ZEUS®

Endovascular Interventions *The Brain*

Challenges and Opportunities

Globally, strokes remain the second leading cause of death and the third leading cause of disability.* Endovascular treatment has been proven to significantly improve outcomes and reduce both long-term disability and mortality after ischemic stroke. However, despite advances, endovascular treatment is limited by a lack of interventional devices of appropriate strength, thickness, diameter, and flexibility.

*https://www.who.int/bulletin/volumes/94/9/16-181636/en/

Market: Medical Device

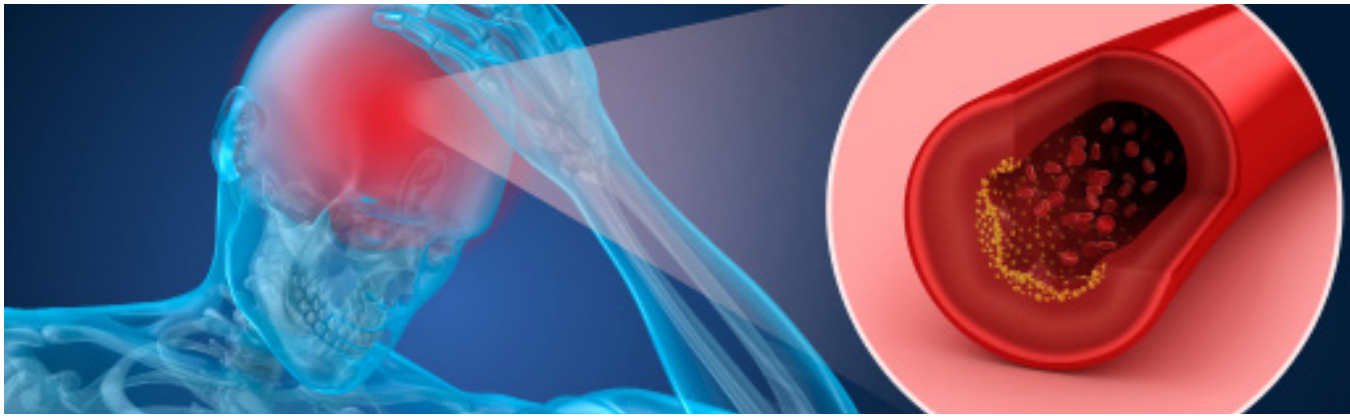
Sub-Market: Neurovascular

Treatment: Ischemic Strokes

Body Part: Brain

Category: Catheters

Zeus Product: StreamLiner™ Series



Ischemic Stroke

Arteries bring fresh blood, carrying oxygen and other nutrients, to the brain from the heart and lungs. This blood also takes away waste such as carbon dioxide.

Blood clots may form if the arteries become too narrow, cutting off the critical supply of fresh blood.

This can occur as a result of several different diseases, with the most common being cerebral atherosclerosis, or the narrowing of the arteries in the neck or head.

A **thrombotic ischemic stroke** happens when a blood clot forms in an artery directly supplying blood to the brain.

An **embolic ischemic stroke** occurs when a blood clot travels to the brain after developing in another part of the body.

Once ischemic stroke occurs, **immediate medical intervention** is critical.

To treat an ischemic stroke, doctors must quickly restore blood flow to the brain. This can be done with IV medication or through emergency endovascular procedures, where ischemic strokes are treated directly inside the blocked blood vessel.

87%

of strokes are ischemic strokes.

