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Microabrasive blasting can precisely target specific areas of a part, such as this stent, to impart the required surface finish.

Comco

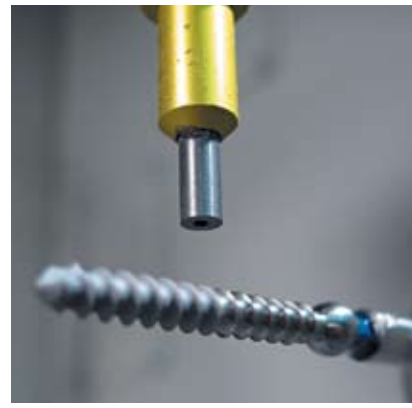
It's a BLAST

➤ BY ALAN RICHTER, EDITOR

The role of microabrasive blasting when finishing implantable medical parts.

Perfection is relative when producing precision parts. That's why tolerance specifications exist. But, certainly, to treat patients effectively and avoid possible litigation, surgeons need implants that are free of "imperfections." That typically requires implant manufacturers to use surface finishing processes after machining to remove minute defects, blemishes and burrs and to prepare a part's surface to withstand the corrosive environment inside a human body.

One of the methods available is microabrasive blasting. Medical implants, such as stents, shunts and cages, are commonly blasted to deburr them, remove discoloration and oxide layers from surfaces, remove pulse marks and striations left by laser machining, cut or remove laser slag (remelt), decrease the propensity for microcracking and lightly texture the surface to improve adhesion characteristics, according to Patrick Byrne, marketing manager for Comco Inc. The Burbank, Calif., company manufactures microabrasive blasting equipment. "For just about any type of machining that leaves a burr or leaves a finish that isn't what manufacturers want on the finished product, they'll use microabrasive blasting," he said.



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Bone screws are often blasted with a powder comprised of spherical microsized glass beads, which peens the surface to impart a smooth, consistent satiny finish.

Abrasive Types

Abrasive particles can be as large as 250 microns, such as crushed walnut shell for paleontological applications involving fossil cleaning, but most medical applications apply abrasives from 10 to 150 microns, with an emphasis on the smaller end, because the parts are usually small and a high level of precision is critical. "A lot of stent manufacturers want 17.5- to 25-micron abrasive," Byrne said.

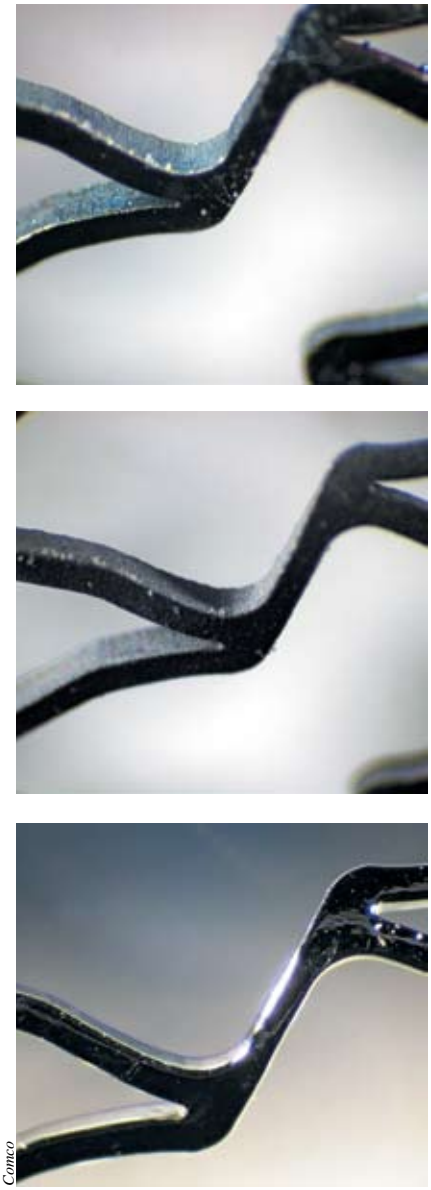
He added that, in general, the larger the abrasive, the more aggressive it is. The level of aggressiveness also depends on the air pressure being used to deliver the abrasive, which ranges from 40 to 160 psi, and on the size of the nozzle opening, which ranges from 0.018" to 0.060" on a typical microabrasive blasting machine and up to 0.125" on a microabrasive production blaster.

