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Industry Series

# Medical Equipment Industry Report

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Sample Only

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# INTRODUCTION

### About this Report

The *Medical Equipment & Supplies Industry Report* includes news, opinions, commentary, analysis, data, and statistics on the U.S. medical equipment and supply industry. This report has been prepared in an easy to use format for the reader to drill down to key sections. This report mainly covers the medical equipment, devices and related supplies. The report may also offer information on some aspects on the closely related pharmaceutical, managed care, and healthcare facilities industries. This report covers the economic analysis of industry players and the strategies they may pursue under certain industry conditions. We have included supportive statistics to back up our assertions. We have included a financial statistics section that allows the reader to gauge the industry prospects even better.

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## INDUSTRY ENVIRONMENT

**Pricing Trends Continue to Favor Medical Device Manufacturers.**

The medical device pricing environment has shown remarkable strength despite many economic uncertainties in the marketplace. There are several reasons that can be used to explain the strength in medical device pricing. This includes, technological innovation, reimbursement rates, lack of competitive offerings, and demographic changes.

Technological innovation has enabled companies to maintain their operating margins since new products carry high unit prices. Unit prices are introduced into the marketplace at a higher since device manufacturers need to recoup their investment in product development for the initial early adopters of new products. In addition, patent-protection can sometimes lead to abnormally higher pricing in some markets. For instance, Johnson & Johnson's new drug-eluting stent product will allow them to price much higher with almost no direct competition for some time since the product is patent-protected.

High reimbursement rates by hospitals and HMO's helped to support medical equipment device pricing in 2002. Higher reimbursement reduces margin pressures for device manufactures which less discounting is necessary.

Competitive offerings suggest another rational explanation for the strength in medical equipment pricing. In many markets, there are only two major competitors in the market place. This infers that these companies can charge a much high price because of a lack of available substitutes. Indeed, it's very difficult for an upstart or small company to generate any significant inroads into one of the major medical device equipment makers business because the high cost of product development has a tendency to discourage companies from breaking into the market. Therefore, medical equipment prices tends to be abnormally higher than in a more competitive market with many product substitutes and competitors. In addition, many industry players are in niche markets that are not large enough to attract other medical equipment companies. Niche product companies can garner a large market share in a small but growing sector and charge premium prices. For instance Varian Medical can charge a high price for its niche product in the manufacture of machines that irradiate tumors. Also, medical device companies do not face as much price competition as related healthcare sectors such as pharmaceutical companies face against generic drug companies. There are numerous examples of this phenomenon. For example, in the dental equipment market, Dentsply and Patterson Dental are virtually the only two suppliers of dental equipment. Currently, in the drug-eluting stent (DES) market, only Johnson & Johnson is able to market its product in the United States.

Demographic changes offer one of the most profound reasons for strong pricing patterns. Increased demand for products from baby boomers increases the demand for many products especially in the area of orthopedics, angioplasty, and cardic–related products.

The  Producer Price Index (PPI) fell 1.4 percent in 2002 for all manufacturing but the medical device /equipment industry experienced a 1.2 percent for the year. This is strong indication that these medical equipment companies have greater pricing power against HMO's, hospitals, and the government due to favorable reimbursement trends.

| MEDICAL EQUIPMENT - PRODUCER PRICE INDEX | | | |
|---|---|---|---|
| | | | |
| (As of 2002 Total) | | | |
| **Market Segment** | **Year** | **PPI** | **Net Change** |
| Orthopedic Apparatus | 2002 | 173.3 | + 11.5% |
| Surgical Instruments | 2002 | 140.2 | + 3.0% |
| Diagnostic Apparatus | 2002 | 135.2 | + 2.6% |
| X-Ray Apparatus | 2002 | 110.7 | + 2.1% |
| Irridation Apparatus | 2002 | 105.5 | + 2.1% |
| | | | |
| **Annualized - 2002** | | | |
| | | | |
| Source: *DOL* | | | |

**The Coronary Stent Market is Weak.**

The global orthopedics industry grew about 10 percent in 2002. With an additional 8 to 10 percent growth rate forecasted for 2003.

