

Precision Cutting Options for Medical Devices

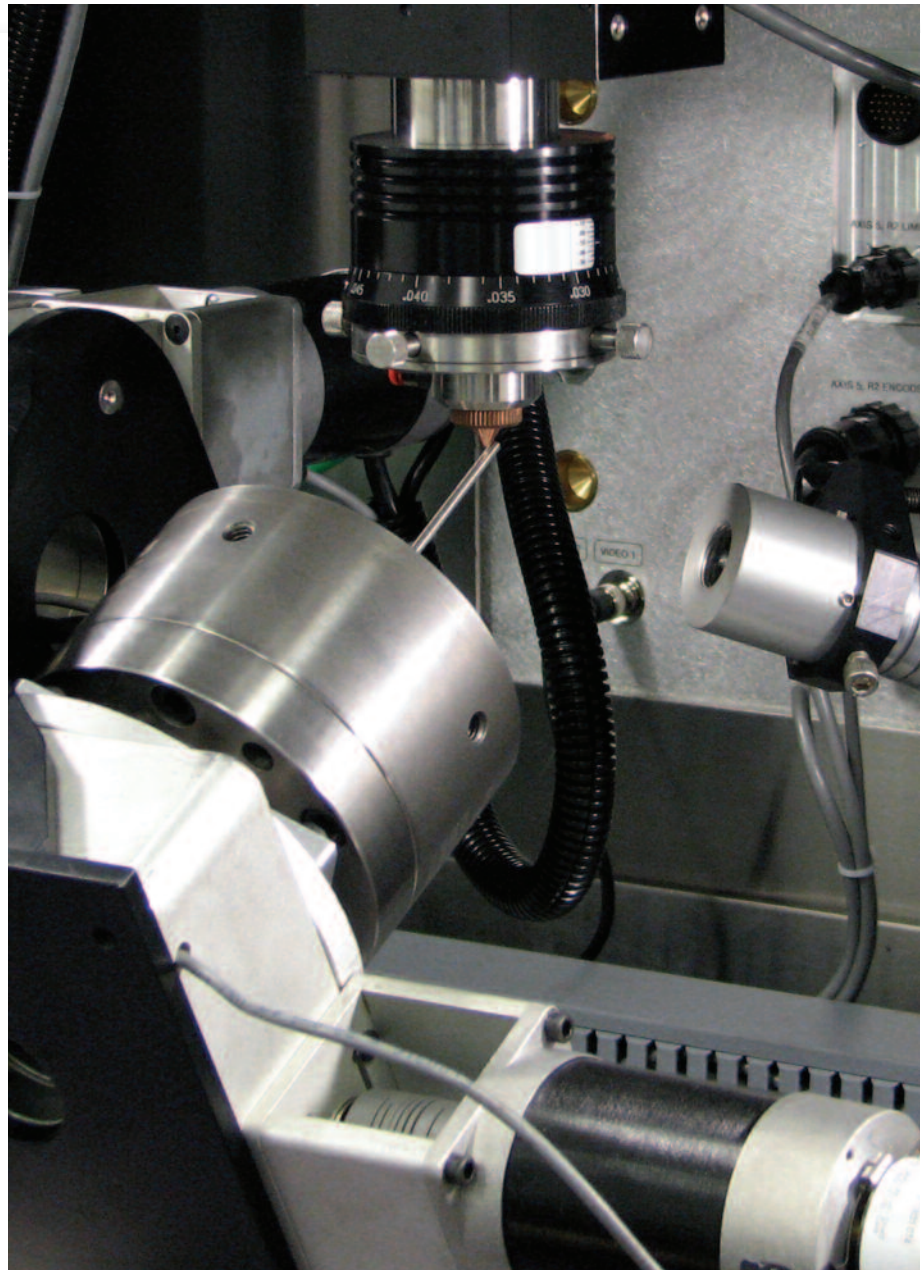


Table Of Contents:

Introduction:	3
Laser Technology Background	3
Precision Laser Cutting – A Non-Traditional Approach	4
Primary Benefits Of Laser Cutting	4
Solid State Laser Choices	5
Fiber Laser Features & Benefits	5
“Gas Assist” Laser Cutting	6-8
“Gas Assist” Laser Cutting Features & Benefits	8
Laser Marker Cutting	9
“Gas Assist” vs Laser Marker Cutting	10
Competing Non-Laser Processes-Wire EDM	11
Other Metal Cutting Processes	12
Turnkey Laser System Integration-The Key To Success	13
Enclosure and CNC Motion Options	13-14
Two Dimensional Tube Cutting	15
Three Dimensional Tube Cutting	16
CAD Design & Post Processing Software	17

Precision Cutting Options for Medical Devices

introduction:

Medical device manufacturers continue to demand more reliable, faster and more cost effective manufacturing solutions to stay competitive in the global marketplace. Precision cutting of thin metal tubular structures such as rigid endoscopic and arthroscopic devices, biopsy tools, needles and cannulas are no exception. The most common materials used in these surgical and implantable medical devices are stainless steel, cobalt chrome alloys, nickel alloys, titanium and Nitinol. There are several methods available to cut these metals including laser, EDM, water-jet, chemical machining and grinding.

