from photonics.com: 08/01/2010
http://www.photonics.com/Article.aspx?AID=43367

Cut, Mark, Drill, Repeat

Laser Machining Drives Improvements in Medical Devices

Lynn Savage, Features Editor, lynn.savage@photonics.com

Increasingly, the medical devices used to support good health and provide emergency and long-term care are not being designed to sit on a rack or table next to a patient’s hospital bed. Instead, they are being made small and light enough to be clipped onto clothing, to be worn like a bracelet or badge, or to be implanted directly into the body. Ultimately, the aim of medical device design is to provide doctors and nurses with better tools that are always within reach, to improve the overall health of patients with treatments that have fewer side effects, and to keep people out of hospitals altogether, thus reducing health care costs.

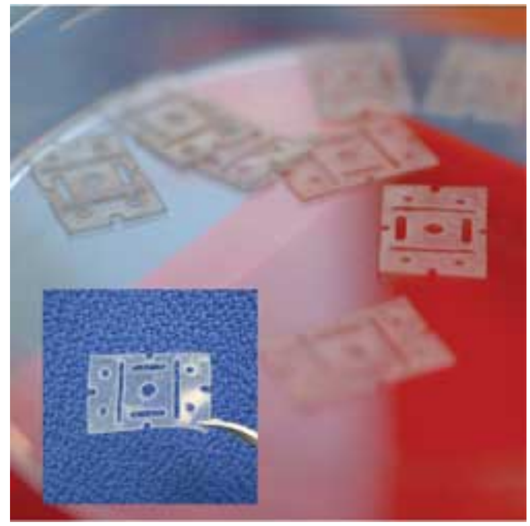
Some of the most common medical devices today are sensors that detect and read out biometrics such as blood pressure or sugar/insulin response and implants such as stents for helping keep open clogged or damaged arteries or tissues.

Once upon a time, medical device manufacturing consisted mostly of stamping sheet metal and pouring molten metal into molds. This type of manufacturing has not gone away, but it is being supplanted by new techniques – such as laser-based machining – that promise to achieve two chief goals: reducing the size of the apparatuses and increasing the use of novel materials inside them.

A wide variety of lasers are available to manufacturers, meaning that materials ranging from 1/4-inch sheet metal to thin-film polymers can be processed to precise tolerances. Courtesy of Laser Micromachining Ltd.

Efforts are under way to design sensors that can closely track health-related patient biochemistry and the effectiveness of pharmaceuticals and other treatments. Similarly, stents, novel artificial bone and other tissues, and inserts such as catheters and artificial retinas are continuously being redesigned. To make these sensors and inserts smaller, stronger and more effective, materials such as the shape-memory titanium-nickel are being tested and used. Manufacturers are finding that lasers can effectively work a wide variety of novel materials.

Contract manufacturers such as !%Resonetics LLC%! of Nashua, N.H., work with a multitude of materials, including polymers, glass, ceramics and ultrathin sheets of metals and alloys. They drill, cut, scribe and mark tiny device components and turn them into catheters, stents, dental implants and biosensors that help track diabetes and heart health. A relatively simple catheter once took weeks of tooling by hand or with large industrial machines, but now it can be created in a fraction of the time, using lasers to prepare the major components and finish the final product.



According to Nadeem Rizvi, co-founder and managing director of Laser Micromachining Ltd. in St. Asaph, UK, polymers and thin metals are the core materials used in most medical devices, but they don't paint the whole picture.

"The standard requirements of high quality, high tolerances and repeatable results have not changed and are not likely to." Nadeem Rizvi, Laser Micromachining Ltd.

"There seems to be a trend toward thinner materials with finer features and also a growing demand for devices with precision structures in combinations of materials (e.g., polymers on glass or thin coatings on different base materials)," he said. "There is also quite a lot of interest in completely new materials, such as biodegradable polymers for implants and tissue-engineering applications."

