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# THE FUTURE OF LASER MICRO MANUFACTURING IN MEDICAL DEVICE MARKETS



PREPARED AND PRESENTED BY RESONETICS



# INTRODUCTION

#### LASER MICRO MANUFACTURING TECHNOLOGIES AND ITS IMPACT ON MEDICAL DEVICE MANUFACTURING

Laser micro manufacturing is a compilation of technologies developed to address an everincreasing demand for micro-scale manufacturing in the Medical Device and Advanced Diagnostics Markets. These technologies include laser ablation, laser cutting, laser drilling, and laser welding.

Each technology addresses a common medical device manufacturers' need to fabricate microscale medical devices in metals or polymers. The advantage of using a laser over traditional mechanical processes includes no part contact, ability for micron scale features and minimal heat-input. These combined advantages are enabling miniaturization to occur across multiple medical device applications with a direct path from prototyping to production.

This article provides details on laser micro manufacturing technologies and applying them to medical devices.

# LASER ABLATION

Laser ablation is a method of selectively removing material resulting in micron scale features on micro or macro scale metal or polymer components. The material is selectively removed via vaporization resulting from the exposure to a focused laser beam as shown in figure 1. Resonetics employs a variety of laser tools including CO2 diode-pumped solid-state, excimer and ultrafast (picosecond and femtosecond) lasers.



Figure 1. Schematic of Laser Ablation Process

Laser ablation has been a beneficial process for advanced micro manufacturing of medical device applications because it offers a wide range of material compatibility resulting in a diverse scale of products.

## LASER ABLATION FOR MEDICAL DEVICES

Laser ablation continues to gain popularity and demand as R&D engineers understand its benefits in miniaturization of devices.

#### **EXAMPLE MEDICAL DEVICE APPLICATIONS:**

- Fine wire coating removal
- Single and multi-lumen catheter tip shaping and outside diameter removal
- Balloon surface texturing
- Micro implants
- Micro instruments



# UNIQUE APPLICATIONS

## **3-D LASER ABLATION**

As laser ablation technology enables new advancements in the medical device industry, new applications are materializing that push the boundaries of micro manufacturing.

One example is 3-D ablation, which was a process developed to support unmet customer needs in the neurovascular market.

#### CHALLENGE

A customer required a metal part that was ten times smaller than a Swiss CNC machining process could provide.

#### SOLUTION

Resonetics developed a micro-scale ablation technique that enabled this neurovascular application through a combination of advanced ultrafast laser technology, motion control and custom software. This technology proved versatile enough to serve additional applications in the ophthalmic and cardiovascular markets.

See figures 2 and 3 (right) for application examples of 3-D ablation.



Figure 2. Micro Jaw Nitinol Components Outside Diameter 1.1049mm, 0.0889mm Wall Thickness



Figure 3. 3-D Laser Ablation of Nitinol Component. Dimensions: ID 0.137mm / OD 0.343mm

#### LASER ABLATION CONTINUED.

### WIRE STRIPPING

Another unique application of laser ablation is laser wire stripping. This process involves the removal of the outer coating to expose the underlaying layer or the core metal wire.

#### CHALLENGE

In figure 4 below, we show crosssections of an ideal multi-layer coated wire (I) and a real wire with (exaggerated) non-concentricity issues (II). The coating layers are thicker in some locations and thinner in other locations around the wire. If we laser strip the wire in an open-loop process (i.e. delivering the same number of pulses at all rotational locations), then the end result is an uneven, nonuniformly stripped wire with remaining coating layers as well as a possibility of core wire damage at some rotational locations (III, IV).



#### SOLUTION

To ensure 100% removal of each coating layer and to minimize undesired incursion into the next layer, Resonetics developed and patented a unique closed-loop process control called ASSURE End Point Detection™. By monitoring the plasma plume at the ablation point, whose signature discriminates between materials of subsequent layers and detects presence and type of remaining material, the laser can turn on and off to avoid going too deep in the thinner sections of the wire coating or removing too little in the thicker sections (V, VI).



Figure 4. Laser Wire Stripping Using ASSURE End Point Detection™, Wire Diameter 0.100mm

The major benefit of ASSURE End Point Detection™ is that coated wires can be stripped uniformly and consistently, independent of the inevitable variation of the wire coating from lot to lot or even within the same spool.

