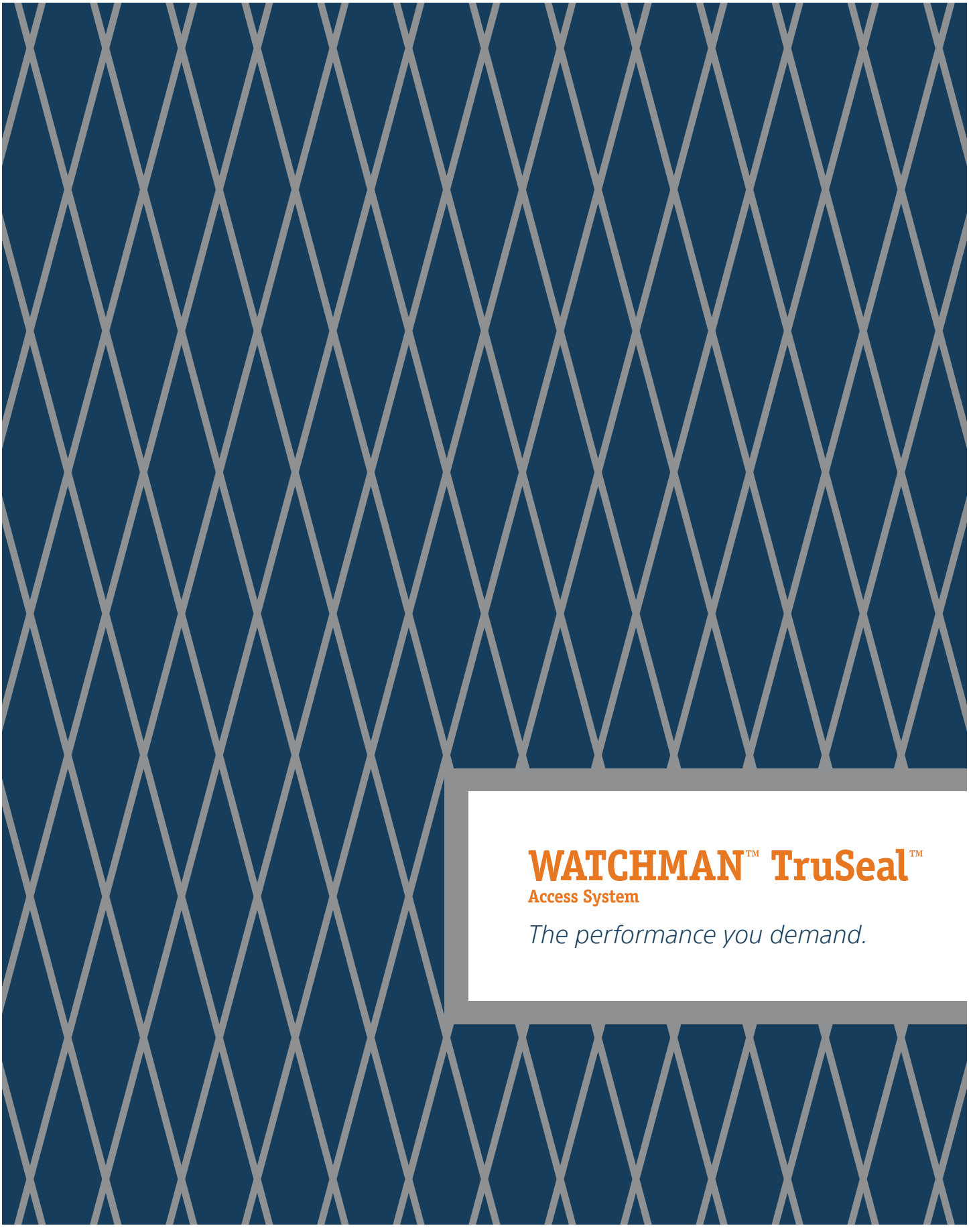
