MAKING MEDICAL PARTS

Managing the machining of medical parts includes tracking cutting fluids.

Managed Fluid Care

► BY TECHNICAL EDITOR CHARLES M. BOYLES, CPE

The medical implant market has been growing steadily, a trend that's expected to continue as aging baby boomers generate additional demand for implantable spare parts. Implant manufacturers, however, anticipate some fallout and, possibly, new regulations in the wake of recent litigation (see sidebar, page 44).

In December 2000, implant manufacturer Sulzer Medica Ltd., the Winterthur, Switzerland-based parent company of Sulzer Orthopedics Inc., Austin, Texas, recalled 40,000 hip implants—26,000 of which were installed—and about 1,650 knee implants, because the implant recipients were experiencing significant pain after surgery. The problem centered on bone tissue being unable to attach to the metal implants.

Investigators identified the sources of the problems as the presence of cutting-fluid residue on the implants and inadequate final cleaning operations.

Fluid Care

A fluid is chosen for medical manufacturing because of its cooling and lubricating abilities, as well as its biocompatibility. While water-soluble fluids are most commonly used, oil-based and synthetic cutting fluids are used as well.

The presence of any cutting-fluid residue on implants, even a nontoxic residue, limits the bone tissue's ability to attach to the implant. It's much like trying to get glue to stick to an oily surface. Therefore, ensuring finished parts are free of residues is a primary consideration.

Removing cutting-fluid residue from surgical-grade medical parts is a cleaning procedure, as compared to a sterilization process, which destroys harm-

Precision machining and mirror finishes

The manufacture of implants calls for precision machining and polishing of castings, forgings and bar stock.

A variety of materials are used for implants. Ti-6A-4V, a lightweight alloy containing titanium, aluminum and vanadium, is used for hip implants. Knee implants are made from cobalt-chrome-molybdenum castings. An implantable grade of 316-L, 316-LVM, is for spinal implants. And an ultrahigh-molecular-weight polyethylene is for sockets.

In addition, the castings and forgings are near-net shape and, on average, 30 percent of the raw material ends up as chips.

Machining tolerances for most implants range from ±0.005" to ±0.010" on most dimensions. However, on parts such as hip replacements, where stems and balls are mated with a precision taper, tolerances are held to ±0.0005".

Finish requirements are exacting and based on performance—not cosmetics. Hip and knee implants must be polished to a mirror finish. And many designs include metal-to-plastic contact. Pits or scratches larger than 0.001" and more than two or three imperfections in a given area are unacceptable, since they will cause joint failure. A small pit or scratch on a metal-to-polyethylene part abrades the polyethylene as the ball joint articulates and generates minute shavings, which the human body cannot purge.

Mating parts for hip implants have surface finishes of $4R_a$, to allow better adhesion to the surrounding bone, while other articulating component surfaces need to be polished to 0 to $1R_a$. —*C. Boyles*

ful organisms. Cleaning processes are primarily mechanical or chemical. For example, detergents in hot water break down or dissolve cutting fluids, and ultrasonic cleaning generates high-frequency vibrations that loosen residues and physical contaminants.

In addition, passivation (the process of treating a metal so it's less chemically reactive) incorporates nitric acid to consume any free irons or other materials on a part. The detergent wash and passivation treatments remove synthetic-coolant residues, but they do not affect chrome-cobalt or titanium. Cleaning also may include rinsing parts with deionized water and warm-air drying.

Sterilization eliminates microbes on an implant. An autoclave sterilizes parts by subjecting them to 250° F steam, applied at 20 psi, for 20 to 30 minutes. Gamma radiation is also used to sterilize parts. The process involves bombarding parts that are in their packages with gamma rays.

Compliance

Hospital implant suppliers must be certified by the U.S. Food and Drug Administration. However, their suppliers—producers of machined medical implants—have latitude in choosing their level of regulatory conformance.

For example, the part producer may choose to supply components with specified dimensional tolerances and nothing more. In such a case, the customer accepts some, or all, of the responsibility for cleaning and sterilizing the implantable parts. Or, the part producer may decide to be ISO- or FDA-certified.

If a company is ISO 9000-certified, then it complies with the requirements and procedures set forth in its certification. It also commits to produce parts to specified dimensions and tolerances, then documents and validates its processes. There may or may not be a commitment to clean or sterilize machined parts. However, if the company has a cleaning or sterilization process, it must be validated, documented and certified.

In addition, customers receive information about every fluid or compound that contacts their product during manufacturing—from the time the raw stock enters the part producer's front door until the product ships.

The information details the nature of the fluids used in machining, including

Implant manufacturers go to court

The sheer number of people engaged in strenuous sports and an aging population has resulted in more and more broken bones and a growing demand for hip, knee and shoulder implants machined from titanium. They cost $20,000 to $50,000 per installed joint.

According to John Engelhardt of Knowledge Enterprises, a Cleveland-based orthopedic research firm, orthopedic implants represent a $12-billion-a-year industry. And, the number of people receiving implants is growing. *The Journal of the American Medical Association* estimates that 20 to 25 million patients currently have some type of implanted medical device.

