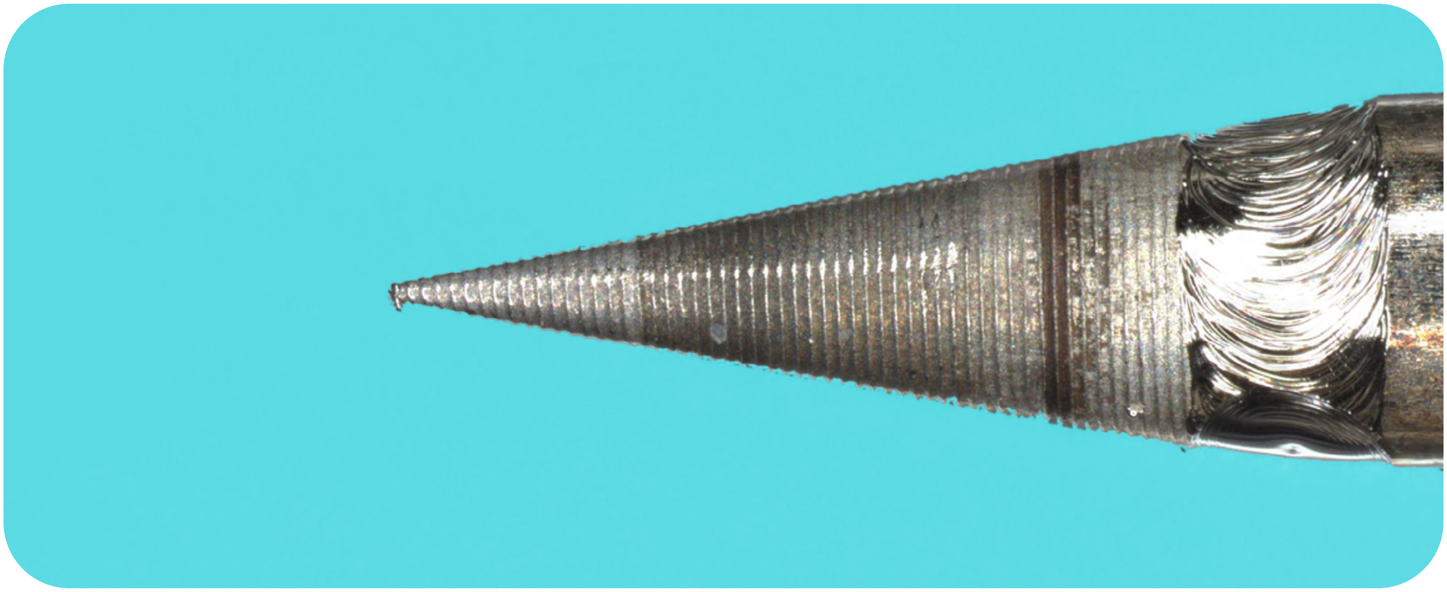
DEVICETALKS TUESDAYS

Design Considerations for Complex Laser-Cut and Welded Components

TECH BRIEF



Presenters:

Tom Brinkman, R&D Engineering Manager, VitalPath
Katherine Soojian, Director, R&D Engineering, VitalPath

Moderator: Tom Salemi, Editorial Director, DeviceTalks

VITALPATH℠

Overview

Maintaining structural integrity of complex laser-cut and welded component designs that must navigate tortuous paths in the body is critical. The precision that laser processing can add to a wide range of components not only improves catheter design and performance but also can help bring even highly complex catheters to market quickly. Integration of laser processes within the overall design and manufacturing process enables rapid prototyping and helps move catheter-based devices seamlessly through product development and into pilot production.

VitalPath manufactures custom, highly complex catheter solutions for medical device companies, specializing in meeting customers' most challenging requirements, such as single or multidirectional deflection, pushability, kink resistance, and torque response. VitalPath draws on its extensive experience and technical expertise with in-house laser processes to optimize the entire product life cycle, from concept to reality, accelerating time to market in complex catheters for the cardiovascular, electrophysiology, neurovascular, peripheral vascular, and structural heart markets.

Context

Through real-world customer stories, the presenters highlighted VitalPath's laser cutting and machining capabilities for catheter-based devices.

Key Takeaways

Nitinol laser-cut hypotubes meet complex requirements for various catheter applications.