The medical equipment and supplies industry will get a boost from rising Medicare re-imbursement rates that will average about 7 percent per year.

**State Budget Pressures Worry Medical Supply Industry.**

USBR economists are forecasting a fiscal 2003 budget deficit hovering at about $315 billion. The reasoning is partially attributed to President Bush's ill-conceived tax cut that will likely do more to enhance the federal budget deficit than to instill an economic revival in the U.S. economy.

The major problem and issues are at the state level with the mushrooming costs of Medicaid. According to the Congressional Budget Office (CBO)

Medicare will pursue more flexible reimbursement policies that will encourage the use of more cost-effective plans. For medical equipment producers, there could conceivably be more pressure on maintaining their operating margins in an environment that emphasizes price in the purchasing decision. As more baby boomers become eligible for Medicare, the entire health systems resources will be strained with increasing costs to the program.

**Weak U.S. Dollar's Impact on Foreign Sales.**

The weak U.S. dollar has not materially impacted foreigners' ability to purchase medical equipment and devices. This is likely the result of few foreign competitors in global markets that can compete with U.S firms. Thus, U.S. manufacturers have been able to keep sales high despite the weak U.S. dollar in foreign markets.

## MARKET OVERVIEW

The medical device market represented a global market of about $190 billion in year 2002. Approximately $75 billion dollars of medical devices and equipment is sold in foreign markets. In fact, medical devices are growing faster abroad than in the United States.

The industry is comprised of two major sectors: equipment and supplies. The medical equipment sector encompasses value-added, high technology products for small patient populations. This surmises charging much higher prices over the smaller volume of product output. These products include orthopedic devices, implantable defibrillators, external defibrillators CAT scanners, magnetic resonance equipment, and ultra-sound equipment. But these products also face more risk from technological innovation from competitor offerings.

The medical supplies market is a lower margin, high volume mature business which consists of commodity products such as needles, hospital garments, kits, gloves, syringes, disposable products, and anesthesia products. This industry segment has low growth potential and should be relatively stable for the foreseeable future.

| Medical Equipment - PRODUCER PRICE INDEX | | | | | | |
|---|---|---|---|---|---|---|
| (Year 2003) | | | | | | |
| **Company** | **X-Ray** | **Dental** | **Surgical** | **Optical** | **Elec Mech** | **Opthamal.** |
| January | 194.0 | 194.0 | 176.7 | 106.2 | 96.3 | 124.0 |
| February | 111.0 | 197.7 | 175.6 | 106.2 | 96.0 | 124.4 |
| March | 111.0 | 198.6 | 176.1 | 106.0 | 94.8 | 124.4 |
| April | 111.1 | 198.7 | 177.2 | 106.6 | 96.2 | 124.4 |
| May | 112.4 | 198.8 | 175.7 | 106.5 | 96.6 | 124.1 |
| June | 112.4 | 199.1 | 176.1 | 105.2 | 96.3 | 124.2 |
| July | 112.4 | 199.2 | 176.0 | 105.3 | 95.2 | 124.3 |
| **Annualized 2002** | **110.7** | **191.7** | **173.1** | **107.5** | **96.1** | **124.2** |
| | | | | | | |

The Producer Price Index (PPI) figures above show that medical equipment industry pricing strengthening year over year from 2002 to 2003. Most sectors shown increased industry pricing due to limited market competition for certain key high technology medical equipment markets.

## INDUSTRY TRENDS

### Shift to Drug Eluting Stents (DES).

The medical supply industry is shifting its focus from bare metal stents to drug eluting stents. A rapid adoption rate is expected because of the benefits of its efficacy. Johnson & Johnson initially introduced (DES) in Europe in 2002. They should be receiving FDA approval for sale in the United States sometime in the Spring of 2003. In addition, Boston Scientific introduced their version in Europe in 2003. Both companies should be strongly positioned in the marketplace relative to Guidant's stent business which is still marketing their bare metal stents that will wane once DES encumbers the entire U.S. market. The competitive dynamics will markedly change as the coronary stent market will transistion into drug-eluting stents.

