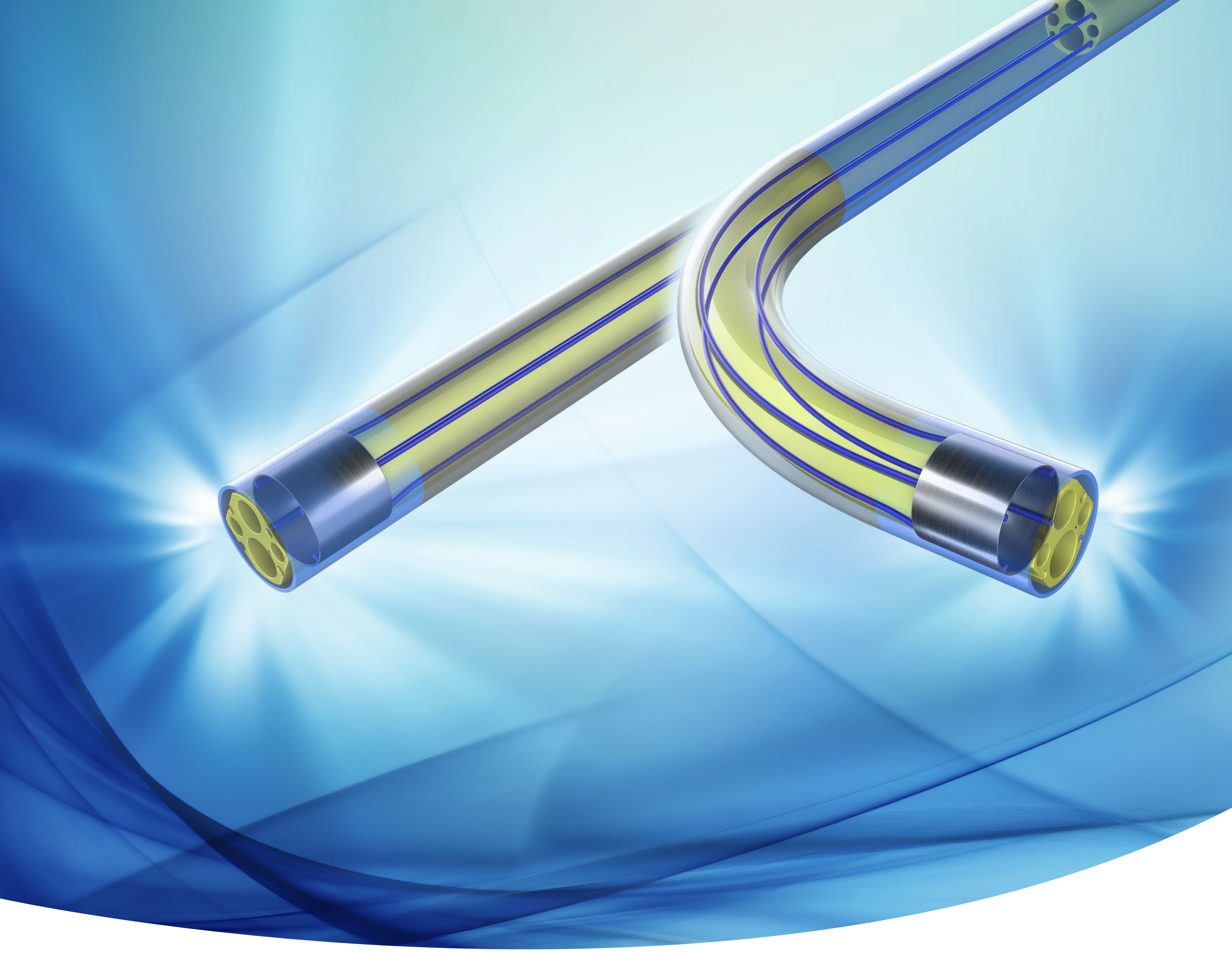

INCORPORATING **ADVANCED STEERABILITY** INTO YOUR CATHETER

KEY CONSIDERATIONS FOR DESIGN AND DEVELOPMENT

Freudenberg Medical, Minimally Invasive Solutions

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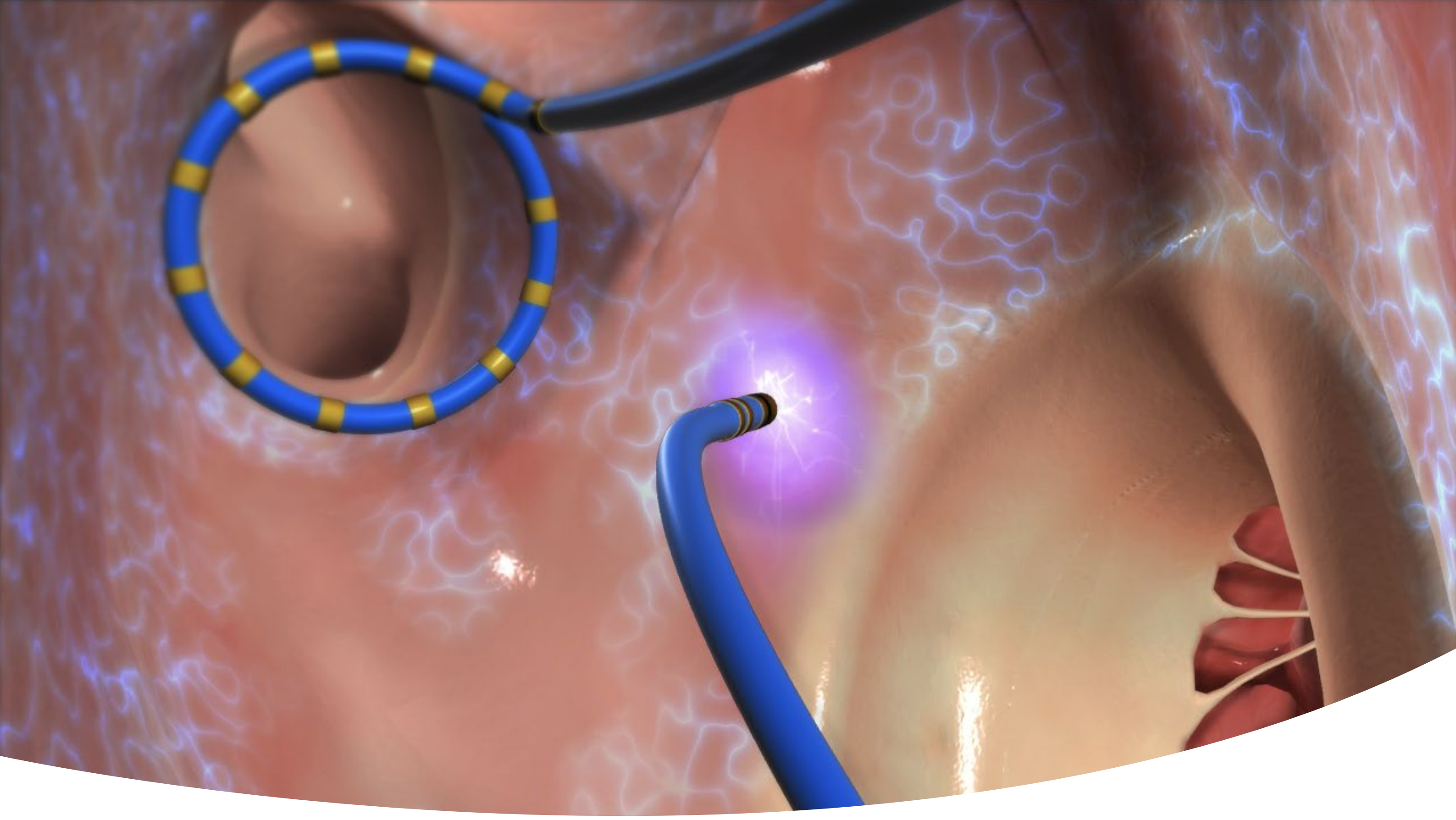

As medical technology continues to advance, physicians who specialize in minimally invasive procedures also have advancing expectations — for better performance and improved functionality in the catheters and delivery systems they use. One of the most important parameters is the ability to steer a catheter 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 PROCEDURE & CLINICAL USER'S NEEDS

Today's advanced interventional procedures typically necessitate the use of steerable catheters, commonly operated by the physician, however in recent years there has already been a notable increase in the application of robotic assistance in specific cases. This advancement may eventually result in the transition from a solely human-operated interface to a mechatronic or hybrid approach. Despite this evolution, the technical specifications for a steerable shaft remain unchanged.

