SPECIAL FOCUS: MAKING MEDICAL PARTS

Demographics tell the story. It's estimated that nearly 10 percent of the world's population will be over 65 by the year 2010, up from less than 7 percent in 2000. And when those baby boomers reach their golden years, they'll be looking for new vacation homes, new hobbies—and new body parts.

As old joints wear out and break down, demand for artificial replacements will surge. Industry sources say the market for reconstructive implants is growing at a rate of about 7 percent a year. An estimated 600,000 hips and an equal number of knees were replaced worldwide in 2000, representing about $4 billion.

In light of this expanding and increasingly important manufacturing segment, we present three articles about producing medical parts. This first one profiles a manufacturer of implants. The second ("Smooth Operators") discusses available options for deburring medical components. And the third ("Managed Fluid Care") examines the critical task of tracking metalcutting fluids used to machine implants and medical instruments.

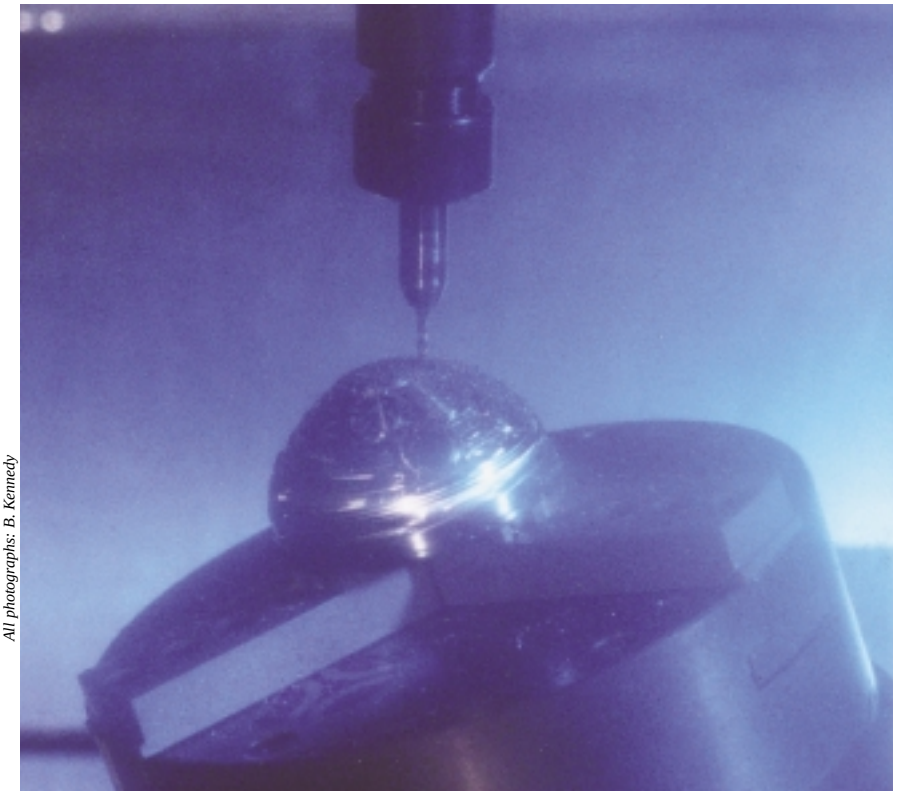
Prescription for Perfection

► BY BILL KENNEDY, CONTRIBUTING EDITOR

"Machining is machining," stated Don Wagner, president and owner of Cycam Inc., a contract CNC machine shop that produces medical components. His smile, however, suggested that he knows that's not always the case.

After some prodding, he conceded that the "products we make are more difficult than many machined components because of the angles, radii and tolerances involved, as well as the workpiece materials we machine."

Cycam, Houston, Pa., manufactures components for replacement hips, shoulders and knees, as well as a variety of other orthopedic devices. The work is highly specialized—as



All photographs: B. Kennedy

Cycam uses carbide tools to produce its medical parts, whether they're made of metal or plastic. Here, an endmill machines a hip implant.

Cycam's Larry Jedlicka said that a lot of people assume they can run plastic parts faster than metal ones. That's not always the case, though, because plastics "move" as they are machined. The movement prevents profile cutting at high speeds.

are the end products.

Consider implants. They replace some of the body's most intricate parts. A typical hip implant consists of a stem, ball and cup that replace all, or parts, of the femur, femoral head and the acetabular socket in the pelvis. The stems and cups are made of tough alloys, such as titanium, stainless steel, aluminum and cobalt-chrome. Bearing surfaces are manufactured from ultra-high-molecular-weight polyethylene.

Cycam also produces the instruments surgeons use in the operating room to confirm fit and function before implanting the actual replacement joint. Instruments can be made of stainless steel, titanium or any of a variety of plastics.

