<td>American College of Emergency Physicians:</td>
<td>American Medical Directors Association:</td>
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<td><a href="http://www.acep.org">www.acep.org</a></td>
<td><a href="http://www.amda.com">www.amda.com</a></td>
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<td>American College of Gastroenterology:</td>
<td>American Medical Group Association: <a href="http://www.amqa.org">www.amqa.org</a></td>
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<td><a href="http://www.acg.qi.org/acghome.html">www.acg.qi.org/acghome.html</a></td>
<td>American Pediatric Surgical Association: <a href="http://www.eapsa.org">www.eapsa.org</a></td>
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<td>American College of Medical Genetics:</td>
<td>American Orthopaedic Association: <a href="http://www.aoassn.org">www.aoassn.org</a></td>
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<td>American Orthopaedic Foot and Ankle Society: <a href="http://www.aofas.org">www.aofas.org</a></td>
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<td><a href="http://www.acnucmed.com">www.acnucmed.com</a></td>
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16.4. Annex III: The Authors of the Study

Darren W. Alch, is an attorney with Jenkins & Gilchrist’s Health Care Group. He is also an adjunct professor of law at the University of Houston Law Center25, teaching FDA law. His practice includes general health law and regulatory aspects of the health care industry with special emphasis on drug and medical device law, pharmacy law, as well as provider compliance. Darren is experienced in FDA and state pharmacy law and regulation as they impact compliance, FDA approvals, and marketing of drugs and medical devices. He also has extensive experience in all aspects of healthcare transactions, fraud and abuse (including govern-

ment investigations), as well as Medicare/Medicaid reimbursement with special emphasis on pharmaceuticals and medical devices. In addition to handling preparation of the various licensing and regulatory applications and other filings required for medical care facilities and reimbursement-related filings for individual practitioners and government practices, Mr. Alch is also experienced in representing large laboratory, drug and medical device companies in their operational (including marketing and contracts) issues. Prior to joining Jenkins & Gilchrist, Darren worked in sales and marketing with a large pharmaceutical manufacturer. The experience gave him an inside view of the issues faced by large pharmaceutical companies, as well as the complexities of working with large government agencies such as the FDA. Mr. Alch also served on active duty in the United States Army as an officer following his graduation from West Point in 1988. Contact: dalch@jenkens.com

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Richard M. Franklin, Partner, Baker & McKenzie, a native of Chicago, is a graduate of the Columbia University School of Law and also attended the University of Wisconsin and the University of Freiburg, Germany. He has practiced law for over thirty years. His practice focuses on business and commercial litigation, including product liability litigation. Because Mr. Franklin speaks German fluently and is familiar with the laws and business practices of Germany, Switzerland and Austria, a great deal of Mr. Franklin's practice involves the representation of clients from those countries in U.S. litigation or arbitration. For example, Mr. Franklin was the lead defense counsel for a major Swiss medical implement manufacturer in the defense of product liability claims resulting from allegedly defective orthopedic products designed, manufactured and sold by its U.S. subsidiary. Contact: Richard.M.Franklin@BakerNet.com

David Kouidri, has been the Trade Commissioner of Switzerland, and a member of Swiss Federal Ministry of Foreign Affairs, since January 1998. As an expert in industry promotion initiatives and new market development, Mr. Kouidri markets Swiss industries and business in the US. Among other areas of concentration, Mr. Kouidri is an initiator of numerous high technology based facilitation efforts, specifically in the field of nanotechnology, biotechnology, machinery manufacturing and the environment. He was also a key initiator for the now famous Cows on Parade program that took place in Chicago in 1999. He has been the lead advisor to over 60 Swiss companies regarding entry strategy into the US. Prior postings in the private and public sector include, Vienna, Austria, Paris France, Annapolis Maryland, and Geneva Switzerland, where he worked for the United Nations. Mr. Kouidri holds an MBA in International Business from DePaul University Kellstadt Graduate School of Business in Chicago, and a Bachelor of Science in Marketing from Bentley College in Boston. He is fluent in German and has good knowledge of French. Contact: david@swissbusinesshub.org

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Scot Orgish has been involved in international business for 20 years, and has worked in both the private and public sectors. He graduated in 1981 with a Bachelors degree in Marketing from Texas Tech University. Upon graduation, he moved directly into international business spending 4 years in Germany and 2 years in Puerto Rico, as a manufacturers’ agent doing business with the U.S. military. In 1988, he returned to Texas where he earned a Masters Degree in International Management as well as an MBA in Finance from the University of Texas at Dallas. Upon graduation, in January of 1990 Mr. Orgish worked as a Senior Project Manager at Martek & Associates, a private consulting firm engaged in international marketing, consulting, and acquisitions. In March 1991, he joined the Swiss Consulate General/Swiss Business Hub in Houston as Trade Commissioner where he currently assists Swiss companies with the U.S. market. Contact: scot@swissbusinesshub.org

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Daniel Wuersch, is the Managing Partner of Wuersch & Gering LLP, an international boutique firm with 15 lawyers in New York. His practice focuses on corporate law, mergers & acquisitions, corporate finance and strategic partnerships and marketing agreements. He is admitted to the bar in New York and Zurich, Switzerland. He acquired his Dr. iur. degree at the University of Zurich Switzerland in 1989. In 1991, he obtained an LL.M. degree at the Georgetown University Law Center, Washington, D.C. In addition, he attended graduate and post-graduate courses in international law and EU law at the University of Lausanne, Switzerland and the London School of Economics. Prior to co-founding Wuersch & Gering LLP in 1997, he practiced international corporate and securities law with Morgan Lewis & Bockius (1996-1997) and Fried, Frank, Harris, Shriver & Jacobson (1991-1996) in New York, as well as Homburger / Baker & McKenzie in Zurich, Switzerland (1988-1990). He has written and co-authored books and articles on United States and Swiss corporate and contract law and the law of the European Union. Mr. Wuersch is a frequent speaker on legal issues involving business activities of foreign companies in the United States. He is the President of the Swiss Society of New York and a member of the Chapter Board “Doing Business in USA” of the Swiss American Chamber of Commerce. Contact: daniel.wuersch@wg-law.com

Mark S. Zolno, is the founder of Katten Muchin Zavis Rosenman’s Customs and International Trade Group. His experience is in tariff classification, rates of duty and valuation of imported merchandise; country-of-origin marking and labeling requirements; customs compliance assessments; customs penalty cases; and antidumping and other unfair trade practices. Mr. Zolno has represented clients before numerous U.S. federal regulatory agencies and in General Agreement on Tariffs and Trade (GATT) and World Trade Organization (WTO) trade negotiations, NAFTA origin verifications and other international trade dispute resolutions. Contact mark.zolno@kmzr.com