MAKING MEDICAL PARTS

Medical-component finishing options.

Smooth Operators

► BY GARY WARD

Savvy manufacturers constantly address and re-assess various production processes to meet dynamic market demands, be they just-in-time manufacturing, environmental issues or systems automation. But for a medical-device manufacturer, the added pressure of adhering to strict U.S. Food and Drug Administration guidelines and cost-cutting demands from managed-care organizations (MCOs) only renders the job more difficult.

Makers of artificial joints, fracture-management devices and surgical tools face unique hurdles, such as cost-effectively achieving the optimal surface finish. Although a few manufacturers reduce costs by producing parts with a lower-quality surface finish, that's not an option for the vast majority. These manufacturers painstakingly review and compare various surface-finishing techniques, media and compounds in order to maintain process control and meet FDA guidelines—a challenging task.

This article examines various finishing options available to medical manufacturers to help them succeed in this endeavor.

Handwork vs. Mass Finishing

Most medical devices, implants and surgical tools start out as raw forgings made from stainless steel, as well as titanium, nickel-cobalt and other exotic alloys. After the piece is descaled, it is machined to meet the proper dimensions. Then the part is either finished manually or mechanically to meet the final surface-finish requirement.

Manufacturers whose part production entails a lot of handwork, such as air blasting, abrasive belting or manual buffing, increasingly may find that these processes are more costly than the market will bear. Hand finishing often costs more than mass finishing and generates costly health claims, such as those for carpal-tunnel syndrome.

With increased pressure from MCOs to reduce costs, many medical manufacturers are re-evaluating processes to reduce or, when possible, eliminate handwork from the finishing process. Plus, mass finishing can improve the consistency and repeatability of the desired finish. Although hand buffing can produce a finish of 1 R_a or less—compared to the 2- or 3-R_a finish produced by mechanical methods—only a trained eye can see the difference.

Optimal Mass Finishing

Medical manufacturers employ many types of mass-finishing methods. The most common are circular vibration, centrifugal-disk and barrel finishing, drag finishing and shot peening.

The most popular mass-finishing machines are vibratory bowls (Figure 1). They employ a spiraling and oscillating action that causes the finishing media and parts to spiral around the bowl. Vibratory bowls can remove heavy burrs, sharp edges and grind lines, and finish multiple parts simultaneously. This type of finisher is often chosen for its ability to internally separate and unload parts.

Though less popular than circular vibrators, centrifugal-disk finishers offer

Many medical-part manufacturers use mass-finishing equipment to meet stringent requirements.

All photos: USF Surface Preparation Group

an abrading performance that's seven to 10 times higher. A centrifugal-disk finisher is used mainly for removing large burrs or radiusing small- to medium-size parts. Surface finishes from 6 to 10 R_a can be achieved with the proper media and compounds.

As the name implies, centrifugal-barrel machines also utilize centrifugal force. These machines combine two rotational motions to produce high gravitational forces that multiply the weight of the abrasive media and the parts being processed by up to 25 times the static weight of the total mass. Having an average volume of ¼ cu. ft. to 6 cu. ft., and a workload capacity of 50 to 60 percent, centrifugal-barrel finishers are often used when processing lightweight, small- to medium-size parts. The process imparts finishes that appear almost buffed.

Another common mass-finishing method is drag finishing, which involves attaching components to special fixtures and "dragging" them in a planetary motion through a bed of grinding or polishing media. The design of a drag finisher ensures that parts cannot impinge on each other.

Shot peeners also offer unique advantages. By bombarding the metal surface with steel shot, ceramic beads or glass beads, peening optimizes the performance of medical implants. In addition to increasing fatigue life, shot peening produces a textured surface that stimulates bone growth and augments adhesion of the implant to the surrounding bone.

Media Selection

As with mass-finishing equipment, a variety of media is available.

Most media are a blend of abrasive grit, such as aluminum oxide or silica carbide, and binder. Together, the grit and binder create a uniform shape and consistency. The two most common media are ceramic and plastic.

Ceramic media are bound by river clay, kaolin clay or porcelain, whereas plastic media are usually bound by urea-formaldehyde or polyester. In addition, dry-polishing media have a place in medical manufacturing. Each type has its advantages.

Figure 1: Vibratory bowls—the most popular mass-finishing machines—employ a spiral and oscillating action, causing the finishing media and parts to spiral around the bowl.

Plastic media are often used for deburring and producing finishes that were formerly hand-buffed (Figure 2). Plastic media resist breaking and can produce finishes as fine as 2µin. Because of their fine, lightweight profile, plastic media also are an excellent choice for economical surface finishing.

Ceramic media remove heavy burrs and flash, and provide a smooth, uniform finish. For medical devices, the addition of silicon carbide helps avoid contamination.

While not as common, dry-polishing media, like walnut shells and treated corncobs, eliminate hand buffing and help impart high-luster finishes at a low cost.

The general rule for choosing media is the higher the abrasive content the lower the binder content, which, in turn, translates into rapid decomposition during tumbling. This decomposition, or attrition, is desirable because it results in an abrasive grit that scrubs and rubs away the part's rough surface.

