

# Orthopedic Growth: Too Much of a Good Thing?

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by Frank Celia contributing writer

While preferable to a shrinking one, a growing market can present its own challenges.

If you are reading this, you probably already know the orthopedic implant market is enjoying some heady days. Although the end of last year saw a slight downturn, double-digit growth is pretty much the norm among manufacturers, and forecasters believe such levels of expansion can be sustained during the next 10 to 15 years. This is a welcomed change from the early to mid-1990s, when the orthopedic market was stagnating.

However, it is not all wine and roses, especially for smaller companies, of which there are many in orthopedics. Prolonged periods of skyrocketing growth can present their own unique challenges. Finding qualified employees and adding increased capacity to handle bigger orders can sap a growing company's time and energy.

Orthopedic manufactures are faced with the additional burdens of shocking jumps in the price of raw materials on one hand and pressure from hospitals and insurance companies to keep unit prices fixed, or even lowered, on the other. Large OEMs expect their smaller vendors to make up for raw material increases by implementing money-saving technology innovations on the factory floor. But there is a limit to what new technology can accomplish, and engineers at these companies say they are nearing it.

Finally, on top of all of this, increased growth has attracted the attention of Wall Street, and venture capital is pouring into orthopedics like never before. Small manufacturers are inundated with offers to sell out to large conglomerates, and many are seriously considering early retirement rather than facing the rigors and headaches of a continuous bull market.

## **Favorable Outlook**

Between 1993 and 2003, the orthopedics industry grew from revenues of \$6 billion a year to \$17 billion. According to Knowledge Enterprises, Inc., a consulting firm based in Chagrin Falls, OH, specializing in orthopedics, global industry revenues amounted to \$22.9 billion in 2004, a 16% increase over those for 2003.

A worker operates a coordinate measuring machine (CMM). Photo courtesy of Hower Tool. Experts estimate there are about 200 orthopedic manufacturers worldwide, and the vast majority report annual sales of \$5 million or less. It is not uncommon to hear stories of small companies doing \$4 million annually in business suddenly expanding to \$40 million in the space of two or

three years. Everybody appreciates growth, but that kind of growth, occurring that quickly, can be frightening.

“We have 92 employees right now,” said Joe Davis, vice president of 3-D Machining, Inc., based in Riviera Beach, FL. “Five years ago, we had 16. It’s crazy. As much as people feel good about having so much business, it can as big a problem as when you don’t have enough. We joke that we have so many machines running on the floor and they are like monsters that have to be fed. The challenge is to keep that work coming in.”

Larry Whitney, vice president and chief operating officer of Precision Technologies, Inc., of Norwood, NJ, agreed that there is an anxiety level to growing too quickly. A company may grow from \$10 million in revenues a year to \$50 million, but then there is immense pressure to keep up that level of performance. A drop back down to \$25 million a year can be devastating. “That is a big hill to fall down,” he observed.

Finding and keeping qualified employees is the most significant challenge in a growing market, according to officials at these companies. Locating qualified machinists and engineers is never easy in any manufacturing industry, but it is even tougher in the medical device field because of the higher levels of precision necessary to produce quality healthcare products and parts. It is not a skill set that can be taught in trade schools, and the learning curve is substantial. After the long training period, employers must pay competitive salaries and benefits or risk having employees lured away by other manufacturers. Many device manufacturers say they have been forced to turn down business simply because they lack the qualified staff to perform the additional work.

Skilled labor is a problem,” said Brad Rosenkranz, vice president of sales and marketing of Marox Corp. in Holyoke, MA. “And it is not just in our part of the country. We are hearing about labor shortages from everyone across the board.”

Rosenkranz added he believes part of the problem is that manufacturing jobs have developed a poor reputation in the past decade or so. The news media consistently harp on the theme of manufacturing jobs being lost or shipped overseas, leaving young people with the impression they must gravitate toward the service industry to make a decent living. The industry should make an effort to get word out that segments of the manufacturing world remain vibrant, he said.

Marox is doing its part by forging and maintaining good relationships with local trade and vocational schools, Rosenkranz said. The company also organizes field trips in which local schoolchildren are bused to the facility to take a guided tour of the factory. “We explain to them what it is about to be in the world of CNC machining, that it can be an exciting career,” he explained.

Another company that has been forced to put extra effort into finding quality employees is Onyx Medical Corp. in Memphis, TN. Vice President of Sales and Marketing Jodie Gilmore lamented that, in the United States, students who do not attend four-year colleges or universities are viewed as disadvantaged career-wise, when in fact the medical device industry holds so much opportunity for them. She also pointed out that in other countries—European ones in particular—students who are not academically inclined are often given the opportunity to join

apprenticeship programs in which they are taught a skilled, vocational trade, such as CNC machining. “Certainly our type of business would be greatly enhanced if we had a program like that throughout this country,” she said.

The problem of labor shortages will most likely be an ongoing one, since the current market growth in orthopedics is expected to continue. Financial analysts believe that the underlying fundamentals of the industry are and will continue to be strong. An aging population and widespread adoption of new technologies such as ortho-biologics and new spinal products should continue to fuel growth in the coming years.

The only storm cloud on the horizon is pressure on pricing, and it is not something to be taken lightly. Many hospitals say they are losing money on hip and knee replacements, especially with Medicare patients. Meanwhile, federal investigators have also been nosing around the contractual relationships between physicians and implant manufacturers, looking for evidence of kickbacks. Should indictments and convictions ensue, that could be just the leverage hospitals and insurance companies need to keep prices fixed or have them lowered. (See “Specter of Price Controls Causes Worry,” on page 26).