The reason the drug-eluting stent market is so important is because it will change the competitive dynamics of the market. The justification for switching from coronary stents to drug-eluting stents has significant healthcare benefits to all participants from patient to hospital. Coronary stents are small metal tubes inserted into a coronary artery following angioplasty. Angioplasty is a procedure during heart surgery in which a catheter with a small balloon at the end is inserted into a blocked artery to clear blockage. The stent is then inserted to keep the artery open when the balloon catheter is removed. This entire procedure restores blood flow to the heart and eliminates the need for invasive coronary bypass surgery. However, vessel closure can still occur through a process s called restenosis where the stent is placed in the body. This can result in death from cardiac complications, heart attack, or repeated surgeries to restore the heart. Thus, all very expensive processes and procedures for the hospital and patient.

A drug eluting stent compound via a polymer allows for a measured release of the drug over a period o f time can lower the possibility of restenosis and prevent lengthy and costly healthcare. Restenosis is a conditions that is caused by the surgery itself rather than through natural means.

### Strategic Acquisitions and Alliances.

Medical equipment suppliers are still on an acquisition binge by buying smaller companies that have unique product portfolios or products where the acquiring company is not strongly positioned. Johnson & Johnson is negotiating a purchase of Scios for its congestive heart failure drug called *Natrecor*. With Johnson & Johnson's financial strength and marketing expertise, sales will expand much more rapidly.

Medical companies are establishing joint ventures with companies to reduce the development costs and risk of marketing new products. But joint ventures are also being used where one company may not be familiar with a market and another firm has the marketing expertise or knowledge of market conditions. Some companies have strong development and manufacturing capabilities while others have patent-protected technologies but limited marketing expertise. Therefore, alliances makes more sense for many medical device companies.

Endovasc, Inc. and TissueGen, Inc. formed a joint venture that pioneers new cardiovascular and metabolic drug therapies. Both companies share in the development and risk. Developing drug-eluting stent products separately would be more expensive and risky for both companies.

Yamanouchi Pharmaceutical Co. Ltd.granted an exclusive license to Medtronic Sofamor Danek Co. (A subsidiary of Medtronic Inc.). Medtronic Sofamor Danek will assume development, regulatory application, sales/marketing management of rhBMP-2 in Japan. Yamanouchi will supply the rhBMP-2 to Medtronic and retain the right to co-promote the product.

EaglePichler, Inc. and Nanogram entered an alliance to develop and manufacture implantable medical batteries based on Nanogram's patented nanomaterial technology. Both firms will be able to take advantage of each iother's strengths. EaglePichler is strong in manufacturing while Nanogram has a patent protected product with limited manufacturing capability.

### Patient Monitoring Systems is Growing in Importance.

Patient monitoring systems are being used more today than ever before due to a lack of staff and consolidation in the hospital industry. Currently, patient monitoring systems are used in critical care applications but they will increasingly be used in sub-acute areas. The reduction in physician and nurse to patient ratios within critical care units in hospitals is fueling the growth for reliable, easy-to-use patient monitoring systems. In addition, hospitals and HMO's are attempting to lower costs and improve efficiency. Thus, they are promoting the usage of wireless and portable technologies such as telemetry, ambulatory ECG products, and ambulatory vital signs equipment.

### Online Medical Consortiums.

Medical equipment manufacturers have organized a internet-based medical product and supply auction site to enhance sales and increase efficiency. Customers can use the online network to order products and supplies and compare pricing between different companies. The network, called Global Healthcare Exchange, matches buyers and sellers of medical products and supplies. Companies participating in the online consortium include Guidant, Becton Dickinson & Company, Boston Scientific, C.R. Bard, GE Medical Systems, Medtronic, Inc, Tyco International, and Amerisource Bergen. Such online networks help manufacturers to maintain control in the entire supply chain from production to end user. In addition, medical equipment manufacturers are able to maintain their gross margins and secure their operating margins more effectively.