Notably, Cycam is one of only a few companies in its field that machines both metal and plastic components.

Tolerances are held to "tenths," or better. And, Wagner said, the company's new machine tools' spindles and reproducibilities are held to millionths. "But we still have to deal with the cutting tools and component interfaces. Our customers perform final lapping and grinding of sphericities to 50-millionths or so."

Nearly Perfect

Workpiece materials enter Cycam's shop as forgings, castings or bar stock. Some forgings have a standardized configuration that allows them to be used for a variety of parts, while others are near-net shape and specific to certain products.

Cutting parameters are similar to those employed in the aerospace industry and are somewhat controlled by the need to produce defect-free parts. Speeds and feeds, for example, can't be so aggressive that they create stresses in a component that may affect its performance later.

"We have to have 99.99 percent of our parts acceptable at the customer level," Wagner said. "We consider ultimate productivity to be the number of pieces we can make in a given period of time that are acceptable to our customers."

Process Planning

Since its founding in 1988, Cycam has experimented with and refined its component-making processes. That knowledge resides in a proprietary database filled with information about the machining characteristics of, and parameters for, the parts it produces.

Cycam takes a methodical approach to process planning for its machine operations. Planning begins with a component's design and choice of workpiece material. The next step is to choose the best tool geometries.

"Whether you use a 35°, 55° or an 80° tool can be determined by the machine tool's capabilities," explained Wagner. "Some machines let you index to a position that might be tangent to the center of a sphere. But if we're doing an elliptically shaped part with a large back cut on it, we might take standard cutting tools and regrind them so we can get the needed clearances. We modify the tool tips and the back relief angles to accommodate the particular machining requirements."

Workpiece material considerations can dictate lead angles, too. A tool with too severe a lead angle might not be able to cut through a casting or forging. Cycam bases tool-related decisions on the raw material it receives and the amount of material that must be removed.

"Sometimes with near-net-shape forgings and castings you don't have a lot of material to work with, so you're going in and out of a cut and some tool geometries won't hold up," Wagner said.

The Pennsylvania shop uses carbide tools to machine both metals and plastics. However, other considerations, including coolant use, dictate that Cycam operate as two divisions—one for machining metals and the other for plastics. Each division is equipped with its own machine tools. For reactive metals such as magnesium, coolant is essential; other parts must be machined coolant-free. Having separate divisions lets Cycam avoid downtime for cleanup between wet and dry operations.

While machining plastic might seem easier than working with metal, it poses its own challenges.

Cycam Manufacturing Engineer Larry Jedlicka said that a lot of people who enter the field figure they can run plastic parts faster. And, he agreed that plastics can be machined faster than metal

Cycam produces a large number of small-lot orders that add up to about 20,000 parts monthly.

parts—"cutting speeds can be in the thousands"—but the problem is that plastics "move" as they are machined.

"Depending on the type of tool, the size you're trying to maintain and the profile you're actually cutting, you may have to slow way down," he said. "For example, you might be using a 1mm endmill to cut a 0.030" radius with a tolerance of 0.05mm. The tool may move only a few-thousandths in the cut." But that's enough to prevent cutting a "profile at high speeds and feeds and maintain that tolerance."

As a result, many of Cycam's part programs are written so feed rates change significantly during the course of a profile cut.

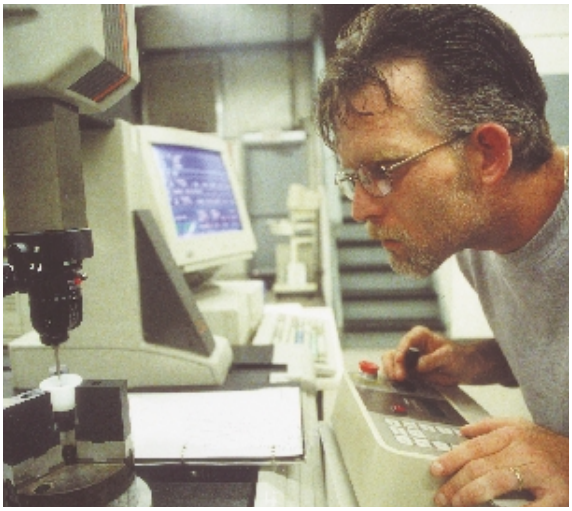
When machining plastics, sharp cutting tool edges and the resultant low cutting forces are important to maintaining good surface finish. The endmills and form tools Cycam uses have proprietary angles that produce a free-cutting edge, Jedlicka said. He added that most of the carbide tools used are uncoated, because coating often requires an edge hone that reduces edge sharpness.

