ACCUMET

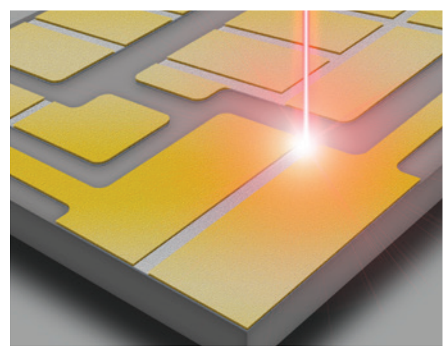
Tech Brief

Eight Benefits of Laser Machining to Designers of Advanced Medical Tools and Devices

INTRODUCTION

With an aging global population and a surge of innovative new healthcare related technologies, it is no surprise that the medical device and tooling industry is expanding rapidly, and competition is increasing. The latest in medical tool and device designs, such as sensors, tubes, and surgical tools and devices, are now demanding levels of precision that are forcing manufacturers to leverage new fabrication techniques and technologies. Market conditions are also driving the need to lower costs while increasing reliability and repeatability. Hence, many manufacturers are turning to laser machining to meet the various process steps such as the cutting, drilling, marking, etching, and welding common and uncommon metals, substrates, adhesives, and circuits.

Prepared for technical design professionals in the medical tooling and device manufacturing business, this technical brief aims to provide insights into laser machining for interested technical professionals and organizations looking into laser processing services for their evolving requirements. Below is a description of trends in the medical devices industry that are demonstrative of the benefits of laser machining, what eight benefits laser machining has over prior fabrication methods for medical devices, and what types of laser machining processes are most commonly being used today.



Benefits of Laser Machining
The very narrow kerf widths, small heat affected zone (HAZ), and speed of laser machining processes provide more precision and efficiency. Illustrated here is laser ablation, a laser processing technique used to remove various layers of materials on microcircuits with microcircuits with optimal control.
One such process technique and benefit is the ability to create a solder trough, which replaces an additive solder damming process during metallization.

Why Medical Device and Tooling Manufacturers are Learning More About Laser Machining/Processing

Competition and rapidly evolving trends in the medical industry are leading to requirements for a smaller, lower cost, and faster processing speeds and shorter lead times for medical device prototyping and development. Some of the latest medical devices have features on the order of microns, require complex features machined on small curved surfaces, are made of new and exotic materials, and require a mix of volumes that don't fit in the business models of most fabrication technologies. Process validation good enough to meet FDA requirements is also a top consideration of any medical device engineering and production team.

Medical Devices and Tools that Benefit from Laser Machining Processes			
Adhesives and Absorber Materials	Dental Tools	Flexible shafts	Radiology devices
Biosensors	Components and materials	Glucose, monitoring devic-es and sensors	Silicone-based Tissue Regeneration
Biomedical substrates	Connectors and Cables	Implant devices	Stents
Bone reamers	Delivery systems	Intravascular Radiation	Surgical tools
Bone saws	Diagnostic and other proce-dural and process instruments, machines and devices	Introducers	Urethral Anchors
Bone shavers	Wafer-Level Devices	Medical	Valve frames
Cannulae	Electronics, PCBs, PCBAs, PFCs	Neuroscience & Neuro-modulation devices	Vascular clips
Cardiovascular Devices	Endoscopic and Laporoscopic Devices	Optical and vision compo-nents	Vena-cava filtration
Catheters	Epoxies and Foils	PVDF Surgical Products	Wound Care Products

Though there have been some advances in traditional manufacturing methods, such as computer-numerical control (CNC) machining, liquid abrasive cutting, water jet cutting, air cutting, plasma cutting, EDM, and ultrasonic welding. There are still limitations to the cost and speed of these technologies which are at odds with the direction medical devices are going. Though promising additive manufacturing methods, such as 3D printing of polymers and metals it will take several more years to be commonplace in medical device manufacture and still pose tolerance, repeatability, and cost challenges. This is where the latest fiber lasers, femtosecond lasers, and precision laser machining techniques come into play.

