Lasers in Medical Device Manufacturing

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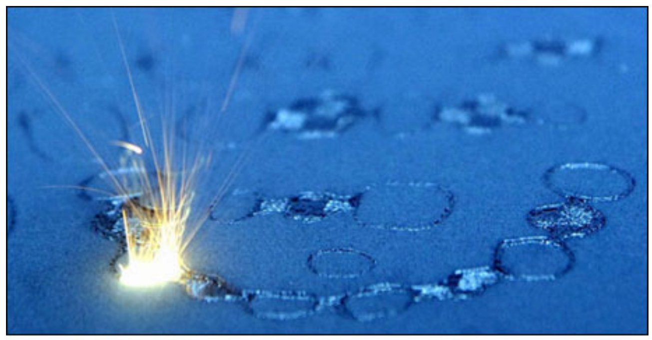
With the latest precision lasers, manufacturers build life-saving medical devices

Patrick Waurzyniak, Senior Editor



Direct metal laser-sintering (DMLS) process from EOS builds up welded layers to construct dental implants and other medical parts.

While lasers for surgical applications get a lot of attention because of innovative uses in life-critical surgeries, LASIK eye procedures, and plastic surgery, deployment of industrial lasers in manufacturing of medical implants, devices, and other components has increased immensely as demand grows with aging populations.

Today's laser-based systems for medical device manufacturing can quickly and precisely cut, weld, fuse, and mark a wide variety of metal and plastic medical components, including surgical tools, dental implants, orthopedic knee, hip, and shoulder implants, and cardio devices such as stents, catheter guide wires, pacemakers, and heart valves.

Precision laser positioning and process control are critical attributes for lasers used to manufacture medical devices and components. Depending on the application, device builders will employ systems based on either gas-based CO_2 lasers, or solid-state laser systems including Nd:YAG and fiber lasers, with the lasers operating in either continuous wave (CW) or pulsed modes. Laser welding of pacemakers remains a big application for manufacturers of increasingly small medical devices. "In medical device manufacturing, hermetic sealing of pacemaker and other metal components is considered the original application of laser welding," says Terry L. VanderWert, president, Prima North America Inc. (Chicopee, MA).

"The process has to be tightly controlled and the fixturing has to be good," VanderWert notes. "With laser welding, a lot of the process success depends on the fixturing to hold the materials to be welded in contact. The laser beam is focused to a spot size on the order of a few thousandths of an inch diameter. You must have the parts in good contact, and maintain the contact during the weld cycle. The advantage of laser welding is that there's very low heat input, not a lot of distortion, so if you get the parts together, you can have a reliable process."

Prima North America's Laserdyne business has been most closely aligned with turbine engine builders, notes VanderWert, who adds that many medical device laser applications have similarities with turbine-engine manufacturing in aerospace, with similar requirements for precision positioning and precise, verifiable control of the process.

"We offer laser products from three to five axes that are appropriate for medical devices, and we have larger machines that are used for aerospace applications with up to nine axes," he adds. "But for most medical devices, the main product is the Laserdyne 430, a three or four-axis system large enough so that one can process a tray of parts. It features *X-Y* part motion and *Z*-axis laser beam motion to maintain focus of the laser beam on the part, and then for rotary or circular-axis parts, it can include a rotary axis providing motion of the part underneath the beam. There can also be a tilt axis—a fifth axis—if that's required, that is often used in welding applications but we've also seen an increase in cutting and drilling applications."

The company also offers its portfolio of Convergent lasers with the newst being the CL 30K, a flash-lamppumped Nd:YAG laser, he adds, and Prima also integrates fiber and CO2 lasers for medical applications.

Reliability, speed, and performance of current lasers is vastly improved over the early lasers that came to market in the early 1960s, notes Mark Rodighiero, vice president, systems, technology, and product development, Miyachi Unitek Corp. (Monrovia, CA). "It's an interesting story, because it's one of these cases where you had a need for materials joining, and reliable industrial lasers that are good enough for real-life industrial production purposes became available at the same time. When lasers were invented in 1960, they were a nice little toy that no one knew what to do with. For a long time, they basically lived in laboratories and were never really considered an industrial tool, because they were unreliable and uncontrollable.

"Right around the late '70s to early '80s, lasers became reliable enough to be used in production," Rodighiero recalls. "They were still finicky—you had to have a laser expert to run these things—but they were there, and during that time the entire world was miniaturizing everything in electronics, and there were very rapid advances in medical-device technologies."

The maturation of lasers at that time also coincided with an explosion in medical device demand that called for manufacturers to build extremely small components out of titanium and other metals including nitinol, the nickel-titanium shape-memory alloy, that aren't easy to weld properly. Heat input from more traditional welding technologies, like TIG welding, made lasers an attractive alternative at the time.

