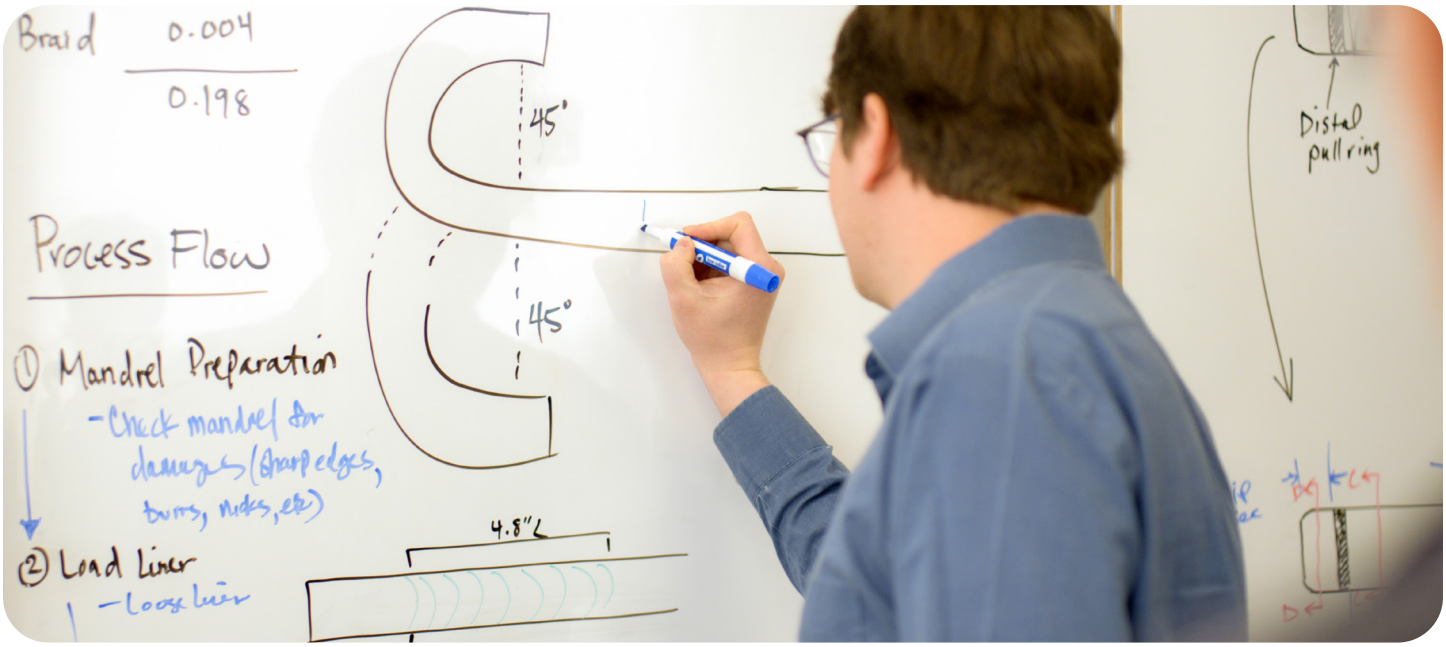
DEVICETALKS
MINNESOTA

Pull Wires, Push Limits: Engineering Precision into Catheter Navigation

TECH BRIEF



Presenters:
Riley Fritz, R&D Engineering Supervisor, VitalPath
Grant Thompson, Sr. R&D Engineer, VitalPath
Tom Brinkman, R&D Engineering Manager, VitalPath
Shane Dusoski, Sr. NPD Laser Engineer, VitalPath

Moderators: **Tom Salemi,** Editorial Director, DeviceTalks
Chris Newmarker, Executive Editor, DeviceTalks

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Overview

Designing and manufacturing precision steerable catheters for complex anatomies requires smart catheter design. Precision engineering plays a key role in designing high-performance catheters with components such as laser-cut hypotubes, reinforced shafts, and integrated pull-wire mechanisms, to meet key steerability, torque response, and deflection control requirements.

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

In this moderated discussion, panelists discussed key considerations in high-performance catheter design.

