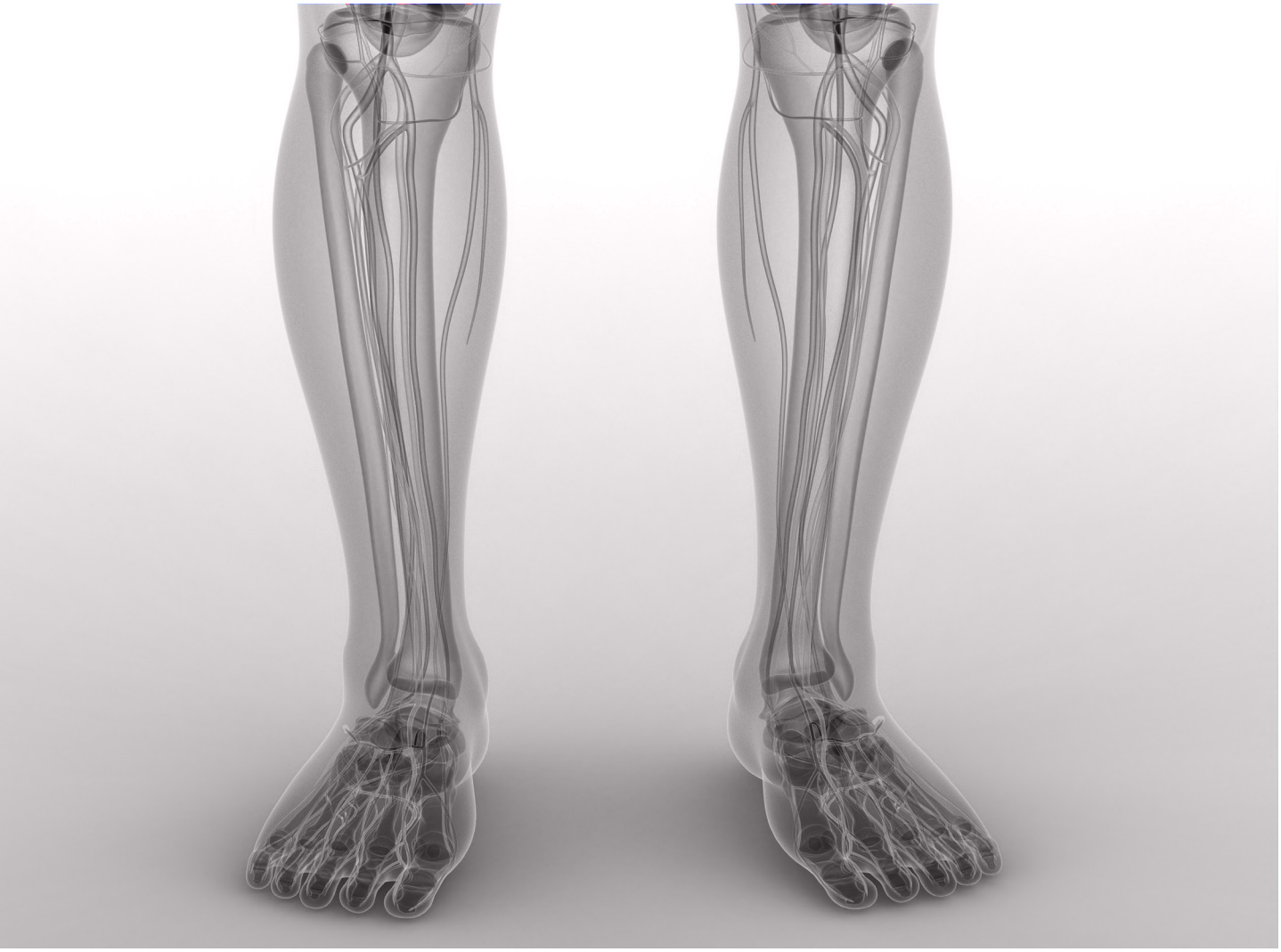

Improving Peripheral Vascular Catheter Production

Minimally invasive catheter-based procedures have revolutionized the treatment of peripheral artery disease below-the-knee (BTK). While the catheters used in these procedures have advanced tremendously over the years, their production is not without significant challenges, particularly when it comes to sourcing the high-performance catheter liners that these devices require. Without dependable, high-quality components, device makers face critical inefficiencies that threaten their ability to meet growing market demand.

Market: Medical Device

Sub-Market: Peripheral

Body Part: Leg

Condition: Peripheral Artery Disease (PAD)

Device: Peripheral Vascular Catheters

Zeus Product: StreamLiner™ NG

Peripheral Artery Disease

Peripheral artery disease (PAD) is the narrowing of the blood vessels in the arms or legs caused by atherosclerosis – a buildup of plaque in and on the walls of an artery. Left untreated, PAD can progress over time, leading to serious complications, including heart attack, stroke, and critical limb ischemia (CLI).