"You have this proliferation of medical devices, pacemakers and all these other components made of titanium that needed to be sealed together," says Rodighiero. "You can't use glue, you can't use solder, and while they used TIG welding for the original pacemakers, the heat input from a TIG welder is brutal. What happens is you can't make packages small enough and light enough that can withstand all that heat.

"The heat input is the issue, and as a corollary to the heat problem, the width of the seam is pretty significant," he adds. "Now, they have micro-TIG systems that are used occasionally, but the heat input is still just astronomical compared to the laser. You have a confluence of challenges. First, the critical demands from medical device manufacturers, and also the fact that characterizes medical-device welding is the devices are small and made from bizarre materials. You see titanium, nitinol, even some tantalum."

Laser technology allows medical device builders to join components with substantially less heat, and permits the use of thinner materials in much smaller packages, because real estate is at a premium in these implantable devices, he adds. A typical pacemaker today could measure about 1.75 x 1.25" (44.5 x 31.8 mm) in a kidney-shaped package. Today's lasers not only have to be reliable, but accurate motion control is required of laser systems to accurately weld difficult-to-handle shapes.

"It beats me how and why they pick these shapes, but they're the most inconvenient things to weld," Rodighiero observes. "Imagine having to go around the perimeter on the edge of that thing, pointing into the surface-ending orthogonal around the entire edge. The point is that, in addition to the laser technology, we have to have wellcontrolled lasers, you have to have a motion system that's up-to-snuff, that can handle the coordination between the motion and the laser firing."

Precision positioning is key to laser welding, and Miyachi Unitek offers its position-based firing for hermetic-package sealing. The company's turnkey laser system currently deployed by customer Terumo Heart Inc. (Ann Arbor, MI) is used to weld seams on its new DuraHeart left ventricular assist system (LVAS). Miyachi Unitek's solid-state Nd: YAG model LW-150A laser system includes a five-axis motion system from Delta Tau Data Systems (Chatsworth, CA) to precision-weld 22 seams on the DuraHeart LVAS, a device that can help keep heart-disease patients alive while awaiting a suitable donor heart.

Miyachi's position-based firing offers users consistent weld overlap for hermetic sealing, with the company's algorithms allowing users to maintain spot overlap when welding parts using up to six axes of motion. The company's turnkey laser systems offer customers a complete package including programming, process expertise, and support, Rodighiero says. "Our systems include the tooling and fixturing that holds the part, cover-gas applications, all the safety devices involved with the lasers, and the motion control," he adds. "The position-based firing for hermetic sealing is a proprietary way that we coordinate the laser with the movement."

Medical implants fabricated with direct metal laser-sintering (DMLS) systems from EOS GmbH (Electro Optical Systems; Krailling, Germany) are manufactured with a laser-based welding process that builds the part up in layers from metal powders, including titanium, cobalt-chrome, and other exotic alloys. While predominantly used for dental copings and bridges, the EOSINT M 270 systems also are employed for building orthopedic prototypes and in the future are likely to be used for implants of all kinds.

The EOS DMLS process has been used by customer Leader Italia srl (Italy) for building its Tixos line of implantable titanium dental screws that help promote bone growth through the microstructure of the components. The laser-sintering process also has been employed by another customer, DEKA Research & Development Corp. (Manchester, NH), to build a titanium Ti64 humeral mount for a prosthetic arm.

"We are competing with traditional processes, such as investment casting," notes Martin Bullemer, EOS manager of business development. "For instance, in the near future, if you have more patient-specific implants, then you will need a flexible manufacturing technology, not an expensive mold."

The M 270 system employs a 200-W Yb:YAG laser, Bullemer notes, to create parts with nearly 100% metal density. "Our process involves powder metallurgy," Bullemer says. "We lay down a powdered metal layer, and we use the laser to solidify it. It's a classic laser-welding process that generates a new metal structure with high density and a rough surface for some applications.

"For instance, many dental manufacturers machine shiny screws and make them a little rougher with etching and cleaning procedures. Still, the final implant is smooth enough so that it is easy to remove if necessary," he says. "On the other hand, you have companies, like Leader Italia srl, who established that a rougher implant surface is better for osteointegration, and therefore better for the patient. Leader Italia srl proved this by growing stem cells on the surface, and is pretty happy with the result."

Other DMLS implants include screws that embed in the jaw where the root of the tooth was, and another component, called an abutment, that fits on top of it. The abutment serves as a seat for either a coping or a bridge and can be designed to be patient-specific, according to Bullemer, adding that all of these parts can be laser-sintered with a high accuracy of ±20 μm.

High-precision lasers now offer precision levels approaching those achieved by high-accuracy EDM systems, but at much faster production rates, notes Robb Hudson, general manager, Laser Technology, DMG/Mori Seiki USA (Hoffman Estates, IL). DMG's line of Sauer Lasertec laser machines features the company's Fine Cutting systems for laser machining of surgical instruments and other medical tools.