Source: John Hopkins Medicine https://www.hopkinsmedicine.org/health/conditions-and-diseases/stroke/types-of-stroke

Endovascular Treatment

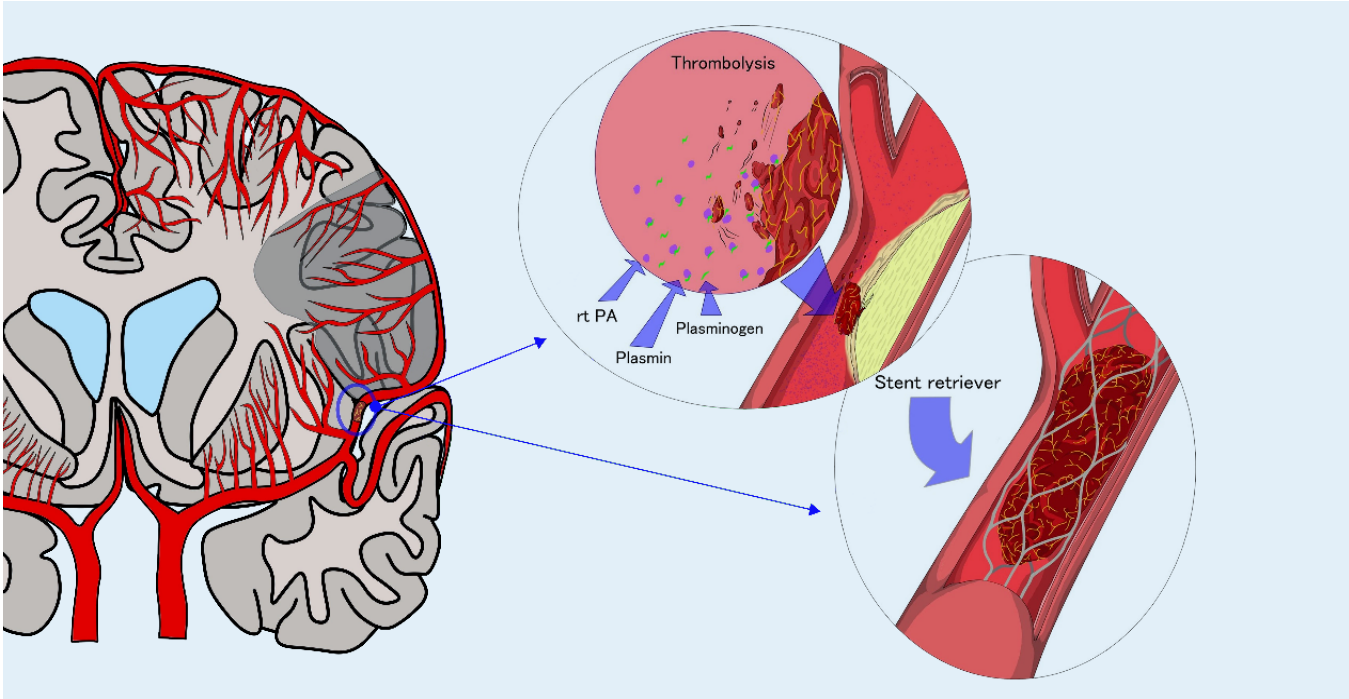
Endovascular therapy has been proven to improve patient outcomes and reduce long-term disability after ischemic stroke.* The ultimate objective of endovascular stroke therapy is to reperfuse the ischemic brain.

There are two mainstays of endovascular treatment: thrombolysis and thrombectomy. These treatments are sometimes used concurrently where appropriate.

Thrombolysis is a treatment which uses thrombolytic medication (clot-busting drugs) to liquefy the clot.

This tissue plasminogen activator (tPA) medication is delivered directly to the brain via a catheter. This treatment is most successful within a short timeframe of the stroke occurring.

Thrombectomy is also a common treatment where the clot is removed from the brain with a stent retriever or an aspiration/reperfusion suction device. The device is attached to a catheter which accesses the lesion site of the brain to retrieve and remove the clot. This procedure is particularly beneficial for people with large clots that can't be completely dissolved with tPA.



*Source: Mayo Clinic https://www.mayoclinic.org/diseases-conditions/stroke/diagnosis-treatment/drc-20350119

Neurovascular Constraints

The treatment of acute ischemic stroke has been revolutionized by the advent of modern endovascular techniques such as thrombolysis and thrombectomy.