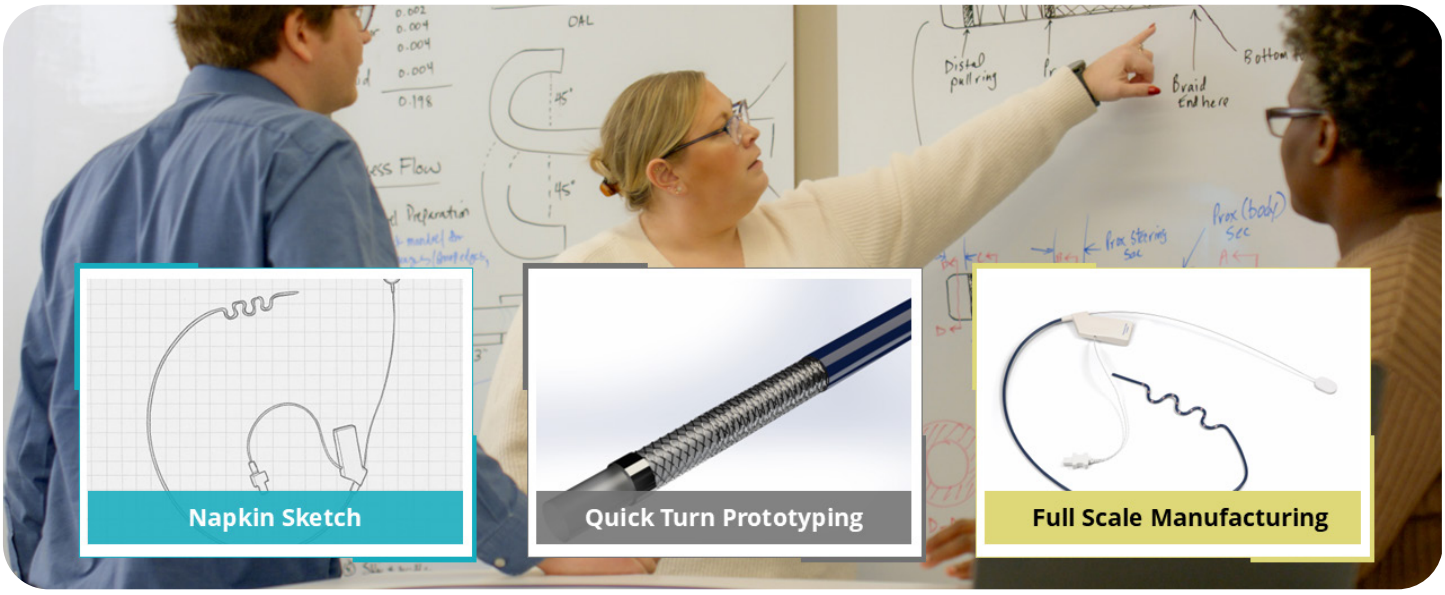
Key Takeaways

Design for Manufacturing is a crucial first step in developing a manufacturable product.

In the medical device space, it is critical to do things both quickly and affordably. Any component that VitalPath works on, whether for internal or external customers, is brought through a DFM (Design for Manufacturing) process. DFM offers an important opportunity to determine and resolve potential issues in the manufacturing process, to ensure the most optimal design to maximize the chances of getting the device to market.

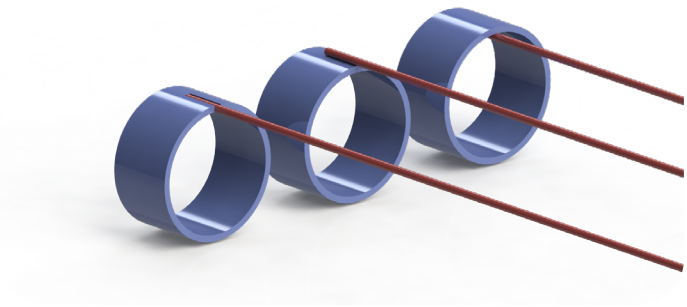
The DFM process starts with a thorough review of all requirements, design inputs, and specifications, as well as the customer's desired outcomes for any known constraints on the device design. This allows the team to make engineering-based decisions about any compromises that need to be made to ensure a product design that can be manufactured without sacrificing key requirements.