### **Material Costs**

Another problem facing implant manufacturers is the rising cost of raw materials. Demand for titanium, cobalt-chrome-molybdenum, tungsten, polymers and the like has increased along with orthopedic growth, and prices have gone up accordingly. Making matters worse, only a limited number of suppliers service the orthopedic industry with these materials; thus, a purchaser’s ability to shop around for price is constrained. The profit margins to be gained by servicing the medical industry are simply not big enough to attract many suppliers to the field. Manufacturers in areas such as aerospace and the military buy in much higher volumes than those in the medical industry and do not require the very tight tolerances and high purity levels needed for medical implants, making them more attractive to these suppliers. Many orthopedic manufacturers say their raw materials suppliers are considering leaving the medical field entirely.

A purchasing manager’s only hope is to forecast his or her company’s raw material needs as far into the future as possible, six months or even a year, if feasible. And this, too, is becoming more difficult because OEMs are pushing for ever-shorter lead times in their orders.

“We do a lot of advanced planning and forecasting so that we can buy in the largest volume possible,” said Jodie Gilmore of Onyx. But sometimes a manufacturer has to bite the bullet and raise prices on its finished product, she said, although this is the last thing that OEMs want to hear. “I think they believe we should continue to optimize our operation and become more efficient and overcome these [raw material] price increases...but we have been doing that for the past five, six, seven years, and ultimately there is only so much you can do to absorb raw material price increases.”

### **Technology**

The past decade has witnessed huge increases in technology, all of which have served to increase productivity and the quality of the finished parts and products.

One trend is that medical devices are becoming smaller and more complex, as OEMs design new implants and instrumentation for minimally invasive surgeries, according to Chris Rawlins, sales manager at Mentor, OH-based Miltronics & Skye, which specializes in machining complex implants for the spine and small bone.

Half pin manufacturing on one of Onyx Medical's nine Swiss style lathes. Photo courtesy of Onyx Medical.

"We have recognized this trend and have invested in the latest machining technology to address the smaller and more complex implant geometries," he said.

Tom Baines, sales and marketing manager at Hower Tool, based in Ossian, IN, explained that his company is committed to state-of-the-art technology on the factory floor. Recently acquired equipment includes:

- Mori Seiki NL 2000 SY Lathe: This is a machining center with a bar feeder. The lathe has two spindles, live tooling and Y-axis for milling off center. The lathe provides the capability to machine parts in one operation that previously required three or four operations, thus increasing part quality while reducing manufacturing cost.
- Brothers HS-70A Wire EDM machine with a rotary table: This machine allows for multiple fixture staging. It can run unattended with automatic threading and large spools of wire.
- Mitotoyo 544 Coordinate Measuring Machine (CMM): This device creates sophisticated programs to ensure that parts are measured constantly over time.

Onyx is known for its state-of-the-art electropolishing line. This is a chemical finishing process performed on the part that removes oils and other manufacturing residues, as well as burrs, and also produces a passive, corrosion-resistant surface. The process accomplishes this by combining a specifically designed chemical with the appropriate amount of DC current to remove metals from the part, improve surface finish and remove burrs. Without an electropolishing line, this process would take three or four steps and still yield less than optimal results. Onyx's system is so well regarded, particularly for its ability to electropolish alloys such as cobalt chrome, that sometimes clients ask the company to electropolish parts that have not even been manufactured at Onyx's site, according to Gilmore.

Onyx will also occasionally grind its own tooling in-house, something Precision Technologies does as well. "Tooling is a key element in being able to produce a quality surface finish, a mirror finish," Whitney explained. "At times we will design our own tooling, which allows us to manufacture the part in the quickest way we can. This keeps costs down, and we can pass along those savings to the customer."

Things that can be done in-house are usually cost savers, so a manufacturer's ingenuity in this regard can have a significant impact on the bottom line. For example, at 3-D Machining, Inc., the company specializes in making drill instruments, which are usually made of heat-treatable stainless steel. A lot of the drills are cannulated, or hollow down their center, but they are too big and thick to be made from tubing. Therefore, companies sell a cannulated bar stock that can be machined into such drills. However, 3-D Machining has its own "gundrilling" machines that can cannulate a drill at less expense per piece than it would cost to purchase the cannulated bar stock.

Finally, even in the metal and kinetic world of machining, computer software can have an impact. The enhanced capacity of computer processors has greatly increased the speed of CNC machines, according to manufacturers. Rawlins of Miltronics & Skye explained that his company can receive solid models from clients, download them into its computer system and ultimately generate process prints, fixture designs and machining programs very quickly. "This technology gives us the ability to help clients meet their aggressive product launch dates and keep production costs down," he noted.

## Venture Capital

Some Wall Street watchers are saying that medical manufacturing companies are to this decade what internet stocks were to the 1990s. There is tremendous opportunity for growth and innovation, and always the chance for small companies to strike it rich with just the right idea or product.

Small Bone Innovations, Inc. of New York City received an infusion of \$42.2 million in second-round financing. The company focuses on orthopedic care for arthritis patients and for those who have experienced trauma in small bones and joints. As reported in a recent issue of Orthopedic Design & Technology, this was the largest-ever investment of venture capital in the orthopedics sector. Such deals are becoming more common.

Venture capitalists are also forming conglomerates that seek smaller manufacturing companies to buy and put under one roof. "We have been approached," said Brad Rosenkranz. "I don't think anyone in our position has not been approached."

Some say selling out to a large organization would likely be an attractive retirement strategy, but most feel the time is right for expansion, not departure. Precision Technologies, for example, which has specialized exclusively in plastic parts, is expanding into metals, despite rising material costs. "We think this market will continue to grow," explained Whitney. "We have been talking about it for two or three years. And our customers encouraged us to do it. They've worked with us for a long time and they like us."

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