

## An Engineer's Guide to Medical Device Manufacturing using Laser Micromachining Technology

### Precision Laser Skiving

Exactly how does laser skiving work?

How does a Laser Job Shop or Laser Contract Manufacturing Services work?

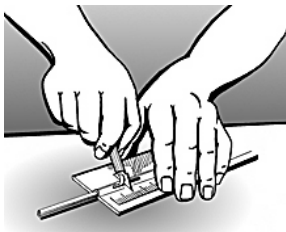
When do you decide to bring the laser micromachining technology in-house?

Medical Device Skiving is a manufacturing term to describe the removal of the outer wall of a delivery device. These delivery devices tend to be catheters which, in association with guide wires, may act as a conduit for a balloon, stent, brush, monitor, drug delivery or evacuation tool.

Traditionally single or multi-lumen catheters, ranging from F3 to F10 in size, can be skived mechanically. This technique involves an operator to place a simple contact template over the plastic catheter. The template has openings with sloped edges to force the plastic tube to the cutting plane. With adept skill, operators swipe across the exposed catheter using a surgical razor blade or knife edge, "skiving" or slicing the outer wall. The skived area can be an oval, ellipse or rectangular in shape.

The advantage of mechanical skiving lies in its simplicity and tradition. Since the manufacturing technique is manual, it does not require complicated tooling. Capacity planning is relatively straight-forward, proportional to the number of production operators. If the skive dimension changes, then the template is changed. If the skive location is changed, then the linear gauge or hard tool must be altered.

The disadvantage of mechanical skiving is interwoven into the very fabric of its celebrated advantages. Since the manufacturing process is manual, premium space in a clean room must be allocated for the individual workstations. Capacity ramp up or ramp down is a human resource management issue. Operator turnover leads to continual training programs which affects quality and yield. Rejects of 10% or higher is not uncommon.



As medical device companies strive for more cost-effective manufacturing solutions, laser micromachining technology is emerging as a new tool for Manufacturing Engineers. Companies are looking for long term outsource partners who can provide volume skiving of catheters and other devices, providing these companies have an infrastructure base of contract manufacturing. Typically outsource laser job shops will require at least 25 laser systems in-house to handle capacity, have multiple clean rooms, a dedicated Operations staff with SPC control and FDA certification knowledge.

For those applications where skiving is in the middle of the manufacturing cycle, laser systems are brought in-house. Often the laser technology is shared with the design engineers who use the laser as a quick turn prototype tool. Clearly, another advantage of laser micromachining technology over mechanical skiving lies in its ability to machine smaller feature sizes. This is especially true for the smaller French sizes which are used in the cardiovascular and neurology arenas for minimal invasive surgery. Also lasers offer tighter skive dimensional tolerances.



Laser Skiving

Also see:  
Laser Cutting  
Laser Drilling  
Stripping  
Precision Etching  
Laser Slots  
Marking

## Exactly how does laser skiving work?

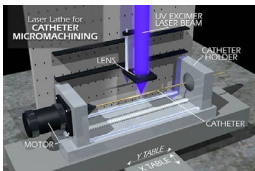
Typically a mandrel is placed inside the lumen. The mandrel acts as both a tool insert and a blocker. The laser beam enters the outside wall of the catheter and will continue to drill through the "other side" if the mandrel is not present. Although a pulsed laser can drill with 0.1micron precision, the "break-through" of the outer wall can lead to scattered laser light hitting the backside. For some multi-lumen devices, this issue may compromise the wall integrity between lumens. Mandrel material selection is based upon the catheter material and cleanliness issues. For multi-lumen catheters, the mandrel can help identify the lumen, especially if the lumen has a distinctive shape or size.

## How does a Laser Job Shop or Laser Contract Manufacturing Services work?

Tooling plays a key role in laser skiving. As a general rule, laser contract manufacturers will have at least 25-50 laser systems on the production floor in a two shift operation. On the other hand, laser job shops tend to operate in one shift with a handful of lasers.

Since this article is dealing with volume manufacturing of medical devices, let's concentrate on laser contract manufacturing only. Established laser contract manufacturers will have invested in a wide assortment of hard tooling fixtures as an obligatory service for medical device manufacturers. These type of mandatory capital expenditures, usually several hundred thousands of dollars, allow the laser contract manufacturer to help the medical device company prototype a multitude of design concepts before any production tooling is conceived. For smaller laser job shops, this type of investment is prohibited. Therefore the prospective medical device company should be cautioned on the amount of NRE charges that a laser job shop service may request for first-time prototyping. However some technical waivers may be required to accommodate the fast track process.