laser technology-background:

Over the past 20 years, laser cutting has been used in an increasing number of manufacturing applications in the medical, automotive, electronics, aerospace and many other industries. In the 1980's most laser cutting was performed with high power carbon dioxide (CO₂) gas lasers, but CO₂ is unsuitable for fine laser cutting due to lack of heat input control and focus spot size. As a result, solid state lasers emitting at a shorter wavelength - typically near 1micron -emerged as the best choice for precision cutting applications. Conventional solid state lasers are now being replaced by fiber lasers that offer a reliable, stable energy source, have exceptional beam quality, high repetition rates and are easy to integrate into production manufacturing machines. Today, fiber laser cutting is most effectively used in the precision cutting of thin wall metal tube materials such as those used in endoscopic and arthroscopic medical instruments.

precision laser cutting – a non-traditional approach

Precision laser cutting, a non-traditional process, is now emerging as the preferred choice for many thin wall metal tube cutting or machining applications, particularly when superior edge quality, tight dimensional tolerances and/or high volume production is required. Laser cutting is an ideal technology for meeting the specialized requirements in the manufacturing of many medical devices including endoscopic and arthroscopic tubular products and components.

Here, the term “surgical precision” aptly applies to the need for clean sharp edges, contours, and patterns found in tools and devices in this burgeoning field. From surgical instruments used in cutting and biopsy, to needles containing unusual tips and side wall openings, and puzzle chain linkages for flexible endoscopes, laser cutting provides higher precision, quality, and speed than traditional cutting techniques. In addition, new laser cutting technologies are now coming on the market, including more powerful fiber lasers which offer increased speed and material thickness capability that can be integrated into turnkey systems with multi-axis motion capabilities. This technology gives the medical device designer the freedom to create more challenging geometries with superior “as cut” edge quality. Figures 1 & 2 depict some of the medical products that are laser cut with fiber laser technology.

primary benefits of laser cutting:

- Non Contact Process
- Minimal thermal input or HAZ
- Sub 0.001” diameter beam width
- High precision with single pass
- Superior “as cut” edge quality
- High level of process control



Figure 1. Biopsy Tool



Figure 2. Arthroscopic Shaver

solid state laser choices:

Today, there are two primary solid state laser options for the fine cutting of thin (>0.020" or 0.5mm) sections of stainless steel, titanium, nickel and cobalt-chrome alloys, and Nitinol: fiber lasers, and pulsed Nd:YAG.

The fiber laser (Figure 3.) is widely accepted as the laser of choice for most thin metal cutting applications. This is attributed to several factors:

- Relatively low cost
- Exceptional beam quality - $M^2 < 1.1$
- Small spot size-narrow kerf width (0.001")
- High focused power density (watts/cm²)
- 50,00 to 100,000 hours of maintenance free operation
- Electrical power to laser conversion efficiency-30%
- Small footprint-ease of integration



*Figure 3.
Single Mode Fiber Laser*

fiber laser features & benefits:

Fiber laser cutting is ideal for working on small diameter, thin wall metal tubes that must be cut to high dimensional accuracy. This is because the laser beam does not have any physical presence and makes no contact with the material. It does not push, drag, or impart force that might bend a part or cause flex that would have a negative impact on process control. It also offers minimal thermal input, with fine control over how hot the work area gets. This is important since small parts heat up quickly and might otherwise overheat or deform.

Fiber lasers are highly focusable to about 25 microns, which is about ¼ of the width of a strand of human hair. This makes it feasible to remove the minimum amount of material to make the cut, resulting in extremely high precision and accuracy.

This laser cutting technology offers exceptional control over pulse width, power, and focus spot size. Because the laser cutting tool does not rely on touching the part, it can be oriented to make any shape or form. Laser cutting is ideally suited for making complex shapes because it is not limited by part geometry.

“gas assist” laser cutting:

This type of cutting is also characterized as “fusion” cutting. In fusion cutting, “gas assist” means that the laser energy delivered to the cutting zone is “assisted” with a coaxial gas flow, that can be either oxygen (O₂), air, or an inert gas depending upon materials and the cut requirements. “Fusion gas assist” fiber laser cutting technology is well suited for precision cutting of stainless steels (300 and 400 series, 17-4, 17-7); MP35N (cobalt-chrome steel alloy); and Nitinol. Figure 4 shows a close up image of the laser cutter focusing optics with the co-axial gas assist nozzle.

