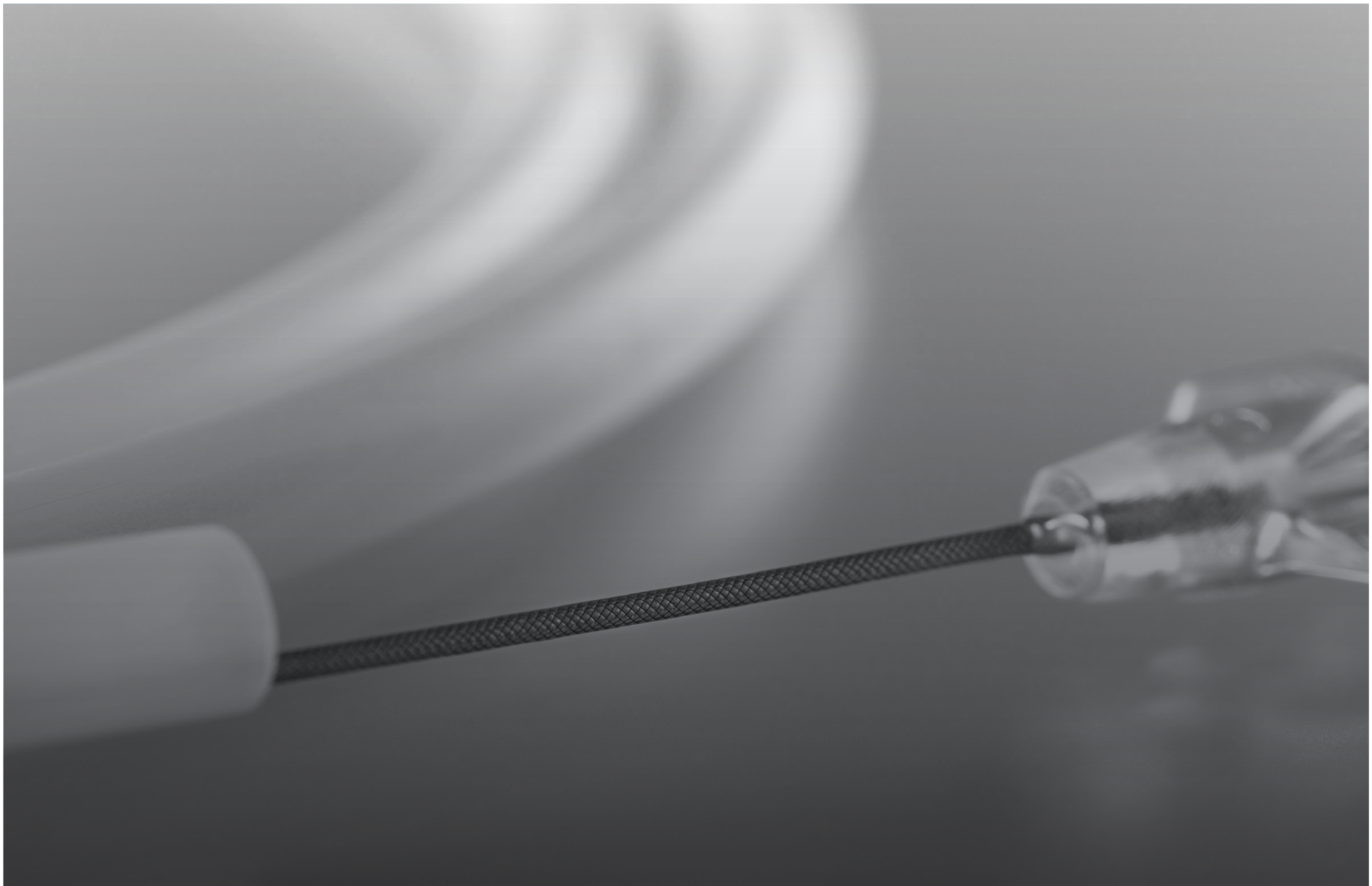

White Paper

Engineering Possibilities: New Liners for Next-Gen Catheters

To advance new therapies deeper into the vasculature than ever before, the catheters of tomorrow must become smaller and more flexible, while still possessing the strength required to deliver these crucial therapies to the treatment site. By providing device manufacturers and engineers more liner options, new catheter designs that once seemed unimaginable can now be explored, helping to extend the boundaries of vascular access via catheterization.

