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MICROMACHINING

Meeting the Minimally Invasive Challenge

As components become smaller, the machining obstacles multiply for manufacturers.

William Leventon

To lessen the impact on patients, minimally invasive surgery relies on small components—in fact, "the smaller the better," says Jyrki Larjanko, product manager for Johnson Matthey Medical Products (San Diego), which machines a number of minimally invasive parts.

Like an intricate part, the job of machining minimally invasive components includes many details. The manufacturer must choose a machine and its proper functions, select a material, finish the parts, and then verify that the parts meet all requirements. Complicating these tasks is the diminutive scale of the parts used in small-incision surgical procedures.

Photo courtesy of PRECISION MEDICAL PRODUCTS INC.

Keeping Tolerances Tight

Trocars and cannulae made by LaVezzi are used in laparoscopic surgery.

When machining tiny parts for minimally invasive surgery, one of the main challenges is holding extremely tight tolerances on part features. "The tolerances are a lot tighter because you don't have the forgiving nature of larger parts moving against each other," explains Al LaVezzi, president of LaVezzi Precision Inc. (Glendale Heights, IL), a company that machines many minimally invasive components for both manual surgical procedures and robotic surgery.

To understand what LaVezzi means, consider a normal pair of scissors. If the two blades don't interact smoothly, it takes more force to open and close the scissors; but it's easy enough to apply the additional force required. In contrast, it can be very difficult to apply the extra force required to move a tiny pair of scissors that isn't operating smoothly during a minimally invasive surgical procedure. Therefore, all the components of these tiny scissors are made very accurately to ensure smooth operation. Tolerances for components like this could be as tight as ±0.0001 in., LaVezzi says.

Tight tolerances must be held on these small parts machined by LaVezzi.

Material Trends

Because they're so tiny, many of today's minimally invasive surgical devices include high-strength materials such as titanium, cobalt chrome, and Type 17-4 stainless steel, as well as plastics like PEEK, Ultem, and Radel. "Small parts have thin walls, so you need more material strength in order for the parts to perform as if they had a lot of meat," explains Greg Murphy, CEO of Mark Two Engineering Inc. (Miami), a manufacturer of minimally invasive components in high- and low-volume processes.

On the downside, the high strength of these materials makes them harder to machine. As a result, there have been changes in the cutters used to machine minimally invasive devices. “In the old days, people used high-speed steel cutters,” Murphy says. “But today, it’s more common for us to use carbide cutters and cutters with high-tech coatings like diamond and titanium nitrate.”

Other disadvantages include the cost of some high-strength materials, as well as increased machining costs and time, according to Murphy. But for many manufacturers, benefits such as increased strength and reduced component weight outweigh the downsides.

Looking specifically at metals, LaVezzi sees Types 465 and 455 stainless steel gaining popularity among manufactuers of minimally invasive devices. Like other high-strength materials, however, these stainless-steel grades present machining challenges—for example, the creation of very small holes, which requires high spindle speeds. Fortunately, “the tooling manufacturers—the people who make things like drills and milling cutters—pretty much keep pace with the new materials,” LaVezzi reports.

Another material option for minimally invasive components is platinum. One popular combination among Johnson Matthey’s customers consists of 90% platinum and 10% iridium, according to Larjanko.

Micromachined parts for electrophysiology catheters, cardiac rhythm management devices, and neurostimulation devices can be fabricated as small as 200 µm—small enough to fit in the eye of a needle. Photo courtesy of JOHNSON MATTHEY

But platinum is extremely expensive, so Johnson Matthey is very careful in how it manages the material. For example, scrap parts and chips from the machining process are melted down to produce new platinum rods that are used in future machining operations. “Nothing gets lost,” Larjanko says. “We can’t afford to waste platinum.”

Due to the high cost of platinum, Johnson Matthey has introduced an alloy developed to replace the precious metal in many medical applications. Called Biomed, the alloy consists mainly of palladium, which is less than half the cost of platinum, according to Larjanko. In addition, he notes, the price of palladium isn’t nearly as volatile as that of platinum. “That’s a big plus for our customers,” he says. “They don’t like the uncertainty of the platinum market, because the volatility makes it difficult for them to do their budgeting.”