A typical rapid prototyping laser system is designed for flexibility, universality and an objective to minimize lead-times as well as providing a cost-effective solution. These type of laser systems tend to be custom. Hence the volume Laser Contract manufacturers tend to design their own laser systems and have an in-house engineering staff to offer the greatest options for the medical device manufacturer. These type of laser systems comprise of large conventional excimer, CW CO<sub>2</sub> or solid-state lasers. For true outsourcing, contract manufacturers tend to invest in +\$300,000 systems so that the fastest laser systems can be built. Although smaller tabletop and sealed off laser systems can be used for job shop services, these lower cost units are slower due to the smaller beam size—resulting in higher piece prices for the end customer. Clearly whenever a medical company contemplates outsourcing, they should not be paying a premium price because the laser job shop fails to invest in the multi-million dollar capital investment.



Be certain that the laser vendor understand the fiscal responsibility. Ask the laser contract manufacturer if they have invested in the largest and faster technology on the market. Conventional UV laser powers should reach 160W. As a customer in a demanding ever-changing marketplace, you deserve the best technology on the market at the best price/performance.

If your medical device design team is larger than your prospective laser job shop, you should reconsider your selection. Market studies have shown that any volume contract manufacturing with Statistical Process Control (SPC) requires a support staff of at least fifty (50) application engineers, technicians and operators. This number is based upon a two shift, six (6) day operation with cross-training of all departmental levels for a given job, including design engineering, manufacturing engineers, production, quality control, quality assurance, incoming receiving, shipping and material control. Don't risk your company's future on the hope of a single craftsman. Maximize your company's success on the collective expertise of a seasoned team. Choose companies with established track records who have the flexibility of handling low volume high premium products to high volume, low cost commodity products. Even if your contract is not a million dollar proposition today, look for laser contract manufacturers with +10 years of experience so that you will receive the long term support with the cost savings associated with experience.

Never make a decision on a large contract without visiting your prospective laser contract manufacturer. Insist on a vendor quality audit. Insist upon seeing Process Flowcharts. Insist upon seeing Quality Assurance Programs. Insist upon seeing the Operational Capacity Planner for two shift operations. Insist upon seeing preventative maintenance schedules with on-call service engineers. Insist upon seeing the company's employee education and cross-training programs. Insist upon seeing at least 25 to 50 laser systems operating under multiple shifts to assure you that there are redundancy programs in place.

Making business decision for your laser outsource partner is not just about who you trust. It's about who you trust if that contact group is no longer there. It's about who you trust if the next contract group is no longer there. Outsource business decisions are based upon critical mass-and depth.

## When do you decide to bring the laser micromachining technology in-house?

This is one of the toughest questions that can be asked of a manufacturing engineer for a medical device company. To put things in context, a product design engineer has a principal responsibility to ensure that design will work if it is built to specification. The Production Manager has the principal responsibility to ensure that the product can be built within the target cost model and meet or exceed the delivery schedules.

But the manufacturing engineer has the dual responsibility of ensuring that product is built to specification but with the equal burden of responsibility that the product can be built on time within the desired cost model. To evaluate this decision tree diagram, the manufacturing engineer must decide whether to build the product internally and justify the capital equipment expenditure and training period to get "up to speed". Or should the engineer recommend to outsource the product and leave the cost and delivery model in the hands of the laser contract manufacturer.

In reality, the manufacturing engineer does not have to make such a clear, "black and white" choice. The engineer may opt to choose a supplier who offer both volume contract manufacturing with the capacity and size to offer high quality products at competitive prices and the ability to design and manufacturer a laser system for sale. Select a company that offers volume manufacturing but with the foresight to offer technology transfer by selling equipment. Be certain that this company can offer you the choice of table top or full production systems so that you can make an informed decision.

Should the medical device company decide to bring the technology in-house, the laser system candidates include:

**Excimer Production Systems** [Maestro Series 1000](#)  
[Maestro Series 2000](#)

**Excimer Prototyping System** [MicroMaster](#)

**Solid-State Production Systems** [Impressario\\_CO2](#)

**Production Systems** [Router](#)

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