

## Medical devices stay strong



### Area Development Site and Facility Planning

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In a weakened economy, the medical-device industry has managed to draw strength from the increasing global demand for high-quality health care.

ALTHOUGH THE economic downturn is flattening many business sectors as if they were Silly Putty, the medical-device industry so far has escaped the same fate. Seemingly impervious to such problems, this vibrant industry's future success is ensured by the world's ever-increasing demand for the pioneering, diverse products it designs to prevent, diagnose, and treat disease.

The industry in the United States clearly reigns as the global leader in innovation, and is the biggest producer and exporter of medical devices. Little wonder, then, that the world's largest medical-technology association - AdvaMed - is headquartered in America. This Washington, D.C.-based group helps tell the sector's success story. Its 1,100-plus members manufacture 90 percent of the \$71 billion of healthcare technology purchased annually in the United States, and more than 50 percent of the \$169 billion purchased worldwide each year. The nation's capital also is home to the Medical Device Manufacturers Association, a national trade group representing more than 160 independent industry manufacturers.

What exactly is the medical-device industry? It's a catch-all phrase for a technology sector comprising medical devices, diagnostic products, and healthcare information systems.

The general public easily recognizes such life-saving, life-enhancing products as artificial joints, pacemakers, MRI imaging, cancer therapy systems, and devices used for minimally invasive surgery. But there are tens of thousands of other important products and activities, perhaps not as well known, including medical contract manufacturing and component fabrication; tubing; adhesives; electronic components and production of medical devices; medical packaging equipment and materials;

motors; plastics and elastomers; testing equipment and services; and hardware and I.V. components.

Some of the industry's major players include:

\* Boston Scientific, Massachusetts: Developer/producer of minimally invasive medical devices; more than 10,000 products (vascular and nonvascular). Fiscal 2002 revenues: \$2.9 billion, a nine percent increase over 2001

\* Medtronic, Minnesota: One of world's largest medical-technology companies in terms of revenues (fiscal 2002: \$6.4 billion). The firm's devices help regulate erratic heartbeats, tremors, and vascular diseases.

\* Varian Medical Systems, California: Manufacturer of integrated cancer therapy systems. Fiscal 2001 revenues: \$773.6 million

\* Biomet, Indiana: World's fifth-largest producer of orthopedic products distributed in more than 100 nations. Member of S&P 500 and employer of 4,000. Revenues for year ending May 2002: \$1.1 billion

\* St. Jude Medical, Minnesota: Designs, manufactures, and distributes medical devices for use in cardiac surgery and cardiac rhythm management; also sells catheter devices. Products sold in more than 100 countries. 2001 sales: \$1.3 billion

\* Stryker Corporation, Michigan: Develops, manufactures, and markets specialty surgical and medical products. Fiscal year 2001 revenues: \$2.6 billion

\* Zimmer Holdings, Indiana: Designs, develops, manufactures, and markets orthopedic reconstructive implants and fracture-management products. Its products are sold in at least 70 countries. Sales for fiscal year 2001: \$1.17 billion

### The Seeds of Venture Capital

A look at the medical-device industry's venture capital (VC) activity provides insights about its strengths. Someone with a bird's-eye view of this is Kirk Walden, national director of venture capital research for PricewaterhouseCoopers.

According to the Austin-based consultant, the life-sciences sector in general - which includes medical-device firms - "has held up quite well in regards to venture capital." In 2000, the peak year in what was historically one of the most volatile markets for VC, medical-device firms represented 2.4 percent of all VC activity in the United States, according to Walden. Just two years later, in 2002, it accounted for nine percent of this action, or about \$1.9 billion. He stresses that the medical-device and

biotechnology industries are "two steady, strong performers" with a special interrelationship among their various categories. "They tend to move in symphony with each other."

On the investment side, firms who tend to invest in these categories "have a more solid understanding of the market," he says, and recognize it as a four- to six-year investment, compared to the much shorter (i.e., 18-month) investment cycle associated with Internet companies not so long ago.

On the market side, Medicare and Medicaid reimbursement policies "are becoming more realistic in terms of devices covered," Waiden notes. "This should help the industry further." Another boon for this sector is the fact that baby boomers are aging. And as they age, he says, they need and/or demand more medical devices to improve their quality of life and, if possible, lengthen their life spans.

Walden predicts that overall VC investments this year will be "relatively flat" when compared to last year's numbers. Yet, he says, "already we have evidence that life sciences will increase their share again of total VC. It's not inconceivable that it could account for at least 10 percent of year-2003 investments."

