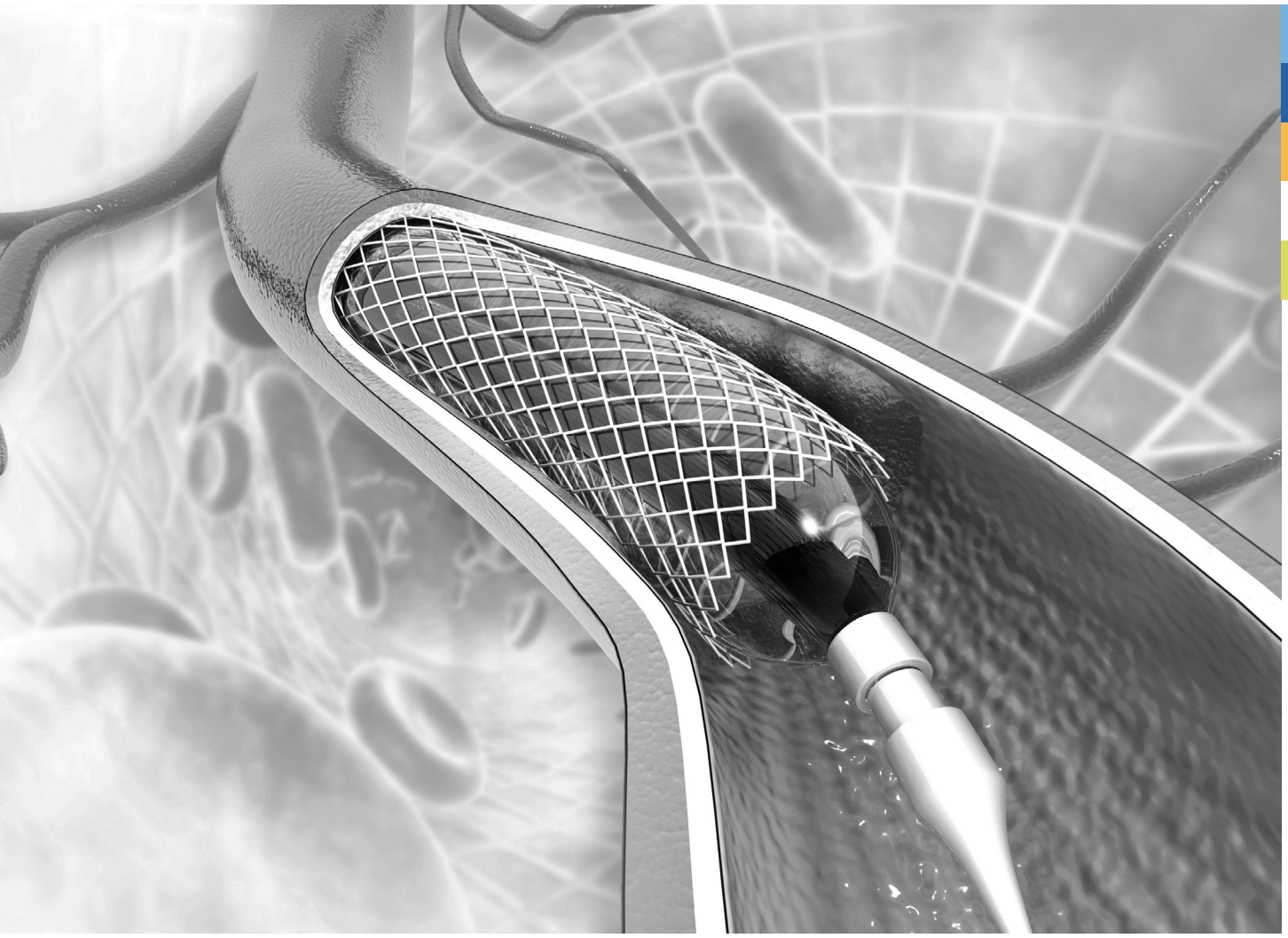
ZEUS®



# Endovascular Interventions *Below-the-knee*

## Challenges and Opportunities

The mainstay of endovascular treatment below-the-knee is typically balloon angioplasty, atherectomy, and thrombectomy, followed by stenting in more serious cases. However, despite advances, routine below-the-knee peripheral vascular intervention is limited as a result of a lack of interventional devices of appropriate length, strength, thickness, diameter, and flexibility.

