

Machined Body Implants Bring A New Walk To Life

Millions of people in the world can't walk without severe pain. They are candidates for a "miracle" - the modern-day replacement of a hip or knee joint.

Just 40 years ago this "miracle" would have been unheard of. Today the operation is a complex, but common surgical procedure. It starts with the manufacture of machined implants tracing their roots to the advancement of manufacturing techniques and materials compatible with the human body. Using advanced multi-tasking machine tools, these implants are machined to the close tolerances required for the intricate movement inside the flesh and bones machine known as the "leg". Exactech, Gainesville, Florida, is an innovation leader in the manufacture and cost reduction of these products.

According to Operations Coordinator Julie Petty, the goal of the Exactech manufacturing team is to improve production efficiencies to a one-day cycle for these products. Petty would like to maintain minimal shelf inventory, and use quick cycle and changeover times to replenish inventory shipped the previous day. This type of manufacturing demands flexibility to produce one-off or small-batch parts quickly, profitably and with precision. One way they've found to do this is with multi-tasking machine tools from The Mazak Corporation (Florence, KY).

Exactech was founded by William Petty, M. D., an orthopedic surgeon, his wife Betty Petty, and Gary Miller, Ph.D., a biomechanics engineer. Because of their positions on the University of Florida College of Medicine faculty, Drs. Miller and Petty had worked with several orthopedic companies as consultants. Dr. Petty had increasing concerns about the cost pressure on medical products. He felt that the industry could do some things differently, and better, to assure superior quality products while responding to the need for medical cost

containment. The Pettys invited Dr. Miller to join in forming Exactech with the intent of making a difference in the orthopedic implant industry. To this end, Exactech was incorporated on November 11, 1985 and has its ISO 9001 certification. In May of 1996, Exactech became a publicly traded company on the NASDAQ Stock Exchange.

After the company started, price pressures accelerated. But even with this, the company has grown at about 35% per year. Their annual sales volume is now close to \$30 million. They currently have 85 employees, 50% more than 1998. The company has a staff for product design and marketing and began in-house manufacturing in late 1998. Independent sales agents market Exactech's implant and biological products to hospitals and surgeons nationwide and in 14 foreign countries.

An Exacting Product Line

Exactech's hip and knee joint implants are produced in an array of sizes to accommodate the wide variation in human anatomy. Exactech's Facilities Coordinator Phil Cripe said that an implant can last 10 to 15 years depending on the activity level of the patient, the design of the device and the surgical precision at the time of implantation. After a recovery time of six weeks to six months, most patients can resume daily activity with little or no pain.

A hip joint is composed of three to four components. It looks like a ball on a shaft that is tapered at both ends and mates with a one or two piece hemispherical cup that represents the socket. The highly polished cobalt chrome ball attaches to the shaft using precision tapers.

The knee joint is typically four components made from precision-machined materials as diverse as titanium, cobalt chrome and high-density polyethylene. Both hip and knee joint forgings require machining to produce the exacting tapers on the parts which have to hold a two to three tenths tolerance.

Cripe said that Exactech supplies both trial implants and regular implants. For a perfect fit, doctors will put in a trial set of implants to test the fit and joint motion. At this point, the doctor can make any changes that are necessary before selecting the final implant.

Cripe added that Exactech is developing a new modular system of hip implant stems to allow a doctor to mix and match for the best size for implant replacement surgery.

After machining, products are inspected, ultrasonically cleaned, packaged and sterilized using gamma irradiation. Products are then available for shipment to Exactech's sales agents.

When Exactech first began manufacturing implant components, they used outside vendors with manufacturing experience in medical product production to produce Exactech designs. Now they are beginning to manufacture their product line in-house as they add capability and capacity.

In-House Manufacturing - Speed, Precision and Flexibility Needed

To develop the capability to manufacture in-house, Cripe, who has an extensive background in medical products, began the task of evaluating various machine tools. Exactech had help from a key vendor setting up their own in-house manufacturing. The hip and knee implants required both turning and milling functions with precision tolerances.