# LASER CUTTING

Laser cutting uses a focused laser beam to melt or ablate material which is removed via a coaxial gas nozzle as shown in figure 5 (right). This process is well-established and used extensively in the manufacturing of medical devices.

Laser cutting typically uses a Nd:YAG or fiber laser. In addition to Resonetics using these lasers, they have also developed ultrafast (picosecond and femtosecond) laser cutting to eliminate heat input which minimizes downstream part processing.

Ultrafast laser cutting can be used for various types of metals and polymers with benefits including; no heat affected zone, clean cut edges and no burrs.

See figures 6 and 7 (below) for application examples of laser cutting.



Figure 5. Laser Cutting Process Diagram

#### EXAMPLE MEDICAL DEVICE APPLICATIONS:

- Thin walled stents
- Delivery system components
- Pull rings
- Bioresorbable scaffolds



Figure 6. Stainless Steel Laser Cut Hypotube (LCT). Larger Diameter LCT 4.572mm OD x 4.2164mm ID



*Figure 7. Small Diameter LCT 0.4445mm OCD X 0.3429mm ID* 

# INNOVATIVE CUTTING PROCESSES

#### APPLICATIONS AND ADVANCEMENTS FOR THE MEDICAL DEVICE INDUSTRY

Resonetics has combined advances in laser and motion control to develop a cost-effective tool for high-volume manufacturing catheter components. This high-speed laser cutting process is called PRIME<sup>™</sup> Laser Cut.

The laser cut hypotubes (LCT) from the PRIME™ process have many advantages over traditional catheter manufacturing methods (such as braided coil construction). Below are key benefits of PRIME™ Laser Cut LCT catheter components:

**Customization:** a key benefit of LCT over traditional catheter construction is the ability to completely customize the part geometry to match the clinical demands of the catheter. For example, if you are designing a catheter with significant stiffness on the proximal end but require uniaxial flexibility on the distal end this can be difficult to achieve with a traditional braiding/coiling technique.

**Torque Transfer:** LCT typically employs interrupted cutting which enables flexibility but maintains a monolithic connection from proximal to distal ends of the catheter. This direct connection ensures a good torque response when functioning the device in-vivo.



PRIME™ Laser Cut Hypotube



Example of Laser Cut Parts

**Kink Resistance:** an additional advantage of the monolithic aspect is optimized kink resistance. As devices become more flexible they inherently have a higher risk of kinking upon insertion/propagation through the anatomy. The PRIME™ process enables the design of flexibility and optimization of kink resistance without sacrificing functionality.

#### INNOVATIVE CUTTING PROCESSES CONTINUED

**Ovality:** a challenge with braided/coiled catheters is flattening or ovality as they move through difficult anatomy. Since LCT is monolithic it does not collapse as it propagates tortuous anatomy. This is critical when passing additional devices through the inner diameter of the catheter.

**Low Profile:** LCT based catheters can start with a relatively thin-wall tube (down to <0.0005") while maintaining the strength requirements of the catheter. Again the monolithic benefits of LCT enable a reduced wall thickness of the catheter which opens up space for larger devices passing through the inner diameter.



Figure 8. Prime™ Laser Cut Examples with Varying Cut Pitches

# NITINOL CUTTING

Resonetics has also developed advances in nitinol cutting using ultrafast laser technology. Nitinol is used extensively for the fabrication of catheter components and implants and is sensitive to thermal heat input. Figure 9 below shows an ultrafast laser cut nitinol part. Beyond the elimination of heat input, ultrafast laser cutting also provides a part that is closer to near net shape which minimizes the downstream requirement for electropolishing.



Figure 9. Nitinol Stent with 0.025mm Strut Width Cut with Ultrafast Laser

# LASER DRILLING

#### **PROCESS AND APPLICATIONS**

Laser drilling is an ablation process that uses a focused laser beam to create micron scale thru-holes. As shown in figure 10 below, the process uses a focused laser beam to drill holes and is considered advantageous for medical device manufacturing due to its precision and efficiency. Laser drilling enables the fabrication of holes down to single microns in diameter, which cannot be achieved by standard drilling methods. The process can also be performed on a wide variety of metals and polymers, eliminating heat damage and maintaining the integrity of the product being manufactured. Some popular applications that use laser drilling are embolic protection filters and infusion catheters.