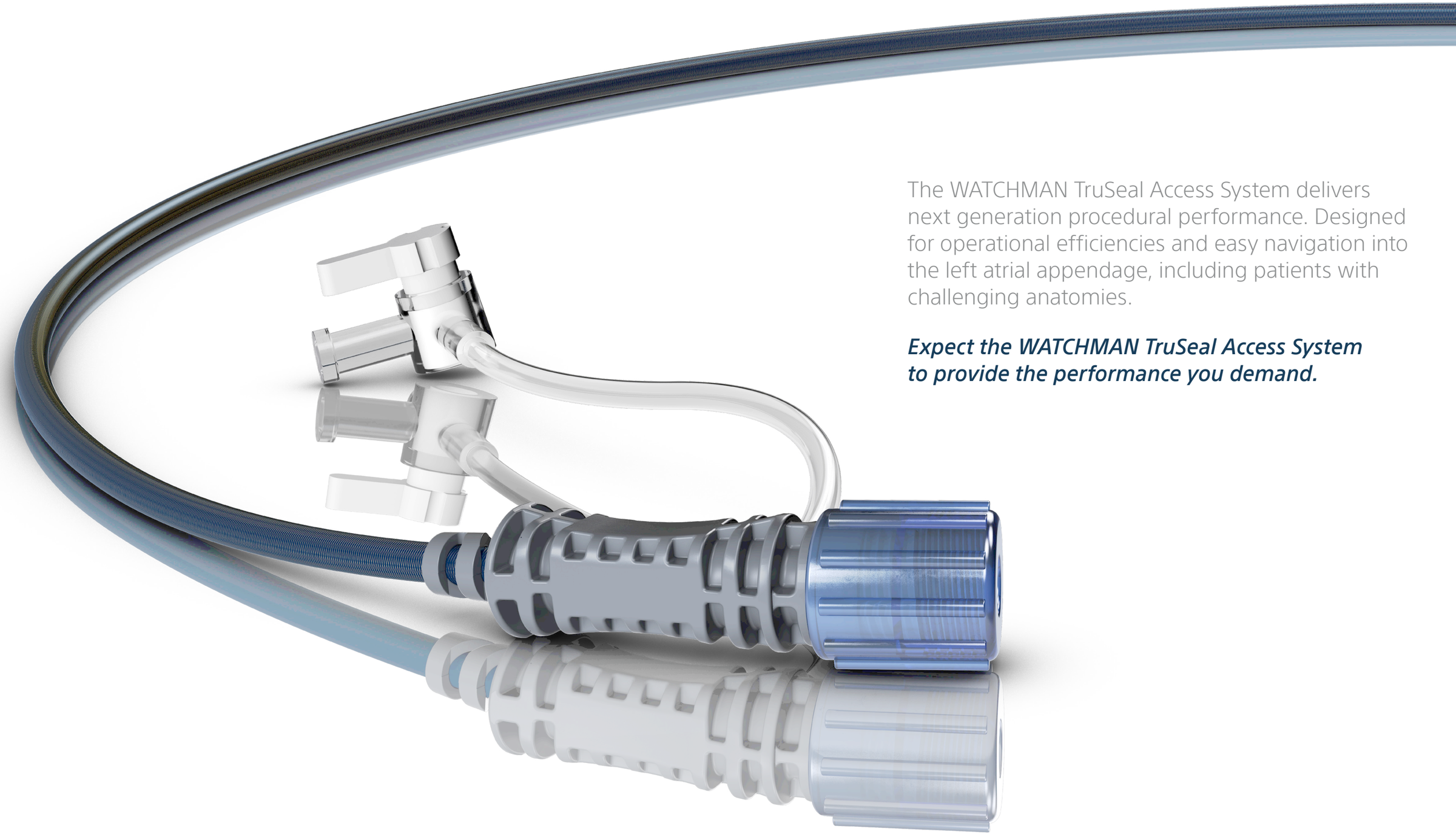