Manufacturers tend to blast medical polymer implants with various types of hard, blocky and sharp abrasives, such as silicon carbide or aluminum oxide, to remove difficult burrs and aggressively impart the required finish. However, a relatively soft abrasive for finishing polymer implants is sodium bicarbonate, commonly known as baking soda. In addition to being beneficial for medical applications because it's water soluble, the abrasive has a shape suitable for cutting or abrading. "It makes a very good abrasive because the individual particles are shaped like little knives," Byrne said. "They're very sharp."

While some implants need a rougher finish for proper tissue adhesion, other medical devices require a smoother, more uniform finish. When that's the case, such as for a titanium bone screw, a powder comprised of spherical glass beads from 35 to 50 microns is available that has the effect of peening the surface. This provides stress relief and imparts a consistent matte finish. "It doesn't polish the surface to a high shine, but it does give it a satin finish," Byrne noted.

Part of the Process

Sometimes microabrasive blasting is only part of the processing performed after machining to achieve the required surface finish. That's usually the scenario at Relucent Solutions LLC, a Santa Rosa, Calif., contract manufacturer that focuses on processing stents. According to Steve Parmelee, the company's director of process development, the majority of stents are made of nitinol (NIckel TItanium Naval Ordnance Laboratory), a family of intermetallic materials containing a nearly equal mixture of nickel and titanium that is described as having shape memory and superelasticity. The company also processes stainless steel and cobalt-chromium stents, as well as other parts.



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These images show a magnified section of a nitinol stent before microabrasive blasting (top), after blasting (middle) and, finally, after electropolishing.

How Relucent processes a stent depends on the application. (A stent is a short, narrow tube often in the form of a mesh that is inserted into an anatomical vessel to keep a previously blocked passageway open.) "For an application that's going into the body for the life of the patient, you'd be concerned about corrosion and fatigue resistance," Parmelee said. "For a short-term implant, maybe it's just corrosion resistance."

The raw tubing that a stent is made from is cut with a laser, so the material has microscopic areas in its heat-affected zone where the metal's crystalline structure has been rearranged. This creates layers of oxide buildup that can be brittle. To eliminate any imperfections in the metal part, Relucent typically performs microabrasive blasting, chemical etching and electropolishing. Blasting or etching or both are needed before electropolishing because the oxide layers and discoloration that laser machining creates impairs the ability of electropolishing to create the desired finish. Relucent performs electropolishing on about 95 percent of its products using a variety of application-specific chemical solutions.

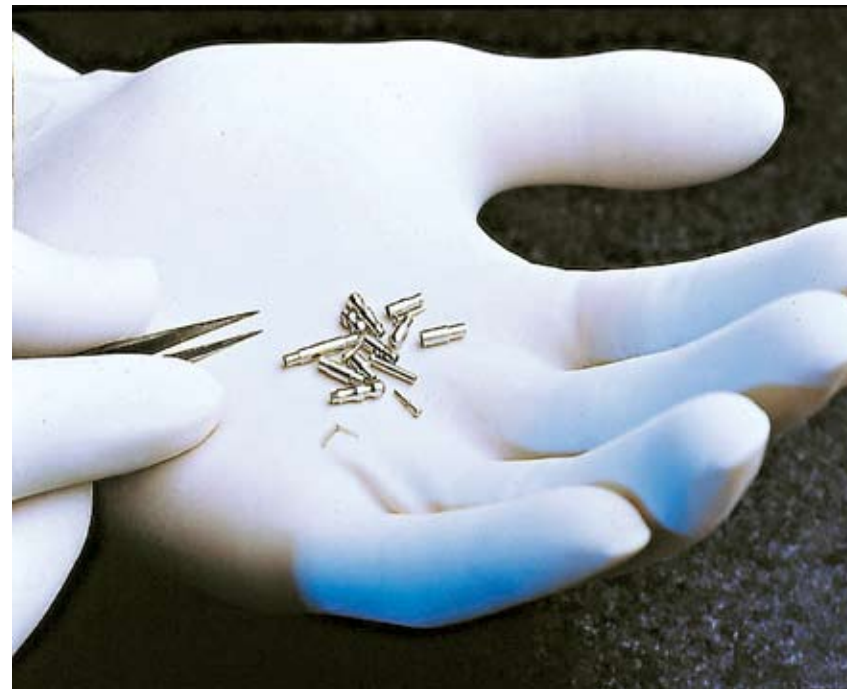
Parmelee compared the processes to various grades of sandpaper: "With abrasive blasting, you're using rough-grit sandpaper. With chemical etching, you're using medium-grit sandpaper. And with electropolishing, you're going in with fine-grit sandpaper and cleaning everything up to make it shiny, reflective and reduce the part's overall surface roughness."

