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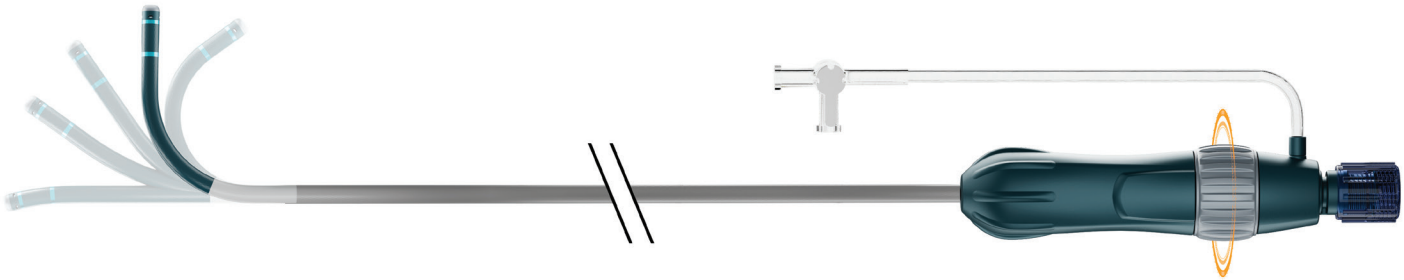
WATCHMAN TruSteer™
ACCESS SYSTEM

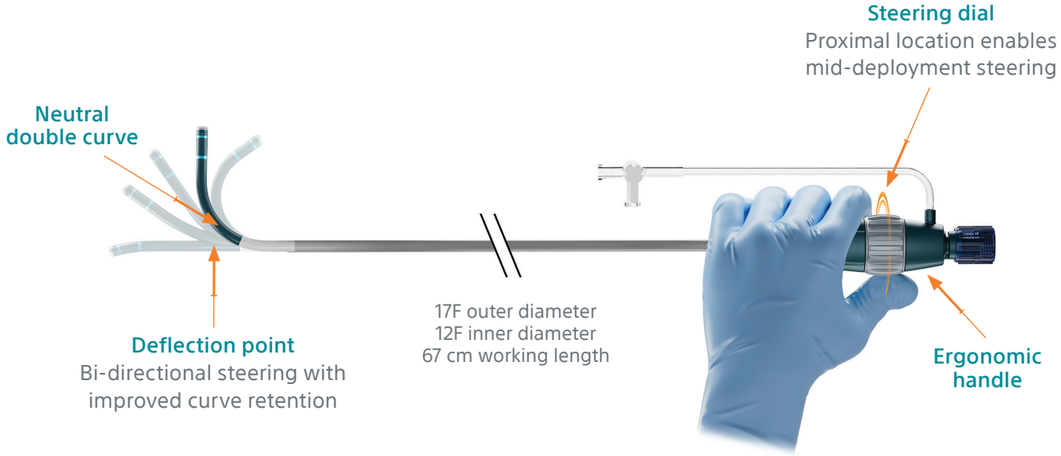


WATCHMAN TruSteer Access System

Precision for Every Anatomy

Designed to improve implant success, the WATCHMAN TruSteer™ Access System optimizes coaxial device positioning in the widest range of LAA anatomies.