WATCHMAN™ TruSeal™

Access System

The performance you demand.



The WATCHMAN TruSeal Access System delivers next generation procedural performance. Designed for operational efficiencies and easy navigation into the left atrial appendage, including patients with challenging anatomies.

Expect the WATCHMAN TruSeal Access System to provide the performance you demand.

New valve features are designed for operational efficiency and optimized procedural performance

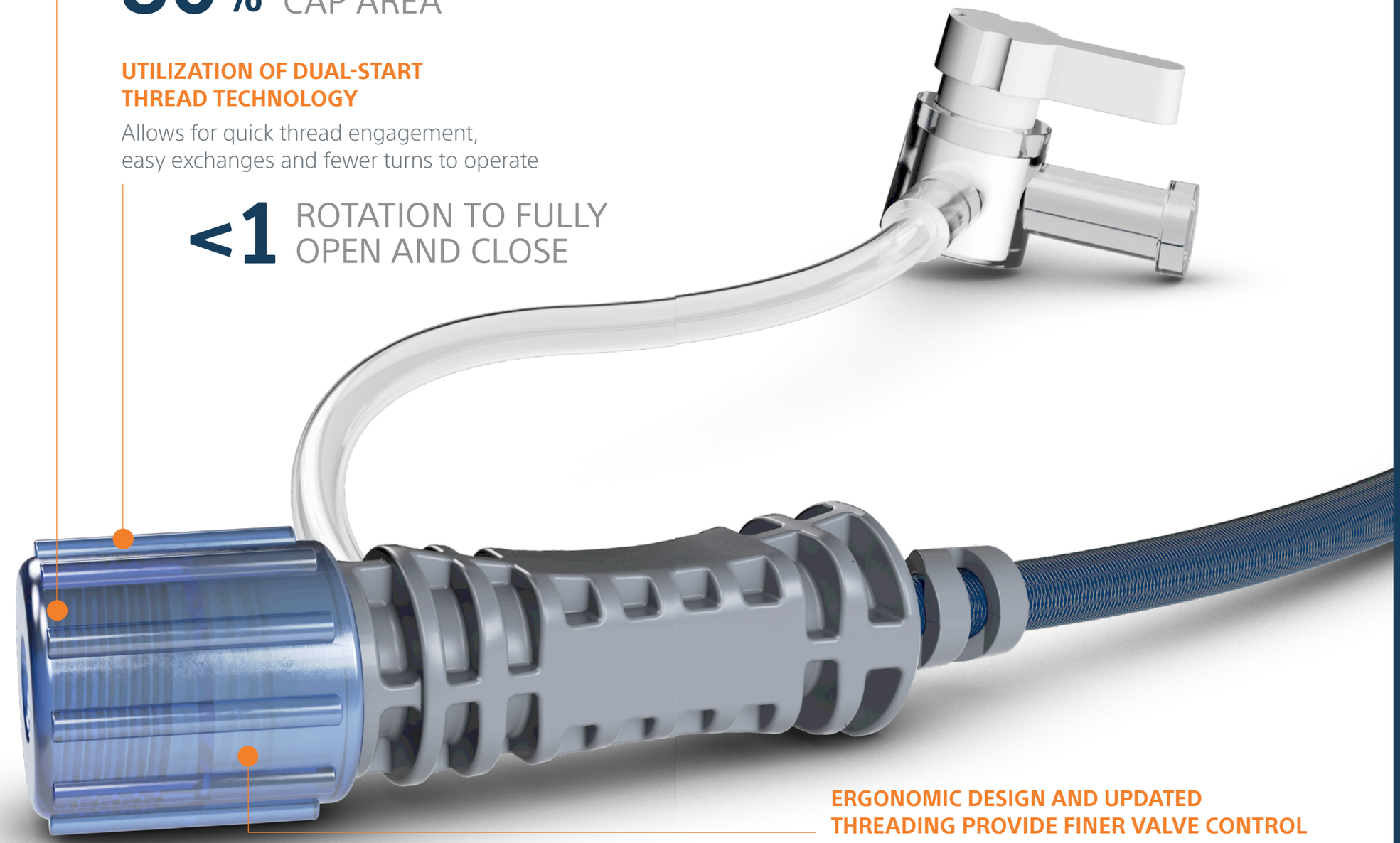
LARGER CAP WITH ENHANCED RIDGES ALL FOR EFFICIENT VALVE HANDLING

80% MORE CAP AREA

UTILIZATION OF DUAL-START THREAD TECHNOLOGY

Allows for quick thread engagement, easy exchanges and fewer turns to operate

<1 ROTATION TO FULLY OPEN AND CLOSE



ERGONOMIC DESIGN AND UPDATED THREADING PROVIDE FINER VALVE CONTROL

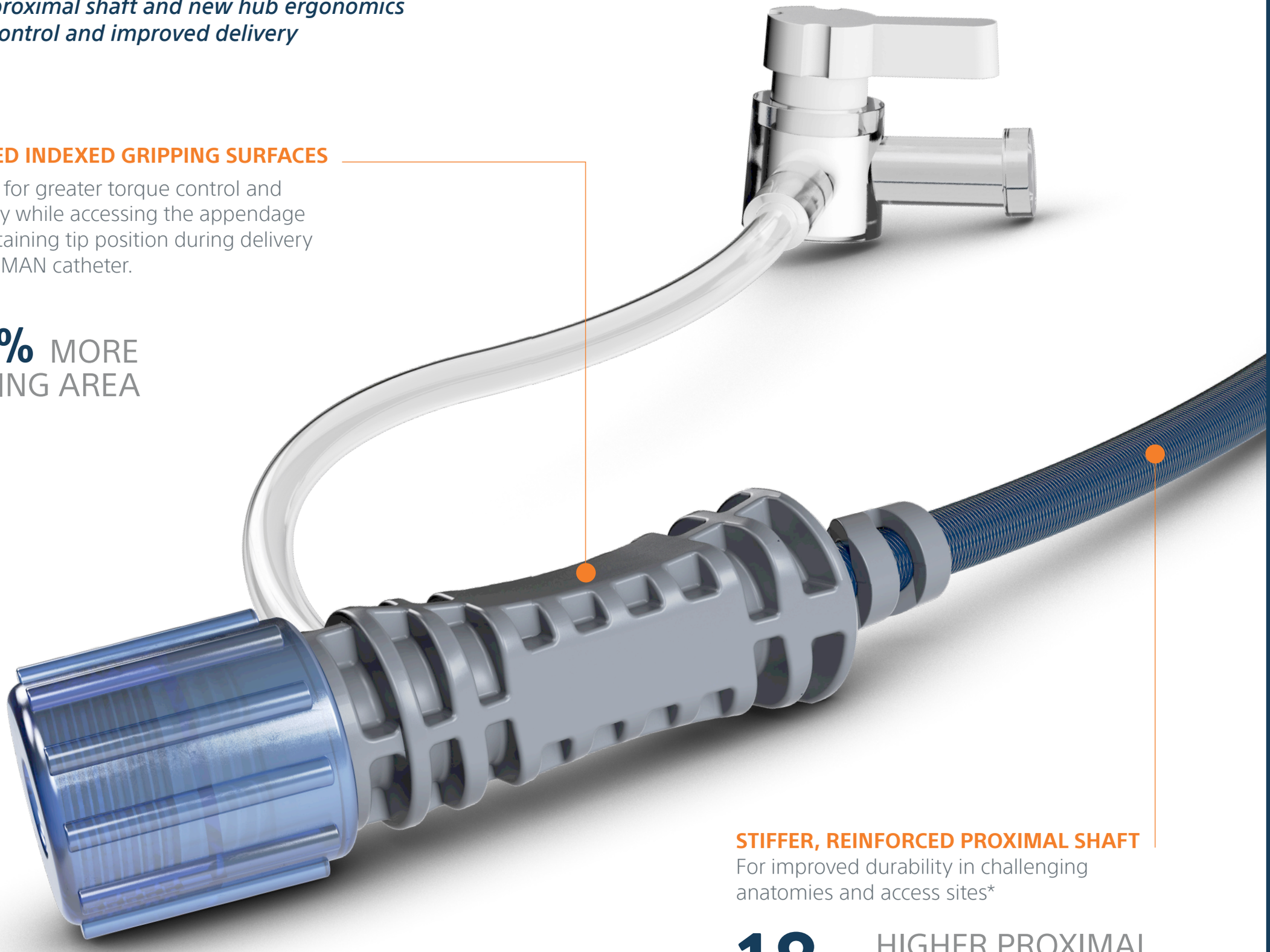
Maintains seal performance while positioning and locking the guidewire and pigtail catheter