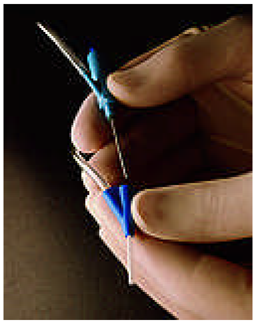
According to Johnson Matthey, electrical-discharge machining (EDM) processes can create Biomed parts with tolerances as low as ±0.0002 in. The material’s radiopacity makes it suitable for marker bands, which enables components made from Biomed to be seen with a fluoroscope during minimally invasive procedures.

Biomed is gaining popularity among manufacturers of new minimally invasive surgical devices, Larjanko reports. But he adds that most makers of existing devices are sticking with platinum to avoid the difficulties of a new FDA approval process.

In addition to metals, a few of Johnson Matthey’s customers are using FDA-approved plastics for minimally invasive parts. The machining of plastics is very different from the processes used on metals, according to Larjanko. Differences include the tooling and coolants used to machine metals and plastics, as well as machine speeds and feeds. Johnson Matthey uses Swiss screw machining on these plastics rather than EDM, which can only cut conductive materials, Larjanko notes.

Parts of the Process

Before machining can begin, pieces of metal or plastic must be properly fixtured. Precision Medical Products Inc. (Denver, PA), a manufacturer that uses special CNC honing equipment to make tiny cutters for minimally invasive eye surgery, uses fixturing that consists of a hardened steel plate dotted with V-locators with angled interiors that position and center workpieces. This arrangement allows for the machining of hundreds of parts at a time, according to George Weaver, vice president of marketing for Precision.



An ophthalmic vitrectomy cutter with an infusion catheter is delivered packaged and sterile. Combining plastic and metal processes can ensure a successful and efficient new product launch. Photo courtesy of PRECISION MEDICAL PRODUCTS INC.

When it comes to the fixturing and manufacturing of minimally invasive components at Mark Two, Murphy says that "most of our stuff has to be looked at under a microscope, which makes it different from manufacturing normal medical components." In addition, consumable tools such as drills, mills, and grinding wheels must be in the miniature to subminiature range. Instead of half- or quarter-inch end mills, for example, Mark Two uses end mills down to 0.005 in. in diameter to machine parts for minimally invasive devices.

Minimally invasive components are so small that it's difficult to fixture the parts multiple times in order to machine different facets of the design. "So you want to complete the parts in one operation, if possible," LaVezzi says.

Therefore, LaVezzi's company recently purchased another five-axis Willemin-Macodel unit that can machine all the facets of small parts in a single operation, completing everything but common secondary tasks such as deburring and polishing. Such machines cost half a million dollars or more, LaVezzi says, but they reduce machining costs and time by reducing the number of steps required to make small parts.

At Johnson Matthey, EDM, laser, and Swiss screw machines allow the company to make tiny parts for today's minimally invasive surgical procedures. The latest machines can also hold the supertight tolerances required by customers. "Some customers are now asking us to hold tolerances of ten thousandths of an inch," Larjanko says. "Ten years ago, machines couldn't do that. But the newer machines we're getting here can hold tolerances of ±0.0003 in."

The latest machines offer other advantages as well. For example, Larjanko notes, some of the newer EDM machines can produce parts without burrs or recast layers, thereby eliminating secondary operations. In addition, new machines have faster processing speeds, which reduce cycle times.

Machine programming has also gotten faster and easier. "You used to have to sit down next to the machine and spend three or four hours writing the program" for a job, Larjanko recalls. "Now we can just download the customer's design into the machine and the software will generate all the code by itself."

Along with the advantages of the latest machines come a few downsides. For one, new machines are more expensive than their predecessors, Larjanko notes. They are also very sensitive to vibration from outside sources such as large trucks passing by a plant. "You needed to anchor the old CNC machines to the concrete floor," Larjanko says. "But you can't anchor the new machines because vibrations would throw off your dimensions and tolerances."

Some manufacturers may be able to lessen these problems by reducing their overall machining load. Mark Two has managed to do so by developing a technique to cast complex parts.

Sidebar:
Novel Process Aims to Cut Machining Requirements

Finishing the Job

After machining, components can be put through a variety of finishing processes such as electropolishing, which dulls sharp edges and produces a shiny surface finish. In addition to electropolishing, Mark Two offers bead blasting for surfaces that shouldn't shine. Murphy says shiny device surfaces can be a problem in the operating room, where surgeons can be bothered by reflections of high-intensity lights.