But the implant business is not without its problems. On Dec. 8, 2000, Sulzer Orthopedics, Austin, Texas, recalled approximately 17,500 installed hip implants. According to the *Austin American-Statesman*, reports from surgeons about patients with problem hip implants date back to July 2000. By April 2001, more than 500 lawsuits had been filed against Sulzer and plans to separate Sulzer Orthopedics from its parent company, Sulzer Medica of Switzerland, were under way.

Sulzer's knee implants were the subject of a recall, too. As of August 2001, Sulzer announced that about 1,500 people would have to have their knee implants replaced. The implant problem was associated with an oil residue on the titanium parts, which prevented bone tissue from adhering to the metal. The settlement figure for litigants has risen from an early estimate of $350 million to $780 million.

Also, according to the FDA, in August 2001, French manufacturer Saint-Gobain Desmarquest began a recall of zirconia-ceramic femoral heads—the ball portion of a hip prosthesis that connects a femoral stem to the pelvis. A higher-than-expected fracture rate was cited as causing the recall of parts manufactured after a process change occurred in 1998. The number of affected patients is expected to be fewer than 9,000.

In an effort to improve implants and their performance, a panel from the National Institute of Health is seeking data gathered from used implants. The panel considers this type of information vital to helping implant manufacturers improve the next generation of implants.

Members of the institute also reported that patients often have unrealistic notions regarding implants, such as that they last forever. (They don't.)

However, in spite of the recent implant recalls, the University of California at San Francisco reports positive results for a new prosthetic device for patients suffering from leg cancer. The device—a compliant prestress system—directs stress to the bone, which heals to a metal surface much like a fracture heals. This transference of stress is critical because bones grow under stress.

The difficulty with conventional implants, which tend to fail after 10 to 20 years, is that the bone tissue around the metal disappears. Most implants preclude bone stress, which causes the bones to atrophy and shrink away from the implant. This causes the implant to loosen.

The promising new device is designed as an alternative to amputation for those with leg cancer.

—C. Boyles

way oils and spindle lubricants. In terms of coolant residues, a company must define a cleanliness standard that specifies how the product will be cleaned.

Kevin Gilbert, quality-control manager at Integra Medical, Etna Green, Ind., said: "By the time I put a machine on the floor, I know all the details involved. I've documented that I have the correct components with it. I've developed the preventive-maintenance program. I've gone through all the safety checks. And I guarantee that it's been installed correctly and that I can maintain it, including coolant use. This level of compliance eliminates any variables that can affect the operation. So, in accounting for every possible variable, I prove that the variables present cannot affect final product quality."

Validation

Validating a cleaning process for implants means testing for the presence of cutting-fluid residues. Testing must be conducted by a certified, independent laboratory.

The first step in the process is for the implant manufacturer to supply the laboratory with a cleaned implant and a sample of the cutting fluid used to machine it. The laboratory soaks the implant in a suitable chemical bath for an appropriate period of time—24 hours or more. Then the lab removes the implant and tests the solution for any residue of the supplied cutting fluid. By knowing the composition of the cutting fluid, any traces left on the implant can be quantified.

If the type of fluid used to machine a part is changed—or any new process is introduced—the validation procedure is repeated. A machined part would have to sit in the new fluid for 24 hours and then undergo cleaning. Next, a sample of the fluid would be sent along with the part to the testing lab. The laboratory would report back on how much cutting-fluid residue (in ppm or ppb), if any, remained. This validation procedure is necessary before a customer would accept parts manufactured with the new fluid.

FDA Certification

FDA certification is similar to ISO certification and requires compliance with Title 21 CFR, Subsection 820. At the FDA-certified level, cleaning and sterilizing processes must be validated through testing procedures with a bioburden study—an analytical test sequence to specify a sterility-assurance level.

Lab testing must prove there are no hazardous constituents or residues left that could cause problems. The machined parts go through the cleaning process and then are sterilized.

"FDA-certified" means a company has quality and inspection systems in place and that it maintains them. Additionally, when a company is certified by the FDA, the agency can schedule an audit to verify compliance. Compliance translates as an extremely detailed manufacturing-tracking system. Certification means the company informs the FDA that its manufacturing processes conform to Good Manufacturing Practices, and that they are governed by a quality system.

A GMP for managing cutting fluids, for example, covers the cleaning portion of the process and emphasizes the elimination of tramp oil. A cleaning process may focus on eliminating contaminants and odors. For part-cleaning tanks, verification may include daily testing of the solvent-to-water ratio to determine solution strength. Some GMPs call for part cleaning between operations, such as turning and milling, to ensure residues don't cake, set up or become sticky.

From Ore to the OR

When an implant arrives at an operating room prior to surgery, everything involved in manufacturing it must have been documented. Also, each item has a unique part and lot number that is traceable back to the raw material from the forge, foundry or mill—a continuous chain of custody.

Surgical equipment, implants, instrumentation and even Band-Aids must comply with Title 21 CFR, Subsection 820 regulations.

Compliance includes process, equipment and quality validations for a machine. It even includes CAD systems and CNC programs.

This level of oversight helps ensure that equipment—and implants—perform correctly over the long haul.