## INDUSTRY SEGMENTS

### Orthopedics

The orthopedics sector should continue to see growing demand which will be heavily influenced by an aging population. Treatments for degenerative spine disease represents the fastest growing segment of the orthopedic market. Currently, there is a market of about 500,000 patients that undergo treatments for spinal disease.

**Cardiology**

The cardiology sector is witnessing renewed interest from new innovations such as drug-eluting stents which will replace bare metal stents in the market.

| Quarterly Financial Statistic Composites | | | | |
|---|---|---|---|---|
| | | | | |
| ( As of Yr. 2003 QT. 2 ) | | | | |
| **Company** | **Rev. ($)** | **Earnings ($)** | **GPM (%)** | **OPM (%)** |
| Alaris Medical | $127.8 | (35.9) | 53.0% | 16.7% |
| Bausch & Lomb | 512.5 | 28.3 | 58.3% | 10.9% |
| Beckman Coulter | 551.8 | 52.2 | 47.8% | 14.7% |
| Becton Dickinson | 1,165.4 | 130.0 | 46.5 | 14.9 |
| Boston Scientific | 854.0 | 114.0 | 72.4% | 20.2% |
| C.R. Bard | 354.2 | 49.5 | 56.9% | 19.2% |
| Datascope Corporation | 89.1 | 6.3 | 57.8% | 9.9% |
| Dentsply Corporation | 417.9 | 44.2 | 49.0% | 16.9% |
| Guidant Corporation | 944.9 | (97.1) | 75.3% | - |
| Medtronic Corporation | 2,147.8 | 487.1 | 74.8% | 32.3% |
| St. Jude Medical | 81.9 | 67.4 | 22.1% | - |
| Steris Corporation | 259.3 | 16.5 | 41.1% | 10.1% |
| Stryker Corporation | 891.7 | 107.5 | 63.3 | 19.2% |
| Zimmer Holdings | 411.1 | 89.0 | 76.0% | 32.7% |
| | | | | |
| GPM = Gross Profit Margin | | | | |
| OPM = Operating margin | | | | |
| Source: *USBR Research* | | | | |

Fina

Financial data shows that manufacturers engaged in high technology medical device markets generally garner higher gross profit margins than companies engaged in low tech medical supplies. High-tech medical device manufacturers such as Boston Scientific, Stryker, Medtronic, Guidant , and Zimmer Holdings have margins above 70 percent.

## INDUSTRY ISSUES

### Environmental Concerns Pose Difficult Challenges for Healthcare.

The aging U.S. population will pose tremendous challenges for state and federal government planning. This results from larger amounts of people in retirement and fewer numbers of people in the overall workforce. Life expectancy increases as a result of new drugs, exercising, and better dieting has resulted in people living longer. Actuary estimates of those aged 65 will increase to 78 years of age by the year 2075. With people living longer, the medical system will be compressed for more funding as people in the active workforce decline. Even if there were no declines with active workforce participants, healthcare funds would still be severely depleted because there is no additional funding to offset the increased life expectancy.

These factors infer that federal government re-imbursement rates may be even lower in the future than they are today. And this represents significant risk to all healthcare companies including medical equipment and supply firms.

### FDA's New Goal to Speed Device Reviews.

A potential boon to the medical device industry is the FDA's initiative to speed the review of new medical devices. Under the Medical Device User Fee and Modernization ACT (MDUFMA), the FDA is committed to reducing the cumulative review time that the agency requires to approve expedited and traditional pre-market approval applications. Such an initiative could help the industry to increase their time-to-market with new high technology medical devices. In addition, this would also reduce the cost of developing new devices since the industry could recognize a faster return on investment with new product development. However, such a process could also be like a "double-edge sword". Faster time-to-market could also make device makers more susceptible to product liability lawsuits if products are not thoroughly tested properly.

## COMPANY OVERVIEW

### Medtronic Corporation

Medtronic is well-positioned in the cardiac rythym management, spinal fusion, and cardiac surgery market. However, the company is not competitive in the drug coated coronary stent market. The company will continue to benefit from higher reimbursement rates.

### Becton Dickinson.

Becton Dickinson recently announced its plans to discontinue conventional needle sales in the United States.