Nitinol is a highly elastic material, making it an excellent choice for applications, such as catheters, that need to withstand greater force on the part. Its shape-setting property is another key characteristic that makes it an optimal material for catheters and other parts. Through controlled heat treatment, Nitinol can be shaped into a new permanent form.

In the case of catheter-based devices, it is important during the design process to understand the difference between:

- A component that adds stiffness and robustness that is integrated into the catheter; and
- A catheter with a component situated at the tip that performs the treatment.

For two customers whose catheter-based devices required Nitinol laser-cut hypotubes with shape-set characteristics, VitalPath's Design for Manufacturing (DFM) process yielded two differing approaches according to each part's specific application:

Component integrated into the catheter

A customer needed a Nitinol laser-cut hypotube with a specific laser-cut pattern, heat-set angle, and specified Af (austenite finish). The manufactured part would be located near the distal end of the device, providing a specific shape set and angle to the catheter and acting as part of the reinforcement structure of the catheter.

The load on the catheter required fine struts between the openings of the part to withstand the force without cracking or breaking, which made Nitinol the best material due to its significant elasticity.

The part also had to be electropolished. Electropolishing changes the dimensions of the part, which requires the laser program to compensate for the material that would be removed through electropolishing. The amount of compensation varies depending on the part features, which added complexity to the laser cutting process.

VitalPath was able to leverage its considerable experience to optimize the part design, including determining the correct temperature and time for heat setting using a fluidized sand bath (the primary factors for heat set angle and Af optimization). Additionally, during the laser cutting process development, VitalPath not only considered the physical design but also the process itself, to optimize reliability and efficiency and maximize output.

Figure 1: Nitinol laser cut hypotubes—Component integrated into catheter

Functional application of therapy

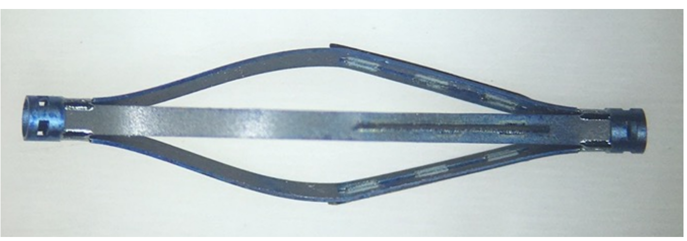
Another customer needed three components (arms, collars, and blades) laser cut from Nitinol that would then be laser-welded together. The design had to meet specific outer diameter (OD) measurements of each part, as well as the assembled length.

Because the part was being used to directly apply the treatment, understanding how the component would be delivered to its destination in the anatomy was critical to defining part requirements such as pushability, deployment forces, torque transmission, and others, to ensure robustness and performance.

However, during the heat set process, weld integrity was flagged as a concern. To heat set the part at the correct size, the collars would be compressed to expand the arms outward, which provided a space in which to slide the heat-set ball. However, that expansion would cause the welds to come apart.

VitalPath iterated on the design and eventually solved the issue by focusing on weld optimization, which ultimately ensured that the integrity of the part greatly exceeded the functional requirements.

Figure 2: Nitinol laser cut hypotubes—Used to deliver therapy



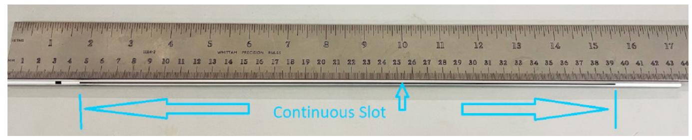
Materials properties influence laser cutting design.

A component such as a stainless steel hypotube can be integrated into the proximal end of a catheter, either within a handle or as part of a deployment mechanism. The slot within a stainless steel hypotube can also drive the functionality of the end technology, so it is critical that the part works precisely and seamlessly.

Maintaining a thin wall in the hypotube is important for tolerance stack-up, but it adds a challenge in the laser cutting process for a long, continuous cut. When a VitalPath customer requested an hypotube with a continuous slot cut along its entire length, the laser cutting process in initial samples caused the material to dilate, creating jagged edges due to internal stresses and an outer diameter that failed to meet requirements.

Working with material suppliers to understand the material properties, VitalPath improved the laser cutting optimization to eliminate the material flaring issues. Mating components—which are often of dissimilar material—were also being considered in the design to ensure a smooth, linear alignment with no binding or friction.

