cover story

BY BILL KENNEDY, CONTRIBUTING EDITOR

The Power of Light

A Cleveland manufacturer applies the power and precision of lasers to machine complex medical parts.

Medical technology is advancing at a nearly incomprehensible speed. Researchers continually devise new lifesaving treatments, as well as the implants, devices and tools needed to implement these treatments.

Medical components are becoming ever smaller and more precise, and they are made from materials that pose unique challenges for parts producers.

One company that has enjoyed great success meeting these challenges is Norman Noble Inc.

The Cleveland manufacturer was founded just after World War II. Initially, it turned and milled munitions-related components. Today, more than 90 percent of its work involves medical parts.

During its 6 decades of existence, Norman Noble has developed expertise in nearly all aspects of manufacturing. Its metal-removal capabilities include CNC turning and milling; wire, sinker and microhole EDMing; and abrasive waterjet machining. One of the keys to handling increasingly complex medical products is the company's laser-machining department, which boasts more than 120 machines.

Comprehensive metal-removal proficiency, coupled with heat-treating, stress-relief, coating, plating, inspection and packaging skills, enable Norman Noble to serve as an integrated single-source supplier and a

All images: Norman Noble

partner in the design-to-manufacturing process.

Chris Noble, vice president, said: "We do engineering concepts and prototypes, build for clinical trials, and move from there to ISS—initial shelf stock—of a product. Then we support the market launch and whatever share of the market the customer wants, be it 10 percent or 90 percent. We haven't come across a product that we could not fully support."

Manufacturing the products requires the company to have knowledge of a dizzying variety of materials and processes. Among the products Norman Noble makes are a 1.00mm-OD, 0.50mm-ID, 316-L stainless steel medical washer with 0.20mm holes, made via microhole EDMing; a 6061 aluminum bone-saw guide that involves milling and drilling, microhole and wire EDMing, laser etching and hard anodizing; and a 0.07mm-thick titanium cable sheath with a 0.25mm-dia. hole made via CNC milling and wire EDMing.

While most of the parts are small, some are downright tiny, such as a titanium part intended to be implanted in the eye for treatment of glaucoma. The part, about 0.001" in diameter, is turned, drilled and slotted on a customized Swiss-style CNC lathe.

Because Norman Noble has expertise in practically all metalworking technologies, it can offer a unique perspective on which is the most productive for a specific job.

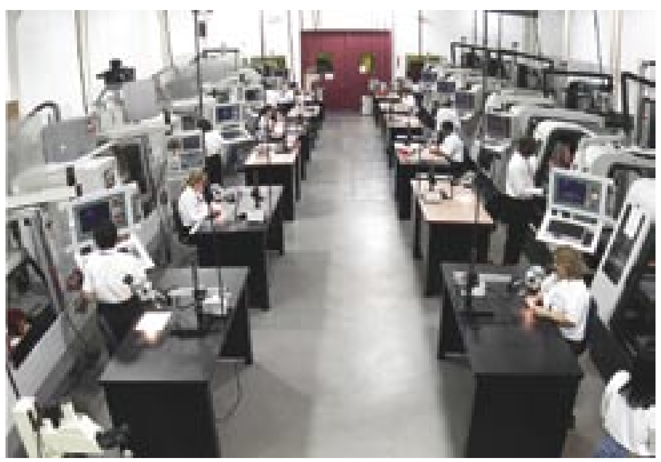
Often, the most productive method is laser cutting. Norman Noble uses lasers to cut, weld and etch. Chris Noble estimates that over half the parts the company makes involve some form of laser processing.

Because laser machining puts no cutting force on a workpiece and minimizes fixturing requirements, it permits the production of the small, flexible, close-tolerance parts required in many medical applications.

The decision to use a laser rather than another type of machine is governed by the same requirements faced by any metalworking shop: to meet the customer's dimensional and quality specifications in the fastest and most cost-effective way possible.

Different Lasers Used

With a laser, an energy source such as a flash lamp stimulates a solid-state or gaseous lasing medium. The medium absorbs some wavelengths of light and emits a coherent, powerful stream of other wavelengths. A lens directs the output to a spot on the workpiece, where the beam melts a small section. An assist gas blows away melted material.



With more than 120 lasers, Norman Noble has one of the world's largest laser-machining operations.

For most of its precision work, Norman Noble employs solid-state Nd:YAG (neodymium:yittrium aluminum garnet) lasers. The company also uses more powerful CO_2 lasers for cutting thicker material.

While laser energy in some wavelengths actually vaporizes material, the company's laser R&D department manager, Jeff Miller, said the lasers Norman Noble applies generally ablate material. He compared the cutting action to that of an acetylene torch.