**Stryker Corporation**

Stryker is strong in the spinal implant, arthroscopy, and surgical instrument markets. We expect the company to continue its high performance.

**Boston Scientific**

Boston Scientific should be able to strengthen its position in the drug eluting stent market thanks to the approval of Johnson & Johnson's drug eluting stent product called *Cyper DES* by the FDA. Boston Scientific's product , called *Taxus DES*, has already receive regulatory approval  and should be on the market as early as fall 2003.

**Guidant Corporation.**

Guidant Corp. will face increased competition in the coronary stent market from Johnson and Johnson' superior drug eluting stent product. Guidant risks losing substantial market share as a result of the drug-eluting stent on the market because it may be 18 to 24 months before they develop a competitive product. Market share losses will be rapid and significant.

## INDUSTRY OUTLOOK

In the long-run, medical equipment industry prospects appear bright when considering changing demographic trends. As baby boomer s age, the increased need for drug-eluting stents and angioplasty products become even more lucrative for manufacturers. We do not see legislation that will limit pricing for device manufacturers. Instead, the market place will determine industry pricing behavior. However, we feel that cost pressure from Medicare and Medicaid could impact pricing decisions.

We will continue to see increased product demand with a fixed number of companies. Pricing should continue to be strong since many products require very small production runs which will mean higher unit prices to cover a manufacturer's fixed costs.

## INDUSTRY FORECAST

We look for continued grow in the medical equipment and supply industry over the short run three to five years. However, there appears to be some concern with the impact that state budgets will have on continued industry growth. Budget cuts at both the state and federal level could considerably impair gross margins for medical companies.

| Medical Equipment Market Value Forecast | | | | |
|---|---|---|---|---|
| | | | | |
| (in Billions) | | | | |
| **Sector** | **2004** | **2005** | **2006** | **2007** |
| Cardiology Devices | $14,483 | $15,316 | $16,189 | 16,725 |
| Orthopedic Reconstuction | 4,972 | 5,208 | 5,566 | 5,812 |
| Pacemaker Market | 4,301 | 4,322 | 4,366 | 4,392 |
| Heart Rythm Device Market | 3,678 | 3,940 | 4,236 | 4,522 |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| Source: *USBR Forecast* | | | | |

## INDUSTRY CHARACTERISTICS

Demand for medical devices and supplies remains fairly constant from year to year. Sales are heavily dependent on population trends such as the age of patients. Sales are most impacted by the amount of change in the managed care industry. Sweeping changes in the HMO business can result in rising or falling earnings.

The medical device and supplies industry is regulated by the U.S. food Drug Administration which regulates the performance and usability of the products. The industry is also impacted by consumer product safety legislation.

Medical products companies operate in a rapidly changing environment in product life cycle risk and purchasing behavior. The development of a more cost-effective solution could render a product obsolete very quickly. Interestingly, third party players play an active role in the success of these firms such as the payer, patient, and hospital.

Medical products companies produce technology-intensive, proprietary items, and commodity products. Many medical products companies operate in more than one segment to reduce overall business risk.

Medical equipment industry is exposed to product liability claims. Medical device companies face increased product liability for injuries resulting from the usage of their products. They must assume much of the risk of claims. In June 1996, the Supreme Court ruled that medical device makers can be sued for injuries even if the Federal and Drug Administration (FDA) approved the product for safety.

#### Barriers to Entry

The medical equipment industry has significant barriers to entry which includes economic, regulatory, and legal obstacles that prevent small or new companies from entering the medical equipment field. In addition, small device companies, it is difficult to compete with larger companies with large sales forces and economies of scale in competing for contracts with large hospital supply purchasing collectives and individual clinical sites and physician offices.

Significant research and development expenditures are required for the medical equipment product development process. Rival firms have difficulty competing with entrenched products that have been proven safe and effective unless the new device can be proven to be highly superior or significantly more affordable. To introduce a new device into the marketplace, the medical equipment manufacturer must have clearance from the Food & Drug Administration.