The Laser Machining Advantage

The value of laser cutting, welding, marking, drilling, and other laser machining techniques has become increasingly known in the medical industry, causing further evolution of laser machining technologies to serve medical device manufacturing needs. Laser cutting, marking, and drilling resolutions/tolerances have improved dramatically, speed has increased, and laser machining contract manufacturers like Accumet have gained greater skill and expertise by servicing the needs of the medical device industry.

Following are eight key benefits of laser machining that applies to many different medical industry applications.

1. Precise Temperature Control. The high-performance materials used in medical devices often have desired material properties that are extremely sensitive to severe temperatures. For example, nitinol's super-elasticity and shape memory behavior is adversely affected by the temperature profiles typical in micromachining cutting and Tig and Mig welding processes. Fortunately, laser cutting and welding of nitinol, and other delicate materials including polymers, adhesives, and foils, can be performed reliably with minimal heat-affected zones (HAZ). The temperature exposure of a material during laser manufacturing can be controlled in the range of micrometers, including how deeply the beam penetrates a material. The ability to program and precisely control the laser's output power and material exposure time, makes laser cutting a highly reliable and repeatable process.

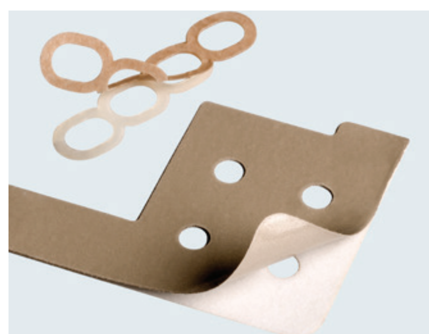
2. Incredible Geometric Tolerances. Medical device geometric features are becoming more complex and new applications and techniques are being pioneered. Moreover, these new geometries often require much tighter manufacturing tolerances that are extremely repeatable. Modern laser machining beam widths are extremely small, some laser frequencies are even small enough to provide tolerances in the realm of tens of micrometers. Laser machining controllers are also extremely precise and consistent in the cap X and Y plane, allowing for complex and tightly spaced curves and segmentation during laser cutting, and laser welding of fine wires. Automation features available with laser cutting tools also enable much smaller tolerances with software-driven operation based on CAD Models.

Benefits to Medical Implants
Implant technology is advancing rapidly with medical designers exploring various metal combinations for longer implantation and durability. Combinations like titanium and steel become challenging to weld properly and cleanly with any other method than Yag laser welding. Shown here is a component of an advanced knee replacement.

3. High Repeatability. The level of automation and software control driving some laser machining processes, as well as the very tight tolerance control, provides a level of repeatability and quality difficult to achieve with other manufacturing technologies and methods. The precise control of laser power, pulses, and processing temperature further enhances the overall repeatability of laser machining. Laser machining systems also have very high up-times with little need to re-tool processing components, which means there is little variation in the machine itself from part-to-part and batch-to-batch. Laser machine operators familiar with medical device manufacturing qualification requirements may also have expertise in methods to enhance overall repeatability and qualification assurance protocols.

4. Faster Processing Speed and Shorter Lead Times. As many medical devices designers may be interested in iteratively improving a design with a short delivery window, or prototyping several design variations simultaneously, cost effective and rapid manufacturing is often a necessity. Traditional precision manufacturing technologies, such as CNC machining, EDM, and casting sometimes require substantial lead times for fixture, tool, and mold designs. Making modifications to these processes can also incur large extensions on lead times, as well as huge costs in the case of mold making. The software driven approach to laser machining systems and simplified setup enables much shorter lead times and faster job processing speeds. Also, the high up-time of laser machining tools means that there is very little lost time, and job-to-job transitions can be performed without long tool cool-downs and warm-ups. As with most manufacturing and medical technologies, time is money, and laser machining tools provide competitive advantage for prototyping and production volume manufacturing.