**Market:** Medical Device

**Sub-Market:** Endovascular

**Treatment:** Peripheral Artery Disease (PAD)

**Body Part:** Foot

**Category:** Catheters

**Zeus Product:** StreamLiner™ Series

# Peripheral Arterial Disease

Commonly referred to as **poor circulation**, Peripheral Arterial Disease (PAD) occurs when plaque forms in a leg artery, blocking blood flow. When plaque accumulates, it fully or partially blocks and narrows the artery, restricting blood flow to tissues in the leg and other parts of the body. This is sometimes called hardening of the arteries, or atherosclerosis.

Poor blood flow increases the risk of developing open, infected sores on the skin, and without treatment can cause foot or leg tissue to die, sometimes **requiring amputation**.

Diabetes increases the risk of plaque build-up in the arteries, which can cause dangerous blood clots. For this reason, **PAD and diabetes** are common causes of leg or foot amputations.

PAD also puts patients at a higher risk of cardiovascular disorders, with severity of symptomatic PAD correlating with cardiovascular outcomes.

With early diagnosis, PAD may be corrected or at least improved with lifestyle changes and medication. However, more advanced PAD e.g. *Critical limb ischemia (CLI)* that is causing severe pain and limited mobility may require **endovascular treatment** or **open surgery**.

**>200**
**million people**

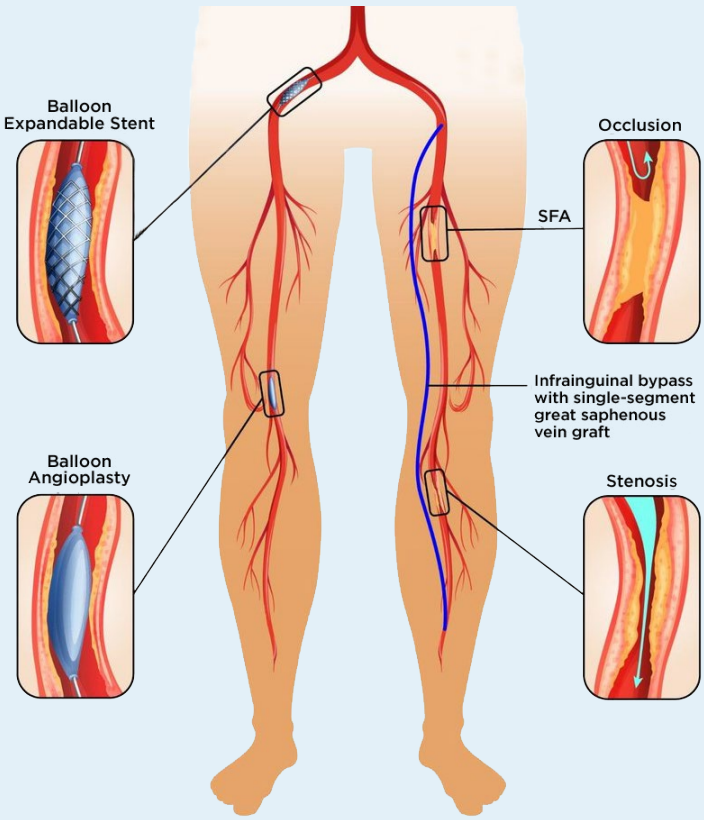
**It is estimated that >200 million people have PAD worldwide, with a spectrum of symptoms from none to severe.**

Source: 2018 Update on peripheral artery disease: Epidemiology and evidence-based facts

# Endovascular Treatment

Given availability of both endovascular and open surgical options, a 2017 research program* used population-based data to demonstrate that an endovascular approach is associated with **improved amputation-free survival** over the long term with only a modest relative increased risk of subsequent intervention.

The mainstay of endovascular treatment to increase circulation blood flow is typically *balloon angioplasty, atherectomy, and thrombectomy,* followed by stenting in more serious cases. Recent advances have broadened the options for treating PAD, including the use of *drug-eluting stents* and *drug-coated balloons* to deliver effective therapies.




