**WATCHMAN® Access System**

**Access Sheath with Dilator**

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**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.
4. Advance WATCHMAN Access System over guidewire into ostium of LAA. 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 bleed 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.

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

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

**Carefully advance pigtail catheter through Access Sheath into distal portion of the LAA under fluoroscopy 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, cleaning, sterilization and storage of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly or indirectly arising from the use of this instrument. 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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