Lots of Small Lots

Cycam provides the medical industry with two types of service. One is to handle overflow orders for large manufacturers. As a certified vendor, it acts as an extension of the manufacturing operations of global giants such as Johnson & Johnson and Bristol-Myers Squib.

In its other role, it produces prototypes for testing and clinical trials, and conducts pilot manufacturing programs.

Overflow and prototype work mean short production runs. Cycam's file of completed products numbers about 4,000, of which 1,000 are considered "active." Three hundred to 400 jobs are in progress at any one time.



In-process inspection of a plastic medical component.

Wagner said, "Look out on the floor. You won't see large volumes of work, but there's a large volume of orders out there: orders for 10, 15 or as many as 50 parts. It all adds up to about 20,000 parts a month."

Overflow orders result from short-term changes in demand, so lead times are relatively short—2 or 3 weeks. Lead times for a new product or process are 10 to 12 weeks.

Rush jobs, though, are not out of the question. In special situations, such as a trauma case in which a patient's joint is damaged and he requires a custom product, Cycam can respond quickly. Such specials are produced by modifying an existing design. The customer furnishes a wire-frame model that it sends to Cycam electronically along with a drawing of the part. The turnaround time for these parts is days instead of weeks.

An assortment of medical components Cycam manufactures, which include a knee extension and the cup for a hip implant.

Small lot sizes, tight lead times and expensive, labor-intensive parts mean Cycam can't afford to make trial parts or scrap.

"You have to have manufacturing systems in place to handle it," Wagner said. "We have documentation, work instructions and procedures that go to the floor with each product. They tell the operators what to do with each type of material and each type of product."

To save even more time, Cycam maintains tool carts preloaded with all the tooling and fixturing necessary to produce a particular component.

Continual Upgrading

To stay competitive, Cycam must continually invest in technology, including software. Schedule and quality pressures make manufacturing software a crucial element of its operations.

Cycam invested $150,000 in systems software in 2001. "We've developed our own software, we've had people develop software for us and we've bought some standard packages," said Wagner.

The company also regularly upgrades its manufacturing equipment. In the last 2 years, Cycam has replaced 20 of its 30 machine tools. This has allowed the company to reap substantial productivity rewards.

As an example, Wagner cited the capabilities of the company's newest machines—6-axis Mazak Integrex lathes with CNC heads. "Where we used to have to grind up a bunch of special tools to do a complex surface, now we are able to program the cutting tool to go around the part so we can do a complex surface with one or two tools."

Acquiring the latest technology also helps the company stay competitive.

"Some of the products we made in the 1980s we are able to manufacture today at the same price, even though material, labor and shipping costs have

gone up," said Wagner. This enables Cycam to charge the same amount as it did in the late '80s and still make money.

Close Collaboration

Producing a medical component is a joint effort between Cycam and its customer. The customer handles the initial product design. This includes determining the needs of the patients who will use the implant and engineering the form, fit and function to ensure it provides maximum mobility and range of motion. The customer also chooses the material that will give the implant the best functionality and longest possible life.

Cycam contributes its manufacturing expertise and works with the customer to design the manufacturing processes. The key is to design and verify a process that will provide reproducibility part after part.

In general, a customer's requirements govern the manufacturing processes utilized. And once a process is verified, Cycam sticks with it.

"If we want to change what we're doing, we have to get approval," said Wagner. "When we replace a machine tool, we have to revalidate the processes on the new machine and submit them to our customer as if we were doing them for the first time."

Likewise, any company that performs contract work for Cycam must conform to the same requirements Cycam does. Cycam's approved-supplier list consists of two levels. One covers raw materials and outsourced processes, such as welding, that directly affect the products Cycam makes. The other includes suppliers whose products indirectly affect products, such as cutting tool and coolant manufacturers.

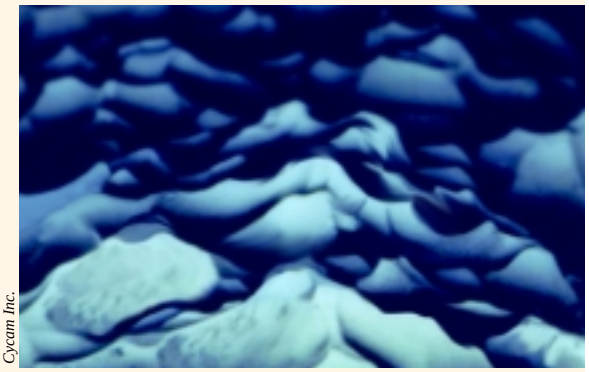
Customer requirements also extend to the facility where the medical devices are manufactured. And the rules don't stop at the factory door. There are customer specifications for packaging and shipping, including the label used on the box and where purchase-order numbers and other information are positioned on it. The reason for the latter is so that the customer's receiving de-

Cycam-developed process helps the body accept implants

The first orthopedic implants, produced in the mid-1970s, were fixed into patients' bones with acrylic cement. In the early 80s, trials began on implants with coated textures into which the bone could grow and create a strong, natural bond. The textures included spherical beads attached via a thermal sintering process, fiber-metal products and various surface finishes.

