# Precision Cutting for Medical Devices

## Laser Systems Offer Designers Freedom to Create Challenging Geometries

Medical device manufacturers continue to demand more reliable, faster and more cost effective manufacturing solutions to stay competitive in the global marketplace. One area where this need is especially prevalent is precision cutting of thin metal tubular structures, like those found in stents, rigid endoscopic and arthroscopic devices, biopsy tools, needles, and cannulas.

The term “surgical precision” aptly applies to the need for clean sharp edges, contours, and patterns found in medical device tools and devices. From surgical instruments used in cutting and biopsy, to needles containing unusual tips and side wall openings, to puzzle chain linkages for flexible endoscopes, cutting must provide the higher precision, quality, and speed now required.

There are several methods available to cut the metals most commonly found in surgical and implantable medical devices, which include stainless steel, titanium, nickel and cobalt-chrome alloys and Nitinol. The major options, lasers, electric discharge machining (EDM), water-jet, and chemical machining and grinding, each have a role to play.

However, precision fiber laser cutting technology is now emerging as the preferred choice for many thin wall metal tube cutting or machining applications used in endoscopic and arthroscopic medical instruments, particularly when superior edge quality, tight dimensional tolerances and/or high volume production is required.

In addition, new laser cutting technologies are now coming on the market, including more powerful fiber lasers integrated into turnkey systems with multi-axis motion capabilities. This technology gives the medical device designer freedom to create more challenging geometries with superior “as cut” edge quality.

## SOLID STATE LASER CHOICES

Laser cutting is ideally suited for making complex shapes because it is not limited by part geometry. Because the laser cutting tool does not rely on touching the part, it can be oriented to make any shape or form. **Table 1** lists the general 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 |

***Table 1 - Benefits of laser cutting***

Fiber lasers and pulsed Nd:YAG (neodymium-doped yttrium aluminum garnet) lasers are the two solid state laser options used most for fine cutting of the type of thin material (<0.020-inch or 0.5 millimeter (mm) found in most surgical and medical device applications. The fiber laser offers some key advantages over the pulsed Nd:YAG technology, including finer focused spot sizes, higher repetition rates, and a lower cost of ownership. For these reasons, it has become the laser technology of choice for thin metal precision cutting.

### Fiber laser

Fiber laser cutting technology offers exceptional control over pulse width, power, and focus spot size. Fiber lasers are ideal for working on small diameter, thin wall metal tubes that must be cut to high dimensional accuracy. Because the laser beam does not have any physical presence, it 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.

Fiber lasers also offers minimal thermal input, with fine control over how hot the work area gets. This is important because 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.

**Figure 1** shows a typical 100W fiber laser. **Table 2** lists the benefits of the fiber laser for cutting thin tubes used in surgical and medical devices.


***Figure 1: a typical 100 W fiber laser***

| |
|---|
| Relatively low cost |
| Exceptional beam quality for excellent cut quality |
| Small narrow kerf width (0.002") provides high cut resolution |
| High focused power density maximizes cutting speeds |
| 50,00 to 100,000 hours of maintenance free operation |
| Electrical power to laser conversion efficiency-30% |
| Small footprint-ease of integration |

***Table 2 - Fiber laser benefits***

Within the category of fiber laser cutting technology, fiber laser cutting with "gas assist," also known as fusion cutting, is frequently used to manufacture medical tubes and components of endoscopic, arthroscopic and other surgical instruments. The term "gas assist" refers to the fact that the laser energy delivered to the cutting zone is assisted with a coaxial gas flow, typically oxygen ($O_2$), though other gases such as nitrogen, argon and air can also be used.

The gas assist feature increases cut speed and "as cut" edge quality. The oxygen flow blows away the molten material and also serves as a heating element, because the heated material reacts with it and heats up. The heat reaction caused by the presence of oxygen adds about 30 to 50 percent more heating energy to the cutting area. **Figure 2** shows examples of medical products cut using this technology.