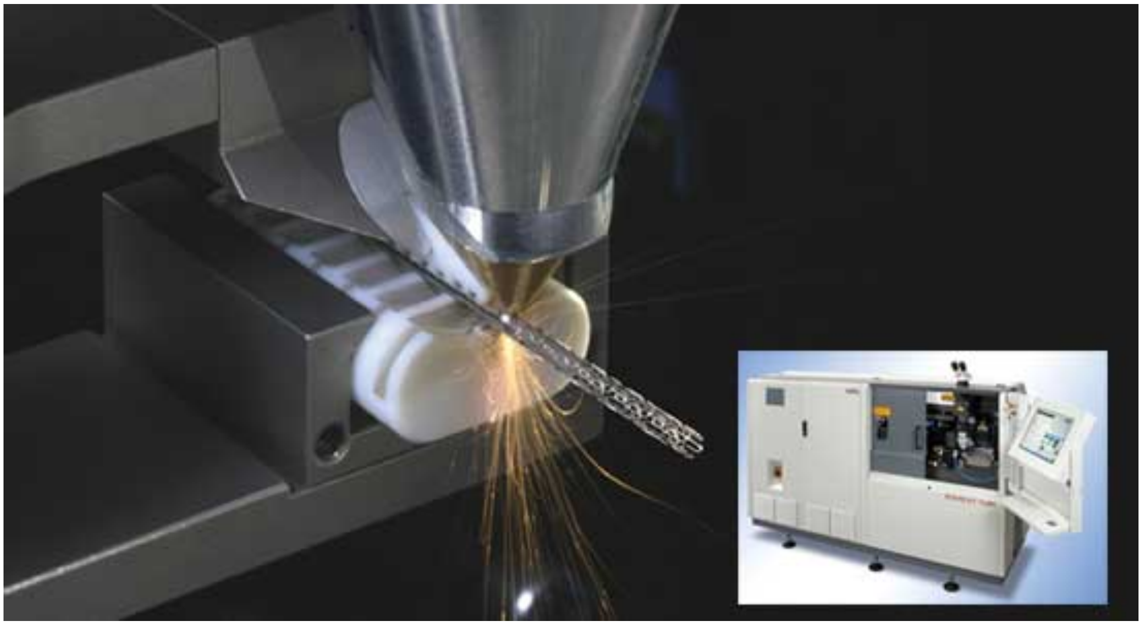
Drill, laser, drill

Among the multitude of steps that comprise medical device manufacturing, the key ones are forming the basic shape of each part; drilling or punching holes, notches and other shapes where needed; attaching the parts together; and marking all or some of the parts for later identification. Where large mechanical presses once were used to stamp out shapes from 1/4-in. sheet metal like a cookie cutter, lasers now can cut and trim ultrathin sheets of metals and polymers to very close tolerance. The difference between techniques has enabled metal tubes to shrink to such a small size that stents are now ubiquitously used in patients' arteries, ureters or similar tubular structures.

Similarly, laser-based welding, ablating and structuring, and marking or scribing all take the place of traditional manufacturing methods, while improving the form and function of the final product.

Drilling might be the most common manufacturing step improved upon by laser machining. Tiny holes in many medical appliances – for example, the via holes that transport fluids from one chamber to another in a portable sample analyzer – can be made microns in diameter and millimeters long. Traditional drilling techniques cannot match the performance of lasers in this regard.

Sintering, a process in which a material in powdered form is shaped and turned into a solid part via applied external heat, also is being matched up with lasers. Laser sintering, the 3-D equivalent of 2-D laser printing, can create medical components of very tiny size to very small tolerances.