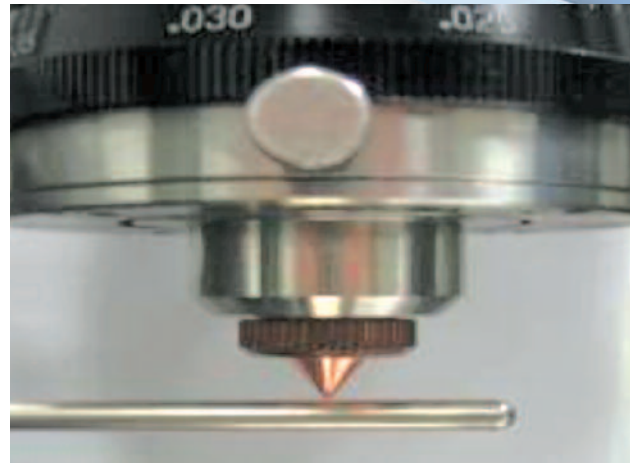


Figure 4. Close up of a laser cutting gas assist nozzle

The fusion gas assist cutting method can be used for both on-axis (90° to surface) and off-axis (angled to surface) cutting. The process is simple and easy to implement using a co-axial gas nozzle integrated into the focusing optics. A highly focused fiber laser beam with a spot diameter of approximately 25 microns, is focused on the cut site. While the material is still molten, a 0.02-inch diameter gas jet nozzle that is coaxial with the laser blows away the molten material. The desired features are produced using this continual cycle of melt, then melt ejection. The distance between the laser and the material needs to be maintained precisely. Figure 5 illustrates a basic fiber laser cutter with gas assist.

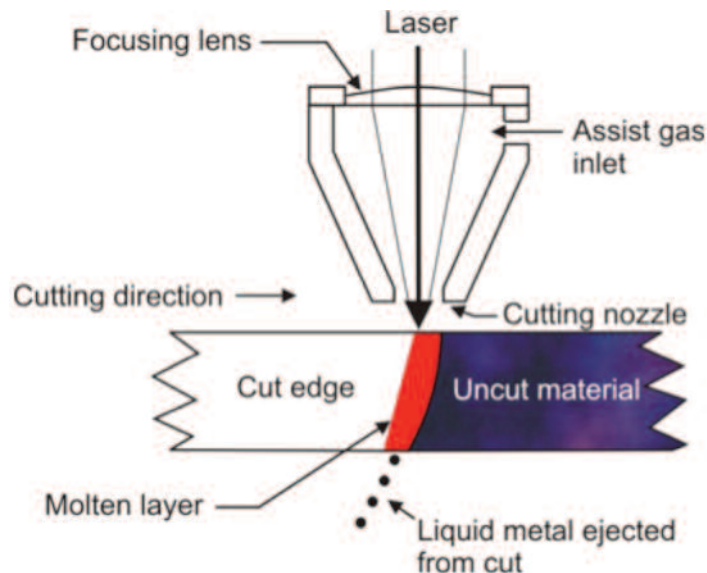


Figure 5. Cross section of gas assist cutting nozzle.

Laser cutting with gas assist produces superior cut quality and high resolution cut paths, a key requirement for manufacturers of medical tube tools and components. This significantly reduces the amount of post-processing needed. The recast layer (a small amount of material that doesn't get blown away during the process) is usually less than 0.0005-inch thick. Cut width (or kerf width), can be extremely small – typically less than 0.001-inch. Dimensional accuracy is very important to measuring cut quality – it must match the print. The dimensional accuracy of fiber laser cut parts is extremely precise, at about ± 0.0005 -inch. This accuracy is very useful for producing the saw tooth cut designs used in arthroscopic shavers and other surgical cutting tools.

The selection of the assist gas depends upon the material and the type of cut required. Oxygen can be used to increase cut speed and “as cut” edge quality. The oxygen serves two purposes - it blows away the molten material and, by reacting with the hot metal, creates additional heat within the cut. This reaction adds 30 to 50 percent more heating energy to the cutting area. Figure 6 clearly shows the “as cut” edge quality and smooth surface-better than 12 micro-inches (0.3048μ). In other cases air, nitrogen or argon may be used, as there is less heat reaction and even cooling of the cut either the laser power is increased or the cutting speed decreased.