*Annals of Surgery. 265(2):424–430, FEBRUARY 2017 | https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6174695/

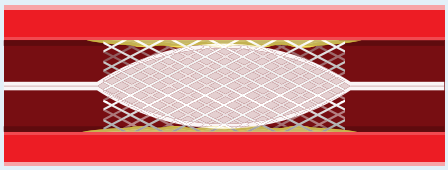
# *Below-The-Knee* Constraints

When compared with open surgery for PAD, catheter-based treatment offers a much lower periprocedural risk, but is limited by lower initial success, requiring repeated procedures for effective treatment, particularly for infrapopliteal *(below-the-knee)* intervention.

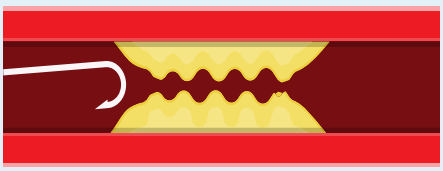
For example, blood vessels in the foot are **smaller in diameter** and **highly tortuous**, making them difficult to access and navigate. This, in addition to the fact that lesions in these body parts are often **severely calcified**, can mean repeated procedures are required for effective treatment. However, extensive infrapopliteal stenting in conjunction with poor outflow may actually elevate the risk of **stent thrombosis** or **distal embolization** complications.

## The Challenge for Today's Device Engineers

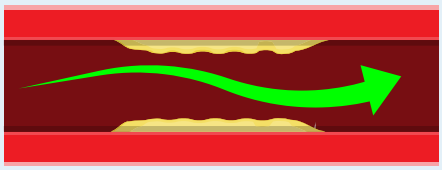
It is clear that a reliable endovascular treatment for PAD in the lower extremities will be largely dependent on, and aided by, the availability of more **advanced device design.** However, despite many advances, the challenge for engineers remains: creating a catheter that offers the right mechanical properties of strength and flexibility, and that is small enough for successful below-the-knee intervention.



Balloon Expandable Stent



Occlusion



Stenosis

IT'S FINALLY HERE
STREAMLINER™ SERIES

# An ultra-thin PTFE catheter liner offering unparalleled *trackability*, *flexibility* and *pushability*.

For microcatheter designs, the StreamLiner™ series allows **greater access to the smallest vasculatures and most complex anatomies** to deliver lifesaving therapies. A critical requirement for below-the-knee peripheral vascular intervention (PVI).

### Larger Lumen Size

A PTFE liner with thinner walls results in a greater lumen size for improved **flexibility** and kink resistance.

### Greater Tensile Strength

The higher strength of StreamLiner™ PTFE catheter tubing translates into improved **pushability** and supports better **trackability**.