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Advancements and limitations.

Recent advancements in catheter technologies have revolutionized the medical industry and tremendously improved patient care. Procedures that once required open surgery are now successfully completed using minimally invasive catheter-based techniques, often with improved outcomes.

Unlike early catheters, modern vascular catheters are comprised of highly specialized materials and sophisticated components. The inner liner, braid reinforcement, and outer jacketing material are all carefully chosen and precisely engineered to produce a device capable of traversing complex anatomies and delivering life-saving therapies. While catheter technologies have advanced tremendously over the years, the historical and somewhat limiting options for ultra-thin PTFE catheter liners has posed a significant challenge.

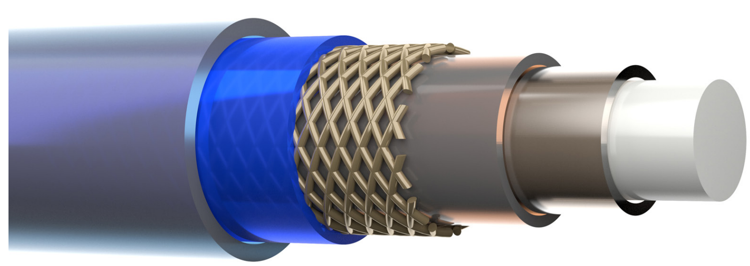
Until recently, catheter liners requiring wall thicknesses < 0.001″ (0.025 mm) have been limited to two production methods: film cast and free extrusion. Each of these processes results in PTFE catheter liners with performance tradeoffs involving flexibility and strength. Now, thanks to newly patented technology, a third process has emerged, expanding the design options for newer and more advanced vascular catheters.

A Balance of Properties

Designing a modern vascular catheter requires the mechanical properties of the finished device to be considered. Materials used in catheter construction are not merely selected for their stand-alone properties, but rather their contribution to the device's overall performance. Additionally, not all materials under consideration can be used in all instances. For catheter liners especially, four factors are of particular importance and play a significant role in dictating device performance: flexibility, wall thickness, strength, and lubricity.

A number of different materials have been explored for use as liners over the evolution of catheter technologies. Materials ranging from polyimides (PIs), high density polyethylene (HDPE), to fluoropolymers have all been tried with varying degrees of success. From these, fluoropolymers, and in particular polytetrafluoroethylene (PTFE), have emerged as the materials of choice for catheter liners. PTFE is chemically inert, tolerates steam sterilization and autoclave temperatures, and possess the lowest coefficient of friction of any polymer resin – an especially useful trait for a catheter liner, helping provide a highly lubricious lumen wall. Important also is that PTFE liners can be produced with extremely thin walls (< 0.001″). In addition to added flexibility, thin walls help to minimize the overall profile of the catheter and maximize lumen potential.

While PTFE has emerged as the material of choice for most vascular catheters designs, some PTFE liners, depending on the manner in which they are produced, may not provide a satisfactory balance of functional properties. Oftentimes a liner may exhibit high tensile strength, but have insufficient flexibility or walls that are too thick for certain applications. Alternatively, a liner may possess desirable wall thickness and flexibility, but the tensile strength may be insufficient for the catheter's design. In both scenarios, jacketing and braiding material may need to be added, subtracted, or modified to compensate for the liner, potentially limiting the performance of the catheter as a whole. Liner selection for a catheter's intended design and application is therefore a delicate balancing act of wall thickness and mechanical properties. More options for PTFE catheter liners that could better match the combination of size, flexibility, and strength could thus play a significant role in improving catheter performance and procedural outcomes.



Fusing Sleeve | Jacket | Braid | Bond | Liner | Mandrel

Current Methods - Free Extruded vs. Film Cast PTFE Liners

Historically, two methods have been used to produce thin walled PTFE liners: free extrusion and film cast. In free extrusion, fine PTFE powder is mixed with an organic solvent / lubricant and is compressed to create a preform. The preform is passed through a paste extrusion machine to produce thin-walled PTFE tubing. Following extrusion, the tubing is sent through a devolatilization and sintering oven to finally produce the super-thin-walled tubing. The extrusion process causes crystallites within the PTFE matrix to unwind and form fibrils which are oriented in the axial, or extrusion, direction. These directionally oriented fibrils contribute to the strength and rigidity commonly found in free extruded liners.