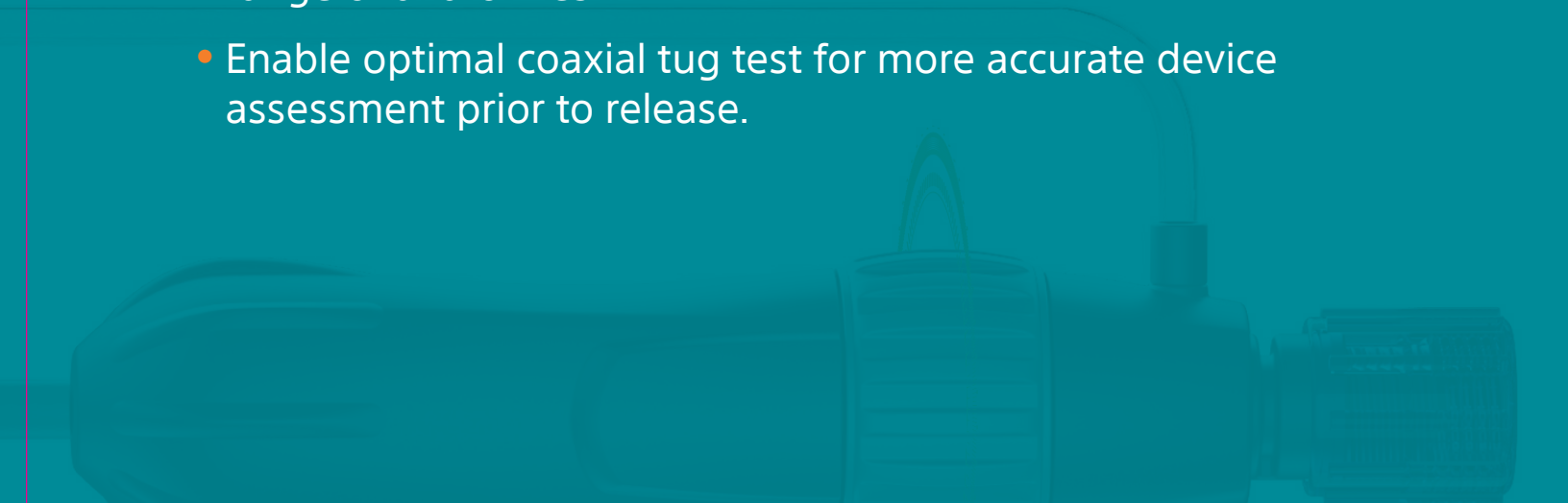
WATCHMAN TRUSTEER ACCESS SYSTEM



Steering for better control

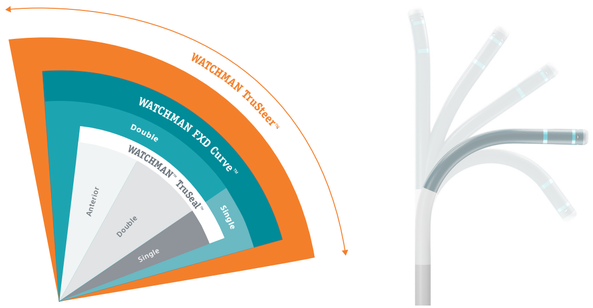
The WATCHMAN TruSteer™ Access System has bi-directional steering and a new ergonomic handle that allow you to:

- Control **WATCHMAN FLX™** Pro device deployment trajectory for optimized device positioning.
- Achieve a greater range of motion to reach the widest range of anatomies.
- Enable optimal coaxial tug test for more accurate device assessment prior to release.



BI-DIRECTIONAL STEERING

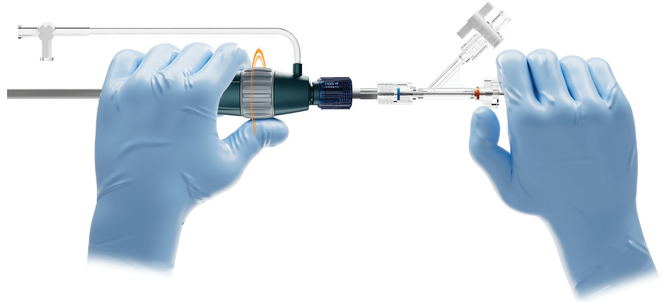
Bi-directional steering and a wider range of motion to allow access to the **greatest range of anatomies**.



A greater range of motion to reach a wider range of anatomies

ERGONOMIC HANDLE

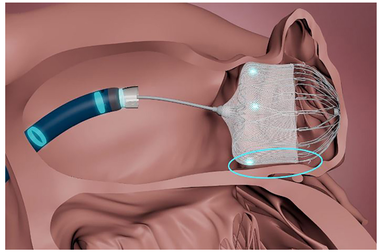
Ergonomic handle designed to give you control for **optimized device positioning** more consistently.

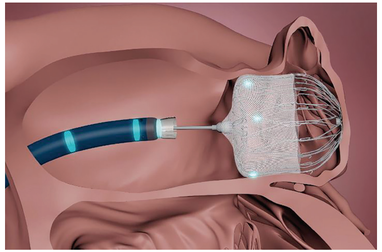


Controlling the sheath in three dimensions results in optimal coaxial device placement more consistently, without the need for excessive torque.

REDUCE CORE WIRE BIAS

Coaxial alignment after deployment results in more accurate contrast shot and confident tug assessment before release.





The WATCHMAN TruSteer™ Access System, combined with the WATCHMAN FLX™ Pro Radiopaque markers, are designed to guide intuitive adjustment during deployment to achieve optimal device position in the most challenging anatomies.