5. Reduced Contamination from Flux, Pigment, and Debris. Many medical device and appliance technologies are required to pass strict FDA requirements and quality assurances protocols. Areas where contamination is a particular concern are with medical appliances used in surgeries and implanted devices. Most traditional machining technologies produce a substantial amount of debris, or involve complex chemical processing stages. Flux, pigments, and solvents must thoroughly be removed to meet the stringent quality requirements. In the case of laser machining, many of these steps are unnecessary, as laser cutting, welding, ablation, drilling, marking, and other processes don't require any chemicals, flux, or pigments and the laser machining produces minimal debris.



Benefits to Adhesives and Foils
By laser cutting adhesives and foils instead of die or machine cutting, designers can count on the cleanest and tightest cuts, and avoid skewing often caused by the physical pressure of die or machine cutting.

6. More Durable Markings. The rigorous sanitation requirements for many reusable medical appliances and tools frequently requires the tools to be placed in extremely harsh sanitization chemicals or under high heat and moisture environments. Most marking technologies, and even early laser marking, had difficulty maintaining marking that doesn't flake, erode, or develop oxides or corrosion byproducts. The latest laser marking techniques are precise and controlled enough to produce marks that don't produce debris or fade away even after many sanitation cycles. Many single-use or implanted medical devices and appliances require marking also, and highly durable, pigment free, and debris free laser marking is also a viable solution for these applications.

7. Reduced Machining Costs and More Cost Effective Validation. Medical devices and appliances requirements often place them in a high cost category for traditional machining. The levels of precision, repeatability, and purity expected for medical applications may be far too expensive to be performed by technologies other than laser machining. Modern laser machining tools require very little maintenance and can readily be automated, reducing the overall cost of operation compared to many machining technologies. Validation protocols required by medical quality assurance standards can also often be performed easily with laser machining technologies high controlled processing features, further reducing the manufacturing overhead for laser machining services, respectively.

8. Enables Advanced Materials and Approaches. Beyond nitinol mentioned earlier, the latest medical devices are often high-mix parts with a wide range of materials in a single part. Part sealing, mixed material welding, and machining of a wide range of materials is often required to produce a single medical device. The precise control over the laser beams frequency, power, and pulse enable laser machining technologies to operate on a very wide range of materials. Various and mixed metals and polymers can be laser cut or welded, including clear polymers and the latest in organic bio-absorbable materials.

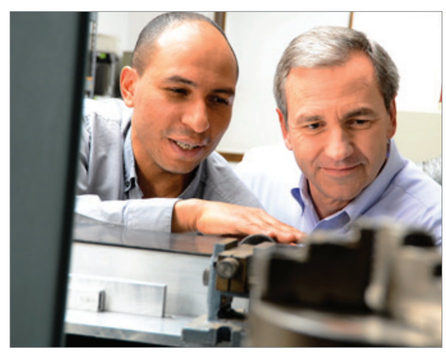
Medical Materials Available for Laser Machining			
Stainless Steels	Platinum Alloys	Cobalt Chromium	PLLA
Titanium	Magnesium Alloys	L605	PLDLA
Nitinol	Niobium	MP35N	Polymers
Nickel Alloys	Tantalum	PLGA	Clear Polymers
Composites	Glass	Ceramic	Bio absorbable

Benefits to unique surgical equipment
This tube has been uniquely rotary cut by a laser to provide optimal bend radius, flexibility and torsion control for procedures such as laparoscopy, endoscopy, and colonoscopy.

CONCLUSION

A laser machining center experienced in the advanced processing techniques enabling today's medical device innovations, can be an extremely valuable service partner and supplier.

Laser machining technology is advancing rapidly and is extremely cost-effective and fast. Piece parts of even the most complex medical devices, which are often comprised of many unique, high performance materials, benefit from the adaptability and reliable control of programmable laser machining procedures.



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