Blasting, however, offers unique benefits compared to the chemical finishing processes, Parmelee noted. Blasting enables precise control of the metal-removal process whereas the strength of a chemical solution degrades over time as it absorbs ions, water and other elements. Although a blasting nozzle wears over time, it's a slow degradation that can be charted and handled accordingly. In addition,

chemicals attack all part surfaces fairly evenly, whereas blasting is able to independently target specific surfaces, such as the OD or ID, with some residual removal on a laser cut surface as well.

"When you want to do a repeatable process and employ statistical process control, blasting offers a tremendous advantage over the chemical-based processes," Parmelee said.

Comco's Byrne added that although microabrasive blasting is powerful enough to remove an oxide layer, it does so without changing the dimensional integrity of the stent. He also pointed out that process repeatability isn't operator-dependent. "The biggest advantage of the process is that once you've got it dialed in, an operator doesn't have to be really adept at working on parts to get a repeatable result every time."



Johnson Matthey Medical Products

A selection of platinum micro medical components produced by Johnson Matthey Medical Products.

Finish Requirements

Rather than target a specific surface finish measured in R_a, Relucent focuses on removing a certain percentage of material, from the low single digits to as high as 30 percent for an "absolutely pristine polish," according to Parmelee. The ultimate goal, he noted, is to move toward a quantifiable measurement for surface roughness. Relucent is able to measure that via white-light interferometry, a process that uses the interference of light waves for precise surface measurement. However, customers rarely specify an exact finish. Parmelee said: "It's easy for me to ask, 'What are your surface finish requirements?' Especially when working with a startup, they don't have a team of people to work on a project like that. So it is much more secure or safe for a customer to say, 'we want X amount of removal because, basically, we've done that once and it worked.'

"The name of the game is to find the minimal amount of removal that gives you the optimal surface finish," Parmelee added. "That's really where the rubber meets the road for us."

That's Precious

In contrast, Johnson Matthey Medical Products, San Diego, processes all the microcomponents it manufactures to specific R_a surface finishes. The most common specification is 32µin. R_a, with a large percentage down to 16µin. R_a, which is the finest available for internal surfaces. The company can achieve a finer finish on exterior surfaces. "It depends on the part geometry, but 8µin. R_a is something we've been able to achieve with no problem," said Jyrki Larjanko, engineering manager.

The company measures surface finishes directly from the material, even for parts smaller than 0.010", with a specially designed profolometer.

Because its parent company is a major platinum broker, Johnson Matthey Medical Products machines many parts from platinum, whether nearly pure or alloyed with iridium. The most common platinum alloy it machines contains 10 percent iridium. Other metals the company machines include 99 percent gold, nitinol, titanium and stainless steel, such as MP35N. The company is also conducting research on Biomed 1000, a radio-opaque alloy containing palladium. The alloy doesn't contain platinum and has a lower per-ounce price but is capable of meeting the mechanical and physical properties of platinum-based materials.