ORDERING INFORMATION

WATCHMAN TruSteer™ Access System Ordering Information

Reference Catalog No.	Description	Curve	Order Number (GTIN)	ID	OD	Barcode
M635TU90050	WATCHMAN TruSteer Access System US	Double	00191506022310	12F (4.2 mm)	17F (5.6 mm)	

WATCHMAN FLX™ Pro LAAC Device Ordering Information

Reference Catalog No.	Description	Size	Order Number (GTIN)	ID	OD	Barcode
M635WU60200	WATCHMAN FLX Pro LAAC US	20 mm	191506004583	–	12F (4.0 mm)	
M635WU60240	WATCHMAN FLX Pro LAAC US	24 mm	191506004590	–	12F (4.0 mm)	
M635WU60270	WATCHMAN FLX Pro LAAC US	27 mm	191506004606	–	12F (4.0 mm)	
M635WU60310	WATCHMAN FLX Pro LAAC US	31 mm	191506004613	–	12F (4.0 mm)	
M635WU60350	WATCHMAN FLX Pro LAAC US	35 mm	191506004620	–	12F (4.0 mm)	
M635WU60400	WATCHMAN FLX Pro LAAC US	40 mm	191506004637	–	12F (4.0 mm)	

Please contact your Boston Scientific sales representative for more information.

BRIEF SUMMARY

WATCHMAN TruSteer™ Access System

RX ONLY

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

INTENDED USE/INDICATIONS FOR USE

The WATCHMAN TruSteer Access System is intended to provide vascular and transseptal access for the family of WATCHMAN FLX LAAC Devices with Delivery Systems.

CONTRAINDICATIONS

Do not use the WATCHMAN TruSteer Access System if:

- Intracardiac thrombus is present.
- An atrial septal defect repair or closure device is present.
- A patent foramen ovale repair or closure device is present.
- Any of the customary contraindications for other percutaneous catheterization procedures (e.g., patient anatomy too small to accommodate imaging probe or required catheters) or conditions (e.g., active infection, bleeding disorder) are present.
- There are contraindications to the use of anticoagulation therapy, aspirin, or $P2Y_{12}$ inhibitor.

For additional contraindications associated with the Closure Device, refer to Closure Device IFU.

WARNINGS

Use of the WATCHMAN TruSteer Access System for implantation of the family of WATCHMAN FLX LAAC Devices should only be performed by interventional cardiologists and/or electrophysiologists who are educated in percutaneous and transseptal procedures and who have completed the required Physician Training for the family of WATCHMAN FLX Devices and WATCHMAN TruSteer Access System.

- For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the Access System and/or lead to Access System failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the Access System and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the Access System may lead to injury, illness, or death of the patient.
- Careful consideration should be given to use of the Access System in pregnant and/or breastfeeding women due to the risk of significant exposure to X-rays and the use of anticoagulation medication.

For additional warnings associated with the Closure Device, refer to Closure Device IFU.

PRECAUTIONS

- The LAA is a thin-walled structure. Use caution when accessing the LAA and deploying, recapturing, and repositioning the Closure Device.
- Use caution when introducing the WATCHMAN TruSteer Access System to prevent damage to cardiac structures.
- The WATCHMAN TruSteer Access Sheath should not be deflected with the Dilator inserted to prevent damage to the steering function and to cardiac structures.
- Only position Access System under image guidance.
- Do not advance the WATCHMAN TruSteer Access Sheath without a pigtail catheter or without forming a Closure Device/ Implant width approximately twice (2X) that of the Access Sheath.
- Use caution when introducing the Delivery System to prevent damage to cardiac structures.
- Ensure Access Sheath is free from anatomical structures prior to removal.
- Remove and replace Access Sheath if it becomes kinked before proceeding with the procedure.
- To prevent damage to the Delivery Catheter or Closure Device, do not allow the Closure Device to protrude beyond the Delivery Catheter when inserting the Delivery System into an Access Sheath.

Continued

Brief Summary *Continued*

ADVERSE EVENTS

Potential adverse events which may be associated with the use of an LAAC Device or implantation procedure include but are not limited to:

Air embolism, Airway trauma, Allergic reaction to contrast media, anesthetic, Closure Device material, or medications, Altered mental status, Anemia requiring transfusion, Anesthesia risks, Angina, Anoxic encephalopathy, Arrhythmias, Atrial septal defect, Bruising, hematoma, or seroma, Cardiac perforation, Chest pain/discomfort, Confusion post-procedure, Congestive heart failure, Contrast-related nephropathy, Cranial bleed, Death, Decreased hemoglobin, Deep vein thrombosis, Device embolism, Device fracture, Device thrombosis, Edema, Embolism, Excessive bleeding, Fever, Fistula, 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, Myocardial erosion, Myocardial infarction, Nausea, Oral bleeding, Pericardial effusion/tamponade, Pleural effusion, Prolonged bleeding from a laceration, Pseudoaneurysm, Pulmonary edema, Radiation injury, Renal failure, Respiratory insufficiency/failure, Stroke - Hemorrhagic, Stroke - Ischemic, Surgical removal of the device, TEE complications (e.g., throat pain, bleeding, esophageal trauma), Thrombocytopenia, Thrombosis, Transient ischemic attack (TIA), Valvular or vascular damage, Vasovagal reactions

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

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