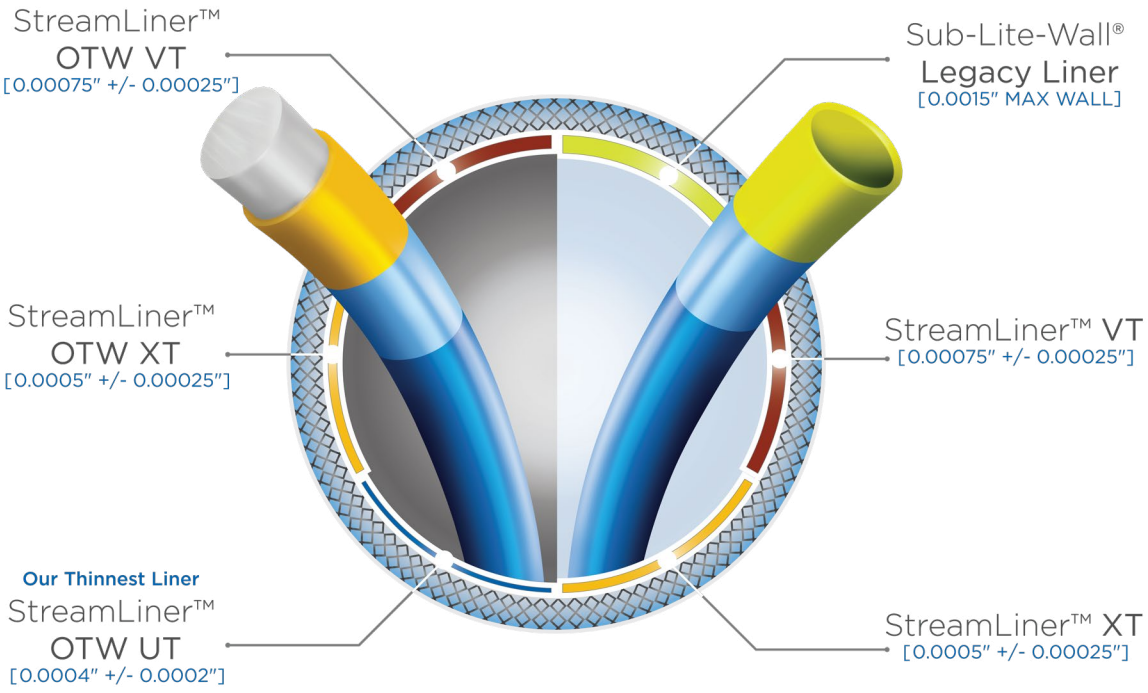
# StreamLiner™ Series

## Free Extruded - *StreamLiner™ XT and VT*

Accommodating the most in-demand catheter sizes down to the smallest microcatheter, our free-extruded StreamLiner™ XT and VT sizes open up new designs that require optimum strength for delivery, but thinner walls to improve flexibility and tractability.

## Extruded Over-The-Wire - *StreamLiner™ OTW*

Equivalent to a film cast PTFE liner, but with inherently more strength, StreamLiner™ OTW allows for new catheter designs that can more easily navigate through the smallest and most tortuous vasculature to provide life-saving therapies.



FEATURES

# StreamLiner™ Series

## Extremely Thin Walls

Wall thickness as low as 0.0004" / 0.0102mm. These super thin walls allow for a minimized outer diameter to successfully traverse the smaller vasculature of the foot, or a maximized inner diameter for atraumatic delivery of treatments and devices below-the-knee.

## Tight Tolerances

Maximum wall thickness tolerance of ± 0.0002" / 0.0051mm. Our advanced proprietary processes allow us to manufacture PTFE liners to tight tolerances, enabling device engineers to create catheters to exact specifications for use in numerous below-the-knee scenarios.

## Strength and Flexibility

Over-the-wire liners offer superior strength and comparable flexibility to film cast liners. In a below-the-knee setting, these are vital mechanical properties that should be considered to ensure that catheters can easily and safely access and track through the small and tortuous vessels below-the-knee.

## Bridges the gap between film cast liners and free extruded liners...

***"StreamLiner™ OTW bridges the gap between film cast liners and free extruded liners by providing extremely thin walls, flexibility, and strength. These features enable more catheter design options, which ultimately translates to better tractability, deliverability, and overall performance – all without compromising patient safety."***

Matt Allen,
Senior Product Line Manager,
Zeus Industrial Products, Inc.

FEATURES

# StreamLiner™ Series

## Low Coefficient of Friction

The low coefficient of PTFE allows a device such as a PTA balloon or thrombectomy device to easily and safely slide through the delivery system, or track over a guide wire, reaching the foot without any friction, resistance, or snagging.

## Biocompatible

StreamLiner™ liners are certified USP Class VI, giving OEMs important assurance that these liners won't compromise their design when components of the catheter are tested, and ensuring it's safe for use in the living tissue of the body below-the-knee.

## Sterilizable

Sterilizable by ETO and autoclave methods, the most popular sterilization methods approved and largely used by the industry for below-the-knee devices.

## Chemical Resistance

Safe to use concomitant with various contrasts for below-the-knee diagnosis procedures, and also with drug therapies like drug-eluted stents, drug-coated balloons, and embolization. Unreactive towards almost all commonly encountered chemicals and bodily fluids.

## Opens the doors to new possibilities for catheter manufacturers...

*"Zeus continues to lead with its technological innovations in PTFE liners. Using a state-of-the- art process, our new StreamLiner™ OTW lineup opens the doors to new possibilities for catheter manufacturers. Currently, no other polymer solution provider can supply an extruded PTFE liner with comparable wall thickness, flexibility, and strength. Zeus is the only company in the market capable of delivering flexible PTFE liners extruded over wire with the lowest wall thickness."*

Bob Chaney, Senior Vice President,
Global Sales & Marketing,
Zeus Industrial Products, Inc.