Which regions gobble up the most VC monies for medical devices? By leaps and bounds the number-one place in 2002 - again - was Silicon Valley, according to Walden. A "very strong" second-place: San Diego, which received about eight percent (approximately \$147 million) of total medical-device monies last year. Third place: Minnesota, recipient of 5.3 percent of the industry's VC (\$100 million). "Another strong state is North Carolina; the Research Triangle area in particular. It received about five percent of the total - \$95 million." The remainder of VC investments "are shared around the country," he notes.

#### Industry Trends Supporting Growth

Kathleen Poulous, vice president of sales for MedPanel Inc., a provider of research services, offers a few insights about developments affecting the medical-device industry. In her estimation, two major trends will keep the industry growing: an aging global population and an increased global demand for access to quality health care. "Having spent the last several years in global market-development roles, I continue to see an increase in per-capita health allocations," Poulous asserts. "Granted, this varies drastically based on the country, but the trend is increasing, not decreasing, on a global basis."

Growth areas within the medicaldevice industry include orthopedics, cardiology, and oncology, she adds. "The aging global population plays a role in all three of these

areas, as does the demand for access to better-quality health care. Oncology is a strong area of Ricus and the industry is looking for devices that make the delivery of chemotherapy safer, easier, more specific to the tumor, and more convenient for both the patient and the caregiver."

One AdvaMed study recently conducted by The Lewin Group delves deeper into the forces affecting the industry's structure. Some of the study's findings:

- \* The outlook for the medical-device and diagnostics sector is "robust," with ongoing technology innovation expected to be fueled by advances in biomaterials, tissue engineering, genomics, and computing.

- \* Large companies dominate the market in sales; the largest two percent are responsible for almost half of all sales. Small, entrepreneurial companies "have significant roles in innovation." (According to one industry observer, in the past few years many fledgling medical-device firms have made it part of their "exit" strategy to be bought out by bigger firms desperately seeking innovative products that they cannot produce themselves.)

- \* About 80 percent of the medicaldevice industry is made up of companies with fewer than 50 employees. Although accounting for just 10 percent of total sales, firms with revenues of less than \$100 million are responsible for 28 percent of industry R&D spending.

- \* The majority of R&D spending about \$8.9 billion - comes from private sources, and goes primarily for product-specific applied research. Fueled by competition, "R&D spending has increased 20 percent on a cumulative annual basis since 1990."

- \* "The healthcare delivery system affects innovation through efforts to reduce costs and manage utilization, which has resulted in lower prices and increased consolidation in the...industry," the report states.

- \* "If not addressed, healthcare-market and public-policy trends will impede technological innovation by the medical-device industry as well as access to new technology."

#### Expansion Advice

Boston; Minneapolis-St. Paul; and Orange County/San Diego are traditionally the most attractive regions for medical-technology manufacturing. But which other U.S. locations are welcoming such companies, including medical-device firms? Last year this topic was explored in the November/December issue of MX (formerly Medical

Device Executive Portfolio). The article profiled 10 highly suitable yet lesser-known regions where industry players may want to consider new or expanded facility sites in the near future.

1. **CENTRAL INDIANA:** The state offers "a substantial foundation for the growth of experienced researchers," according to the article. The Central Indiana Life Sciences Initiative, a public-private partnership of health industry, government, and academic leaders, was recently launched to "increase the number of life-sciences jobs, businesses, and research opportunities."
2. **UTAH:** Nearly 300 biomedical firms here post "an estimated \$1.8 billion in annual revenues and \$1.4 billion (estimated) to Utah's economy." Existing and expanding biomedical firms receive state R&D income tax credits.
3. **SEATTLE:** Washington and Greater Seattle support about 200 biotech and med-tech companies. Draws include "state incentives, deferrals, and credits for high-tech firms," plus the presence of facilities such as the Fred Hutchinson Cancer Research Center, the University of Washington, and Pacific Northwest National Laboratory.
4. **KANSAS CITY:** The "coordinating body" for area life-sciences research is the Kansas City Area Life Sciences Institute. Research focuses on "cancer, human development and aging, cardiovascular diseases, infectious diseases, and neurological diseases."
5. **MICHIGAN:** The state offers America's "tenth-largest life-sciences work force," and supports more than 300 life-sciences firms. "Pharmacia and Pfizer invest more than \$1.2 billion annually in research and development, while Michigan's major research institutions add more than \$400 million."
6. **PITTSBURGH:** Med-tech manufacturers like the city's access to "strong academic and clinical research facilities," pins R&D by the UPMC Health System, University of Pittsburgh, and Magee-Women's Research Institute. The area's life-sciences industry employs more than 100,000 workers.
7. **CHARLESTON:** Bio-med firms are now joining medical-device manufacturers already established here such as Varian Medical Systems, C.R. Bard, Berchtold, Hill-Rom, and Getinge. Big draws: "AAI International's pharmaceutical development center, one of a handful of facilities [providing] contract formulation, development, and testing services," plus Medical University of South Carolina, which annually attracts "more than \$124 million in research funding and grants."
8. **TENNESSEE:** "Memphis ranks second in the country in medical-device and

instrument manufacturing," according to MX. Nashville, a "healthcare-industry capital," supports more than 220 Healthcare firms, including Medtronic, Smith & Nephew, and Wright Medical.