Figure 3: Hypotube with a continuous slot along its length



Design and materials impact pull ring cost and performance.

Pull rings are used in catheter steering and deflection and are an important component of the catheter assembly. Whether the design type is wire embedded, top of ring, or inside the pull ring, and whether the wire is round or flat, the standard design is to attach between one and four wires to the pull ring, depending on the required axis of motion.

However, the welding process anneals a small portion of the wire, which leads to some loss of tensile strength. (Usually, the tensile strength after welding is 80-85% of the tensile strength of the wire.) This loss must be accounted for in the design. There are a variety of different tensile strengths of wire out there from standard spring temper to High tensile so be sure when designing parts to account for this loss. It is important to keep in mind that high tensile wire typically adds an additional cost of 10-15%.

Wire straightness also impacts the process—and cost—of manufacture. VitalPath recommends wire with less than 0.02 inches per foot straightness variance measured per ASTM F2819.

> "You need to weigh the design intent versus the cost. Obviously, if you have a four-wire pull ring, that's going to increase the cost significantly compared to a one-wire."
>
> Tom Brinkman, VitalPath

VitalPath offers full vertical integration of laser processes.

VitalPath offers .030” to .050” high laser marked characters on plastics and metals, including full-length catheter marking. Laser marking has several advantages over traditional pad printing, including:

- No smearing or rubbing off.
- No custom-made tooling required.
- Short lead time for changes.

VitalPath also offers laser ablation as part of the manufacturing process. Tolerance stack-ups in complex catheters are an increasingly common design concern. Laser ablation increases precision and reduces costs over manual processing, and can be controlled to within extremely tight margins, depending on the material. The ability to remove jacketing in a highly precise manner allows VitalPath to maintain structural reinforcement of the overall shaft while keeping the OD to a minimum, as well as work with smaller components.

Along with greater precision, laser ablation also enables process automation, speeding proof of concept and eventual time to market while decreasing overall costs.

Figure 4: Laser marking can be done on different materials

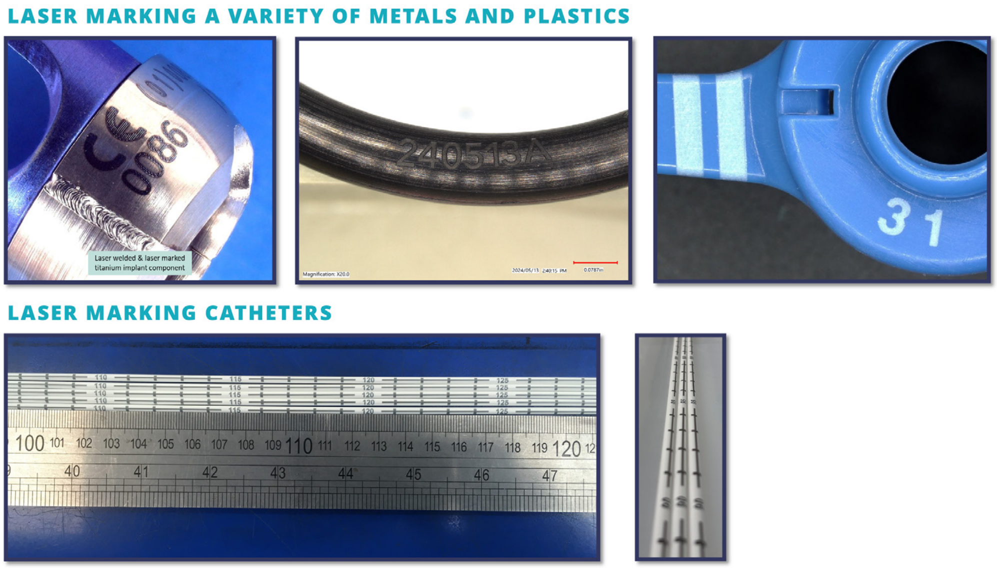
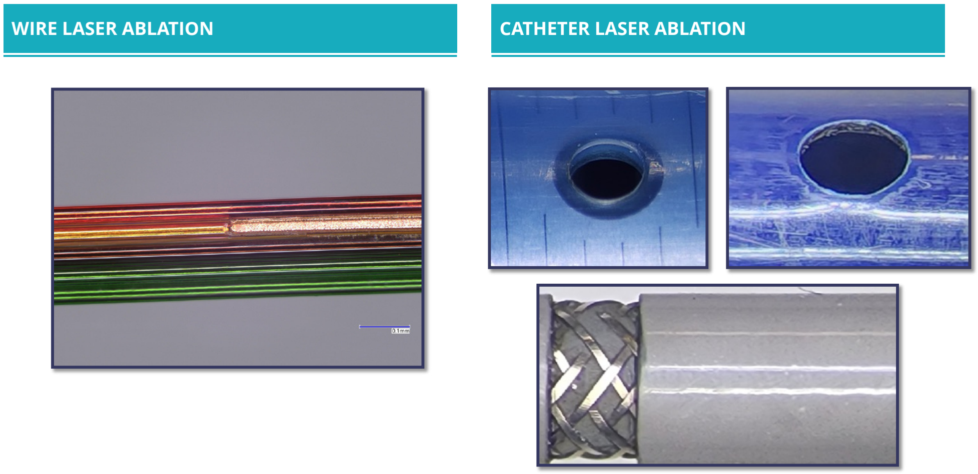