APPLICATIONS

# StreamLiner™ Series

## Guiding Catheters

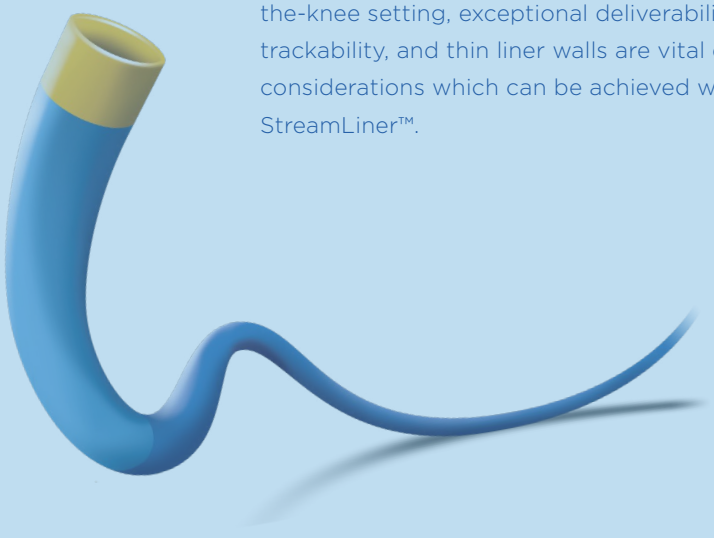
Guiding catheters must have the greatest lumen size possible to carry the device below-the-knee, whilst still retaining a low overall profile so that it can easily navigate to a lesion site through challenging anatomy; a property that StreamLiner™ can successfully deliver.

## Support Catheters

Support catheters used in below-the-knee scenarios must be easily able to access and track through small and tortuous vessels. With unrivalled lubricity and super-thin walls, the StreamLiner™ series of liners enable device designers to create support catheters that meet these needs.

## Angioplasty Balloon Catheters

Balloon angioplasty is the most common and typical intervention in below-the-knee endovascular treatment scenarios. When designing balloon catheters for use in a below-the-knee setting, exceptional deliverability, trackability, and thin liner walls are vital design considerations which can be achieved with StreamLiner™.



## Microcatheters

Microcatheters are used to navigate the vast network of tiny veins found within the body, making them ideal for below-the-knee applications. As small walls are a vital property of microcatheters, the use of StreamLiner™ super thin liners means the outer diameter is minimized, while real estate in the microcatheter itself is maximized.

## Aspiration Thrombectomy Catheters

Aspiration thrombectomy offers potential advantages for treatment of acute lower limb ischemia over other more traditional methods. The highly trackable and highly atraumatic nature of the StreamLiner™ series makes it particularly suitable for the design and production of aspiration thrombectomy catheters to be used below-the-knee.

## Atherectomy Catheters

The use of atherectomy for the treatment of PAD is increasing as an adjunctive treatment to either conventional or drug-coated balloon angioplasty, with results*, although limited, associated with lower repeated rates of revascularization procedures. StreamLiner™ liners are a key component in the development of atherectomy catheters for use in below-the-knee settings.

*https://pubmed.ncbi.nlm.nih.gov/30499198/

AVAILABLE SIZES - STREAMLINER™ SERIES

# PTFE StreamLiner™

All material can be etched on the OD and available in metric and standard dimensions.

| PTFE StreamLiner™ Standard Capabilities | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Resin | ID | Inside Diameter | | Nominal Wall Thickness | | Wall Tolerances | | Max Cut Length | |
| | | in. | mm | in. | mm | in. | mm | in. | cm |
| PTFE | XT | 0.004 - 0.040 | 0.102 - 1.016 | 0.0005 | 0.0127 | 0.00025 | 0.00635 | 86 | 218.44 |
| PTFE | VT | 0.004 - 0.120 | 0.102 - 3.048 | 0.00075 | 0.01905 | 0.00025 | 0.00635 | 86 | 218.44 |