Catheter balloons are a common component used in several minimally invasive procedures. Some procedures require functionality beyond simple inflation such as localized drug delivery. Laser drilling enables the fabrication of drug delivery balloons by creating micro-scale holes across the surface of a balloon. A perfect case, where balloons are represented by ideal geometric forms (typically cylinders and cones), this can be achieved by a simple set up and alignment procedure and straightforward multi-axis positioning control. However, real-world balloons can deviate from ideal geometric form, which requires new process control strategies.





#### EXAMPLE: LASER DRILLING APPLICATIONS

- Embolic protection filters
- Infusion catheters
- Flow access holes
- Micro hole arrays



Example of Laser Textured Balloon

#### LASER DRILLING CONTINUED

### **BALLOON AND CATHETERS**

A good example of drilling is an array of holes covering the conical end of a balloon (shown in figure 11, right). For this application, a scanning mask method is used as described in US Patent 7,812,280 "Method and apparatus for laser micromachining a conical surface". However, when the conical end of the balloon is not a true cone, the geometric distortion affects the hole pattern as it is mapped onto the cone. To deal with this problem, Resonetics' has developed a process control method for on-line, automated machine vision mapping of the balloon geometry, and a proprietary algorithm to provide real-time adjustments.



*Figure 11. Laser Drilled Holes Covering the Conical End of Balloon* 



Figure 12. Holes Drilled in Polymer Catheter Extrusion

Another application example is laser drilling multi-lumen drug delivery catheters. In such catheters, the drug is distributed through small satellite lumens. The requirement is to drill small holes or arrays of holes through the outer wall of the satellite lumens without perforating the inner wall. This is accomplished by incorporating an in-situ optical inspection to detect inner wall damage as an end-point detection control method to prevent excessive ablation of the lumen inner wall.

# LASER WELDING

Laser welding is a process that joins together two parts of similar material composition without the use of a filler metal. As shown in figure 13, this process utilizes a focused beam to locally melt and fuse metal with minimal heat affected zone. The low heat input aspect of the process maintains the integrity of the base material and prevents distortion of the final assembly.



Figure 13. Schematic of Laser Welding Process

### LASER WELDING FOR MICRO SCALE DEVICES

#### **APPLICATIONS AND TECHNOLOGIES**

Laser welding is particularly useful for micro scale medical devices that are too small to be joined by traditional welding methods. The process is used across several medical device markets including neurovascular, structural heart, ophthalmic, electrophysiology, interventional cardiology and sports medicine.

Resonetics is called upon to provide solutions in laser welding applications that have a high level of difficulty or complexity. These applications typically require a focus on the following process control concerns:

**Geometry control:** Part geometry cannot vary more than 10% of the smallest part feature, dictating single micron tolerances on all parts.

**Part fixtures:** Fixture design and fabrication requires specialized laser micro manufacturing capabilities.



Figure 14. Laser Welded Wire to Pull Ring

#### LASER WELDING CONTINUED.

Laser stability: Laser systems must be industrial, robust and stable, requiring the precise measurement, monitoring and control of the laser power. Low cost jewelry welding lasers lack the power stability to guarantee a stable process.

**Part handling:** Part manipulation requires skilled technicians who use micro-manipulators with the aid of optical microscopes.



Figure 15. Laser Welded Wire to Cannula

From the beginning, laser welding processes are designed with manufacturability and repeatability in mind, accelerating the product time-to-market by allowing contract manufacturers to deliver quick-turn prototypes, followed by scalable volume manufacturing.



Figure 16. Thin Wire Welding 0.075mm Diameter Nitinol Wire Assembly (Top), High Magnification View of the Laser Weld (Bottom)

Moving seamlessly from development to production requires expert laser knowledge of the process parameters, material weldability, geometry control, fixture design/manufacturing and part handling. Collectively these factors are critical for a successful implementation of micron-level laser welding for the most difficult medical device applications.

#### EXAMPLE LASER WELDING APPLICATIONS:

- Pull ring assemblies (Figure 14)
- Thin wire components for delivery systems (Figures 15 & 16)
- Micro implants

## CONCLUSION

This technical paper has highlighted laser processes including ablating, cutting, drilling and welding. It discusses the latest technology breakthroughs and how you can use them today.

At Resonetics, we specialize in applying the leading edge laser processing techniques to your medical devices. We help you develop and iterate quickly to get your device to market fast. To challenge our laser experts or to learn more, contact us.



# RESONETICS

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