> "Start with the fastest thing to get tested, based on your best estimate of what the product requirements are, then add complexity as you go, because you . . . don't want to over-engineer it from the start."
>
> — Grant Thompson, VitalPath



VitalPath helps customers prioritize the most critical parts of the device for development to spec while using generic placeholders for less important details, which increases the chances of being able to move forward to the next steps of development and eventual go-to-market.

However, sometimes the process begins even earlier, as customers are increasingly requesting design companies to assist with developing the product specs. In these cases, having the in-house expertise to develop specs based on customer goals, device purpose and constraints, and any other factors optimizes time and cost resources. VitalPath's engineering experts have the knowledge and experience required to support customers who need greater assistance in the design process.

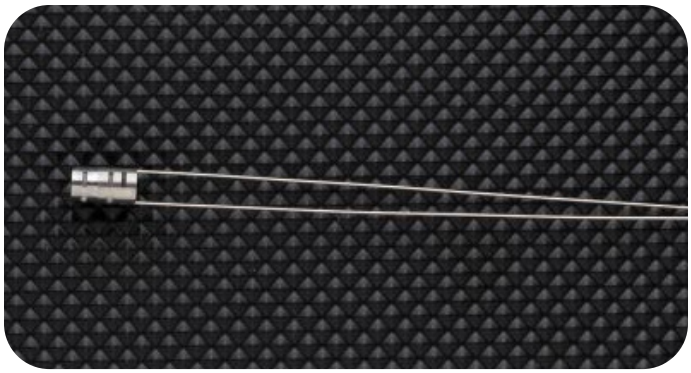


Key considerations in integrated pull wire assembly design.

When designing a steerable catheter, the most cost-effective approach is to use a welded pull ring assembly. Pull rings are made with between one and four round or flat wires, depending on the desired capabilities. When it comes to steerability, there are three basic designs of pull rings:

1. Wires welded on the outside of the pull ring
2. Wires welded on the inside of the pull ring
3. A wire inserted through a slot in the pull ring and embedded in the material itself

Steerable catheter designs vary based on several additional key performance and structural characteristics, depending on the device requirements and constraints discovered during the DFM process:



Wire Tensile Strength

Tensile strength is a key factor that affects part performance. A wire welded to a pull ring will have 80-85% of its tensile strength, as laser welding causes a "heat affected zone," which is an area of annealing (softening) in the wire.

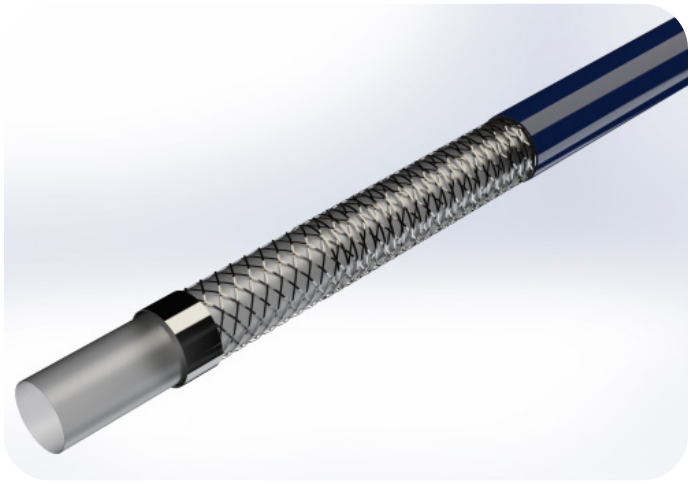
Different types of wire offer different tensile strengths, from spring temper wire with lower tensile strength to ultra-high-tensile-strength wire, which offers up to 20% more tensile strength over spring temper wire.

Wire Straightness

Wire straightness also impacts the catheter product, as greater wire straightness makes processing easier, resulting in better outcomes.