A second method of producing ultra-thin-walled catheters liners is through a film cast process. Film cast is a process by which a PTFE dispersion is applied or coated onto a metal core wire such as stainless steel or copper followed by sintering. The film cast-sintering process is repeated until the desired coating thickness is achieved. Lastly, the wire core is withdrawn leaving the super-thin-walled PTFE tubing. Unlike extrusion, the film cast process produces no molecular orientation of the individual PTFE chains creating a product with isotropic properties. This feature results in a liner that is more flexible, although weaker, than a comparably sized free extruded liner.

While both film cast and free extrusion can produce super-thin-walled PTFE liners, the different production processes result in somewhat differing features and design considerations for the catheter. Liners with high tensile strength, for example, may be preferred for catheters deploying devices under compression or that exhibit a radial force, such as flow diverters, embolization devices, stents, or mechanical thrombectomy devices. Liners with low tensile strength and high flexibility may be preferred for catheters used in small and complex vasculatures such as below-the-knee and above-the-neck. While highly maneuverable, these catheters may be limited in the therapies that can be delivered. Free extruded and film cast liners, thus, have their areas of specialization, and choosing between flexibility or strength can present limitations in catheter design.

Molecular Orientation - Free Extruded vs. Film Cast

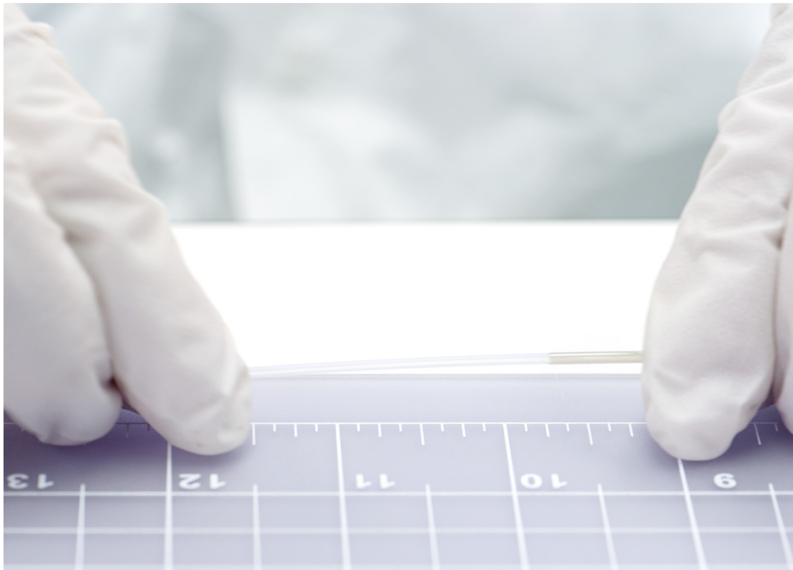
Film cast process produces no molecular orientation of individual PTFE chains.

Extrusion process causes crystallites within the PTFE matrix to unwind and form fibrils in the axial direction.

Bridging the Gap - A New Type of PTFE Catheter Liner

The increased prevalence of vascular disease and the growing number of vascular catheterization procedures has added urgency to the need for newer tools and better treatment options. As a result, device engineers and manufacturers are constantly striving to produce new catheters capable of navigating deeper into the vasculature to deliver life-saving therapies. Super-thin-walled catheter liners that are both strong and flexible present new possibilities for gaining access to the most difficult to reach treatment sites and positively affecting procedural outcomes. In this light, Zeus has developed a new type of catheter liner that can bridge the gap in performance between free extruded liners and film cast liners. Building on the concept of controlled fibril orientation, this new liner is extruded "over-the-wire" (OTW) employing the wire concept from film cast combined with Zeus' proprietary extrusion process. The result is a liner with comparable wall thickness and flexibility to that of film cast liners, but with greater strength. These new liners, as part of Zeus' Sub-Lite-Wall™ (SLW) StreamLiner™ series, provide device makers more options for next generation catheter designs and precision properties customization.