The laser cutting point "is very, very small and very, very precise," he said. Typically, the cutting-point diameter is about 0.0007" and precision means holding a ±0.0002" tolerance, with kerf widths narrower than 0.001". Miller said that the laser beam itself is not hot, but the temperature at the cutting point can range from about 1,100° C to as high as 4,000° C, depending on the melting point of the material being cut.

Laser output may be continuous or pulsed on and off. Pulsed operation permits higher peak powers for a given laser wattage. The majority of Norman Noble's lasers are flash-lamp-pumped, which, Miller said, provides the most accurate control.

A number of parameters control a laser's cutting performance. The pulse length of the beam can range from a few microseconds to several milliseconds. Shorter pulse lengths are effective when making detailed cuts in thin materials, while longer lengths provide greater pulse energy for cutting thicker materials. The frequency of the pulse also can be adjusted to control the speed and quality of the cut. Pulse frequencies for welding might be one cycle per second, while cutting frequencies can be 10,000 cycles per second or more.

At Norman Noble, most laser machining is done with a fixed laser and moving workpiece. The workpiece feed rate helps determine surface finish. "If you're running a certain frequency, say, 500 pulses a second, and a 10-ipm feed, you can figure out how far apart those pulses are going to be," Miller said. "Triple your feed rate, your pulses just got that much farther apart. So it has a direct impact on surface finish."

Why Laser?

Laser machining offers a variety of advantages when producing the small and often flexible components common in medical-parts making. Cutting forces on the workpiece are zero, minimizing distortion and fixturing concerns. The concentrated beam creates a relatively small heat-affected zone in the workpiece. And because the cutting tool is a beam of light, there is no tool wear.

However, in lamp-pumped systems, the flash lamp degrades over time. Lamp life ranges from a couple of days to a couple of months, depending on factors like the lamp's power and the specific application.

Another consideration is the size of the heat-affected zone, which is directly related to the amount of energy that enters the material. "You can have too much energy," said Miller. "But if you've done your process development right, in an average Nd:YAG laser running a 0.001" kerf, you're going to see a 0.0001" to 0.0002" heat-affected zone."

Regarding the preconception that lasers are ineffective on reflective material, Miller said Norman Noble routinely cuts reflective materials, but doing so requires high energy density. He cited pure platinum, "which is very reflective, and we cut a lot of it. If your laser spot size is 0.0012", to be able to cut platinum you're going to need three times the energy within that 0.0012" spot that you would in cutting a stainless steel piece."

As an example of an application where laser machining may not be the preferred method, Miller named deep-hole drilling. When making deep holes with a laser, taper affects precision. "The thicker the material gets, the more taper you are going to see, and the greater the impact on your tolerances," he said. "Until you actually penetrate the workpiece, every pulse of energy that hits the material is coming back out the hole it entered. Every pulse that comes out is removing material all the way out the hole. You start getting a little bit of a volcano effect."

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Miller compared laser machining to other metal-removal processes. "As far as wire EDMing goes, if the material is 0.020" thick or less—and it's anything but copper—the laser beats it every time," he said. Wire EDM accuracy depends on how fast the machine runs. Operated slowly to produce the highest accuracy, the EDM can hold a tolerance of about ±0.0005". Laser machining, typically, provides an accuracy of ±0.0002" at "four to five times the throughput" of a typical wire EDMing application, Miller said.

Norman Noble laser-machines stents. A typical stent is made from 316-L stainless steel, is about 15mm to 35mm long, has an OD of about 1.2mm and a wall thickness of 0.008mm.

For a part that will be implanted in the human body, burrs are simply not acceptable. Miller characterized the burrs left after conventional machining as "firmly attached to the part. The material you've displaced is parent material. You're not going to be able to chemically clean the part and expect that ridge of burr to be removed."

Laser machining, on the other hand, leaves recast material, or dross, at the edge of some cuts. "Because you have developed oxides on the surface, the dross is not parent material," Miller said. "It's resolidified molten material that has been removed. Because it's full of oxides, it falls off when you chemically clean [the part]." The thickness of a typical accumulation of dross is 0.001" or less.

Stents and Lasers

Norman Noble first employed laser machining in the manufacturing of stents, the small tubes that are inserted in blood vessels and other bodily passageways to keep them open. The most familiar stents are those used to prop open arteries in the heart after angioplasty.

A typical stent is made from 316-L stainless steel, is about 15mm to 35mm long, has an OD of about 1.2mm and wall thickness of 0.008mm. Today's stents, unlike their predecessors, are not simple tubes. They incorporate complex patterns of slots and holes that may be 0.003" or 0.004" wide, 0.015" long and arrayed around the tube OD in every shape imaginable, Miller said.

Norman Noble first investigated using lasers to make stents in 1990. At the time, Miller, a veteran toolmaker, was sinker EDMing the parts. It was clear, however, that as stent geometries became more complicated it would be impossible to produce them via EDMing.