9. AUSTIN: Texas' state capital, education-focused Austin nurtures about 85 bioscience firms producing medical devices, pharmaceuticals, preventive medicines, lab tools/analysis, and more. The University of Texas helps to boost this growth industry, as does an emerging bioprocessing consortium.

10. TUCSON: Arizona's southern region is populated by 60-plus firms engaged in life-sciences technology. Bio firms primarily work in medical devices, pharmaceuticals, medical imaging, industrial products, and biomaterials. To complement such private-sector efforts, the University of Arizona is establishing a \$60 million Institute for Biomedical Science and Biotechnology.

No matter what locations it considers, a medical-device firm should check candidate locations to determine if they can provide a labor force with the technical capability to match the firm's level of automation. Today's production processes are far more complex and technical than ever before, and require more technical expertise on the part of workers who must handle a more automated system. Moreover, experts say prospective expansion areas also should be reviewed in terms of available temporary labor, since the medical-device manufacturing business does tend to experience peaks and valleys.

Another key location challenge is finding environments that are highly supportive of medical technology, including research and medical institutes and educational systems. These facilities, both public and private, are important for the development of medical devices. University partnerships in particular can be of great service, providing not only advanced R&D but also customized training in specialized, emerging technology that is of interest to a particular medical-device company.

These same areas often offer hightech science parks with infrastructure and neighboring bioscience tenants supplying other advantages helpful to a relocating firm's overall business strategy. Of course, having suppliers and customers nearby - or a transportation system that connects to them cost-effectively - is a bonus, too.

### The Industry Overseas

While the medical-device industry in the United States is robust and innovative, in other parts of the world the industry also is flexing its R&D and distribution muscles.

The European market "continues to be a leader in new products and sustained

growth," asserts European Medical Device Manufacturer (EMDM), Europe's leading sourcebook for designers and manufacturers of medical devices. Each of the publication's seven yearly issues includes more than 150 descriptions of the newest materials, components, equipment, and services related to the industry.

EMDM reports that by 2005, the UK, Germany, France, Italy, and Spain will represent five of the world's 10 largest markets for medical equipment. It also predicts that Europe will remain the vanguard of product innovation. "The process of obtaining the CE mark for a product is much faster than it is in the U.S., which means that new and innovative products can hit the market faster via the European gateway," the publication states. "This is a boon to manufacturers of cutting-edge technology products, with consumer demand for these products at an all-time high... The European medical-technology market now has the ability to do business easier and faster than ever before. It is more lucrative and attractive than at any other time in its history."

EUCOMED, the European Confederation of Medical Devices Associations, is the largest trade association representing the medical-device industry (more than 3,000 businesses) in Europe. Members include manufacturers and distributors of medical devices and accessories, plus related European associations. According to EUCOMED, about 7,000 individual medical-technology entities operate on the continent. Small and mid-size companies together (as many as 250 employees) comprise 94 percent of its medical-technology businesses.

EUCOMED's industry data state that the UK exports 20 percent of its production; Germany, 17 percent; and Ireland, 35 percent. Major exported products include in-vitro diagnostic devices and electromedical, anesthetic, and respiratory equipment. Key markets are the United States, Japan, the CEEC (a network of Central and Eastern European nations), and "Australasia." Early 2000 data collected from association members indicate that the European medical-technology market should sustain six percent growth during 2003, and total about \$55 billion.

In particular, Ireland has an interesting tale to tell. According to the Irish Medical Devices Association, the industry here employs 18,000 people through approximately 80 medical-device firms. Remarkably, 13 of those companies are among the top-25 medical-device companies in the world.

Across the ocean, Medical Devices Canada is the trade association representing more than 125 industry manufacturers and distributors. Its four sector groups focus on cardiovascular, diagnostic, orthopedic, and ophthalmic products. And Down Under, the Medical Industry Association of Australia (MIAA) reports that the continent's

500-plus industry firms directly employ 10,000 workers, and local sales exceed AUD\$2 billion. AREA

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