In addition to their mechanical properties, StreamLiner™ OTW liners also offer manufacturing benefits. Supplied over silver plated copper, these liners are available in discrete cut lengths rather than spooled, simplifying the catheter production process. Traditionally, film cast liners that are supplied in a continuous spooled form must undergo several steps before use. They must be cut to length, loaded into a tensioner to straighten them, and then removed. Furthermore, the additional handling of spooled liners prior to beginning catheter construction can harm the etched PTFE surface, a vital feature of the liner. Cut-to-length liners, conversely, can go directly into braiding machines expediting production and helping to preserve critical surface bondability.



Testing and Evaluation

To characterize the new PTFE StreamLiner™ OTW liners, tensile testing and dynamic mechanical analysis (DMA) were performed on three sets of PTFE liners: Zeus' StreamLiner™ OTW liners, Zeus' StreamLiner™ XT free extruded liners, and film cast liners. Two of the film cast sample liners were produced by Zeus while a 0.0167″ inside diameter (ID) liner was purchased. Samples with comparable liner wall IDs and wall thicknesses were selected for testing. Sample liner IDs ranged from 0.0167″ to 0.0717″; sample wall thicknesses ranged from 0.00050″ to 0.00068″. Tensile testing was done according to ASTM D638, Standard Test Method For Tensile Properties. DMA was performed using temperature sweeps from -100 °C to 300 °C. DMA liner samples were heated at a constant rate of 3 °C / minute while being displaced at a constant amplitude of 15 µm and fixed frequency of 1 Hz.

Table 1: Properties Comparison of OTW, Free Extruded, and Film Cast PTFE Liners

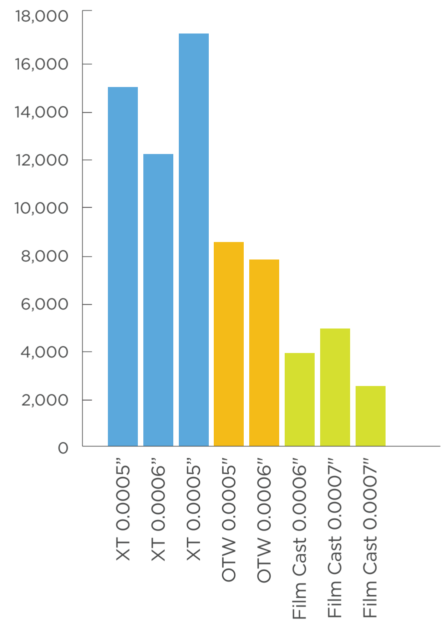
	StreamLiner™ XT (Free Extruded)			**StreamLiner™ OTW**		**Film Cast**		
Inside Diameter (ID)	0.0205″ (0.521 mm)	0.0400″ (1.020 mm)	0.0684″ (1.737 mm)	0.0167″ (0.424 mm)	0.0705″ (1.791 mm)	0.0167″ (0.424 mm)	0.0169″ (0.429 mm)	0.0717″ (1.821 mm)
Wall Thickness	0.0005” (0.013 mm)	0.0006” (0.015 mm)	0.0005” (0.013 mm)	0.0005″ (0.013 mm)	0.0006” (0.015 mm)	0.0006” (0.015 mm)	0.0007” (0.017mm)	0.0007” (0.017mm)
Tensile Modulus at 23°C (ksi)	189.0	189.5	242.5	43.9	65.1	52.0	42.8	68.8
Tensile Strength at Break (psi)	15,120	12,280	17,360	8,520	7,750	3,950	4,930	2,480
Elongation at Break (%)	361	277	379	438	345	314	544	138
Storage Modulus at 23°C (ksi)	289.8	178.8	291.5	90.1	58.4	99.5	81.6	68.3
Storage Modulus at 37°C (ksi)	176.0	106.9	167.5	66.2	41.2	60.8	56.6	29.8

Tensile testing and DMA of StreamLiner™ OTW, StreamLiner™ XT, and film cast liners:
Test results showed that the StreamLiner™ OTW sample liners possessed tensile strength that was intermediate between extruded XT and film cast liners with equivalent flexibility to film cast liners. *(Values are representative).*

Strength

Testing revealed several distinct characteristics among the three liner types. Tensile testing showed that free extruded StreamLiner™ XT liners exhibited the highest tensile strength at break (Table 1). This result emphasized the strengthening effect of extrusion and polymer chain / fibril alignment. Film cast liners, with no molecular orientation, exhibited the lowest tensile strength. OTW liners were intermediate in tensile strength gaining some molecular orientation from extrusion but do not attain the full strength of XT liners. Elongation at break for all three types of liners was similar across all ID sizes with the exception of the film cast liners which showed greater variation.