Mark Two is also assessing REM surface finishing, which is used on some small medical parts. REM is a chemical-mechanical process developed by REM Chemicals Inc. (Southington, CT) that removes the “peaks” of a finish without affecting the “valleys” in order to produce smoother, flatter surfaces.

To assess finishes, a profilometer is generally used to measure the profile of a surface and quantify its roughness. However, at Precision, Weaver found that no profilometer was available to measure the finish on its super-small ophthalmic cutter. So the best that Precision could do was validate a process for producing the desired finish and then stick with that process, Weaver explains.

At the end of the manufacturing process, components are cleaned to remove metallic fines or chips, as well as machining fluids and other contaminants that may have found their way onto the parts. Various cleaning methods can do the job, but their effectiveness is limited by air bubbles that form in small blind holes and cavities.

To eliminate these troublesome bubbles from the process, Omni Components Corp. (Hudson, NH), a company that machines stainless-steel tubulations for the handles of cauterization devices that can be used in minimally invasive surgery, uses a system featuring a vacuum pump. The process removes all air from the work chamber, allowing cleaning fluid to flow into holes and cavities. “Even parts with very small blind holes can be flushed effectively under that vacuum condition,” says Rick Holka, president of Omni Components.

Checking the Work

A key to successful machining of minimally invasive components is an inspection system capable of checking very small dimensions. Such a system might require both a touch probe and machine vision equipment, LaVezzi notes.

Similar to the manufacturing process, it is difficult to fixture a small part for inspection. Therefore, LaVezzi says,
“you don’t want to measure one facet of a part and then fixture it in another way to measure another facet of it. You want to do as much measurement as possible in one operation.”

Helpful in this regard are multifaceted inspection machines that can take measurements with both probes and vision systems. So is a tool LaVezzi calls a rotary dynamic probe, which can be inclined at any angle to take measurements of a fixtured part, eliminating the need to fixture the part multiple times to measure different features.

Touch probes are larger than some of the parts machined by Johnson Matthey, so the company often relies on vision-system inspection, according to Dan Faupel, quality manager at the firm’s San Diego facility. Vision systems at the Johnson Matthey plant can magnify objects up to 1000 times and offer measurement accuracies of ±0.0005 in., Faupel reports. “Some of the parts we make have holes with diameters smaller than a human hair (in the 0.006–0.007-in. range), so a vision tool is pretty helpful in checking those dimensions,” he says.

But the advantages of vision systems come at a high price. Johnson Matthey has four machine vision systems that cost about $40,000 and another roughly twice as expensive, Faupel says. He adds that optical comparators, another type of inspection device, are much less expensive than machine vision systems, costing about $15,000.

Moreover, certain part features and configurations aren’t ideal for vision inspection because of the importance of adequate lighting. For example, vision systems can have difficulty measuring hole depths and checking holes with diameter transitions, Faupel says.

At the facility of Precision, operators use a noncontact optical system to check the dimensions of the company’s tiny ophthalmic cutters. Data logged during the inspection process helps Precision meet what Weaver calls the biggest challenge in machining the parts: holding tolerances measured in ten-thousandths of an inch.

To maintain the required tolerances, Precision relies on monitoring systems based on statistical process control (SPC), which is a tool that allows users to spot trends in the machining process. These trends can be seen by viewing charts based on multiple measurements taken during the process. Automatically created by a DataMite data-logging system, the charts show whether a process is in control or drifting out of control and in need of adjustment. In addition to providing critical help to plant personnel, SPC data can be supplied to customers “so they can see precisely what they’re buying,” Weaver says.

Conclusion

Due to the size of the current crop of minimally invasive surgical components, the term *machining* is often replaced by *micromachining*. But Larjanko is starting to hear a new term: *nanomachining*. “We’re not quite there yet,” he says, referring to the state of the technology. “There are only a few very expensive experimental machines for nanomachining.” But as minimally invasive components continue to shrink, it’s probably only a matter of time before many manufacturers are tackling the problems—and reaping the rewards—of machining on a scale still smaller than that of today’s smallest parts.

***William Leventon** is a freelance writer based in Somers Point, NJ.*

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