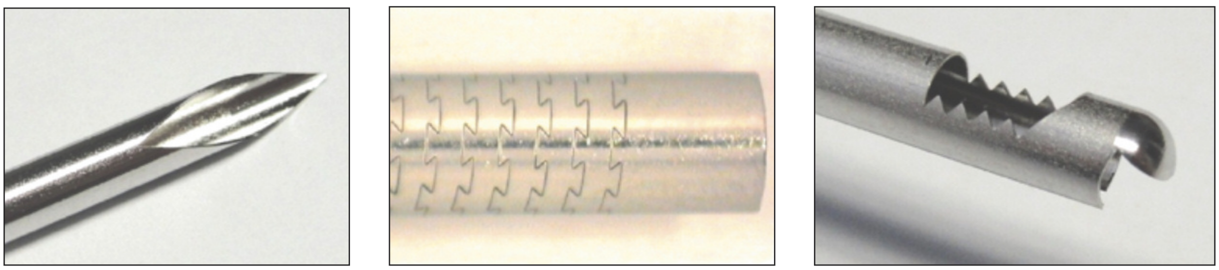


***Figure 2***

The fusion gas assist cutting method can be used for both on-axis (90º 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.

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 3** shows a close up image of the laser cutter focusing optics with the co-axial gas assist nozzle.

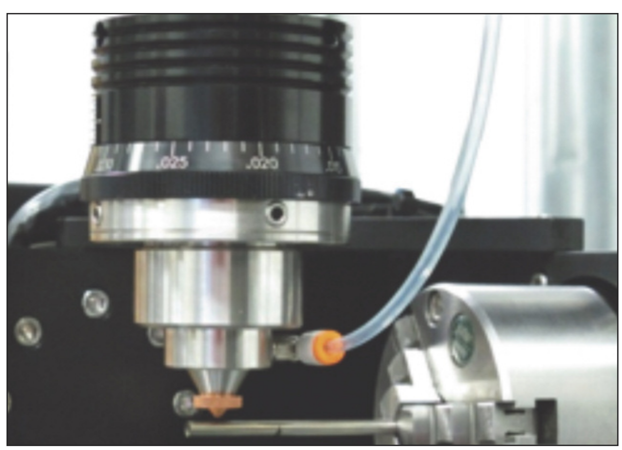


***Figure 3 – Interior of 5 axes multi-axis laser fusion cutting system***

The laser cutting with gas assist method 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. Another advantage is that little dross or burr is left on the underside of the cut that can become attached and re-solidified.

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.

Fusion gas assist cutting requires an intense laser source to quickly heat up the metal to the melting point as the oxygen is applied to remove the molten metal from the cut kerf at the same time. 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 average power of 200 watts or more are ideally suited for this application in stainless steel, nickel, titanium, Nitinol and other grey metals.

**Figure 4** illustrates the "as cut" edge quality and smooth surface that laser cutting with fusion/gas assist can produce – better than 12 micro-inches (0.3048 μ). **Table 3** lists the benefits of the technology.

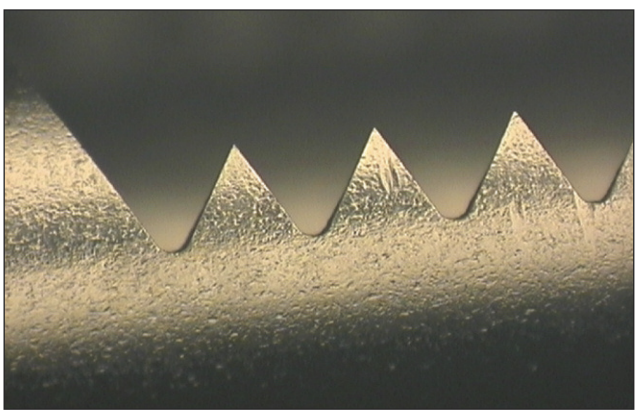


***Figure 4 – Laser with gas assist as cut edge quality***

| |
|---|
| Highest cut quality |
| Dimensional accuracy (±0.001) |
| Little or no dross/burr on exit side |
| Cut kerf width <0.002 in |
| 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) |

***Table 3 – Fusion gas assist laser cutting feature and benefits***

Another type of laser cutting is the fine melt ejection method, which uses a pulsed fiber laser marker for cutting metals typically less than 0.02-inch / 0.5 mm thick. Such a system costs significantly less than a fusion cutting system integrated with a multi-axis programmable CNC motion package. This method is also suited for cutting thin reflective metals, for example copper or gold.