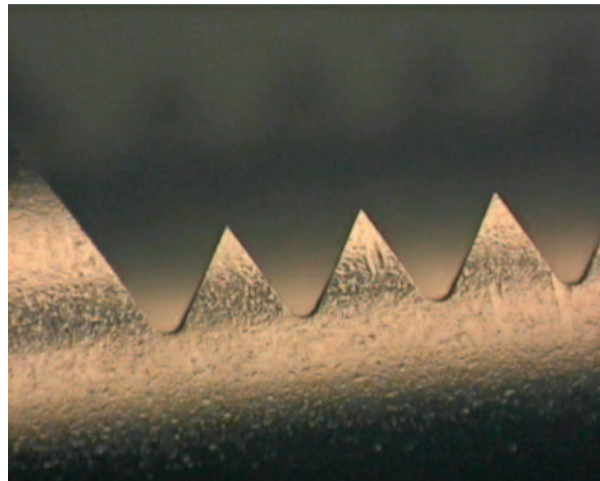


Figure 6. “As Cut” edge quality <12 micro-inch

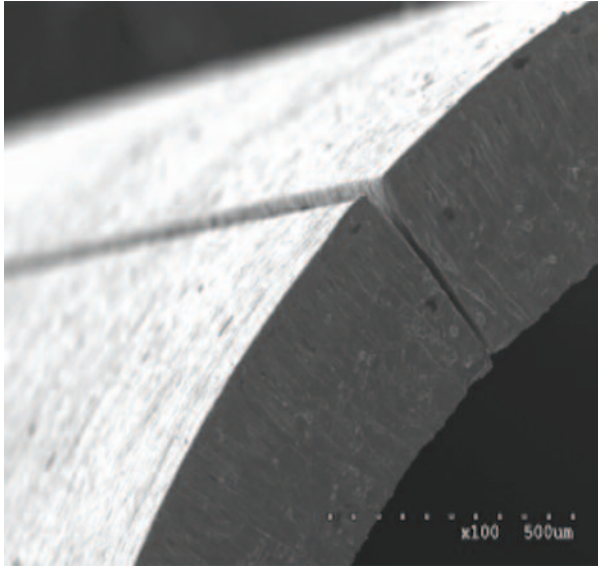


Figure 7. Narrow kerf width

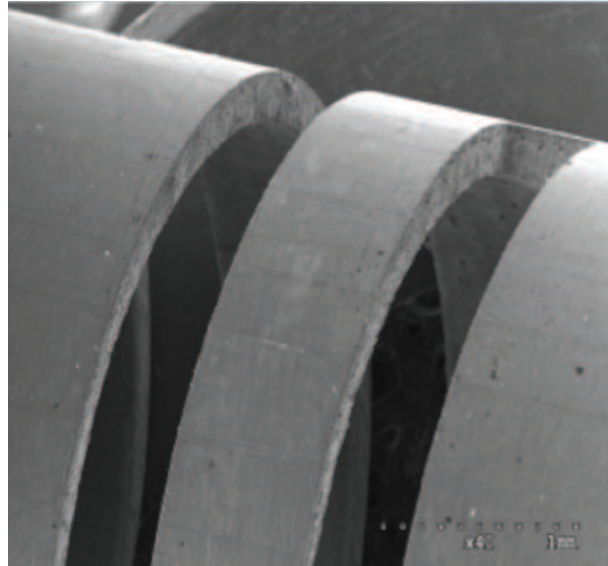


Figure 8. No backside dross or slag

Another advantage of fine cutting with fiber lasers is that little or no dross or burr is left on the underside of the cut which can become attached and re-solidified. Figures 7 & 8 clearly demonstrate the clean, sharp “as cut” quality, narrow kerf width and little to no backside dross or slag.

Fusion gas assist cutting requires an intense laser source to quickly heat up the metal to the melting point as the oxygen assist is applied to remove the molten metal from the cut kerf. Most arthroscopic and endoscopic tubular devices employ this type of cutting. Careful process optimization is required to control the cut quality, minimize the heat affected zone and maximize cut speed. Single mode fiber lasers with an average power of 200 watts or more are ideally suited for this application in stainless steel, nickel, titanium, Nitinol and other grey metals.

“gas assist” laser cutting features & benefits:

- Highest cut quality
- Dimensional accuracy (+/- 0.0005”
- Little or no dross/burr on exit side
- Cut kerf width <0.001”
- Highest resolution cut paths
- 3 dimensional geometries
- Minimal heat affected zone (HAZ)
- Off-axis cutting
- Exceptional “as cut” roughness <12 micro-inches (0.3048 microns)

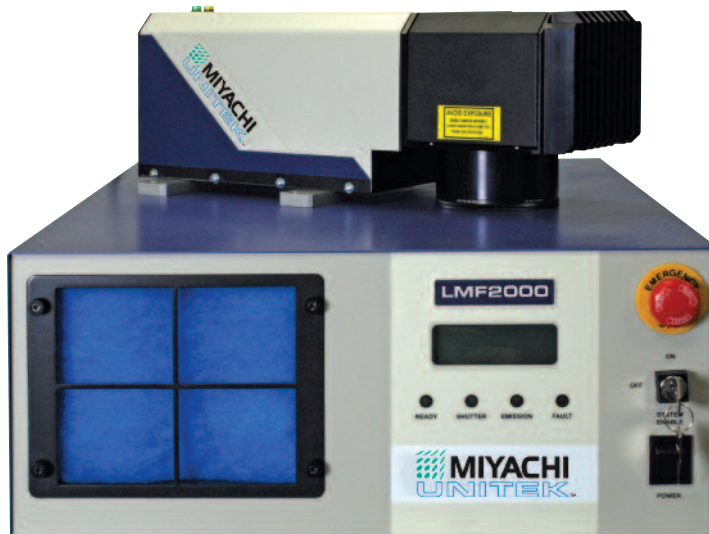


Figure 9. LMF2000 Fiber laser marker/vaporization cutting unit

laser marker cutting:

Another type of laser cutting utilizes a pulsed fiber laser *marker* for cutting metals under 0.5mm thick. A pulsed fiber laser marking system employing high speed XY galvo beam delivery is significantly lower in cost as compared to a fusion cutting system integrated with a multi-axis programmable CNC motion package, and is ideally suited for cutting thin reflective metals such as copper or gold.

Laser marker cutting employs a short pulse fiber laser with 20 or more watts of average power and the necessary pulse flexibility and shaping options to optimize the cutting process. This type of laser is also used for drilling small diameter holes at a high rate of throughput. A typical pulse profile incorporates a steep high peak output of 20-30ns, followed by a long flat tail. The high peak power helps the laser energy to quickly couple to the material while the long tail, up to 200ns, provides for deep penetration and high material removal rates. By selecting the optimum laser parameters, material is removed in thin layers, one after another, until it is fully cut or drilled.