PAD is a growing global health concern. While figures vary, PAD is estimated to affect between 200–236 million people worldwide.[1,2] When looking at trends in the prevalence of PAD, systematic reviews have estimated that the number of people living with PAD increased by roughly 45% between 2000 and 2015.[2,3,4] It's clear that despite advancements in medicine around the world, PAD remains a growing health concern.

Today, the treatment of PAD largely depends on the severity of the disease. It can range from simple lifestyle changes to open surgery or, in the most severe cases, amputation of the affected limb. However, advancements in endovascular devices and surgical techniques have resulted in more widespread adoption of minimally invasive surgical interventions to treat this condition.

From guide to delivery catheters, there are a multitude of devices used in these minimally invasive interventions, especially in treating lower extremity PAD – the most common type. As the prevalence of PAD has continued to rise, so too has demand for catheters capable of delivering new, innovative therapies into the complex vasculature below-the-knee (BTK), with industry reports suggesting the global peripheral vascular devices market is projected to grow at a compound annual growth rate (CAGR) or 5.8% from 2025 to 2030.[5]

>200 Million

People Affected By PAD

Source:
https://www.ahajournals.org/doi/10.1161/CIR.0000000000001153

Global peripheral vascular devices market projected to expand at a CAGR of

5.8%

Source:
https://www.grandviewresearch.com/industry-analysis/peripheral-vascular-devices-market

Scaling to Meet Market Demand

Manufacturing peripheral vascular catheters to treat PAD is a complicated and time-consuming process that requires the coordinated effort of many cross-functional groups within an organization. R&D engineers must first design an effective catheter, after which procurement teams are tasked with sourcing a reliable supply of materials for the design. Once the correct materials have been sourced, quality engineers must then visually inspect all incoming components to ensure they conform to the appropriate specifications. Next, manufacturing engineers take the materials and assemble the device, after which quality engineers perform final inspection and proof testing on the completed catheter assembly.

At any point in the process, a nonconforming component can wreak havoc on operational efficiencies and yields. Perhaps the most critical component, and the costliest should it not conform, is the catheter liner. Today, many peripheral vascular catheters employ film-cast PTFE liners due to their desirable mix of ultra-thin walls, lubricity, and flexibility. However, as liner dimensions decrease, the difficulty of manufacturing them without error using legacy casting methods can increase. Inherently, existing film-cast liners are prone to surface imperfections and pinholes as a byproduct of the legacy casting process, which can have a negative impact on performance, as well as yield and production efficiencies.

In a best-case scenario, nonconforming liners are identified on the initial incoming inspection before additional components, such as reinforcement or jacketing, have been added to the build. While generally effective, initial inspections are not guaranteed to successfully identify all defective materials. In worst-case scenarios, an issue with a liner is either not detected until the final inspection – at which point the device is scrapped after considerable resources have already been invested; or it is not detected at all – potentially leading to safety concerns in the field.

In all cases, inadequate materials pose a significant and costly challenge to device makers. It's clear that manufacturers looking to meet growing market demand would prefer a more reliable liner option, one that provides better peace of mind and allows them to scale production efficiently while maximizing yields.

Typical Production Challenges

- **Sourcing Quality Liners with Predictable Lead Times**
- **Heavy Reliance on Incoming Visual Inspections to Spot Liner Defects**
- **High Cost of Inadequate Components**
- **Managing Excess Inventory (Cost of Supply)**

Minimize Defects, Maximize Strength and Performance

INTRODUCING STREAMLINER™ NG

An ultra-thin and flexible film-cast PTFE liner engineered for *maximum strength* with *minimal defects*.

As a result of Zeus' proprietary film-cast process, which minimizes defects and pinholes, StreamLiner™ NG catheter liners take flexibility, mechanical performance, and reliability to the next level while still featuring the exceptional sizing and tolerances that the StreamLiner™ series is known for.

Remarkable Burst & Yield Strength

Zeus' proprietary film-cast process results in remarkable burst and yield strength, helping enhance mechanical performance of the finished device.

High Concentricity

StreamLiner™ NG liners feature highly consistent wall thicknesses, helping to provide tighter OD tolerances for the finished device, as well as improved consistency in device performance.

Minimal Scrap

Fewer pinholes, fewer problems. The ultra-low occurrence of imperfections and pinholes in StreamLiner™ NG liners can help improve manufacturing efficiencies and production yields.

Exceptional Sizing & Flexibility

True to the StreamLiner™ name, StreamLiner™ NG catheter liners are available in a wide range of sizes, with IDs as low 0.017″ (0.432 mm) and nominal wall thicknesses down to 0.0005″ (0.0127 mm).