Figure 5: Laser ablation

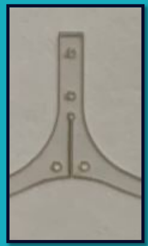


Polymers: Supporting Innovation

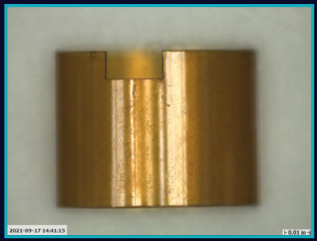
VitalPath offers laser cutting and machining for metals; however, there is an increasing need in the market for plastics and polymers, which offer key advantages over metals, including lower cost and greater availability. To help customers leverage these advantages in innovation, VitalPath's femtosecond laser system combined with a galvanometric scanner (galvo) can also laser cut plastics and polymers.

> "As a company that works in a variety of different markets within our industry, we are really seeing some of these polymer capabilities being used in a diverse range of novel applications. [Polymers] open up the possibilities that we have at our disposal when we're thinking about catheter applications."
>
> Katherine Soojian, VitalPath

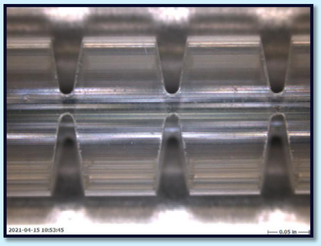
Polyester Film
- Color: Clear
- Thickness: .010"



Polyimide Tube
- Color: Amber
- Wall Thickness: .0015"



Pebax
- Color: Transparent
- Wall Thickness: .0118"
- Lumen Thickness: ~.042"



Additional Information

To learn more, visit **VitalPath**

Biographies

Tom Brinkman

R&D Engineering Manager, VitalPath

Tom Brinkman has 30 years of experience from process development to design for manufacturability, new product development and R&D for CDMOs as well as OEMs. With a history of progressive engineering leadership positions at VitalPath, Hutchinson Technology, and Olympus, much of Tom's focus has been dedicated to the design, development, and manufacture of components and micro components. At VitalPath, Tom brings his unique depth of knowledge related to materials and design considerations to OEM customer partnerships to ensure complex components function as intended as part of the full catheter device.

Katherine Soojian

Director, R&D Engineering, VitalPath

Kate Soojian's 17 plus years of experience in the design, development and manufacturing of minimally invasive catheter-based devices at medical OEMs and CDMOs gives her a unique perspective and approach to new product development. As Senior R&D Manager at VitalPath, Kate leads a team of engineers who creatively approach the unique challenges of their medical OEM customers' as they partner to bring devices for novel applications to market

Previously, she held engineering leadership positions at Creganna Medical, Hologic, Teleflex Medical, CRI, Aria CV, MIVI Neuroscience, and Viatar CTC Solutions. Kate has her B.S. in Biomedical Engineering from Worcester Polytechnic Institute.

Tom Salemi (Moderator)

Editorial Director, DeviceTalks

DeviceTalks Editorial Director Tom Salemi has been writing and talking about the medtech industry for over two decades. Prior to joining WTWH Media, Tom organized conferences, wrote feature articles and broke news for industry-leading business-to-business publications. Tom lives north of his native Boston with his wife, two sons, and Daisy the Dog.