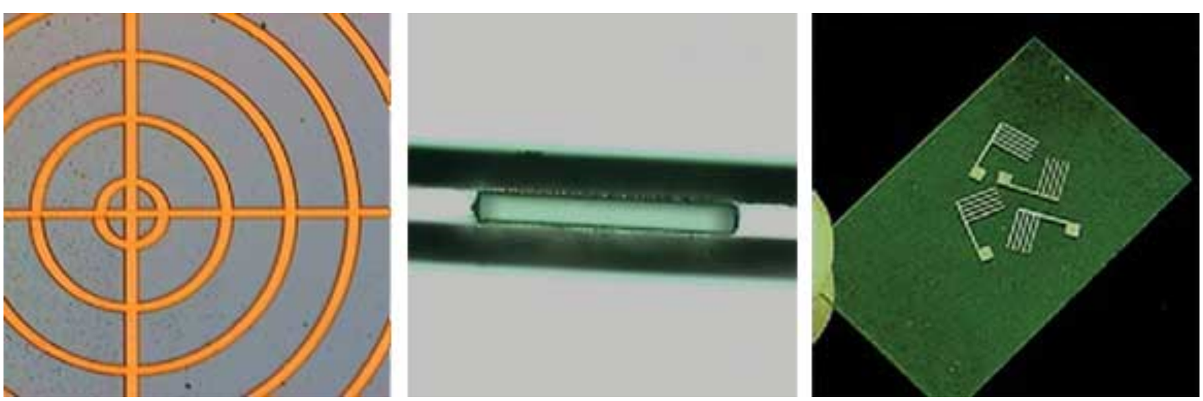


Systems such as Rofin-Baasel's Starcut Tube (inset) are used to manufacture precision-cut parts, including slender cylinders for stents and catheters. Courtesy of Rofin-Baasel.

"Lasers are quite a flexible tool, especially compared with stamping and other manufacturing technologies," said Dieter Mairhörmann, international sales manager (medico) for Rofin-Baasel of Starnberg, Germany. "Fiber lasers and CO_2 lasers are common for sintering."

Prototyping

Besides fulfilling the steps required for manufacturing mass quantities, the other major service offered by laser micromachining companies is rapid prototyping – the creation of model components (or whole devices) in time frames typically shy of a week. This service offers the ability to audition several design options for a single device idea without large expenditures of either time or cash. Designing and building prototype medical devices previously took much longer, discouraging the pursuit of either big new ideas or subtle design tweaks.



Laser-based manufacturing can perform nearly all of the tasks required to build medical devices, including drilling, structuring, cutting, trimming and marking. Courtesy of Laser Micromachining Ltd.

“One of the main benefits of using laser machining for product development,” Laser Micromachining’s Rizvi said, “is that different design ideas can be tried quickly and the results used to develop the most effective product solution.”

Norman Noble Inc. of Highland Heights, Ohio, is one of several companies that offer prototyping services, working with materials ranging from nitinol to thin metals to bioabsorbable polymers. Companies such as Norman Noble and Laser Micromachining provide the manufacturing prowess, while laser makers provide the base technology.

Mairhörmann said that implant makers and other medical technology clients are fairly knowledgeable about lasers because they know the parameters required. The manufacturers’ customers – the device designers – are, on the whole, still catching up with the possibilities of laser machining for both prototyping and mass production.

“Clients who are not so aware of laser technology nonetheless are very quick to appreciate the benefits of laser machining, once they see how it can help their businesses quickly and cost-effectively,” Rizvi said. “Still, from time to time, we will get an inquiry about drilling a 1-μm-diameter hole through 10 mm of metal, and we have to explain that lasers can’t do everything.”

Next up

Despite the learning curve that some device designers still must experience, laser machining equipment and services are largely commoditized. No sea changes are expected. Rapid prototyping services likely will increase, especially as new powderized base materials are developed. Rizvi and others believe that sintering and structuring – using lasers to shape or deposit materials into 3-D parts – also will gather steam. Increasingly, innovations will be coming from startups and other small, nimble companies.

According to Terry Young, Julie Eatock and Dorian Dixon in a recent article in the *Journal of Manufacturing Technology Management* (Vol. 20, Issue 2, pp. 218-234), the majority of innovative, new-to-the-world medical devices are being developed by small companies. To the authors, large, more established companies seem complacent, spending their energies on incremental upgrades to existing devices. And these derivative products are less likely to exceed expectations of success than are novel items.

Technological improvements likely will be incremental, especially concerning lasers themselves. The use of fiber lasers likely will continue to increase, while wavelengths will shrink further into the ultraviolet as customer demand for finer, smoother features increases. Because shorter laser pulses mean that less heat is transferred to the material, femtosecond lasers will get a close look as successors to picosecond systems.

In all, the growing demand for better and more widely available health care in the US and globally will drive the design and manufacture of small devices that preserve, protect and monitor the health of nearly everyone. Those who make lasers and those who use them to make medical devices have a long road of success ahead of them.

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