"For medical, we use our Fine Cutting systems," Hudson says. "We're not focusing so much on the stent market, because that's a little bit different in that you're typically running 3-6' [0.9–1.8-m] long tube stock, and our machines cannot accommodate that type of long workpiece. We're focusing more on fine cutting for surgical instruments, for instance endoscopic or arthroscopic surgical tools, the little cutters that go in and shave away cartilage or other tissue inside a joint."

The DMG Lasertec line includes very high-precision machines, among them the Lasertec 20 and 80 systems used for medical laser machining. "If you look at these systems, the linear accuracies on the machines are in the 8-10-µm range for *X-Y*, and they're very dynamic machines—the rotaries are all direct-drive torque motors, so there are no belts, no gears, no pulleys, no backlash problems," Hudson adds. "They're all accurate down into the 10–12 arc-sec range, and so it allows us to do very detailed fine cutting quickly and efficiently.

"In the past, a lot of these surgical instruments have been cut with wire EDM, and we are now able to do the work much more quickly with laser," Hudson adds, "so the customer's throughput's better, and they don't have to maintain as many workstations on the floor. It cuts down on floor-space requirements, and enables each department to produce the same number of parts per year. Obviously, with fewer workcells you have generally fewer operators, so you're going to economize there as well."

The machines feature DMG's LaserSoft 3D software, which in part helps the systems approach precision equal to EDM, Hudson adds. "I would say that for surgical instruments we're well within the limits of what they're looking for. There are some medical applications that are tangential to the medical industry—certain molds, fine stampings, or impression molds—where we're finding laser technology replacing EDM. Through our lasertype shape machines or ablation machines, we can go in and do very detailed work, and replace a lot of the high-time-on-machine requirements to manufacture very detailed electrodes for the sinker EDM market."

Other orthopedic laser applications include lasers cutting intricate bone saw designs with the HV line of hybrid 2-D lasers from MC Machinery Systems Inc./Mitsubishi Laser (Wood Dale, IL), according to Jeff Hahn, Mitsubishi national product manager. "It's kind of a secretive industry," notes Hahn, "but a couple of our customers make bone saws, usually in very thin stainless, anywhere from 0.02 to 0.06" [0.51–1.5-mm] thick."

The saws have intricate blade designs, and the customers usually have employed the Mitsubishi HV Series lasers, notes Hahn. "Our HV hybrid line historically is our most accurate machine, because they want really tight tolerances," he adds, "where they try to hold ±0.001–0.002" [0.03–0.05 mm] on a part."

A good example for pulsed laser processing is the production of implantable orthopedic plating systems, where high cutting quality, low heat input, and process flexibility play a significant role, notes Juergen Stollhof, program manager, microprocessing, Trumpf Inc. (Farmington, CT). "Whether plating systems for facial and hand surgery or for spinal implants, via CAD/CAM-linking and without tool changes, diverse shapes of implants can be cut quickly and efficiently," he adds. "The laser parameters can be adapted to the material thickness over a range of 0.3–3.5 mm. In this case, the pulse power ranges from 0.6 to 5 kW, with pulse durations of 100–200 µsec. The cutting angles are adjustable, and the quality of the cuts is characterized by smooth surfaces and sharp edges."

Current stents are cut with pulsed solid state or fiber lasers, Stollhof adds. "Both lasers produce a fusion cut with molten material formed inside the tube. The latest approach for future stents is based on an ablation process," he notes. "Because of the pulse duration of less than 10 picoseconds, Trumpf's TruMicro Series 5000 allows for the cutting of various types of materials. Metal alloys and ceramics as well as polymers can be cut with a negligible heat-affected zone [HAZ]. Green or UV-light-emitting lasers help to optimize this cold material processing. Cutting of stents by ablation results in such a high quality edge that the majority of postprocessing is eliminated, and the manufacturing process can move directly from ablation cutting to electro-polishing."

Laser-marking applications also are key as medical regulations require that parts be traceable back to the manufacturer, and even to lots. "Part identification is definitely the main driver for medical," notes Peter Grollmann, Trumpf product manager, laser marking. "However, there are also some functional marks that are required on parts, for instance, on tubes and catheters, where there are some marks that tell you how deeply an instrument has penetrated into the body."

For laser marking, Trumpf offers three types of lasers including YAG, vanadate, and fiber lasers, Grollmann says. "The most often-used process in medical is socalled annealing, and in the annealing process, you basically heat up the surface of the material right below the melting temperature. You create a very, very thin oxide layer, and this creates the mark. The texture of the surface does not change.

"If you have a very smooth surface finish from the manufacturing process of the metal, you can anneal a part and if you move your fingers over the surface of the part, it's perfectly smooth. This is why pacemakers, implants, and bone screws are annealed, because nobody wants germs or dirt to be caught in a hole created by a mark, which could create the possibility of infection."

WANT MORE INFORMATION?
DMG/Mori Seiki USA, P: 847.593.5400
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