However, there are a number of challenges that device manufacturers and end users, such as doctors and physicians, face.

The arteries and blood vessels in the brain are **much smaller** in diameter, when compared to coronary arteries for example. The arteries are also **highly tortuous**, making them difficult to both access and navigate.

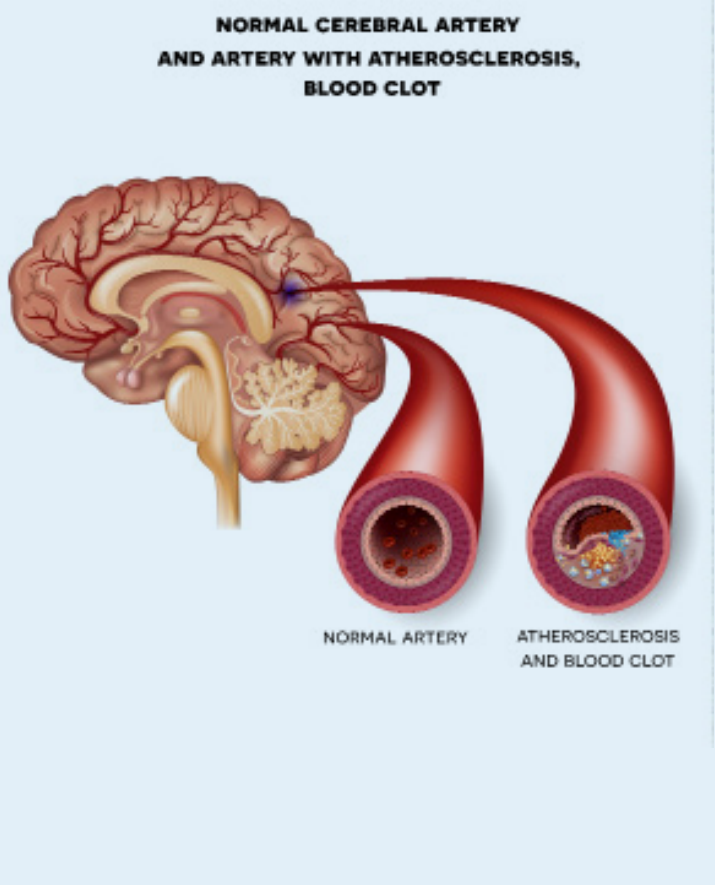
Soft and flexible catheters, which are easily able to navigate to the affected area of the brain, are essential.

However, these catheters must also be capable of delivering medication or other therapies to the brain to treat the clot. Without the ability to deliver these therapies, the catheter is futile in a neurovascular setting.

The Challenge for Today's Device Engineers

It takes a unique combination of soft, flexible, stiff, and rigid components to design these high-performance catheters. This can often present a material selection dilemma for the engineer.

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 neurovascular intervention.



IT'S FINALLY HERE
STREAMLINER™ SERIES

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

The StreamLiner™ series allows **greater access to the smallest vasculatures and most complex anatomies** to deliver life-saving therapies to the brain. A critical requirement for endovascular intervention to treat ischemic stroke.

Greater Pushability

Allows physicians to more easily advance the delivery system into the deep and complex vasculature within the brain.

Greater Trackability

Improves the ability of the delivery system to track over a guidewire during insertion, more easily navigating the bends of the tortuous vessels of the brain.

Greater Torquability

Enhances the ability to transmit torque from the proximal end to the distal end of the catheter.