Reinforced proximal shaft and new hub ergonomics for greater control and improved delivery

ENLARGED INDEXED GRIPPING SURFACES

Designed for greater torque control and steerability while accessing the appendage and maintaining tip position during delivery of WATCHMAN catheter.

35% MORE GRIPPING AREA



STIFFER, REINFORCED PROXIMAL SHAFT

For improved durability in challenging anatomies and access sites*

18% HIGHER PROXIMAL KINK RESISTANCE

*Compared to our previous WATCHMAN Access Sheath.

DELIVERY CATHETER

Sheath Material

Braided Pebax® with PTFE liner
and platinum/iridium marker band

WATCHMAN™ LAAC DEVICE

Nitinol frame with Polyethylene
Terephthalate (PET) fabric cover

ACCESS SYSTEM

Hub Material

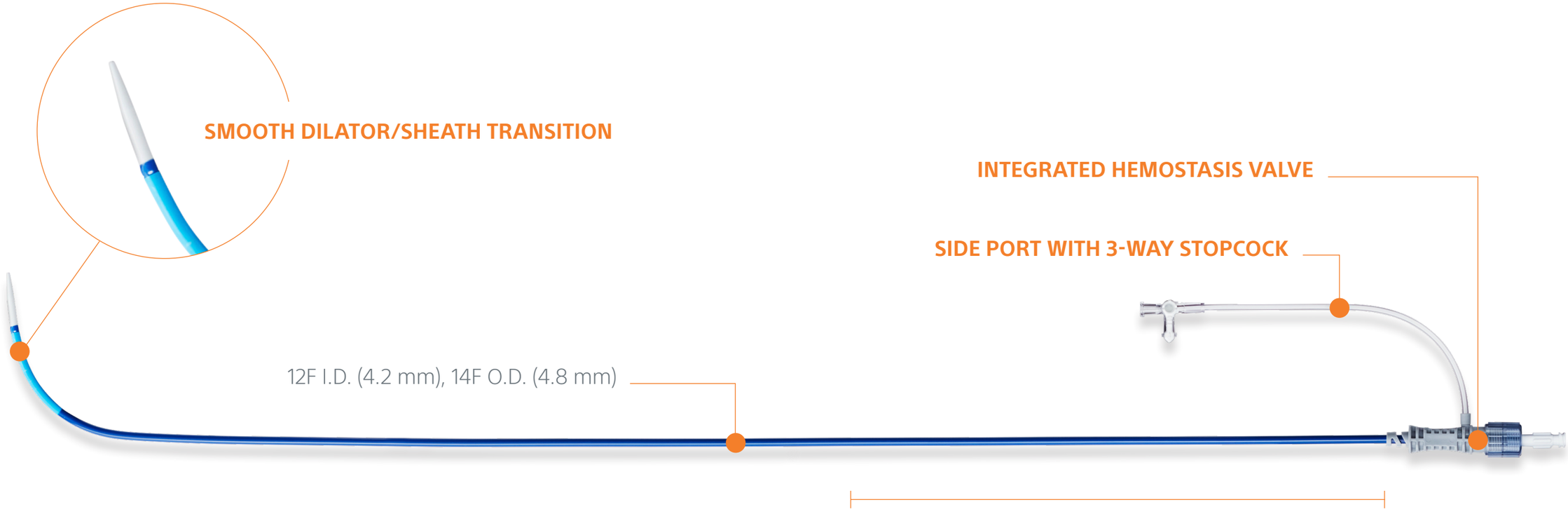
Pebax® with polycarbonate

Sheath Material

Pebax® with PTFE liner and
platinum/iridium marker band

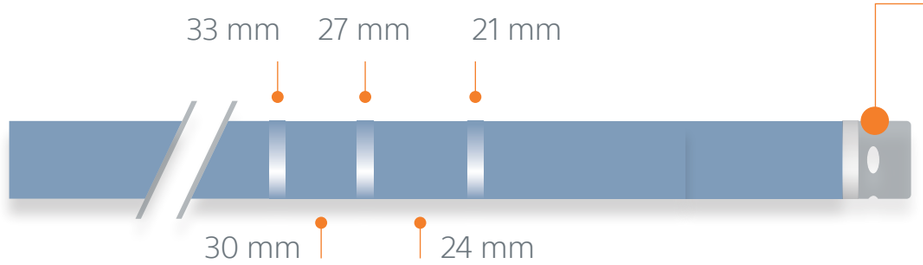
Dilator

HDPE/LDPE high density
polyethylene/Low density
polyethylene (50:50 blend)