Engineers should ask questions and assess 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? How dynamic is the anatomical environment in which the catheter will be functioning? How should it interact with introducers, access sheaths, or other catheters necessary for a successful procedure? Understand the potential tortuosity and assess what may be the best approach for achieving optimal trackability and range of motion.

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STEERING REQUIREMENTS

Specific steering requirements should be determined at the earliest possible stage as there are multiple factors to consider. The simplest design, one-way steering, is typically associated with basic access functionality along key arterial or venous highways.

As the physician advances deeper into anatomical structures, such as deploying devices in the left heart, the catheter must now function in a complex 3D environment that is constantly dynamic. Malpositioning of the catheter becomes a major concern for the physician to avoid perforations, unsatisfactory placement of a device in the target anatomy, imprecise ablation pathway selection or unintended rhythmic disruptions.

Advanced steering options address these risks and include two-way steering (bi-directional,) four-way steering and multiplanar or multidirectional steering. Additionally, there may be a requirement for multiple steering points along the catheter length to enable alternative steering functionality in different planes for the same catheter. Some procedures, such as in structural heart therapies, are associated with high force loads and these advanced steering possibilities must be balanced with the maximum tensile strength of the steering wire sub-assembly.

The steering curve or bend angle, curve diameter and device reach must also be considered. Engineers should precisely know what types of steep curves the catheter must navigate. Does the catheter need to avoid or over-reach sensitive structures? How much precision is required for distal tip positioning and is repositioning of the device a requirement? What will be passing through the catheter and is catheter stability a concern? Different types of catheter tip curls will provide various options from simple curls to looped designs with symmetric or asymmetric approaches.

SHAFT DESIGN

The three key properties of shaft construction are flexural stiffness, longitudinal stiffness, and torsional stiffness. The materials chosen, and how they are engineered and configured along the length of the catheter shaft, affect each of these properties and are 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 transitioning to a more flexible design at the distal end.

REINFORCEMENT

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

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

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 configuration. In either case, the lumens must be kept completely straight along the length of the catheter shaft to maintain planarity. The goal is to avoid twist to prevent off-plane tip deflection. In addition, the central lumen needs to maintain patency even in the deflectable zone. This can be achieved using variable coils, braids, or laser-cut hypotubes. Larger catheters can be more difficult to keep round during deflection due to the higher force needed to deflect, however a coil-braid hybrid approach can work well here.

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 to facilitate other functions that 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 high-quality catheters start with high-quality extruded tubing. It is important to understand the material compounds and additives (e.g. radiopaque fillers, antimicrobial, low friction, stabilizers, etc.) in the tubing material, and how to process them, to ensure a robust, high-quality product that will stand the test of time. High-performing materials for the outer jacket can include multi-durometer PU and PEBA-based thermoplastics or other thermoplastic blends.

MANUFACTURING

A partner with in-house design, development and manufacturing capabilities is advantageous to ensure a well-considered design for manufacturability, and a more efficient transfer to commercialization. It is also important that your 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, this is a vertically integrated company with comprehensive design, development and full device manufacturing capabilities. A partner with a wide range of innovative solutions can further "steer" you to a successful product launch.

Freudenberg Medical is a leading partner for Minimally Invasive catheter design, development and manufacturing, facilitating access, delivery and visualization in the most complex clinical applications. Working in collaboration with its customers, Freudenberg Medical has enabled countless innovations in cardiovascular, electrophysiology, structural heart, peripheral vascular and neurovascular therapies.

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