Miller said he and company president Larry Noble initially joked about using lasers. Later, though, after recognizing the technology's true potential, they acquired a laser machine and modified it to fit their needs.

In stent production today, a tube held in a rotating collet is fed past the laser source. After the pattern is cut through one side of the tube, it is rotated to cut the other sides. "If you have done your homework on your process development," Miller said, "you know how much energy it takes to pierce the first wall without damaging the second wall. The energy diverges once it goes through the first wall. It hits the back wall but it's not doing anything, because it's basically being spread out and absorbed."

Miller said a key to making precise patterns is to initially pierce the workpiece at a point away from the desired toolpath. "You enter waste material somewhere, feed out to your toolpath and cut your profile," he explained.

Millennium Focus

To maximize productivity and quality while reducing costs and lead time, Norman Noble builds its own laser-machining systems. "We don't build the laser itself," Chris Noble said. "The laser is off the shelf, but we integrate a number of custom components, including the CNC, software, optics and the controls for workpiece motion. Unlike contract manufacturers who have their laser systems built by outside integrators, we have the capability of buying the laser and adapting it to our specific needs."

This enables Norman Noble to reduce the lead time required when adding a new system from 6 or 9 months to 20 days.

The company recently put into operation a fifth generation of its laser-machining systems with the trademarked name Millennium Focus. Performance advantages over previous systems include much faster feed rates and the cutting velocity is constantly maintained throughout entire part programs, even those that include tortuous geometries with corner radii as tight as 0.0002" and kerf widths as narrow as 0.0004".

Norman Noble's laser R&D department manager, Jeff Miller, right, discusses laser machining with assistant manager Ray Suhy.

Miller said Millennium Focus lasers run at high frequencies and short pulse lengths, and "provide throughput three to four times that of standard systems. While a standard system typically holds a tolerance of ±0.0002", with the Millennium Focus system we are actually running some jobs right now that we are holding ±0.0001" all day." The improved throughput reduces costs for the customer, he added.

Meeting Multiple Standards

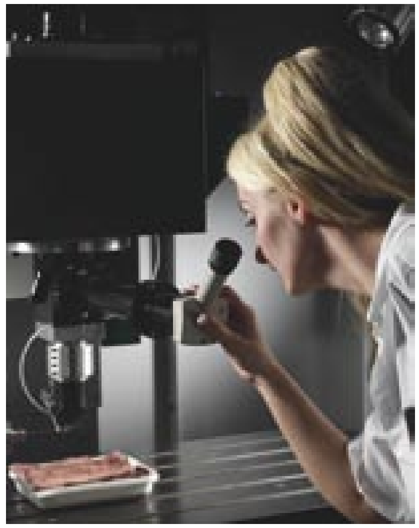
Norman Noble has achieved ISO 9001:2000 certification, as well as certification for ISO 13485:2003, the international standard for manufacturing medical devices and implants. For medical parts, the company also must meet stringent customer requirements and those of the U.S. Food and Drug Administration.

In many respects, FDA documentation requirements are tougher than ISO ones, according to Miller. "The detail is pretty extreme, and the FDA is very interested in production parts and validation of the processes," he said. "They want to know you have control of the process."

Norman Noble has a "lean team," a "yield improvement team" and a "continuous improvement team," all of which examine processes for opportunities to improve productivity and quality. "If a continuous-improvement effort changes a process, and it's a validated part, it absolutely has to go back to the FDA," Miller said. The customer may alert the FDA or the agency may work with Norman Noble directly. Regarding dealings with the FDA, "as long as you say what you do and do what you say, within the guidelines provided, you're golden," said Miller.

Innovation and Motivation

In light of its position as its customers' manufacturing design partner, Norman Noble continually works with breakthrough medical technology. "Five years ago, we set up our laser R&D department to promote the nonstent side of the business," Miller said. Some recent projects are "real interesting," such as R&D work with tiny 0.004"- to 0.005"-ID, 0.006"- to 0.007"-OD tubing.



Norman Noble's inspection capabilities include more than 80 optical microscopes, in addition to an array of video systems, comparators and coordinate measuring machines.

Although a lot of laser work involves tubular parts, Miller said many flat parts are laser-cut as well, such as blades and flat anchors. "We do a flat part that is 0.042" in diameter, cut out of 0.006"-thick stainless steel sheet, that has six 0.006"-dia. holes in it," he said. "We laser-cut, pierce the center and interpolate the holes."

Chris Noble said that every month Norman Noble gathers all its employees in groups and shares with them applications of the products they make. "We show videos and have suppliers in at times to give talks." He said the information is held confidential within the company, "but it lets the employees know what the end use is of this screw or that intricately cut tube."

For Miller, the challenge of making medical parts is complemented by the vital end use of the products. "It's exciting to know that you are part of many of these organizations that are devoted to saving lives. That is really cool," he said. △