Overview

Medical device manufacturers face exceptionally complex challenges. Competition is fierce, the environment is dynamic, the pressure to innovate is overwhelming, and there are continually changing regulatory and compliance standards to meet. As medical device manufacturers introduce new products and penetrate new markets, it's critical that they receive the support of manufacturing partners invested in technologies that provide accurate, consistent, repeatable, and timely results.

For medical devices, the pinpoint precision of lasers is the most valuable technology for cutting, welding, drilling, and marking components. Laser processing is a high performance solution for creating intricate and geometrically complex features in advanced materials within excruciatingly tight tolerances. No other manufacturing tool provides the same stable, accurate energy needed for fabricating precision devices, where quality has a profound effect on patient outcome.

A Brief History of Lasers in Manufacturing

The very first production laser was introduced in 1965. Developed by Western Electric, a major American electrical engineering and manufacturing company responsible for many seminal developments in industrial engineering, it was used to drill holes in diamond dies. Two years later, a German scientist engineered the laser cutting nozzle and used an oxygen assist-gas to cut 1 mm thick steel sheet with a focused CO2 laser beam. Fast forward another couple of years, when three researchers at Boeing wrote a paper concluding that, with significant R&D, laser gas-assist could be an effective tool for cutting hard materials such as titanium, Hastelloy, and ceramic. The first commercially available moving optics CO2 laser cutting system, with a configuration comparable to today's modern equipment, was introduced in 1975.

The technology did not stand still. Foresighted industrial entrepreneurs adapted laser technology for engraving and marking, and the 1980s ushered in the development of laser welding as a precise, clean, high speed, and easily automated solder-free alternative to traditional methods of joining. Lasers for industrial processes continue to get more powerful, accurate, and efficient to meet the ever growing quality and financial challenges of precision manufacturing.

Laser Cutting

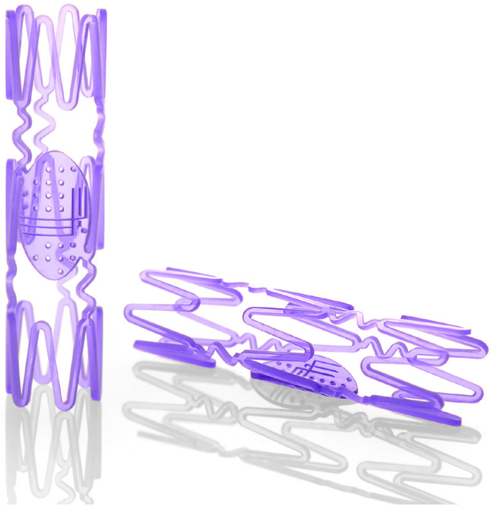
A laser cutter works by focusing the output of a high-power laser on the material to be cut. The intense beam of coherent light heats, melts, or vaporizes the selected area and leaves a clean, burr-free edge with a high-quality surface finish. Precise computer-controlled positioning systems enable lasers to create any geometry with pinpoint accuracy and consistent repeatability. Lasers are capable of creating distortion-free cuts in flat or tubular stock of almost any metal, plastic, or composite material, and create a minimal "heat affect zone" that could potentially compromise the microstructure or properties of the base material.

In the medical industry, every single instrument or device, from customized implants to common, everyday tools of the trade, is subject to the highest quality standards. With its ability to create intricate features and patterns while upholding tight dimensional tolerances, laser machining is a valuable tool for medical device component manufacturing, and developments in laser technology have added very compelling benefits to process capability.

The ability to create ultrafast pulses via the pico- to femto-second ranges with sharply characterized beam profiles; allows manufacturers to meet the stringent requirements for implantable devices such as cardiovascular components, orthopedic devices, as well items like pacemakers and small, delicate parts used in minimally invasive surgeries. By integrating automation solutions, parts with small features and complex micro contours, such as catheters, can be manufactured with precision accuracy and consistency in relatively high volumes — and from a wide variety of materials.

Today's laser cutting equipment, outfitted with high power optics, CNC controls, and micro positioning systems, allow stents with complex features as small as 0.002" to be produced with repeatable tolerances measured in the micron range.

A process called plastic laser ablation uses a high intensity, short wavelength or ultra-fast femtosecond pulse to irradiate polymers to create intricate features in bio-absorbable materials such as PLLA (poly-l-lactide acid), PLGA (polylactic-co-glycolic acid), and PLDLA (poly-l d-lactide acid) to produce medical implant components with no resultant thermal damage to the material.



