THE ESSENTIAL GUIDE TO **HYPOTUBE DESIGN**

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In minimally invasive surgery, the best patient outcome begins with navigating the vasculature safely and smoothly. For catheters utilizing a metal shaft construction, good design begins with a high-performing hypotube. As experts in hypotube design, development and manufacturing we share our insights on what you need to know for your next product design.

THE ROLE OF THE HYPOTUBE

A hypotube provides essential performance characteristics to enable access and delivery within the vasculature including flexibility, push, torque, track, kink resistance, lubricity and fast inflation/deflation times. However, these characteristics can present trade-offs, for example, a hypotube optimized for maximum flexibility can exhibit low push forces.

When designing a hypotube, it is essential to understand these performance characteristics and how optimization of one characteristic can impact others. You want to achieve the perfect balance for your product.

Freudenberg Medical brings you this essential guide to help you optimize your hypotube design and understand the key manufacturing processes required to create the perfect access or delivery catheter.

We recommend that you engage early with our hypotube experts to save you cost and time in the design phase. Our insights, knowledge and expertise will help you achieve the optimal design for your clinical application from the start.

HYPOTUBE PERFORMANCE EXPLAINED

In this section, we explain the key performance characteristics of the hypotube and how these characteristics translate to the physician experience when deploying a catheter within the patient.

WHAT IS HYPOTUBE TORQUE?

The anatomical pathways of the vasculature can be challenging to navigate, often tortuous or highly calcified. It is essential that the physician can rotate the minimally invasive device within the vasculature to reach the target treatment site and torque, a twisting force, aids device rotation. The ability of a device to accurately transmit this torque along its length is measured as torque-ability. When torque forces are not accurately transmitted, it can lead to a build-up of force and an undesirable "whipping effect" along the device shaft. Freudenberg Medical utilizes innovative processing techniques to ensure our hypotube shafts will deliver the necessary amount of torque, with predictability of movement when rotating.

WHAT IS HYPOTUBE TRACKABILITY?

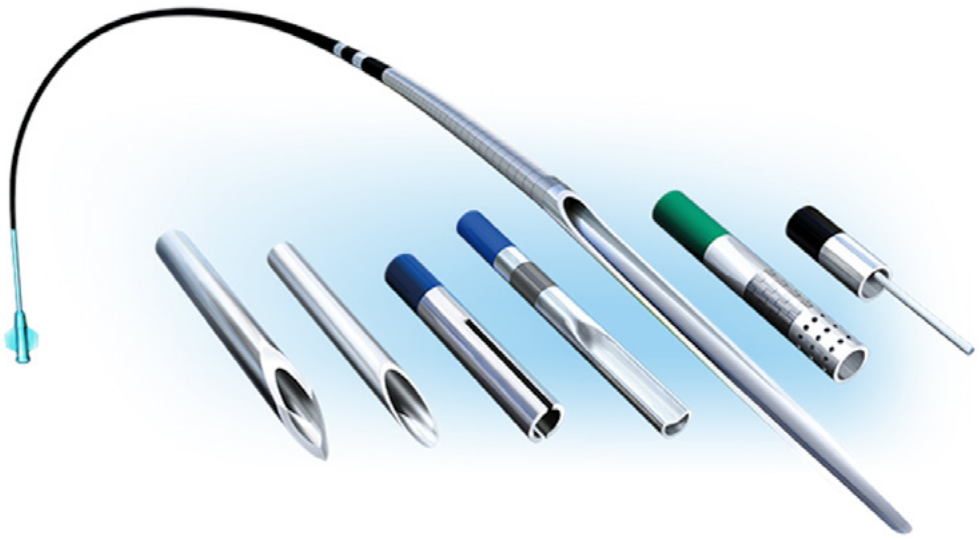
The term trackability is used to measure the overall ability of a device to progress through complex vasculatures and reach the treatment site. Sometimes, the physician will refer to trackability as the overall "feel" of the device or how smoothly it responds to the physician's manipulation. When low tracking forces are present the physician feels the device is easier to manipulate and position. The distal, or treatment end of the catheter, plays a crucial role in overall trackability. At Freudenberg Medical, we use advanced processing technologies to make the distal end of the catheter more flexible, thus aiding trackability.

WHAT IS HYPOTUBE PUSHABILITY?

Pushability is determined by the measure of the transmission of longitudinal forces from the proximal to the distal end of the catheter. Ideally, when a pushing force is applied by the physician, an equal movement of force should be exhibited on the distal tip inside the patient. When transmission forces are high, the physician navigates with confidence, knowing that precise movements to the proximal shaft will translate to precise movements within delicate anatomical pathways or structures, for example, within the crucial anastomotic Circle of Willis structure during neurovascular navigation.

WHAT IS HYPOTUBE FLEXIBILITY?

Flexibility is a measure of the stiffness along the hypotube length and is a critical part of the overall catheter design. Flexibility is a major contributor to the trackability or "feel" of the device and while high pushability or stiffness is desirable, a well-designed hypotube should simultaneously exhibit good flexibility when it is required to navigate acute angles or anatomical structures. Optimizing flexibility and pushability together is key to the perfect hypotube design.



WHAT IS HYPOTUBE LUBRICITY?