| PTFE StreamLiner™ AVAILABLE SAMPLES | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| ID | OPN | ID SIZES | | ID TOLERANCE +/- | | WALL | | WALL TOLERANCE +/- | | CUT LENGTH | |
| | | in. | mm | in. | mm | in. | mm | in. | mm | in. +2/-0 | +5.08/-0 cm |
| VT | 221629 | 0.120 | 3.048 | 0.001 | 0.025 | 0.00075 | 0.01905 | 0.00025 | 0.00635 | 60 | 152.4 |
| VT | 221631 | 0.115 | 2.921 | 0.001 | 0.025 | 0.00075 | 0.01905 | 0.00025 | 0.00635 | 60 | 152.4 |
| VT | 221634 | 0.105 | 2.667 | 0.001 | 0.025 | 0.00075 | 0.01905 | 0.00025 | 0.00635 | 60 | 152.4 |
| VT | 221648 | 0.100 | 2.540 | 0.0005 | 0.0127 | 0.00075 | 0.01905 | 0.00025 | 0.00635 | 60 | 152.4 |
| VT | 221651 | 0.095 | 2.413 | 0.0005 | 0.0127 | 0.00075 | 0.01905 | 0.00025 | 0.00635 | 60 | 152.4 |
| VT | 221646 | 0.085 | 2.159 | 0.0005 | 0.0127 | 0.00075 | 0.01905 | 0.00025 | 0.00635 | 60 | 152.4 |
| VT | 221665 | 0.075 | 1.905 | 0.0005 | 0.0127 | 0.00075 | 0.01905 | 0.00025 | 0.00635 | 60 | 152.4 |
| VT | 221663 | 0.065 | 1.651 | 0.0005 | 0.0127 | 0.00075 | 0.01905 | 0.00025 | 0.00635 | 60 | 152.4 |
| VT | 221652 | 0.060 | 1.524 | 0.0005 | 0.0127 | 0.00075 | 0.01905 | 0.00025 | 0.00635 | 60 | 152.4 |
| VT | 221662 | 0.055 | 1.397 | 0.0005 | 0.0127 | 0.00075 | 0.01905 | 0.00025 | 0.00635 | 60 | 152.4 |
| VT | 221661 | 0.050 | 1.270 | 0.0005 | 0.0127 | 0.00075 | 0.01905 | 0.00025 | 0.00635 | 60 | 152.4 |
| VT | 221640 | 0.045 | 1.143 | 0.0005 | 0.0127 | 0.00075 | 0.01905 | 0.00025 | 0.00635 | 60 | 152.4 |
| VT | 221642 | 0.035 | 0.889 | 0.0005 | 0.0127 | 0.00075 | 0.01905 | 0.00025 | 0.00635 | 72 | 182.88 |
| VT | 221660 | 0.030 | 0.762 | 0.0005 | 0.0127 | 0.00075 | 0.01905 | 0.00025 | 0.00635 | 72 | 182.88 |
| VT | 221655 | 0.020 | 0.508 | 0.0005 | 0.0127 | 0.00075 | 0.01905 | 0.00025 | 0.00635 | 72 | 182.88 |
| VT | 221657 | 0.015 | 0.381 | 0.0005 | 0.0127 | 0.00075 | 0.01905 | 0.00025 | 0.00635 | 72 | 182.88 |
| XT | 217519 | 0.040 | 1.016 | 0.0005 | 0.0127 | 0.0005 | 0.0127 | 0.00025 | 0.00635 | 72 | 182.88 |
| XT | 217524 | 0.0305 | 0.7747 | 0.0005 | 0.0127 | 0.0005 | 0.0127 | 0.00025 | 0.00635 | 72 | 182.88 |
| XT | 217521 | 0.0245 | 0.6223 | 0.0005 | 0.0127 | 0.0005 | 0.0127 | 0.00025 | 0.00635 | 72 | 182.88 |
| XT | 217527 | 0.020 | 0.508 | 0.0005 | 0.0127 | 0.0005 | 0.0127 | 0.00025 | 0.00635 | 72 | 182.88 |
| XT | 217526 | 0.017 | 0.432 | 0.0005 | 0.0127 | 0.0005 | 0.0127 | 0.00025 | 0.00635 | 72 | 182.88 |

AVAILABLE SIZES - STREAMLINER™ SERIES

# StreamLiner OTW™

All material can be etched on the OD and available in metric and standard dimensions.