Laserage
3021 N. Delany Rd
Waukegan, IL 60087-1826
Phone (847) 249-5900
Fax (847) 336-1103
www.laserage.com
sales@laserage.com

Laser Cutting (Cont.)

More powerful laser sources have the ability to effectively machine high strength metals as well as newly engineered biocompatible materials to create devices with a long expected life cycle. By combining precise beam delivery with advanced motion control and part positioning systems, intricate features can be created in implantable medical hardware from the pins, plates, and screws used for bone fracture repair all the way to the complexity of an artificial knee or hip.

This non-contact, high-precision technology enables design engineers to tighten size and placement tolerances and create shapes of any geometric complexity. With no tooling requirements, laser cutting is also an efficient means for creating prototypes to test multiple design iterations, make refinements, validate functionality and compliance, and get new products to the market faster.

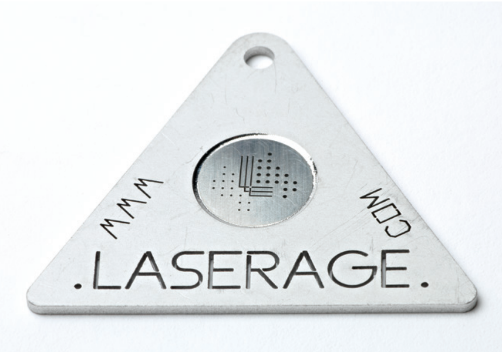
Laser Welding

Laser Welding plays an important role in medical device manufacturing. It is an excellent choice for joining dissimilar metals, heat-sensitive assemblies, and for situations where thermal distortion is a concern. The applications are wide-ranging, from pacemakers and other implantable devices to surgical tools that require a non-porous, sterile surface, to catheter tubing and ultra-fine wires used in cardiac procedures.

For applying thermal energy to a very small area, no other method is as efficient as a laser. By delivering a pulse of light focused on a very narrow spot, the surface absorbs the light, vaporizes the material, and allows it to fuse together and form a strong structural bond. Tightly controlled laser beam and motion parameters result in welds that are quite small and have an excellent cosmetic appearance.

Laser welding equipment with pulse-shaping capability allows for precision welds and high welding rates. No filler is required, which makes it an ideal method of joining two dissimilar metals without any risk of contamination, and little if any joint preparation is required. Millisecond-long pulses effectively weld thin materials, while continuous laser systems are more suitable when deep welds are required.

Advances in materials science and technology have resulted in an explosion of implantable medical devices and hardware that serve a variety of purposes, from monitoring medical conditions and delivering precisely metered medications to restoring mobility to worn or damaged joints. Typically constructed from one or more biocompatible materials, such as stainless steel, titanium, and platinum, they require the type of tight tolerance, clean, and hermetic seal that is uniquely created by a laser welding process.



Many implantable medical devices contain sensitive electronics with tiny, critical interconnects to distribute battery power. Laser welding, with its ability to create micro spots of concentrated power, is perfect for producing high reliability welds in these thin, fragile, and critical assemblies. Surgical instruments, which were traditionally forged or cast from a single block of material, can be more economically produced by machining and laser welding the components, where the perfectly smooth weld surface leaves no minute spaces for germs and bacteria to infiltrate.

Essential to the regulatory requirements of medical device manufacturing, laser welding is a repeatable process that can be statistically proven and easily validated, which simplifies meeting the challenges of regulatory compliance.

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Laser Drilling

As medical technology progresses into new frontiers, devices are getting smaller and their features more precise. Laser drilling has emerged as a practical and sometimes only viable method for creating small holes, as tiny as 0.0005" in diameter. Especially challenging are applications with a large depth-to-diameter ratio, as in micro tubing for drug delivery systems or surgical needles.

Laser drilling is the process of repeatedly pulsing focused laser energy at a material, vaporizing it layer by layer until a thru-hole is created. Short-pulse lasers are capable of drilling holes with exacting precision in materials such as stainless steel, nickel, titanium, and other alloys, as well as polymer and rubber.

In addition to creating holes that are clean and uniform with excellent surface quality, some lasers offer the advantage of virtually no heat affected zone to maintain material integrity, even on thin walled geometries. Lasers are particularly successful in producing micro holes in polymer tubing, which cannot be electro discharge machined, and where mechanical drilling would leave burrs and debris that would be costly to clear and dangerous to leave behind.

As a non-contact process with multi-axis capability and programming flexibility, laser drilling creates holes of any size and shape longitudinally, spirally along the length, or in a specific pattern.

