Boston Scientific

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WATCHMAN® Access System

14F

Access Sheath with Dilator

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℞ ONLY

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

WARNING

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device 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 device 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 device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

DEVICE DESCRIPTION

The WATCHMAN Access System (Access Sheath and Dilator) is compatible with components of all WATCHMAN Left Atrial Appendage Closure Devices.

Contents

Quantity	Description
1	WATCHMAN Access System

INTENDED USE/ INDICATIONS FOR USE

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

CONTRAINDICATIONS

Refer to WATCHMAN Left Atrial Appendage Closure Device with Delivery System DFU.

WARNINGS

Refer to WATCHMAN Left Atrial Appendage Closure Device with Delivery System DFU.

PRECAUTIONS

Refer to WATCHMAN Left Atrial Appendage Closure Device with Delivery System DFU.

HOW SUPPLIED

- The WATCHMAN Left Atrial Appendage Closure Device is packaged separately.
- The WATCHMAN products are supplied STERILE using an ethylene oxide (EO) process.
- Do not use if package is opened or damaged.
- Do not use if labeling is incomplete or illegible.

Note: Contents of inner package are STERILE.

Handling and Storage

Store in a cool, dry, dark place.

PROCEDURAL INSTRUCTIONS

1. Use standard percutaneous techniques to puncture femoral vein and insert 0.035 in guidewire and vessel dilator. Use a standard, commercially available transseptal access system to cross inter-atrial septum.
2. Exchange crossing sheath with exchange length extra support 0.035 in guidewire. Position guidewire in left upper pulmonary vein (LUPV) or loop in left atrium.
3. Prepare WATCHMAN Access System.

Note: Inspect sterile package and WATCHMAN Access System prior to use. If sterile barrier, labeling, packaging, or device have been compromised in any way, DO NOT USE.

A. Remove Access Sheath and Dilator under sterile conditions.
B. Inspect prior to use to ensure no damage.
C. Flush Access Sheath and Dilator with sterile saline prior to use.
D. Insert Dilator into hemostasis valve of Access Sheath until the two snap together.

Note: Do not tighten the hemostasis valve while the Dilator is inserted in the WATCHMAN Access System. The Dilator by itself will occlude the lumen of the WATCHMAN Access System creating hemostasis. Tightening the valve onto the Dilator may damage the valve threads, which can lead to subsequent difficulty in closing the valve and an incomplete seal, once the Dilator is removed.

4. Advance WATCHMAN Access System over guidewire into left atrium (LA). As Access Sheath nears center of LA, unsnap the Access Sheath from the Dilator, hold Dilator and advance Access Sheath into initial position in LA or ostium of LUPV.

Precaution: Use caution when introducing WATCHMAN Access System to prevent damage to cardiac structures.

5. Remove Dilator and guidewire, leaving Access Sheath in LA or LUPV. Allow back bleed to minimize potential for introducing air before tightening valve. Flush the Access Sheath with saline.

   If continued back bleed is observed from the valve after the Dilator is removed despite attempting to close it, loosen the valve cap (counter-clockwise rotation) until the cap spins freely. Then re-attempt closure of the valve while exerting gentle forward pressure on the valve cap during closure (clockwise rotation) to ensure proper engagement of the valve thread. While these steps are being undertaken, manual occlusion of the valve opening using a gloved finger is recommended to minimize blood loss.

Note: These steps may be repeated if necessary. However, if this does not mitigate the blood leak, the user should remove and replace the WATCHMAN Access Sheath before proceeding with the procedure.

6. Confirm LAA size and select appropriate WATCHMAN Device.
   A. Using ultrasound guidance (TEE recommended), measure LAA ostium width and LAA depth in 4 views (0°, 45°, 90°, 135°).
   B. Choose a device based on **maximum** LAA ostium width recorded. Refer to WATCHMAN LAA Closure Device DFU for device selection.

Note: Record multiple angles on cine with contrast prior to advancing Access Sheath into LAA. Use fluoro guidance while advancing pigtail catheter and while advancing the Access Sheath. Stop if resistance is felt.

Precaution: If user notices kink in WATCHMAN Access Sheath, user should remove and replace WATCHMAN Access Sheath before proceeding with procedure.

   C. Carefully advance pigtail catheter through Access Sheath into distal portion of the LAA under fluoro guidance. Carefully advance Access Sheath over pigtail catheter until Access Sheath position into the LAA has been reached, per the WATCHMAN LAA Closure Device DFU. Slowly remove pigtail catheter.

WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

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Do not use if package is damaged.

Recyclable Package