This process does not require gas assist but, a low pressure flow of gas may be useful in protecting the optics and to direct particulates away from the workpiece. As there is minimal material melting with such short pulses, there is very little heat input or thermal damage. Typical applications include micro-electronics, semiconductor, and solar cells/grids. It is also useful for cutting prototype lead frames or other thin sheet metal parts with an underside burr of less than 0.0005”.

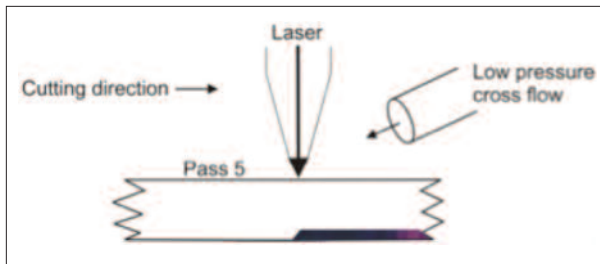
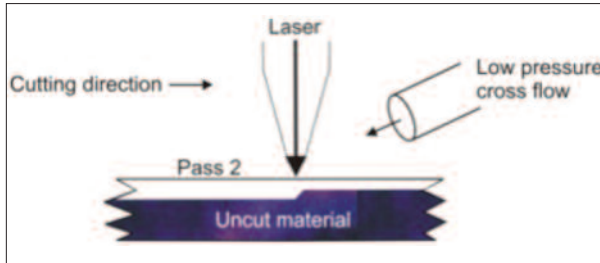
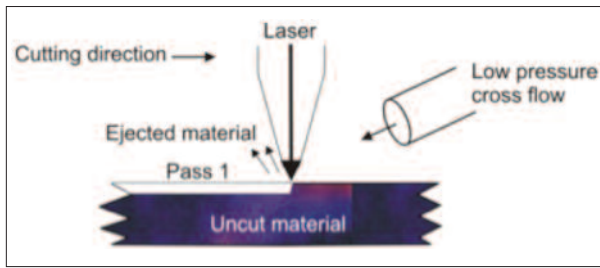


Figure 10. Schematic of the laser machining method to cut with a laser marker, multiple passes are used according to the thickness of the material.



Figure 11. 0.02" thick copper sheet. The XY galvo beam delivery optics completed a 1" x 1" complex cut pattern in about 30 seconds.

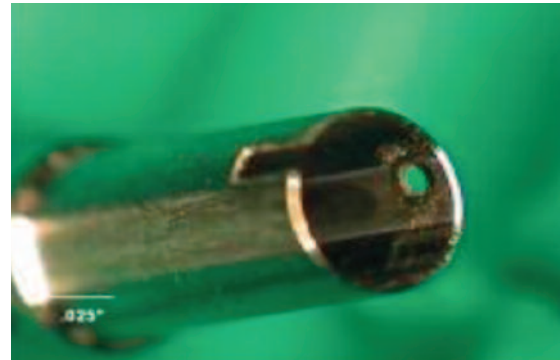


Figure 12. Platinum-iridium tube is difficult to cut and is prone to backside burrs. The laser cut slot is 1mm x 2mm in the 0.006" tube wall.

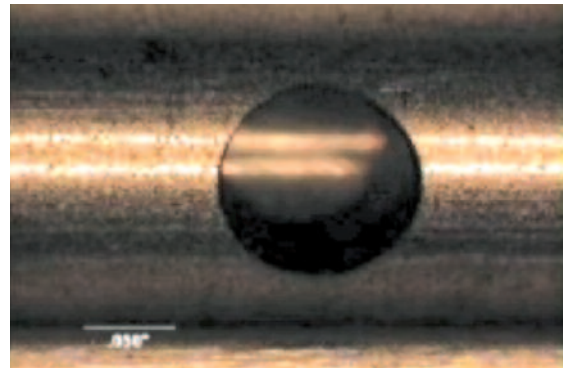


Figure 13. A 2.5mm diameter hole is cut into the 0.015" thick 304 stainless steel tube in around 20 seconds.

gas assist vs marker cutting:

Gas Assist Cutting	Marker Cutting
Highest cut quality	Good cut accuracy
Single pass cut	2 axis cutting
Multi-axis cutting options	Lower cost equipment
Minimal HAZ	High speed XY galvos
Single pass cuts	Multiple pass cuts

competing non-laser processes:

Wire EDM

Wire EDM is the most widely used traditional precision cutting technology for cutting the thin wall metal tubing required for rigid endoscopic, arthroscopic and other medical devices. Laser processing offers faster cutting speed, superior edge quality and greater precision compared with that of EDM, but laser equipment costs are significantly greater.

For some high volume EDM applications, several tube sections may be secured in a special tooling fixture and machined in a single pass. This multi-up EDM process offers a unique advantage over laser gas assist cutting where only one part may be cut at a time.

However, the wire EDM process has several limitations. First, the wire EDM cutting cycle can only proceed in a two dimensional geometry. Bevels or other three dimensional geometries require a separate set up, program and cutting process. This adds significantly more to the total process time. Laser cutting, on the other hand, is capable of cutting three dimensional geometries in a single pass using a 5 axis motion package.