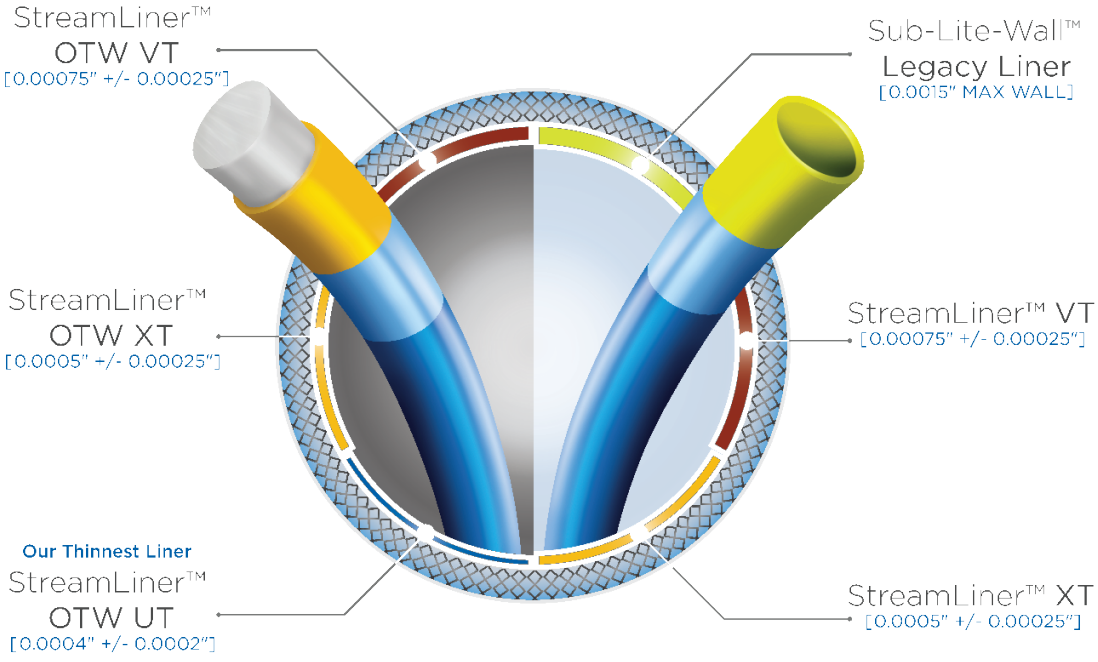
StreamLiner™ Series

Free Extruded - *StreamLiner™*

Accommodating the most in-demand catheter sizes down to the smallest microcatheter, our free-extruded StreamLiner™ opens up new designs that require optimum strength for delivery of therapies such as clot retrievers and stents, but with thinner walls to improve flexibility and tractability.

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

Equivalent wall thickness and flexibility 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 in the body, going deeper than ever before, delivering 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 brain, or a maximized inner diameter for atraumatic delivery of treatments and devices to the brain.

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 specialised neurovascular scenarios.

Strength and Flexibility

The unique combination of strength and flexibility, coupled with extremely thin walls, offers physicians significantly greater control when treating ischemic stroke. It enables the delivery system to be pushed or positioned deep within the tortuous vasculature of the brain without bending or buckling. It also provides the tensile strength required when delivering a stent or any other therapy that requires great radial force during deployment.

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 medical device, such as an atherectomy or thrombectomy device, to easily and safely slide through the delivery system, reaching the brain without any friction, resistance, or snagging.

Biocompatible

StreamLiner™ liners are manufactured from USP Class VI materials, 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 brain.

Sterilizable

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

Chemical Resistance

Safe to use concomitant with various contrasts for neurovascular diagnosis procedures, and also with drug therapies such as thrombolytic medication. 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 line-up 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."

Peter Theirl, Vice President,
Global Sales & Marketing,
Zeus Industrial Products, Inc.

APPLICATIONS

StreamLiner™ Series

Mechanical Thrombectomy Catheters

The catheter used to deliver a device to the brain (such as a stent retriever) must be capable of safely traversing complex vasculature, and accessing the lesion site. The StreamLiner™ properties of strength, flexibility, and extremely thin walls make it particularly suitable for use in this setting.

Aspiration Thrombectomy Catheters

The highly trackable and highly atraumatic nature of the StreamLiner™ series makes it particularly suitable for the design and production of aspiration thrombectomy catheters, for use in neurovascular settings.