FEATURES

StreamLiner™ NG

Proprietary Film-Cast Process

Zeus' novel film-cast process produces exceptionally consistent liners with minimal defects and pinholes, helping pave the way for lower manufacturing costs and higher production yields.

Remarkable Strength

The remarkable burst and yield strength of StreamLiner™ NG provides engineers with more options for designing devices capable of successfully delivering therapies below-the-knee.

Extremely Thin & Uniform Walls

Nominal wall thicknesses as low as 0.000″ (0.0127 mm). These ultra-thin walls enable catheter designs to maintain a minimal outer diameter to successfully traverse the complex vasculature of the lower extremities, or a maximized inner diameter for improved delivery performance of therapies below-the-knee.

Tight Tolerances

Wall thickness tolerance of ± 0.00025″ (0.00635 mm). Our state-of-the-art processes allow us to manufacture film-cast PTFE liners to tight tolerances, enabling device engineers to create catheters to exact specifications for use in specialized applications.

Biocompatible

StreamLiner™ liners are manufactured from USP Class VI materials, giving OEMs important assurance that these liners are safe for use within the body.

High Lubricity

PTFE's low coefficient of friction allows devices, such as drug-coated balloons (DCBs), to slide through the delivery system more easily, helping them reach the treatment location without failure.

AVAILABLE SIZES

StreamLiner™ Series

All PTFE StreamLiner™ catheter liners are produced based on customer specifications, and the table below is a general capability guide. All material can be etched on the OD to enhance adhesion. For even greater jacket-to-liner adhesion, a tie layer coating may also be applied.

PTFE StreamLiner™			
	StreamLiner™	StreamLiner™ OTW	StreamLiner™ NG
MATERIAL	PTFE	PTFE	PTFE
PROCESS	Free-Extruded	Extruded Over-The-Wire	Proprietary Film-Cast
MANDREL	None	Silver-plated copper, Stainless steel	Silver-plated copper, Stainless steel
INSIDE DIAMETER (ID)	0.004″ – 0.120″ (0.102 mm – 3.048 mm)	0.013″ – 0.0915″ (0.330 mm – 2.3241 mm)	0.017″ – 0.0915″ (0.432 mm – 2.3241 mm)
ID TOLERANCE	± 0.0005″ – 0.001″ (± 0.0127 mm – 0.025 mm)	± 0.0005″ (± 0.0127 mm)	± 0.0005″ (± 0.0127 mm)
NOMINAL WALL THICKNESS	0.0005″ – 0.00075″ (0.0127 mm – 0.01905 mm)	0.0004″ – 0.00075″ (0.0102 mm – 0.01905 mm)	0.0005″ – 0.00075″ (0.0127 mm – 0.01905 mm)
WALL TOLERANCE	± 0.00025″ (± 0.00635 mm)	± 0.0002″ – 0.00025″ (± 0.0051 mm – 0.00635 mm)	± 0.00025″ (± 0.00635 mm)
CUT LENGTH	86″ Max.* (2184.4 mm Max.)	86″ Max. (2184.4 mm Max.)	86″ Max. (2184.4 mm Max.)
SURFACE TREATMENTS	Etched, Tie Layer	Etched	Etched, Tie Layer
STERILIZATION METHODS	Autoclave, EtO	Autoclave, EtO	Autoclave, EtO
STRENGTH	●●●●○	●●●◐○	●●●○○
FLEXIBILITY	●●●●○	●●●●◐	●●●●●

** Liners with a Tie Layer have a maximum cut length of 78″ (1981.2 mm).*

StreamLiner™ and StreamLiner™ OTW may be shipped with product labels that feature VT, XT, or UT size designations. VT represents a standard nominal wall thickness of 0.00075″ (0.01905 mm). XT represents a standard nominal wall thickness of 0.0005″ (0.0127 mm). UT represents a standard nominal wall thickness of 0.0004″ (0.0102 mm)

A Critical Development for Catheter Manufacturing

Minimally invasive catheter-based procedures have grown increasingly more effective in the treatment of PAD BTK, helping to significantly improve functional outcomes and reduce patient mortality rates.

As the prevalence of PAD continues to grow worldwide, so too will the demand for minimally invasive devices capable of delivering advanced therapies to treat this potentially fatal condition.

Catheter innovation and production methods, therefore, must keep pace to meet the growing market demand. No catheter component should hinder productivity or yield, yet the liners that these devices fundamentally depend on could be a significant limiting factor. Existing film-cast PTFE liners face inherent limitations as a byproduct of legacy casting methods, often exhibiting a high occurrence of surface imperfections and pinholes, leading to high scrap rates. StreamLiner™ NG can help device makers overcome these limitations.

By embracing StreamLiner™ NG, device makers can not only design and develop stronger and more effective peripheral vascular catheters capable of better treating this debilitating condition, but also do so at scale with greater efficiency and higher production yields.

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