Wire breakage poses a constant threat to productivity. In the wire EDM process, a thin traveling wire passes in close proximity to an electrically conductive work piece. The gap between the wire and work piece is filled with a dielectric fluid. This fluid serves two functions; it provides a current path from the wire to the work piece and flushes away the debris and metal particles created in the EDM process. Flushing efficiency directly influences the process and the conductive debris directly effects wire integrity. Close observation and control over the dielectric flushing solution is critical to preventing wire breakage and downtime. Figure 14, below, shows a typical wire EDM process flow diagram.

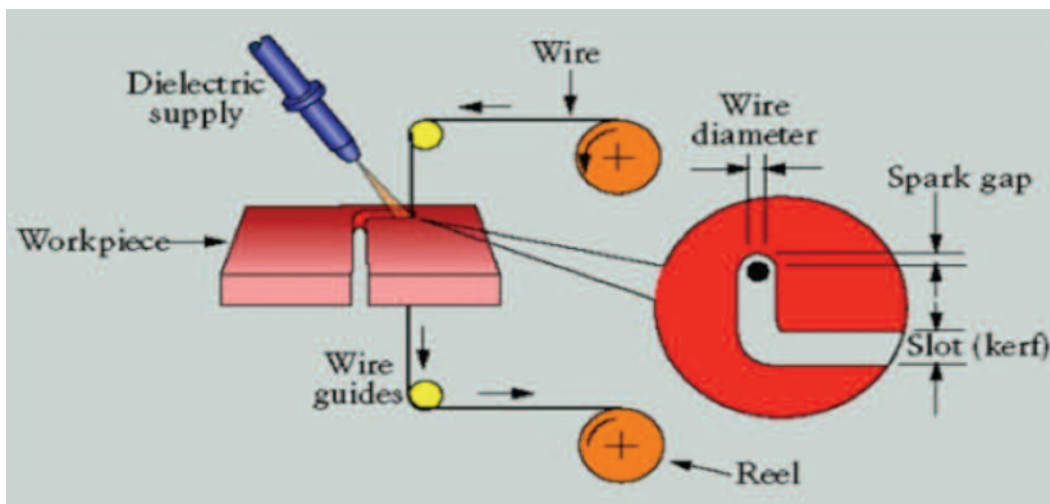


Figure 14. Wire EDM process flow diagram

Wire EDM has a minimum cut width of about 0.004 to 0.006-inch. Wire EDM is not suitable for sharp inside corners and is limited to 0.004-inch inside corner radius whereas lasers can make sharper inside cuts. In addition, if the cut geometry requires transition between aqueous wire EDM and the organic solution probe EDM process, a secondary cleaning step is needed.

Another issue is floor space, especially for factories where space is at a premium. A typical wire EDM machine can be as large as 10 to 12 feet square, while a laser cutting system is 5 to 6 feet square.

A large reservoir of de-ionized flushing water is required for wire EDM cutting. This requires continuous monitoring and adjustment to maintain the correct ion-levels. Wire EDM systems also require considerable machine maintenance and cleaning.

Finally, in order to obtain the same high quality cut as a laser cutting machine, wire EDM may require up to four separate (4) passes which adds considerable process time to the operation. On balance, when edge quality is a major issue, the laser fusion cutting process produces the best results.

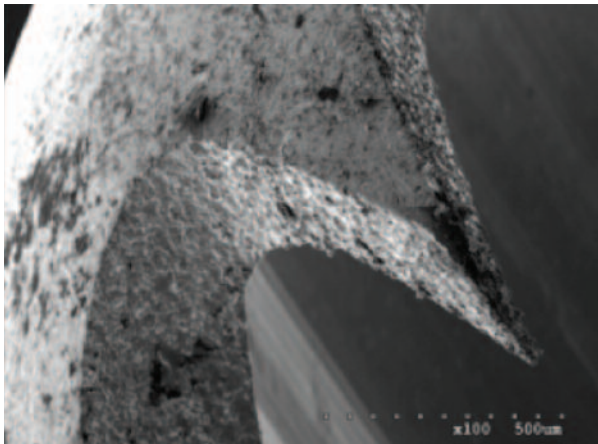


Figure 15. Wire EDM edge quality

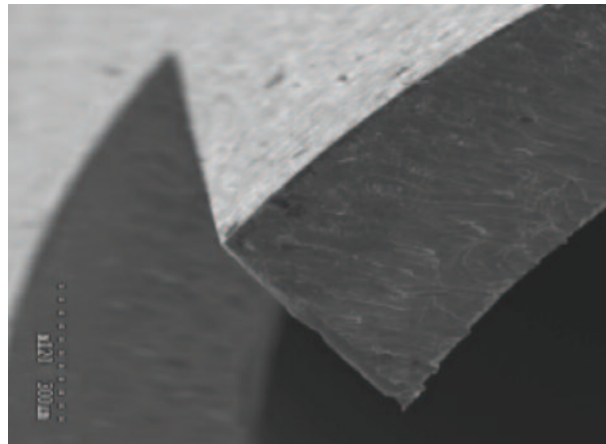


Figure 16. Fusion laser cut edge quality

other metal cutting processes:

Other metal cutting technologies are available including water jet cutting and electro-chemical grinding (ECM). Water jet cutting is slow and has geometric limitations. ECM is a cutting method that gets quality similar to EDM. With ECM, the electrolyte used must be disposed in accordance with OSHA as hazardous waste, and some electrolytes produce hexa-valent chrome when cutting steels. Finally, ECM's use of hard tooling makes it much less flexible than laser cutting.

turnkey laser system integration-the key to success:

The explosive growth of minimally invasive surgery tools gives rise to some unique and innovative device shapes and laser cutting challenges. In addition to the most optimum laser, each application requires a workstation and a motion package with programmable motion, HMI and full featured control software with post processor capability.