Cripe said that he looked at all the various types of machine tools available to produce these components. "I was looking for the right machine tool with very strong support from the manufacturer. We developed a relationship with our local Mazak distributor, John Grabenau of Premier Machinery Inc. He showed us what other manufacturers were doing with Mazak machines and how Mazak and Premier would take care of our needs. One machine that he demonstrated for us was the Mazak Integrex which is a multi-tasking turn/mill machine tool."

Cripe added, "When we compared other machines to the Integrex, there were some that came close to its capabilities, but I couldn't find anything as flexible as Mazak's Integrex. At the time we bought these, there wasn't anything competitive to them that had the same capabilities."

Exactech bought two Mazak Integrex 200SYs. These machines have an advanced turret designed with a 10 HP, 6000 RPM spindle for live tools to deliver the performance of a machining center. The turret also has 5.5" Y-axis movement and 225-degree B axis travel

range in increments of 0.001 degrees. These axes increase the machine's cutting capabilities including crosscut and angular milling, off-center drilling, boring and tapping. With the C axis capability of the main spindle, precision contouring capabilities can also be performed.

Cripe added, "As a company we take technology as far as we can and are creative using it. We spent quite a bit of time with applications engineers at Mazak. They looked at our product line and at the changeovers for parts that we wanted to produce on a daily or weekly basis. We felt that we had a strong case for integrated processing. It allowed us as much manufacturing flexibility as any cell with several machines that we could have put together. Every cutting operation that we wanted was already built into the Integrex. We also now have the flexibility to produce any type of unique prototype and do it with speed and efficiency."

Mazak's Integrex 200SY enables the integration process of part manufacturing for high productivity. It reduces work-in-process and reduces throughput time because parts no longer move from machine to machine with multiple setups. Parts are machined in one setup on one machine, offering the benefits of cost reductions in labor, fixtures, tooling and an increase in dimensional quality.

With the 10 HP secondary -spindle for heavy-duty machining that Exactech ordered, the Integrex can fully complete a part without operator interruption. It automatically transfers the workpiece from the first spindle to the second spindle to complete both ends of a turned part.

Renishaw Model 10 probes are used on the Integrexes to check final part tolerances and speed up quality checks. To prove process capability of the probes, Exactech uses a CMM to check approximately one part in 20 or 30. They also have equipment to test various product materials as well as a large quality assurance lab.

Exactech Manufacturing Engineer Al Bassett said, "The Integrexes have helped compress the time it would take to produce a prototype or a manufactured component. In addition to the Integrexes, we have one Mazak Super Quick Turn 250 MY, a Mazak Quick Turn 15M, and a Mazak VTC-20. Most also have Mazak's new Mazatrol Fusion 640 CNC control."

Dan Szall left a vendor relationship to join the company full time as machining coordinator. He said that the parts Exactech is producing on the Integrex were produced by turning and milling at another vendor's facility." He added that he has worked with a turn/mill machine but it was hard to setup and he preferred producing the implants in a CNC lathe and mill cell. However, he added, Mazak's Integrexes give Exactech excellent capabilities and are nothing like the turn/mill machine he used.

To design their products, Exactech uses Unigraphics CAD systems. Exactech has an Intranet system that is used to download part programs produced from their CAD/CAM systems to the machining centers. The Intranet also links the Mazatrol 640 PC-Fusion CNC controls of each machine tool together. By using an ordinary PC linked to Mazak's Fusion control, Szall can get a tremendous amount of information on the status of each machine such as production status and count, tool data management, simulator for scheduling and operation condition monitoring.

Mazak's Mazatrol 640 PC-Fusion Control fuses these high performance machine controls with all of the capabilities that a PC can provide in a Windows® environment. Two-way communications with Mazak machine tools enable concurrent production planning and execution, meaning a reduction in delivery lead times which helps Exactech with Just-In-Time inventory planning.

Cripe said that they'll never produce all their products in-house. Some products developed and engineered by Exactech are used to help the doctor position and determine the correct replacement implants. The company keeps an inventory of these products, but it is still more cost effective to have them produced by vendors. These products include various types of measuring devices as well as high-speed grinders and drills to remove bone for implant placement or to remove an old implant.

Exactech values its relationships with companies like Mazak who work closely with them to keep Exactech on the leading edge of technology for greater manufacturing productivity.

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