Shaft Reinforcement

Braid reinforcement will provide greater tensile strength and pushability (the ability to advance the catheter through pathways), while coil maintains a rounder inner diameter and offers maximum flexibility—but also a level of compressibility that can cause necking down in the catheter. VitalPath also offers a **hybrid** pairing of braid and coil together in steerable sections, although this design adds wall thickness as well as an additional termination point.



Variable Stiffness

In some designs, the catheter requires variable stiffness along its length based on anatomical needs, which can be achieved through several options:

- Braid: PPI (picks per inch) variation from proximal to distal.
- Coil: Pitched from proximal to distal.
- Hybrid: A flexible coil utilized on the distal end.
- Gradation from harder to softer durometers throughout the length of the device.
- Tapered diameter toward the distal end.

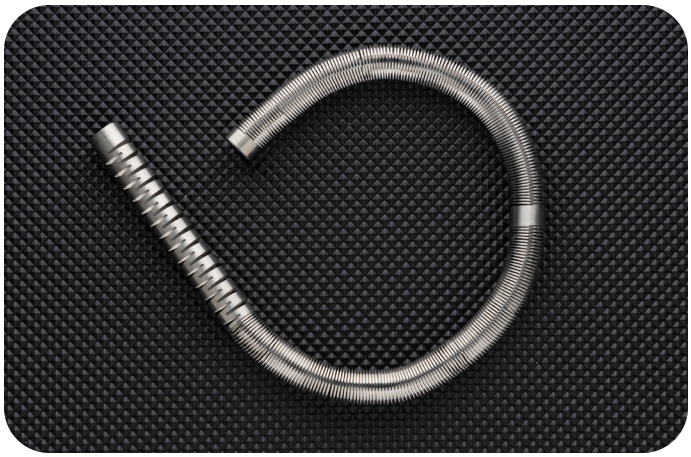
> "While designing for stiffness . . . you also have to have proper reinforcement for your pull wire lumens, otherwise there's risk of them pulling out or tearing out through the jacket."
>
> — Riley Fritz, VitalPath

Pushability

Pushability and steerability are interrelated. Steerable catheters typically have a stiff proximal section, both to help maintain pushability throughout the pathway and to serve as a specific spot for deflection.

Multi-Planar Deflection

Multi-planar deflection design biases the device in a specific direction. This is usually achieved through precise placement of steering lumens (angle and orientation); therefore, the assembly process is especially critical in these cases, as the mandrels must be held straight during the braiding process. Accuracy in assembly is crucial to ensure a predictable experience for the user.



Alternatives to standard pull ring assemblies offer greater flexibility.

Sometimes, a standard pull ring assembly is not a viable option, and customers need an alternative to meet key product requirements. In these cases, the most frequently chosen alternative is a laser-cut hypotube. Laser-cut hypotubes offer much higher-precision steering and deflection, especially in multi-plane applications, and stronger radial force than pull ring assemblies.

There are three main types of laser-cut hypotubes, which can vary in length:

- Continuous spiral cut to achieve flexibility at the tip and stiffness at the end
- Cuts in varying length and pitch to achieve greater flexibility at the tip and a stiffer distal or proximal end
- Cuts in short segments to provide significant flexibility

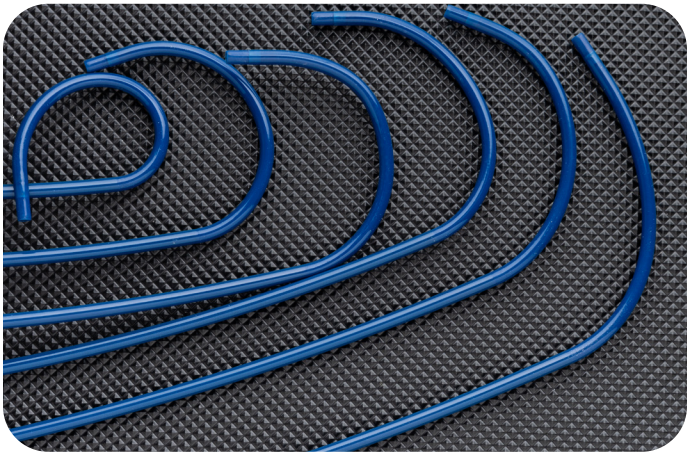
However, laser-cut hypotubes tend to be more expensive than pull ring assemblies, and cost concerns sometimes require a different solution. VitalPath has worked with customers to develop a hybrid approach, pairing a standard pull ring with a laser-cut compressible polymer section, which offers some of the engineered steerability benefits of a laser-cut hypotube at a lower price.