Laser marker cutting uses a short pulse fiber laser with 20 or more watts of average power with 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. By selecting the optimum laser parameters, material is removed in thin layers, layer after layer 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. Since there is little material melting with such short pulses, there is very small heat input or thermal damage. Typical applications for this type of cutting include tube cutting and drilling suitable for some medical applications, micro-electronics, semi-conductor, and solar applications. It is also useful for cutting prototype lead frames or other thin sheet metal parts with an underside burr of less than 0.0005-inch. **Table 4** compares the features of gas assist fusion with those of fine melt ejection.

| Gas assist fusion cutting | Fine melt ejection |
|---|---|
| Highest cut quality | Good cut accuracy |
| Single pass cut | Multiple pass cuts |
| Multi-axis cutting options | 2 axis cutting |
| Minimal HAZ | Lower cost equipment |

***Table 4 – Comparison of gas assist fusion and fine melt ejection***

**Figure 5** shows two examples of multi pass cutting using a fiber laser marker; degating of a 0.004: thick component, and detailed patterns in 0.02-inch copper.

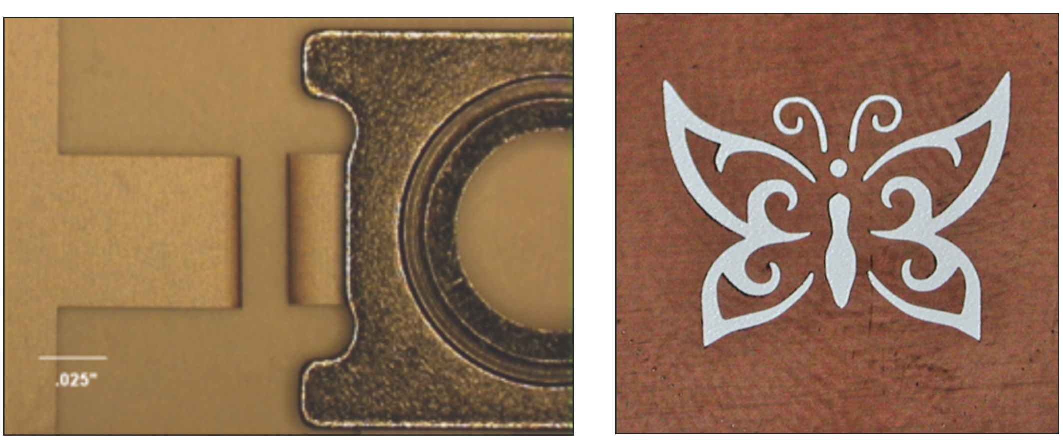



***Figure 5 –Examples of multi pass cutting in 0.004 in thick stainless steel and 0.002 in copper using a fiber laser marker***

## COMPETING NON-LASER PROCESSES

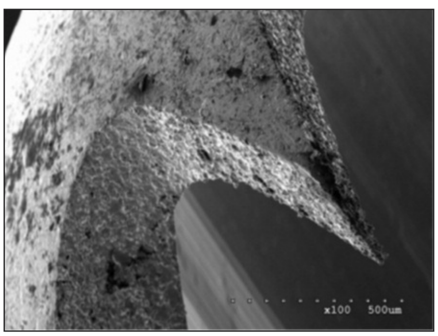
### Wire EDM

Wire EDM is the most widely used traditional precision cutting technology for cutting thin wall metal tubing required for rigid endoscopic, arthroscopic and other medical devices. Cost of wire EDM equipment is significantly less than that of laser equipment. However, laser processing offers faster cutting speed, superior edge quality and greater precision compared with that of EDM. **Figure 6** shows a comparison of cut quality between a single pass EDM and a laser.

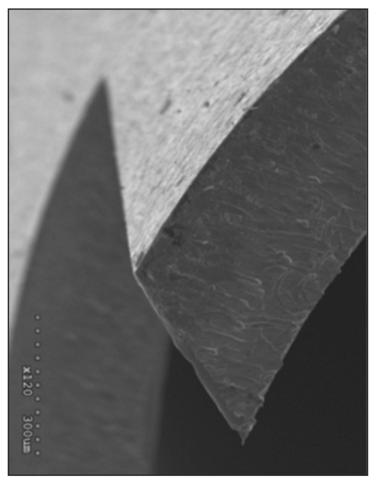
For some high volume EDM applications, several tube sections may be secured in a special tooling fixture and machined in a single pass. This multi-up EDM process offers a unique advantage over laser gas assist cutting because only one part at a time may be cut with laser fusion cutting.

However, the wire EDM process has several limitations. The wire EDM cutting cycle can only proceed in a two dimensional geometry. Bevels or other three dimensional geometry requires a separate set up, program and cutting process, which adds to the total process time. By comparison, laser equipment can cut three dimensional geometries in a single pass, using a 5 axis motion package. Also, wire EDM has a minimum cut width of about 0.004 to 0.006-inch, which makes it unsuitable for sharp inside corners. Lasers can make sharper inside cuts. In addition wire EDM is unable to cut single sided features therefore cutting a single sided slot is not possible.