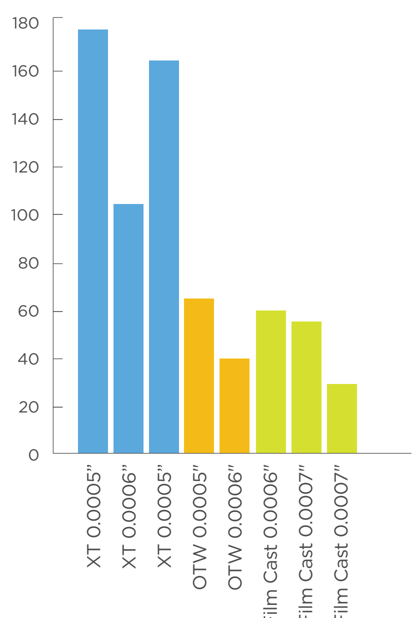
Tensile Strength At Break (psi)
by Wall Thickness



Flexibility

To assess the flexibility of the three liner types, tensile modulus and storage modulus were compared. Tensile modulus provides an indication of a material's resistance to elastic deformation. High tensile modulus indicates a stiffer or more rigid material and vice versa. On a size-for-size basis, tensile moduli of the OTW and film cast liners were comparable and less than that of the XT liners. Similarly, storage modulus, measured during DMA, relates how much energy must be put into a material to deform it, the higher the storage modulus, the more rigid the material (and vice versa). DMA storage modulus results agreed with the tensile modulus testing showing that on a size-for-size basis, storage moduli of the OTW and film cast liners were similar and both less than that of XT liners. Additionally, all liner types and sizes showed reduced tensile and storage moduli (increased flexibility) at body temperature (37 °C) compared to room temperature (23 °C). Together, these results describe a super-thin-walled PTFE catheter liner, StreamLiner™ OTW, that is superior to film cast in strength but which retains the important trait of flexibility to reach small and complex vasculatures.

Storage Modulus at 37°C (ksi)
by Wall Thickness



New Possibilities for Next Generation Catheters

The pervasiveness of vascular diseases has heightened efforts around the world towards developing newer, more advanced catheters and therapies to treat these life-threatening conditions. To advance new therapies deeper into the vasculature than ever before, the catheters of tomorrow must become smaller and more flexible, while still possessing the strength required to deliver these crucial therapies to the treatment site.