Tube cutting requires precision, multi-axis programmable CNC linear and rotary motion. The ability to make intricate cuts in a cost effective manner provides component designers greater freedom, enabling them to design more challenging cut geometries into their medical products.

enclosure & cnc motion options:

Laser cutting applications are normally conducted inside a Class I, eye safe enclosure. These enclosures must meet CDRH (Center for Devices and Radiological Health-Division of FDA) and ANSI (American National Standards Institute) Z136.5 Class I safety standards for high power laser systems. Class I enclosures must include redundant safety interlocks on the access doors and removable panels. All viewing windows must have the appropriate power density value to absorb the laser output at the specified peak power density and wavelength. These enclosures must also have proper warning labels, emergency stop capabilities and indicator lights.

The enclosure must provide a highly stable platform and be suitable for securing the motion system, optics, vision, part handling, lighting, cover gas, electronics, instruments and tooling. Since vibration and shock factors are key considerations, most laser workstations include a heavy steel or granite base plate and vibration isolation footings in addition to an easy open/close front access door with a safety viewing window. The front access door may be manual or pneumatic. It should be sized to allow easy set up, part handling and operation by the operator.

Class I laser systems may operate in any manufacturing environment without the need for safety goggles. Should a door or panel be opened during laser operations, redundant interlock switches will be tripped and the laser will cease emission until a safe operating condition is restored. Implementing advanced laser cutting processes for the manufacturing environment requires innovative system engineering and flexible design concepts.

The laser system design must incorporate all components into a reliable, robust, production worthy machine that meets the customer's requirements. The motion, laser, software, and tooling must all work together to get the desired end product and long term performance. Figure 17 shows the interior of a 5 axis fusion laser.

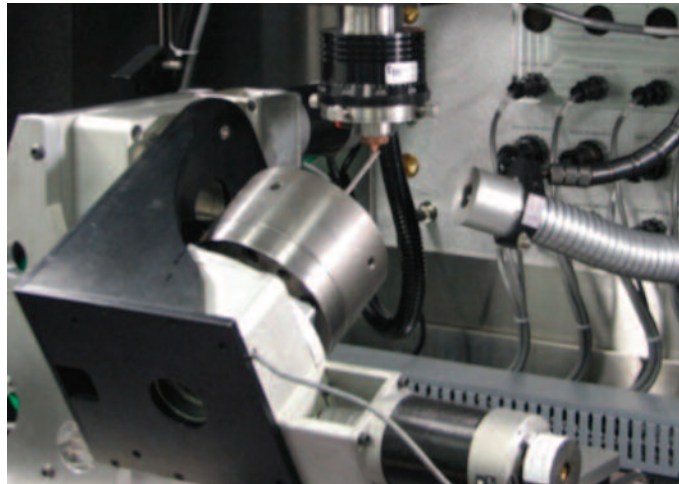


Figure 17. Interior of 5 axis multi-axis laser fusion cutting system

Two dimensional tube cutting:

A fully programmable tube feeder is typically used in conjunction with a 3-4 axis (XYZ & Rotary) CNC motion package for two dimensional cutting of open end tube components. This is the most common laser tube cutting motion configuration and is widely employed for laser cutting cannulas, hypo-tubes and other open end tubular components used in medical devices.

A programmable tube feeder is normally used to accommodate long metal tube sections up to 10 feet in length. When the laser cut cycle is initiated, the tube feeder automatically advances the exact amount of tube material into the laser cutting position. A rotary collet grips and turns the tube while the laser proceeds with the necessary cuts and other part features. When the part is finished, the laser cuts off the completed part to the appropriate length and the process is repeated until the entire 10 foot length of material is consumed. No human intervention is required until the entire 10 foot length of tube is consumed, at which time the operator places another 10 foot tube in the tube feeder and the process is repeated. The major advantage, therefore, of the programmable tube feeder is reduced labor and maximum productivity.