*Source: Amada Miyachi America*




*Wire EDM*




*Laser*

***Figure 6 – Cut quality comparison of single pass EDM and laser***

With the EDM process, a thin traveling wire passes close to an electrically conductive work piece, and the gap between the wire and work piece is filled with a dielectric fluid. The fluid provides a current path from the wire to the work piece and flushes away the debris and metal particles created. Close observation and control over the dielectric flushing solution is critical to preventing wire breakage and downtime, which is a definite productivity concern associated with the wire EDM process.

Another process issue associated with EDM cutting is the requirement for a large reservoir of de-ionized flushing water, which necessitates continuous monitoring and adjustment to maintain the correct ion-levels. Wire EDM systems also require considerable machine maintenance and cleaning.

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. Finally, in order to obtain the same high quality cut as a laser cutting machine, wire EDM may require up to four separate 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.

### Water jet cutting and electro-chemical grinding (ECM)

A variety of other cutting applications may be used, including water jet cutting and electro-chemical (ECM) grinding, but in general these methods are less effective than either laser or EDM. Water jet cutting is slow and has geometric limitations. ECM achieves quality similar to EDM, but ECM requires the disposal of the electrolyte used in accordance with hazardous waste regulations, and some electrolytes produce hexavalent 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

Laser cutting for medical tube tools and components has many benefits, but actually achieving them depends 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.

In addition to the most optimum laser, each application requires a workstation, through the focus head viewing, assist gas, a motion package with programmable motion, HMI and full featured control software with post processor capability. The motion, laser, software, and tooling must all work together to get the desired end product and long term performance.

### Enclosure and CNC motion options

Laser cutting applications are normally conducted inside a Class I, eye safe enclosure. These enclosures must meet FDA's CDRH (Center for Devices and Radiological Health) 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. Enclosures must also have proper warning labels, emergency stop and indicator lights. A variety of other features are required, including a highly stable platform and be suitable for system components, and a heavy steel or granite base plate and vibration isolation footings to handle vibration and shock.

### Two dimensional tube cutting

Tube cutting requires precision, multi-axis programmable CNC linear and rotary motion. A fully programmable tube feeder is typically used in conjunction with a 3-4 axis 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 used for laser cutting stents, cannulas, hypo-tube and other medical device open end tubular components.

A programmable tube feeder is normally used to accommodate10-foot long metal tube sections. 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. The programmable tube feeder reduces labor and maximizes productivity, since no human intervention is required until the entire 10 foot length of tube is consumed.

## Three dimensional tube cutting

A 5-axis CNC motion package, usually consisting of 3 linear axes and 2 rotary axes, is required for laser machining three dimensional features. This is most common in closed end tubular components 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. 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 7** shows the interior of a 5 axes fusion laser.

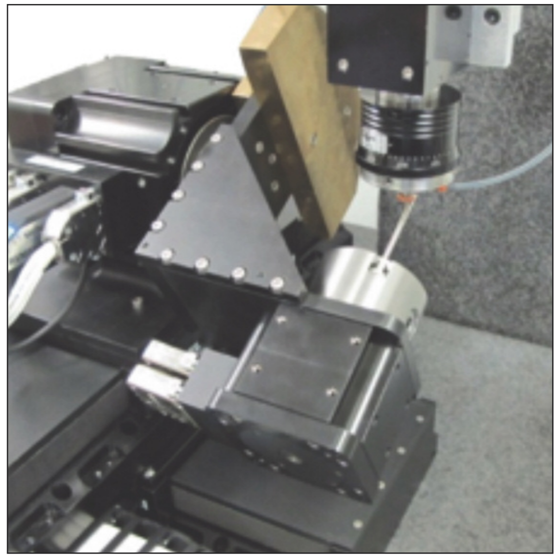


***Figure 7 – Interior of 5 axes multi-axis laser fusion cutting system***

## CAD design and 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 3-dimensional CAD model to a computer with post processing software that generates the tool path instructions and 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 controls for laser process settings and CNC motion programming.

The programming software also provides 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.

## FINAL THOUGHTS

The explosive growth of minimally invasive surgery tools gives rise to some unique and innovative device shapes and cutting challenges. Laser cutting systems are the best option for making intricate cuts in a cost effective manner, providing component designers greater freedom, enabling them to design more challenging cut geometries into their medical products.