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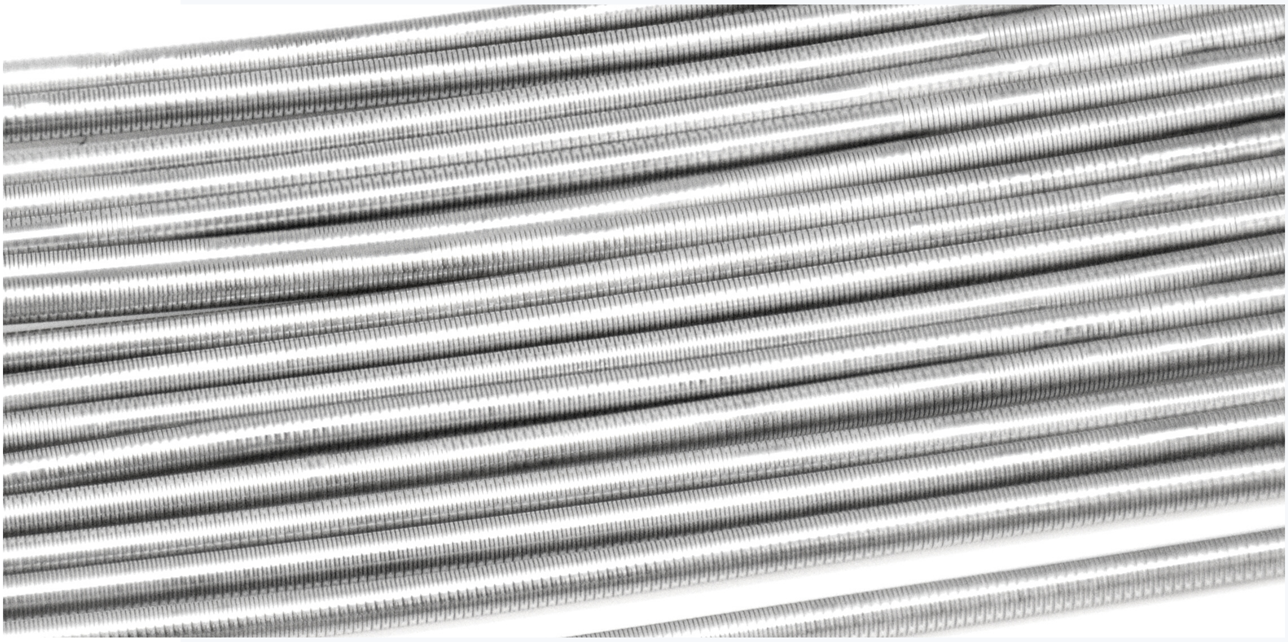
ENHANCED CATHETER PERFORMANCE MADE POSSIBLE WITH LASER CUT TUBING



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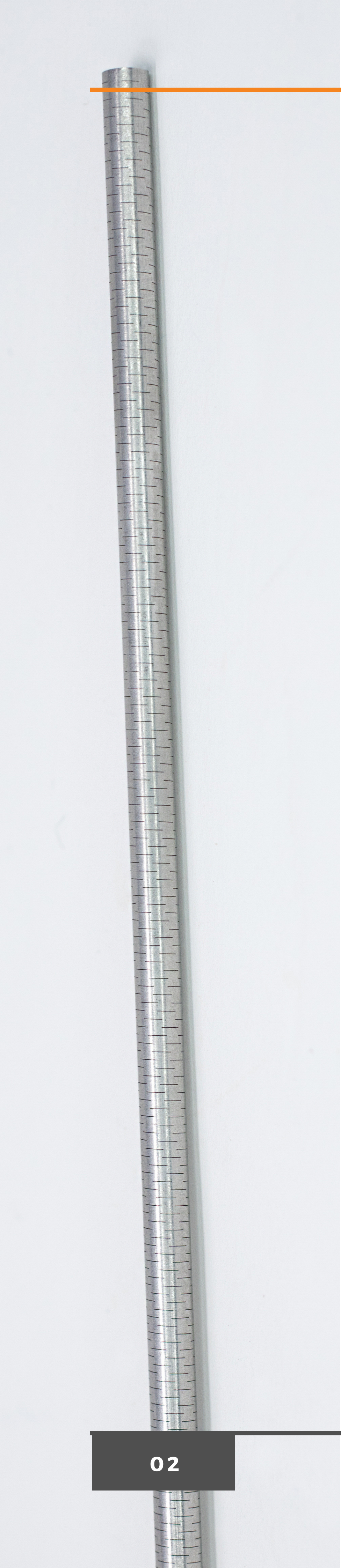
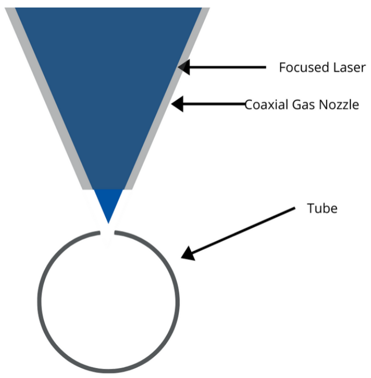