Liquid- and gas-flow devices for drug delivery applications, which require precisely sized and positioned holes to ensure the drug reaches just the target area, are often laser drilled, as is flexible tubing inserted into the body to allow for drainage or to provide surgical instruments access to internal organs. Angioplasty balloons, glucose monitoring sensors, and filtering devices are other examples of devices that frequently have laser drilled features.

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Laser Marking

Medical device manufacturing is one of the most highly regulated industries and as requirements continue to escalate, laser marking plays a vital role toward maintaining compliance with stringent product identification and traceability requirements. These non-contaminating etchings and markings provide long-term legibility without disrupting or adding material to the surface.

Marking lasers produce durable and biocompatible markings with important specification and traceability data and graphical information. As a non-contact form of engraving that offers high processing speeds and consistent high quality marks, they make it possible to convey important product details without using toxic inks or chemicals. The marks they make are flat, so there is no risk of creating fissures or crevices that could potentially harbor harmful pathogens. Using lasers that meet approved guidelines ensures that medical products are FDA compliant and safe to use.

Laser marking is the preferred method for permanently marking surgical instruments and other medical tools and devices with product identification information because the marks are corrosion resistant and can withstand the rigors of repeated sterilization processes such as centrifuging and autoclaving.

In addition to serial numbers, bar codes, data matrix codes, and logos, lasers can produce accurate graduations or other gauge markings that allow precise measurements. Lasers are also an indispensable tool for marking clear, consistent, and indelible tracking and identification information on implanted devices to meet growing regulatory requirements.

Laser marking is compatible with any type of material, and is very conducive to automation. Fully automated systems are capable of presenting, orienting, and laser marking components at very high throughput speeds. These systems are often equipped with vision inspection systems capable of verifying that each individual mark meets the required specification.

Industry Trends

The landscape surrounding the medical industry changes at the speed of light. Barely a day goes by without headlines announcing new breakthroughs in medical science, new technologies for improving patient care, or new regulations to ensure safety, accountability, and patient protection. In this dynamic environment, several themes have emerged that will have a substantial impact on the shape and future of medical device design and manufacturing.

One major trend in the medical device industry is miniaturization. Medical devices and their internal components continue to become smaller and more complex. For delicate part applications, conventional machining techniques will no longer suffice and manufacturers will increasingly rely on the stability of laser systems to cut, weld, drill, and mark micro-sized parts.

Implantable devices have become more commonplace and are supporting processes such as regulating heart rhythms, replacing or repairing existing biological structures, and targeting drug delivery.

Surgery is becoming less invasive, which requires smaller and more precise tools as well as tubes measuring as little as 0.008" to 0.06" in diameter with extremely thin walls to guide them through vascular systems. As parts move further towards miniaturization, medical device manufacturers are adopting laser-based systems for their precision, non-contact processing, and higher speeds.

In another trend, advanced biocompatible polymers are increasingly being utilized in implantable devices, from stents to artificial joints. Biocompatible plastics offer the functional advantage of enhancing healing without the risk of injuring or causing an allergic or toxic reaction in the patient. Plastics are thermally sensitive, and laser micromachining using ultra fast pulsed laser energy is the most viable way of creating fine and delicate features, especially as devices become smaller. The non-thermal laser ablation process promises to emerge as one of the medical device component manufacturer's most valuable tools.

Summary

Laser technology provides an elevated level of accuracy, consistency, control, and flexibility to medical device manufacturing. As a non-contact process with no heat affected zone, laser increases the engineer's ability to process sensitive and highly engineered materials. Advanced computer controls and positioning systems promote accuracy and consistency from part to part and lot to lot.

Lasers have the ability to cut intricate, complex, shapes, precisely drilled micro holes, and seamless welds with striation free edges and smooth surfaces. Minimal tooling requirements promotes rapid prototype development, simplifies execution of design changes, and allows flexible capacity to handle spikes in demand.

The growing complexity of medical devices combined with stringent regulatory validation and traceability requirements compels medical device companies to forge a supply chain of component manufacturers that can unfailingly provide accurate, consistent, repeatable, and timely results. In this intensely competitive industry, where quality, cost, and time-to-market can make-or-break reputation and profitability, it is essential for device makers to partner with suppliers capable of meeting these very tough challenges.

At Laserage Technology Corporation®, we offer technology that has been leading the way in the field of custom laser processing since 1979. Laserage provides ISO 13485:2003 certified medical device component manufacturing services for a variety of medical applications.

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