For medical manufacturing, the FDA has approved the following media: steel shot and grit, stainless steel cut wire, ceramic and glass beads, and aluminum oxide. Monitoring the type and concentration of the compound helps control the overall manufacturing process.

Abrasive compounds, composed of synthetic wetting agents, water conditioners and various abrasives, give additional metal-removal power to the media. And, the compounds help clean the parts and the machine's tub, help emulsify oil and grease, and condition the water. Ultimately, these compounds improve the part's color and surface finish.

Process Control

Process control not only involves the equipment, but also the compounds, media and workpiece itself, as well as how they interact. Like many things, process development is often a matter of trial and error. The ideal situation is for the manufacturer and supplier to work side by side in a sample process lab, where the manufacturer brings the workpiece and the supplier addresses the manufacturer's goals through a

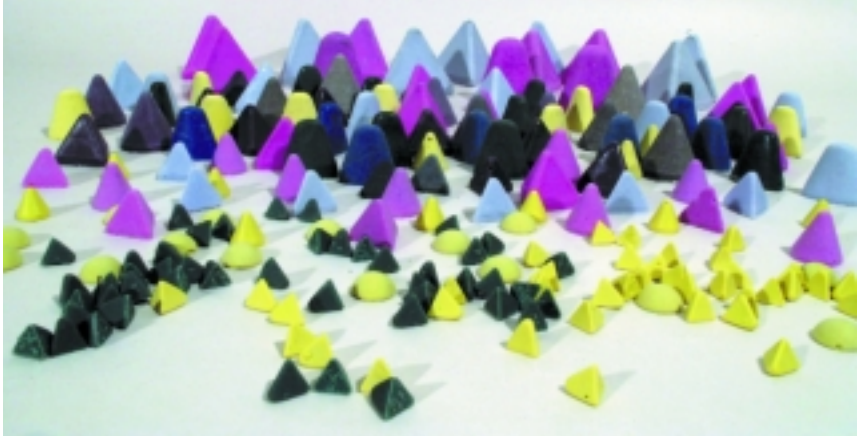

Figure 2: A selection of plastic media, which resist breaking and can impart a surface finish as fine as 2µin.

Do's and Don'ts of Media Selection

When deburring medical parts, proper media selection is critical for cost-effectively achieving the desired surface finish. The following is a list of do's and don'ts to keep in mind when choosing the media.

DO:

- ❍ Use large media for rapid burr removal, provided the finish is not important.
- ❍ Use small and well-worn media for fragile parts and when a fine finish is required and rapid cut-down is not needed.
- ❍ Use a size or shape that won't lodge in holes or recesses.
- ❍ Use more small and less large media when slots and holes dictate the use of two sizes.
- ❍ Choose a media size that can be screened or separated from the parts.
- ❍ Use three to five pieces of media to one workpiece by volume for general ferrous work. By increasing the ratio of media, the finish will be finer, if all other factors are constant. Softer metals require a higher ratio of media to parts.
- ❍ Have a total load (media and parts) of 60 to 75 percent of the barrel's capacity (approximately 90 percent for vibratory machines).

DON'T:

- ❍ Use large media for fragile parts.
- ❍ Use media with sharp edges if a low rhythmic average is desired. The R_a value is the part's average surface finish based on its measured peaks and valleys. The lower the R_a, the smoother and more reflective the surface.
- ❍ Forget to rinse the media after it has been used before placing it in a storage bin.
- ❍ Fail to screen media after use, so worn pieces can be channeled to their respective bins.
- ❍ Use a high volume of parts if nicks or scratches are appearing.
- ❍ Use large amounts of water with abrasive compounds if the fastest action is desired.
- ❍ Mix an acid compound with an alkaline compound, since this can create hazardous pressures and bases.

—G. Ward

consultative process that covers issues such as surface finish and part tolerance.

One solid practice employed by savvy manufacturers and suppliers is "tagging and bagging." This is where one raw part and one finished part are tagged and bagged as representative cases to use as benchmark baselines. Combined with regular service readings and proper record keeping, this process makes it easier to see how an alteration—from tooling to staff changes—can cause production and/or cost variations.

Although it can be time consuming and documentation-intensive, many medical manufacturers often find they need to make a process change. The reasons for making a change vary. They include the need to reduce costs, upgrade quality controls to improve the consistency of a finish, or eliminate a process that generates wastes or chemicals that involve costly disposal expenditures.

Changing a process can take anywhere from several weeks to a year. It's quicker and easier to get a new process—or part—reviewed and approved by the FDA than to change a process. When a company changes an existing process, it typically forms a committee that oversees the project prior to submittal to the FDA. In situations where numerous suppliers are involved, it can be difficult to resolve conflicts if there are difficulties in the FDA review process.

Manufacturers may find it more cost-effective and efficient to purchase their media, compounds and equipment from a single source that will be accountable for the entire process. If a supplier has a limited product line and offers limited services, then the available solutions and resulting manufacturing process will often be limited as well.

Choosing a supplier that offers a wide variety of equipment, media, compounds and deburring expertise is a prescription for success in today's highly competitive medical-device marketplace.

About the Author

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