INTRODUCTION

EVOLUTION OF LASER CUT TUBING

Laser cut tubing (LCT) uses a focused laser to melt or ablate through one wall of a metal or polymer tube and remove the degraded material via a high-pressure coaxial gas nozzle. The process has been used in medical device manufacturing for over 30 years with major advancements following the push for miniaturization for minimally invasive procedures.



For catheter delivery systems, this process has been too slow and costly to incorporate. However, Resonetics has combined advances in laser and motion control to develop a cost-effective tool for high-volume manufacturing of catheter components. This high-speed laser cutting process is branded as PRIME Laser Cut and this paper details:

- PRIME Laser Cut benefits
- How to specify laser cut tube
- Cost savings considerations

PRIME PERFORMANCE BENEFITS

LESS INVASIVE PROCEDURES CONTINUE TO ADVANCE, REQUIRING BETTER TOOLS TO ENABLE ACCESS.

Laser cut spiral and interrupted spiral tubing offer several compelling advantages over traditional manufacturing processes:

Customization: A key benefit of laser cutting 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. With LCT, this custom flexibility can be incorporated easily into the laser cutting process.

Figure 1: Curvature of Laser Cut tube

Torque Transfer: Interrupted spiral cutting maintains a monolithic connection which enables flexibility but maintains a continuous link from proximal to distal ends of the catheter. This direct connection ensures a good torque response when advancing the device.

Figure 2: Example of different diameter/wall thickness of tube

Kink Resistance: A monolithic construction optimizes kink resistance. As devices become more flexible they have a higher risk of kinking upon insertion or advancement. A laser cut tube provides greater strength without compromising functionality.

Figure 3: Example of flexible LCT catheter shafts

Ovality: A challenge with braided/coiled delivery systems can be ovality or flattening when moving through tortuous anatomy. This is a significant issue when passing devices through the inner lumen of a device. A monolithic tubing design is less prone to flattening. 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, Optimized ID: Thin wall tubing (down to <0.0005") can be used with catheters to open up more space to pass larger devices through the inner lumen.

Simpler Design Reduces Labor: A laser cut tube eliminates the need for a tie layer and mandrel. Unlike braid, there are no loose ends to address.