Device performance concerns, such as wrinkling, might also require creative alternatives. For example, a pull ring with laser cuts decreases wrinkling by allowing polymer penetration and increasing lamination.

> "The goal is to make something that, at the end of the day, we can ramp to volume and produce a good quality part at a lower production cost."
>
> — Tom Brinkman, VitalPath

Materials selection is an important component of catheter design.

Customers often pre-select materials based on biocompatibility; however, there are instances in which those materials are not meeting device performance requirements. VitalPath's in-house engineers research and test best alternatives and develop rapid prototypes for evaluation, to help keep the process moving forward.



Speed and cost are the top market differentiators in the MedTech industry.

The industry is evolving rapidly, with new materials, device applications, and manufacturing capabilities. Meanwhile, devices are becoming more complex, impacting catheter requirements and designs.

At the same time, it is just as critical as ever for MedTech companies to meet a short lead time to market to maintain a competitive advantage. VitalPath uses cross-functional teams, ensuring that capabilities are in place for a quick turnaround on device prototyping. In-house expertise helps speed the design, review, and testing processes, and VitalPath has the manufacturing resources to ramp up production when a device is ready for large-volume manufacture.

To learn more, visit **vitalpath.com**

In partnership with medical device OEM customers, VitalPath is driven to help dramatically improve quality of life for patients around the world. This is accomplished by delivering exceptional, high-quality complex catheter solutions through impassioned customer relationships, innovative engineering, and operational excellence. The VitalPath team specializes in meeting customers' most challenging complex catheter design and manufacturing requirements, built on a comprehensive suite of precision component manufacturing capabilities.

The company is ISO 13485:2016 certified with an FDA registered site, including ISO 7 & 8 cleanrooms.

Biographies

Riley Fritz
R&D Engineering Supervisor, VitalPath

Riley Fritz is a senior-level medical device engineer with over 7 years of hands-on experience in new product design, development, and manufacturability. At VitalPath, he partners closely with OEMs to translate challenging clinical requirements into production-ready solutions, with a focus on tight-tolerance components, multi-durometer shafts, and advanced braid and coil configurations. Riley's progressive roles across R&D and process development have equipped him with deep technical fluency in extrusion, reflow, and secondary operations critical to catheter integration. He holds a degree in Mechanical Engineering from North Dakota State University and is known for his pragmatic, detail-oriented approach to accelerating device development under tight timelines.

Grant Thompson
Sr. R&D Engineer, VitalPath

Grant Thompson is a seasoned medical device engineer with over a decade of experience developing complex catheter technologies. Currently a Sr. R&D Engineer at VitalPath, he collaborates with OEM partners to bring innovative devices to market, blending deep technical expertise with strong program management skills. His career spans both CDMO and OEM environments, including neurovascular catheter development at MIVI Neuroscience, giving him a well-rounded perspective on the challenges of device innovation. Grant's work supports a range of markets including structural heart, cardiovascular, and endoscopy. He holds a B.S. in Mechanical Engineering from the University of Minnesota Duluth.

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.

Shane Dusoski
Sr. NPD Laser Engineer, VitalPath

Shane Dusoski is a senior new product development engineer with over 35 years of experience in laser processing components and micro-components for the medical device industry. At VitalPath, Shane leads engineering efforts around advanced laser processing techniques including laser cutting, ablation, and welding of metal hypotubes and polymer composites. Shane brings a rigorous, process-driven mindset to solving complex design-for-manufacturing challenges and accelerating development timelines for high-performance catheter systems.

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.

Chris Newmarker (Moderator)
Executive Editor, DeviceTalks

A professional journalist of 16 years, Chris's career has taken him from Ohio to Virginia, New Jersey and, most recently, Minnesota. His five years at The Associated Press had him covering a variety of subjects. Chris's focus in recent years has been business and technology.