Angioplasty Balloon Catheters

When designing balloon catheters for use in a neurovascular setting, exceptional deliverability, kink-resistant pushability, 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 neurovascular applications such as the delivery of thrombolytic medication to the brain. As small walls are a vital property of microcatheters, the use of StreamLiner™ liners means the outer diameter is minimized, while real estate in the microcatheter itself is maximized to carry therapies to the brain.

Guiding Catheters

Guiding catheters, with or without balloons, must have the greatest lumen size possible to carry the device to the brain 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.

Intermediate Catheters

Intermediate catheters used in neurovascular scenarios must be easily able to access and track through small and tortuous vessels. With unrivalled pushability and super-thin walls, the StreamLiner™ series of liners enables device designers to create intermediate catheters that meet these needs.

*Source: PubMed 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

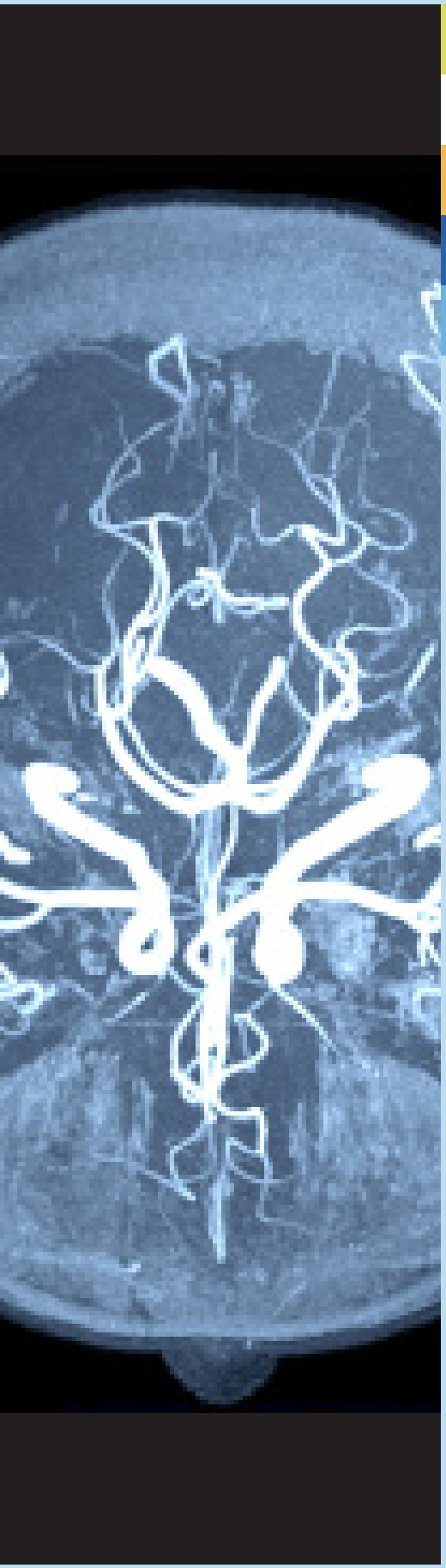
AVAILABLE SIZES - STREAMLINER™ SERIES

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

Ischemic stroke remains one of the most common causes of death and disability around the world. Furthermore, recent studies and reports have alarmingly predicted that the number of strokes occurring in countries such as the USA could double over the next 20 to 40 years.*

Although rates of stroke occurrence are increasing, the outcomes for patients who suffer from ischemic stroke have never been better, largely as a result of advances in endovascular treatment. Endovascular intervention has now become the treatment of choice for many patients who suffer an ischemic stroke.

However, the brain, with its tiny blood vessels and highly tortuous arteries, presents a unique challenge for catheter engineers: designing a catheter with the right combination of properties which can more easily access and navigate the vasculature of the brain, without sacrificing torque, pushability, and trackability – opening up new pathways and delivering life- saving treatments.

*Source: NCBI https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3727892/

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