About 11 years ago, the owner and president of Cycam Inc., Don Wagner, began exploring ways to produce a macro-textured surface that would be part of the parent implant material. Cycam and Techmet, a Glassport, Pa., company, developed a chemical etching process that has the registered trade name Chemtex.

The process involves application of a maskant followed by chemical or electrochemical etching of the unmasked areas.



Cycam Inc.

Photomicrograph of Chemtex-treated surface (50x magnification). The Chemtex process creates a macro-texture on an implant that provides a strong anchoring surface for bone.

Time, temperature and the number of repetitions control the final characteristics of the component surface. The unitary nature of substrate and surface minimizes problems that can arise when coatings are applied to a parent material.

The Chemtex process creates a texture without producing stress in the adjoining material and the etching process produces radiused features with no sharp corners, further minimizing possible sources of stress. It's also slightly less expensive than sintering, Wagner said, and, by changing the maskant application method, the process can be optimized for small or large production runs.

Orthopedic companies have designed about a dozen products that take advantage of the Chemtex process, and Cycam produces about a thousand treated parts a month.

Recently, Cycam began marketing the patented process to potential customers outside the orthopedic industry. For example, because the process increases the surface area of a part, it can increase the efficiency of heat-exchanger elements. And, the controlled roughness the process creates is beneficial when two treated surfaces are to be joined by an adhesive.

One of the more novel applications involves treating the faces of golf clubs. The texture reportedly lets a golfer put more backspin on the ball.

Wagner admitted that some of the Chemtex applications are "way outside what we normally do." But he says that there are a number of applications presently in the testing stages that show good potential.

—B. Kennedy

partment can handle each shipment the same way, minimizing the chance of a mix-up occurring.

"It's pretty hard for someone to just start manufacturing medical components," Wagner said. "There are requirements regarding the facility, as well as for the maintenance of machine tools and use of oils and coolants. When our customers do audits, they look at the complete package—our whole operation. They want us to operate like we're an extension of their company."

FDA Oversight

Another big part of manufacturing medical parts is conforming to government regulations. The U.S. Food and Drug Administration oversees Cycam's work under the Quality System Regulation contained in Title 21, Subsection 820 of the Code of Federal Regulations.

The QS regulation covers "quality management and organization, product design, buildings, equipment, purchase and handling of components, production and process controls, packaging and labeling, product evaluation, distribution, installation, complaint handling, servicing and records."

Included in the QS regulation are current Good Manufacturing Practices (GMPs), promulgated under Section 520 of the Food, Drug and Cosmetic Act. They require manufacturers to have "a quality system for the design, manufacture, packaging, labeling, storage, installation and servicing of finished medical devices intended for commercial distribution in the United States." Needless to say, FDA quality systems and GMP requirements are among the most rigorous in existence.

"We're not making bicycle parts," Wagner said. "These implants go into the human body and they are regulated accordingly."

Compliance verification means Cycam must track and record every aspect of its operations—from raw material to the finished device. And the company tracks and reports on every operation performed by each operator for each shift. It does the same for its inspection processes.

Previously, records were retained for 7 years, but now the retention period is indefinite. Cycam has electronic systems for storing this information both on- and off-site. The information has to be available in the event of a recall, Wagner explained, adding that a formal recall plan is yet another item on the FDA requirement list.

Tracking and documentation extends through every aspect of the organization, including hiring practices. Cycam typically hires new employees as trainees. The training process and evaluation of personnel are covered by FDA requirements.

Binders such as these contain documentation, work instructions and procedures for each procedure Cycam performs. All operations and inspections are verified, and records are stored indefinitely.

"We have to show that we've trained the people and made them competent and capable of performing the tasks we ask them to do," said Wagner. "Then we have to evaluate them continually on their performance, including management review of process and the progress of each employee and department. It's all part of what we have to do to maintain control."

It's also what it takes to be a player in the highly competitive medical component industry. And, the competition is expected to tighten even more in the coming years.

The medical components industry is moving toward adopting Six Sigma quality standards. Wagner said Cycam is too, with its ultimate goal being "zero defects."

"That's very difficult to do in an engineered-product, custom-manufacturing business," said Cycam's president. "The paperwork, the inspection, the diligence and discipline is what it takes to continually try to improve to 99.9999 percent accuracy. We're trying to achieve perfection. That's what our customers are working toward, and they expect us to do the same."