Platinum is desirable for making implantable parts for several reasons. First, it is biocompatible and not susceptible to being corroded by a body's fluids. "The body just won't know it's there," Larjanko said. "And platinum can be inside a body forever."

Also, similar to gold, platinum is an ideal metal for making cut, or marker,

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Relucent Solutions LLC
(800) 630-7704
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bands. These bands enable doctors to see where the tip of their tool is via a radioscope when doing noninvasive work in a patient. "Platinum glows fluorescent inside your body," explained Larjanko.

Third, the metal's high conductivity is beneficial for a pacemaker's leads attached to a heart. "The batteries inside the pacemaker last longer when the electricity flows through platinum because it has low resistance," he said.

But platinum won't react to chemicals, so microabrasive blasting is generally the most suitable finishing process. "Electropolishing won't do any good on platinum," Larjanko said.

Besides blasting a part to achieve a surface finish requirement, the company blasts parts to increase adhesion before it deposits an 8- to 10-micron thick titanium-nitride coating, which increases a part's surface area and enhances conductivity. Larjanko noted, however, that the coating's appearance and properties aren't like the gold-colored TiN coating seen on cutting tools. "It looks like the part was smoked," he said. "The coating is widely used in the pacemaker industry to optimize battery consumption."

Chips produced during conventional machining are recycled, but the minimal amount of material removed during blasting is not worth reclaiming.

Johnson Matthey Medical Products

The left side of this part shows the machined surface without further processing, the middle is coated with titanium nitride, and the right side was blasted with microabrasives to impart a textured surface.

Pricing Issues

What's unusual about ordering components made of precious metals is that in addition to being invoiced for the parts, Johnson Matthey's customers are charged for the metal content based on current market value. To avoid pricing volatility, customers buy a quantity of platinum, for example, from Johnson Matthey at the beginning of the fiscal or calendar year and subtract from that quantity as orders are filled. "Hopefully, they're buying platinum at a good price," Larjanko said. "It's been a roller coaster the last 5 years, from being below $1,000 per ounce troy, it's gone to $1,300 and then dropped to $1,200 in a matter of weeks. That drives people crazy."

However, raw material costs keep the number of shops machining precious metals to a minimum. A shop also needs a security system for its inventory. "A lot of machine shops don't feel comfortable holding a large inventory of platinum," Larjanko said.

Whatever an implant is made of, the raw material is just one of three main contributors to successful product performance, according to Relucent's Parmelee. The other two are component design and surface finish. "Of the things you can control as a stent maker, the biggest thing you control is surface finish." △

Advancing microabrasive blasting

Microabrasive blasting is sometimes called "pencil blasting" because the operator holds the blasting nozzle like a pencil. Fixtured blasting equipment is also available, such as the LA3200 Advanced Lathe from Comco that works by propelling abrasive and air out of up to five nozzles aimed at a part rotating on a spindle.

"The lathe takes the human element out of processing parts in a production environment," said Patrick Byrne, Comco's marketing manager. The operator loads the tooling and selects the program, and the lathe then checks for errors before starting the blast cycle.

He added that a computer controls up to four axes—X, Y, Z and W—in a coordinated motion, and the nozzles are mounted on a blast head that moves along the X and Z axes. This enables the lathe to trace complex contours even on noncylindrical parts, directing the abrasive stream accurately while adjusting speed and acceleration. "If there is a change during the process, the computer knows that and automatically does it when it is moving onto a different section of the part," Byrne said. "And it will do that exact same routine for literally an infinite number of parts."

Comco

Comco's LA3200 Advanced Lathe integrates microabrasive blasting with a machining platform to facilitate stent surface conditioning, for example, on a production basis. Inset: The lathe's Engineering OD blast head has 13 adjustments for precise alignment of the nozzles.

The lathe's Engineering OD blast head has 13 adjustments for precise alignment of the nozzles during prototype and development work. Once correctly positioned, a fixed head can be fabricated for production. According to Comco, the set positions of the fixed head prevent the operator from accidentally changing nozzle alignment. The blast head's quick-change feature enables prompt switching from OD to ID blasting.

—A. Richter