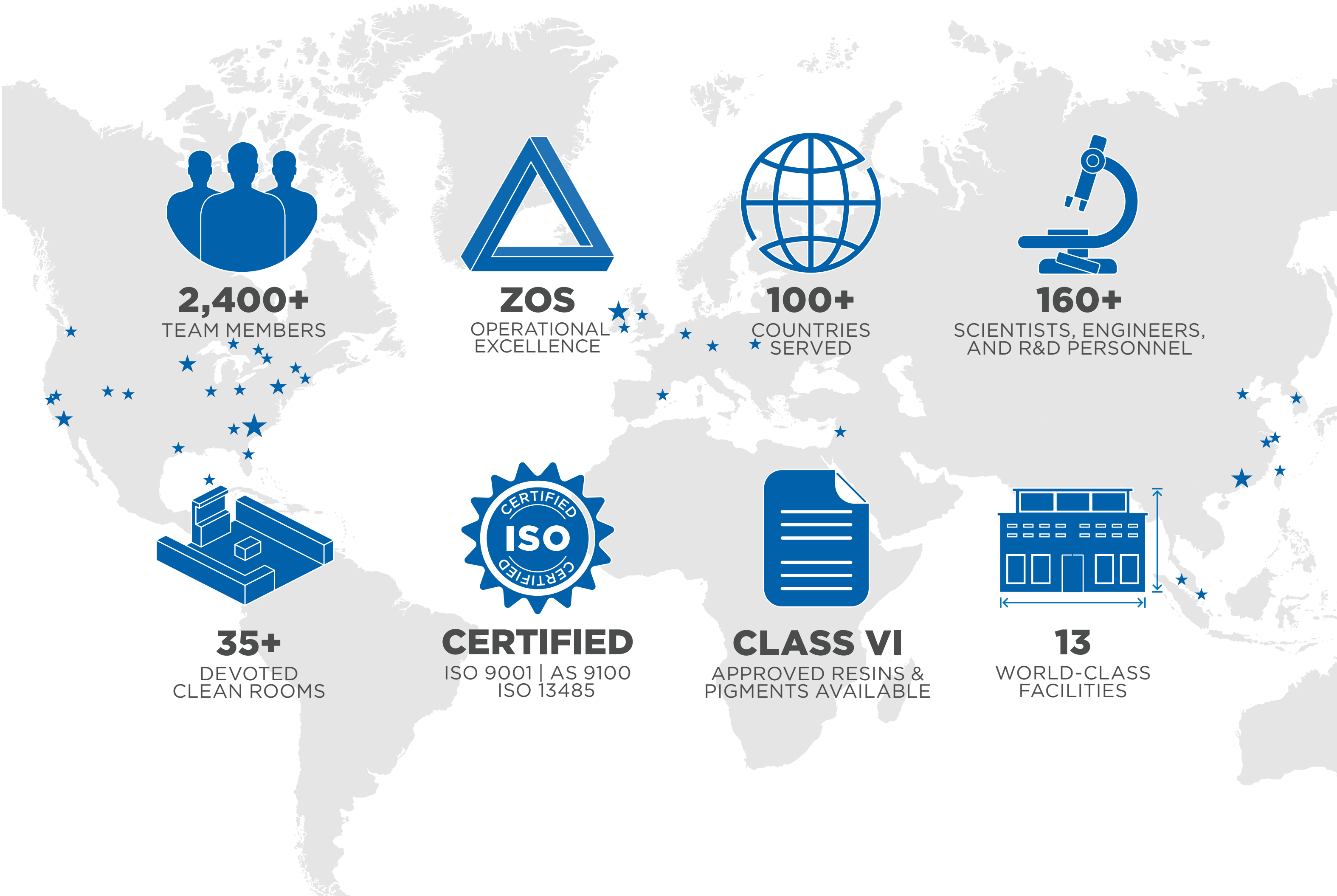
By providing device manufacturers and engineers more liner options, new catheter designs that once seemed unimaginable can now be explored, helping to extend the boundaries of vascular access via catheterization. With the combination of size, flexibility and strength, StreamLiner™ OTW catheter liners open new pathways for success, giving device makers and physicians alike a crucial new tool for successful vascular interventions.

Summary

Discover How StreamLiner™ OTW Can Improve Your Next Design

Have an application in mind for StreamLiner™ OTW? Accelerate your prototyping with free samples from our online Virtual Sample Locker. No purchase orders or payment required, and samples typically ship within 48 hours. Alternatively, Contact our team or call 1-800-526-3842 (+1-803-268-9500 internationally) to discuss how StreamLiner™ OTW can be used in your next design.

Get to know Zeus.



OUR MISSION

PROVIDE SOLUTIONS · ENABLE INNOVATION · ENHANCE LIVES

Zeus, headquartered in Orangeburg, South Carolina, is the world's leading polymer extrusion and catheter design manufacturer. With over 55 years of experience in medical, aerospace, energy, automotive, fiber optics, and other leading industries, Zeus's mission is to provide solutions, enable innovation, and enhance lives. The company employs over 2,400 people worldwide with facilities in Aiken, Columbia, Gaston, Orangeburg, and St. Matthews, South Carolina; Branchburg, New Jersey; Chattanooga, Tennessee; San Jose, California; Arden Hills, Minnesota; Guangzhou, China; and Letterkenny, Ireland. For more information, visit *www.zeusinc.com.*

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