INCORPORATING STEERABILITY INTO YOUR CATHETER

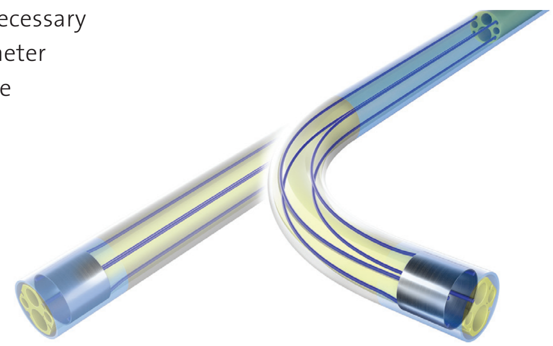
Key considerations for design and development

Anthony Appling, Senior Director Research and Development
Freudenberg Medical, Minimally Invasive Solutions

As medical technology continues to advance, physicians who specialize in minimally invasive procedures also have advancing expectations — for better performance and improved functionality in the catheters and delivery systems they use. One of the most important parameters is the ability to steer a catheter with confidence and ease through challenging anatomies and deflect the tip for precise placement at its final target. In this article, we'll review some of the principal factors to consider.

UNDERSTANDING THE CLINICAL USER'S NEEDS

Ask questions and vet the clinical user requirements upfront. Be sure you understand the anatomical applications, including any necessary interactions with given structures or tissue. What will the catheter be used for? Where will it need to go in the body? Understand the potential tortuosity and assess what may be the best approach for achieving optimal trackability and range of motion.



Four-way steerable multi-lumen catheter

SHAFT DESIGN

The three key properties of shaft construction are flexural stiffness, longitudinal stiffness, and torsional stiffness. The material chosen, and how it is engineered along the length of the catheter shaft, affects each of these properties and is an important factor in overall performance and functionality. Composite shafts, for example, feature a graded stiffness along the shaft, starting at the proximal end with a relatively stiff design and transition to a more supple design at the distal end.

Reinforcement

Good reinforcement along the catheter shaft is especially important in a steerable, deflectable catheter, because it needs to resist buckling or kinking during use. The following traditional methods have been used with success to balance steerability and deflection with the necessary reinforcement:

- Axial pull wires or aramid fibers with distal anchors or bands
- Coaxial rigid tubing that traverses axially
- Compression coils to reduce or prevent foreshortening of the catheter

Some non-conventional methods have also been developed using shape memory polymers, nitinol, and electromechanical tips, but these methods are often cost-prohibitive.

Lumen vs Non-Lumen

A lumened catheter may be constructed with a lubricious multi-lumen or multiple single-lumen layup. In either case, the lumens must be kept as straight as possible to maintain planarity. The goal is to minimize twist to prevent off-plane tip deflection. In addition, the central lumen needs to maintain patency even in the deflection zone. This can be achieved using variable coils, braids, or laser cut hypotubes. Larger catheters are more difficult to keep round during deflection due to the higher force needed to deflect.

For diagnostic or therapeutic catheters that do not require a central lumen, other methods can be used to facilitate tip deflection. For example, for single-plane deflection, the catheter can be anchored to the actuation components and moved axially along fixated wires at the tip and proximal end. A rigid spine can be incorporated to maintain planarity.

OTHER CATHETER FUNCTIONS MAY IMPACT DESIGN CHOICES

Steerable catheters often include advanced functionality, and components that facilitate other functions may impact your design choices. For example, consider whether the catheter has sensors, electrodes, or other electronic components that may need shielding. Carefully select materials to ensure they do not interfere with integrated circuits or sensors. Selecting a different metal alloy is one example. Dielectric materials and their locations must be considered as well.

EXTRUSION

All good catheters start with high-quality tubing. It is important to understand the compounds and additives in the tubing material, and how to process them, to ensure a stable, high-quality product that will stand the test of time. High-performing materials for the outer jacket include PU and PEBA-based thermoplastics or other thermoplastic blends. PTFE or coextruded PEBA/PU with FEP or HDPE are traditional materials used for sheaths or guide catheters.

MANUFACTURING

To help prevent unpleasant surprises late in the process, it's considered a best practice to use the same manufacturing technique and process technologies during design and development as you plan to use for final production. Changes in the manufacturing technique mid-point can adversely affect catheter performance.

A partner with in-house design and manufacturing capabilities is advantageous to ensure design for manufacturability. It is also important that your design partner knows the fundamentals of lean manufacturing. Optimal lean manufacturing techniques and design for manufacturability go hand-in-hand to deliver a best in class device.

Accessing and reaching the target anatomy accurately is one of the key elements of maximizing procedural success. To ensure the success of a steerable catheter system, it is critical to choose a partner with a full range of experience and a deep understanding of different manufacturing technologies. Ideally a company with comprehensive design, development and full device manufacturing capabilities as well as an understanding of proven methods. A partner with a wide range of innovative solutions can further "steer" you to a successful product launch.

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Anthony Appling is Senior Director of Research and Development at Freudenberg Medical, Minimally Invasive Solutions. He has 18 years of experience in product design, development and manufacturing with an emphasis in minimally invasive delivery systems and therapeutic devices.

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