| PTFE StreamLiner™ OTW Standard Capabilities | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Resin | ID | Inside Diameter | | Nominal Wall Thickness | | Wall Tolerances | | Max Cut Length | |
| | | in. | mm | in. | mm | in. | mm | in. | cm |
| PTFE | UT | 0.013 - 0.020 | 0.330 - 0.508 | 0.0004 | 0.0102 | 0.0002 | 0.0051 | 86 | 218.44 |
| PTFE | XT | 0.013 - 0.040 | 0.330 - 1.016 | 0.0005 | 0.0127 | 0.00025 | 0.00635 | 86 | 218.44 |
| PTFE | VT | 0.013 - 0.0915 | 0.330 - 2.3241 | 0.00075 | 0.01905 | 0.00025 | 0.00635 | 86 | 218.44 |

| StreamLiner™ OTW AVAILABLE - 72" SAMPLES | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| ID | OPN | ID SIZES | | ID TOLERANCE +/- | | WALL | | WALL TOLERANCE +/- | |
| | | in. | mm | in. | mm | in. | mm | in. | mm |
| OTW VT | 250740 | 0.0915 | 2.3241 | 0.0005 | 0.0127 | 0.00075 | 0.01905 | 0.00025 | 0.00635 |
| OTW VT | 250738 | 0.084 | 2.134 | 0.0005 | 0.0127 | 0.00075 | 0.01905 | 0.00025 | 0.00635 |
| OTW VT | 250731 | 0.079 | 2.007 | 0.0005 | 0.0127 | 0.00075 | 0.01905 | 0.00025 | 0.00635 |
| OTW VT | 250727 | 0.074 | 1.880 | 0.0005 | 0.0127 | 0.00075 | 0.01905 | 0.00025 | 0.00635 |
| OTW VT | 250706 | 0.071 | 1.803 | 0.0005 | 0.0127 | 0.00075 | 0.01905 | 0.00025 | 0.00635 |
| OTW VT | 250701 | 0.068 | 1.727 | 0.0005 | 0.0127 | 0.0007 | 0.0178 | 0.0002 | 0.00635 |
| OTW VT | 250699 | 0.064 | 1.626 | 0.0005 | 0.0127 | 0.0007 | 0.0178 | 0.0002 | 0.00635 |
| OTW VT | 250674 | 0.060 | 1.524 | 0.0005 | 0.0127 | 0.0007 | 0.0178 | 0.0002 | 0.00635 |
| OTW VT | 250651 | 0.055 | 1.397 | 0.0005 | 0.0127 | 0.0007 | 0.0178 | 0.0002 | 0.00635 |
| OTW VT | 250638 | 0.050 | 1.270 | 0.0005 | 0.0127 | 0.0007 | 0.0178 | 0.0002 | 0.00635 |
| OTW VT | 251109 | 0.045 | 1.143 | 0.0005 | 0.0127 | 0.0007 | 0.0178 | 0.0002 | 0.00635 |
| OTW VT | 251104 | 0.040 | 1.016 | 0.0005 | 0.0127 | 0.0006 | 0.0152 | 0.0002 | 0.00635 |
| OTW VT | 251089 | 0.035 | 0.889 | 0.0005 | 0.0127 | 0.0006 | 0.0152 | 0.0002 | 0.00635 |
| OTW XT | 251070 | 0.0275 | 0.6985 | 0.0005 | 0.0127 | 0.0005 | 0.0127 | 0.0002 | 0.00635 |
| OTW XT | 251060 | 0.0225 | 0.5715 | 0.0005 | 0.0127 | 0.0005 | 0.0127 | 0.0002 | 0.00635 |
| OTW UT | 251054 | 0.017 | 0.432 | 0.0005 | 0.0127 | 0.0004 | 0.0102 | 0.0002 | 0.0051 |
| OTW UT | 251046 | 0.014 | 0.356 | 0.0005 | 0.0127 | 0.0004 | 0.0102 | 0.0002 | 0.0051 |

# The Challenge Remains

Lower extremity PAD is one of the most under-diagnosed atherosclerotic diseases, resulting in severe pain and limited physical mobility for patients, and leading to a significant risk of amputation and associated increase in mortality.

Furthermore, symptomatic PAD has been associated with a 70% increased risk of cardiovascular events, and an 80% increased risk of death, when compared with patients who do not have PAD.

Treatment for symptomatic patients who fail conservative management has traditionally been surgical revascularization.

However, there is increasing evidence to support endovascular intervention in patients where in-line flow to the foot can be re-established.

The challenge for today's device engineers remains: designing a catheter with the right combination of properties which can more easily access and navigate the highly tortuous vasculature below-the-knee, without sacrificing torque and pushability – opening up new pathways and delivering life-saving treatments.

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