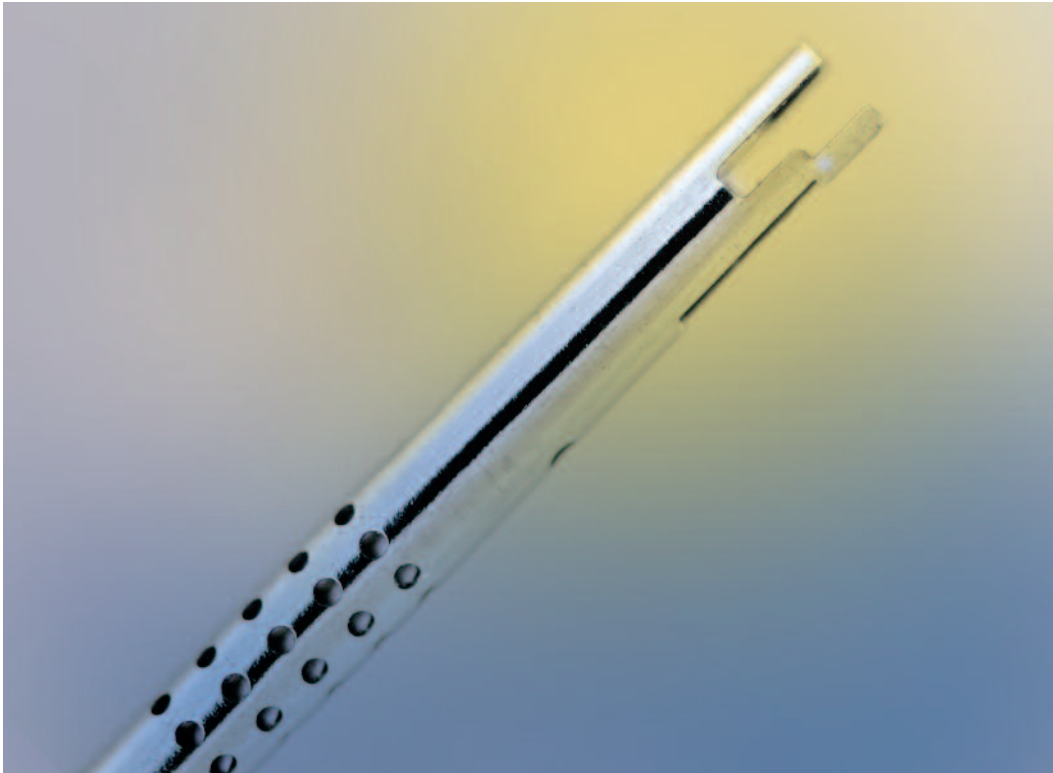


Figure 18. Example of a dimensional laser cut part

Three dimensional tube cutting:

A 5-axis motion package is required for laser machining three dimensional features. This is most common in closed end tubular components as used in arthroscopic shavers and laparoscopic instruments. Manual loading and unloading of each part is usually required since these types of medical components are sealed at one end and pre-cut to their finished length.

The 5 axis CNC motion package usually consists of 3 linear axes and 2 rotary axes. A sixth axis may be incorporated if required. The multi-axis system design permits the medical product designers greater flexibility to choose the best configuration and cut geometry for their particular medical product.



Figure 19. Class 1 enclosures for laser marker cutting system and a gas-assist fusion cutting system

Laser system design engineers have the ability to mix and match system components to control cost and insure a cost effective equipment solution. For example, designers might assign four (4) axes of motion to moving the part and one rotary axis to move the focusing assembly according to what scheme is the best solution for the application.

Laser cutting for medical tube tools and components has many benefits, but actually achieving them depends in no small part on successful system integration. Designers need to develop an entire system where the motion, laser, software, and tooling all work properly and are integrated into a whole that supports the desired process flow. Putting the pieces together can be a challenge; one that is exacerbated by the fact that many integrators do not have a good understanding of the laser cutting tool, its capabilities and its limitations.



Figure 20. CAD design

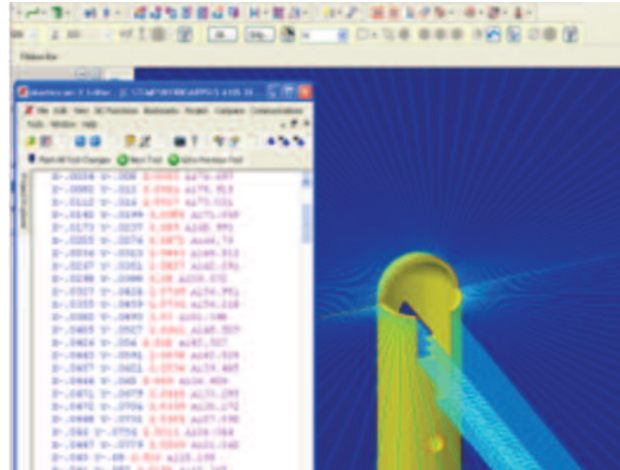


Figure 21. Screen image



Figure 22. Final part

cad design & post processing software

Complex laser cutting operations require full featured programming software for controlling the laser parameters and precision motion functions. This is achieved by transferring a digital 3D CAD model to a computer with post processing software which generates the on-tool path instructions and G code functions for the laser and motion system to complete the actual part. The graphic user interface flat panel display provides the operator/programmer with a full suite of control features including:

Laser process settings

- pulse frequency
- pulse energy
- average power
- other laser functions

CNC motion programming

- CAD input
- tool path
- speed adjustments
- gas assist settings
- laser start/stop

The programming software also provides a full suite of tools for gathering and storing process data to meet FDA validation and in-house documentation requirements. Programming and external communication is provided via a dedicated PC and Ethernet connectivity. Remote programming and system diagnostics may also be possible with the Ethernet features. Figures 20-22 depict the CAD software design image, PC post processing program creation with G code and the final, 'as cut' tube component.

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