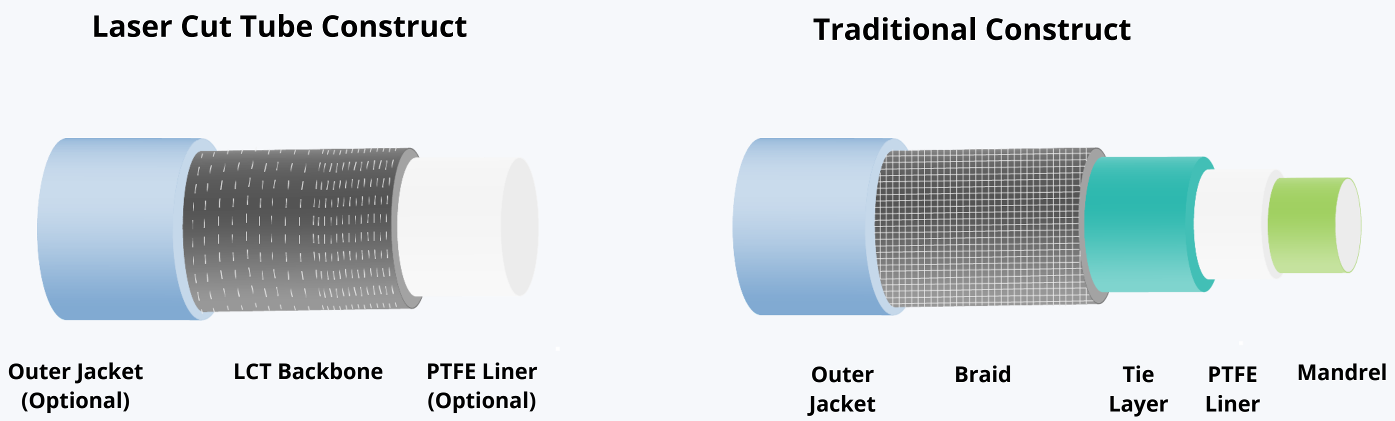


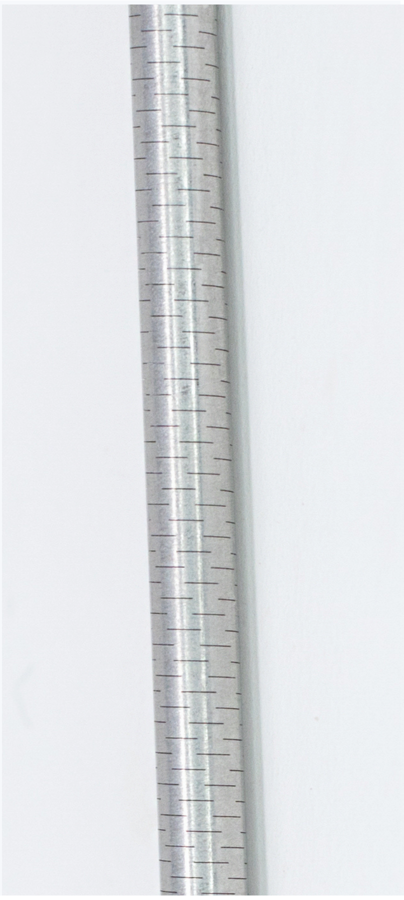
Figure 4: Laser Cut Tube vs Traditional Catheter Construct.

HOW TO SPECIFY?

The following design guide helps to provide our engineers with a starting point to fabricate prototype iterations with various performance attributes for your next catheter.

MATERIAL

The first step of the LCT design process is to select your tube material. The most common tube material is 304 stainless steel but other stainless steel alloys are available including 304L, 316, 316L, 17-4PH, and 17-7PH. Cobalt chrome and nitinol alloys are also options when stainless steel doesn't satisfy the application requirements.



INNER & OUTER DIAMETER

The next major specification includes the outside diameter (OD) and inside diameter (ID). Typically, the OD is set to match the size of the catheter being developed, while the ID is optimized for various performance attributes. The tolerances for both geometries will also be requested.

CATHETER SECTIONS

After the material selection is complete, the next step is to divide your catheter design into sections and sizing. The number of sections is highly dependent on the anatomy being traversed and the expected functional requirements throughout the procedure. The length of each catheter should be considered and specified.
A design table is provided to assist with detailing the catheter selections.

	Section 1	Section 2	Section 3	Section 4	Section 5	Overall Length
Section Length {mm}	100	250	250	100	25	725
Start Distance from Tip {mm}	0	100	350	600	700	
Functional Requirement	Stiff	Flexible - 1	Flexible - 2	Flexible - 5	Flexible - 7	
Omni vs. Uni Axial	Omni	Omni	Omni	Omni	Omni	
Radius of Curvature	NA	NA	NA	NA	50	

Figure 5: Catheter Design Specifications Table Example

A. STIFF OR FLEXIBLE

After the catheter is broken into sections the next determination is the relative flexibility required for each section. Typically, catheters are most flexible on the distal end and are stiffer proximally. Our engineers have developed a flexibility scale which can assist as a starting point.

PRIME Laser Cut Tubing Flexibility Scale with a 1 - 10 Rating

1: 50mm section will have 2mm deflection with zero force.

10: 50mm section will have 50mm deflection with zero force.

B. OMNI VS UNI DIRECTIONAL

The next step in the design process is to determine if the specified section will need to be omni or uni directional. Most designs require omni direction motion which basically means the catheter will have equal flexibility in all directions. However, there are times when a uni directional movement is required. When specified the device will be more flexible in one or two planes of movement.

C. RADIUS OF CURVATURE

The final step is determining how much curvature the catheter will traverse during use. This is typically specified by an estimated radius the device will pass through.

Note: Iterative samples are typically required to get the exact functional result. Prime LCT can be prototyped efficiently to provide quick turn samples with typical turnaround of 2-3 days.

COST CONSIDERATIONS

Once a design is frozen and volume production is underway, average unit pricing for PRIME Laser Cut tubes range from $20 to $75 depending on the complexity and total amount of laser cutting required. Throughout the development process, design iteration will be scrutinized for cost as well as performance characteristics.

CONCLUSION

Medical device designers have a new option to consider when developing the latest catheters and delivery systems. Utilizing advanced laser technology, Resonetics offers PRIME Laser Cut tubing as a fresh alternative to catheter constructs made with metal braid and coils. Once cost-prohibitive, a monolithic tubing construct can be designed with unrivaled customization to create the performance profile needed for the latest advancements in minimally invasive procedures.

WANT TO LEARN MORE?

At Resonetics, we specialize in solving manufacturing challenges with innovative thinking and a sense of urgency. We iterate quickly to help you get your device to market fast.

To challenge our experts or to learn more, contact us.

Stay up to date with what is happening at Resonetics by following us on LinkedIn: *linkedin.com/company/resonetics*

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