Lubricity measures how much the friction between the medical device and the anatomy or companion device is reduced through the application of a coating to the metal hypotube. Freudenberg Medical offers a differentiated and market-leading coating solution called Cambus Coat™, proven to exhibit excellent adhesion and resistance to flaking under the most demanding performance tests. Additionally, Cambus Coat™ is a smooth lubricious coating solution ideal for hypotube and guidewire applications.

WHAT IS HYPOTUBE KINK RESISTANCE?

Intravascular anatomy is challenging to navigate and will require the physician, on occasion, to cross acute radii. Kink resistance measures the hypotube's ability to maintain an intact cross functional profile when bent around a radius. This characteristic is critical in preserving the patency of the internal lumen which plays a critical role in therapy delivery. With this criticality in mind, Freudenberg Medical offer E-Pro™, an advanced metallurgical solution with superior kink resistance over traditional 304 stainless steel hypotube constructions. Due to E-Pro's™ superior kink resistance ability, it also offers the product designer with an opportunity to optimize internal diameters.

WHAT IS HYPOTUBE INFLATION AND DEFLATION TIME?

In addition to being a critical tool in vascular navigation, the hypotube plays an essential role in delivering balloon catheter therapies. Inflation and deflation times describe the length of time it takes an angioplasty balloon to activate and deactivate. When inflated, a balloon creates a temporary restriction of blood flow which can be damaging to downstream anatomy unless it is precisely and accurately controlled. The inner diameter of the hypotube plays a crucial role in determining the balloon inflation/deflation time. In short, the larger the internal diameter of the hypotube the faster balloon inflation/deflation response. We work with our customers to determine the optimal inflation/deflation time for their catheter application, leveraging our wide range of hypotubes in various diameters to find the best fit.

MANUFACTURING THE OPTIMAL HYPOTUBE

An extensive range of capabilities are required to manufacture the optimal hypotube, balancing the performance characteristics discussed above. In this section, we review the key technical capabilities required to deliver a tailor-made product solution for your minimally invasive catheter.

ELECTRICAL DISCHARGE MACHINING (EDM)

EDM is a high precision, machining process used for cutting precision contours in metal material. This method is employed by Freudenberg Medical to produce burr free skives in thin wall tubing. A well-designed skive enables a smooth transition zone between the metal shaft and the distal balloon assembly, improving overall trackability and flexibility of the catheter.

LASER CUTTING

Hypotubes must navigate complex and tortuous paths, therefore, requiring specific bend radii and flexibility. Laser cutting provides various cut geometries assisting with flexibility, torque and compression. Freudenberg Medical engineers work with customers to develop advanced laser cutting profiles for steerable, high-load catheter applications.

PASSIVATION

Hypotube manufacturing employs a range of processing techniques to add or remove features from the metal tube. These processes can introduce contaminants (free iron) on surfaces and it is essential that all contaminants are removed from the hypotube. Freudenberg Medical passivates all its stainless steel hypotubes to the international passivation standard ASTM A 967. Passivation and electro-polishing chemically dissolve contaminants on the stainless steel surface, forming a thin protective chromium oxide layer on the steel which gives it's a "stainless" quality.

LASER ABLATION

Marker bands on a coated hypotube surface help the physician to estimate the longitudinal placement of the catheter relative to key anatomical structures as it is introduced into the vasculature. Freudenberg Medical uses automated laser systems to remove PTFE coating from the outer diameter of the hypotube to create these markers at various intervals along the shaft.

CENTRELESS GRINDING

Centreless grinding is a machining process that uses abrasive cutting to remove material from a metal shaft. A highly accurate outer diameter, thinner walls or intricate features on the hypotube outer profile can be achieved through this grinding process.

LASER WELDING

At Freudenberg Medical we use state of the art laser welding systems to produce spot-welded and seam-welded joints in producing core-wire and other micro-welded assemblies. This welding capability enables our engineers to manufacture a hypotube shaft with advanced form, shape or profile features for the addition of transition elements such as distal core wires.

PTFE COATING

PTFE coating is a popular finish on a hypotube's outer diameter, providing high lubricity to improve device trackability. Freudenberg Medical has developed a proprietary coating technology, Cambus Coat™, a PFOA free coating that offers the highest levels of adhesion over traditional methods.

PAD PRINTING

An alternative method to create the femoral, brachial and radial marker bands discussed above is through the application of a contrasting-coloured ring around the outer coated surface of the hypotube using a process called pad printing. The PTFE hypotube surface is typically black in colour and the pad-printed marker band is typically white to optimize contrast and visibility in the Cath Lab.

INSPECTION

Product quality and consistency are paramount in medical device manufacturing. At Freudenberg Medical, material testing and inspection are an integral part of our manufacturing processes. We follow documented procedures and systems that comply with our customer's requirements.

Thank you for your interest in our essential guide to hypotube design. If you are commencing a product design project that requires a hypotube, we advise that you engage with our experts at the earliest stage. Quick iterative prototyping will save you time and cost in the first phases of design and we offer a specialized program, Navigate®, to boost innovation and the speed of your design process.

Do you have any questions?

Freudenberg Medical
Spiddal Business Park, Spiddal, Galway H91 TRF6, Ireland • +353 (0)91 504633 • infogalway@freudenbergmedical.com