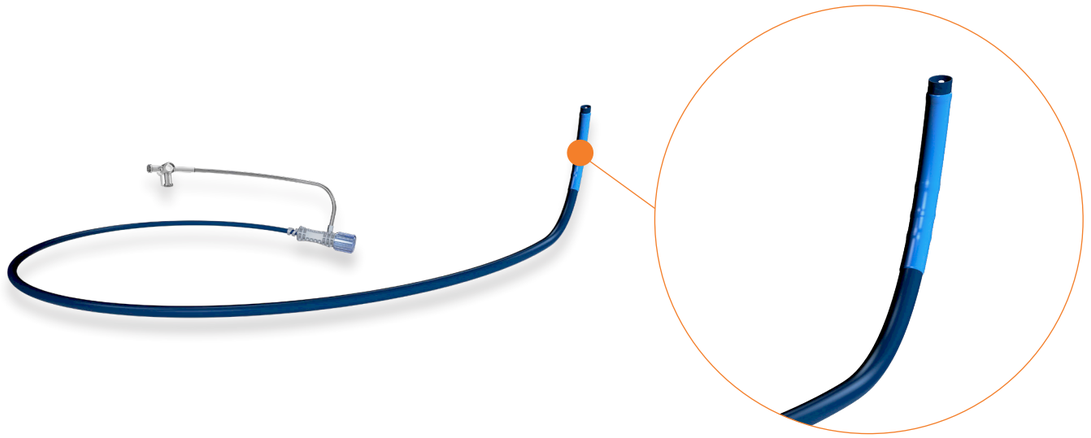
RADIOPAQUE MARKER BANDS

Helps guide precise sheath placement for the WATCHMAN device



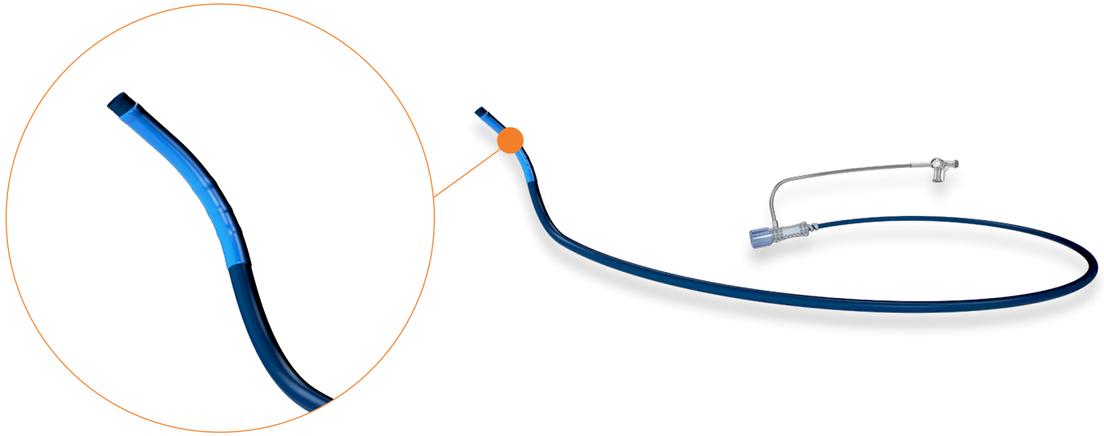
SIDE HOLES

Allows multi-directional contrast for LAA visualization



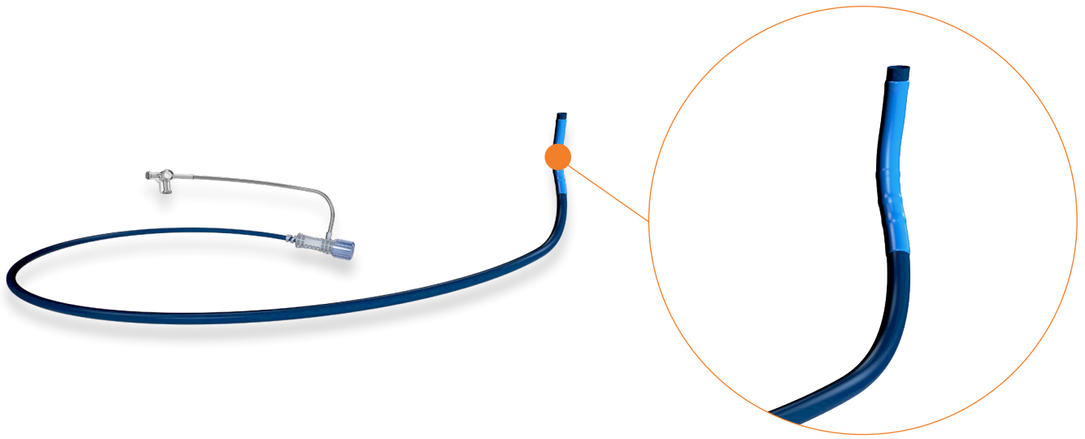
SINGLE CURVE

ORDER NUMBER (GTIN)	REF/CATALOG NUMBER	ID	OD
08714729965701	M635TU70010	12F (4.2 mm)	14F (4.8 mm)



DOUBLE CURVE

ORDER NUMBER (GTIN)	REF/CATALOG NUMBER	ID	OD
08714729965718	M635TU70020	12F (4.2 mm)	14F (4.8 mm)



ANTERIOR CURVE

ORDER NUMBER (GTIN)	REF/CATALOG NUMBER	ID	OD
08714729965725	M635TU70040	12F (4.2 mm)	14F (4.8 mm)

BRIEF SUMMARY

WATCHMAN™ Left Atrial Appendage Closure Device with Delivery System and WATCHMAN Access System

INDICATIONS FOR USE

The WATCHMAN Device is indicated to reduce the risk of thromboembolism from the left atrial appendage in patients with non-valvular atrial fibrillation who:

- Are at increased risk for stroke and systemic embolism based on $CHADS_2$ or CHA_2DS_2-VASc scores and are recommended for anticoagulation therapy;
- Are deemed by their physician to be suitable for warfarin; and
- Have an appropriate rationale to seek a non-pharmacologic alternative to warfarin, taking into account the safety and effectiveness of the device compared to warfarin.

The WATCHMAN Access System is intended to provide vascular and transseptal access for all WATCHMAN Left Atrial Appendage Closure Devices with Delivery Systems.