#### Patents.

Medical device makers protect their proprietary products through both U.S. and foreign patents. Patents can be on technology or improvements. In general, medical device manufacturers are less dependent on patents than drug makers because new devices are usually developed before the patent on an existing device expires.

### Industry Sectors.

#### Orthopedics.

Orthopedics includes replacement hips, knees, joints, and other artificial apparatus.

#### X-Ray Equipment.

X-Ray equipment includes ultrasound systems, CAT scanners, magnetic resonance systems, and irradiation equipment.

#### Cardiology.

Cardiology products include implantable defibrillators, bare metal stents, drug-eluting stents,and related products pertaining to the heart.

#### Opthamology.

These are products pertaining to eye care such as lens care and contact lenses.

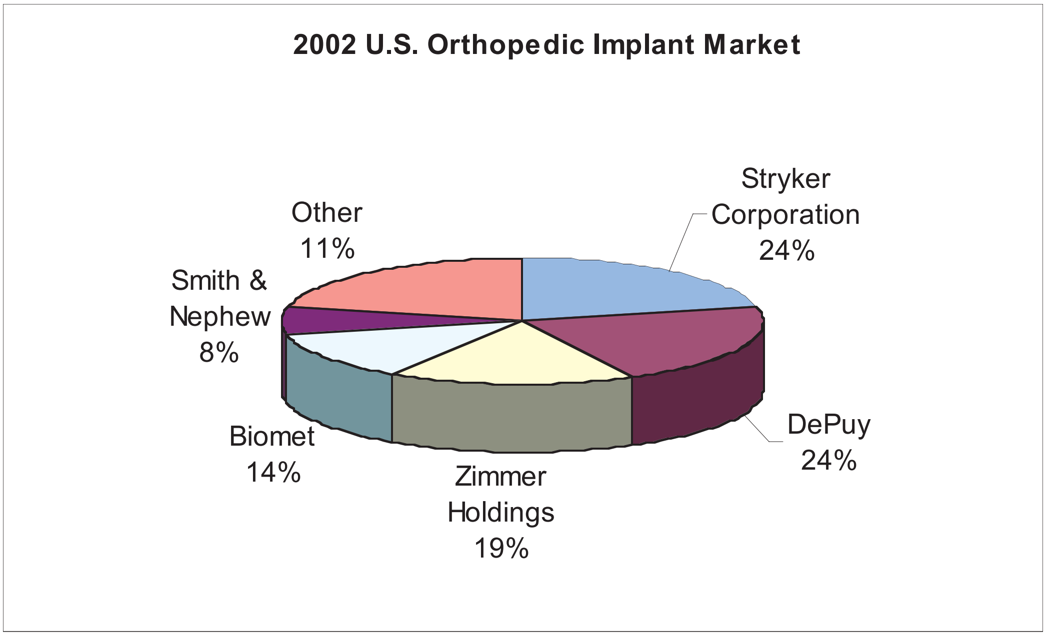
## RESOURCES

U.S. Department of Labor
U.S. Food & Drug Administration
American Medical Association
Health Industry Manufacturers Association
New England Journal of Medicine
Medical Market & Media
Health & Medicine Week

# APPENDIX

## Appendix: A1

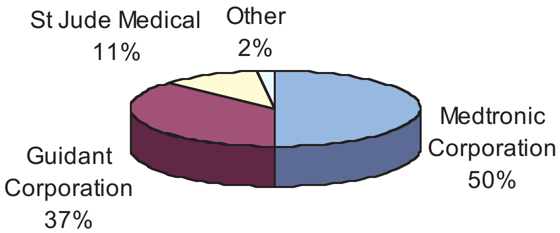
The orthopedic implant market is relatively concentrated wit hthe top two companies in the industry controlling about 50% of the U.S. market. Market share in the orthopedic market is fairly stable and changes in market share is not likely for the forseeable future.



## Appendix A2:

The portable defribrillator market is highly concentrated among both Medtronic and Guidant Corporation wit hhigh barriers to entry. Both companies should contine to dominate this market. However, new technologies and therapeutical products in the health care business has reduced growth in the sector in recent years.

**2002 Portable Defibrillator Market**



# Notes