CONTRAINDICATIONS

Do not use the WATCHMAN Device if:

- Intracardiac thrombus is visualized by echocardiographic imaging.
- An atrial septal defect repair or closure device or a patent foramen ovale repair or closure device is present.
- The LAA anatomy will not accommodate a device. **See Table 46 in the DFU.**
- Any of the customary contraindications for other percutaneous catheterization procedures (e.g., patient size too small to accommodate TEE probe or required catheters) or conditions (e.g., active infection, bleeding disorder) are present.
- There are contraindications to the use of warfarin, aspirin, or clopidogrel.
- The patient has a known hypersensitivity to any portion of the device material or the individual components (see Device Description section) such that the use of the WATCHMAN Device is contraindicated.

WARNINGS

- Device selection should be based on accurate LAA measurements obtained using fluoro and ultrasound guidance (TEE recommended) in multiple angles (e.g., 0˚, 45˚, 90˚, 135˚).
- Do not release the WATCHMAN Device from the core wire if the device does not meet all release criteria.
- If thrombus is observed on the device, warfarin therapy is recommended until resolution of thrombus is demonstrated by TEE.
- The potential for device embolization exists with cardioversion <30 days following device implantation. Verify device position post-cardioversion during this period.
- Administer appropriate endocarditis prophylaxis for 6 months following device implantation. The decision to continue endocarditis prophylaxis beyond 6 months is at physician discretion.
- For single use only. Do not reuse, reprocess, or resterilize.

PRECAUTIONS

- The safety and effectiveness (and benefit-risk profile) of the WATCHMAN Device has not been established in patients for whom long-term anticoagulation is determined to be contraindicated.
- The LAA is a thin-walled structure. Use caution when accessing the LAA and deploying the device.
- Use caution when introducing the WATCHMAN Access System to prevent damage to cardiac structures.
- Use caution when introducing the Delivery System to prevent damage to cardiac structures.
- To prevent damage to the Delivery Catheter or device, do not allow the WATCHMAN Device to protrude beyond the distal tip of the Delivery Catheter when inserting the Delivery System into the Access Sheath.
- If using a power injector, the maximum pressure should not exceed 100 psi.
- In view of the concerns that were raised by the RE-ALIGN1 study of dabigatrain in the presence of prosthetic mechanical heart valves, caution should be used when prescribing oral anticoagulants other than warfarin in patients treated with the WATCHMAN Device. The WATCHMAN Device has only been evaluated with the use of warfarin post-device implantation.

ADVERSE EVENTS

Potential adverse events (in alphabetical order) which may be associated with the use of a left atrial appendage closure device or implantation procedure include but are not limited to:

Air embolism, Airway trauma, Allergic reaction to contrast media/medications or device materials, Altered mental status, Anemia requiring transfusion, Anesthesia risks, Angina, Anoxic encephalopathy, Arrhythmias, Atrial septal defect, AV fistula, Bruising, hematoma or seroma, Cardiac perforation, Chest pain/discomfort, Confusion post procedure, Congestive heart failure, Contrast related nephropathy, Cranial bleed, Decreased hemoglobin, Deep vein thrombosis, Death, Device embolism, Device fracture, Device thrombosis, Edema, Excessive bleeding, Fever, Groin pain, Groin puncture bleed, Hematuria, Hemoptysis, Hypotension, Hypoxia, Improper wound healing, Inability to reposition, recapture, or retrieve the device, Infection/pneumonia, Interatrial septum thrombus, Intratracheal bleeding, Major bleeding requiring transfusion, Misplacement of the device/improper seal of the appendage/movement of device from appendage wall, Myocardia erosion, Nausea, Oral bleeding, Pericardial effusion/tamponade, Pleural effusion, Prolonged bleeding from a laceration, Pseudoaneurysm, Pulmonary edema, Renal failure, Respiratory insufficiency/failure, Surgical removal of the device, Stroke – Ischemic, Stroke – Hemorrhagic, Systemic embolism, TEE complications (throat pain, bleeding, esophageal trauma), Thrombocytopenia, Thrombosis, Transient ischemic attack (TIA), Valvular damage, Vasovagal reactions.

There may be other potential adverse events that are unforeseen at this time.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

1. Eikelboom JW, Connolly SJ, Brueckmann M, et al. N Engl J Med 2013;369:1206-14.

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