Boston Scientific

50726992-01

2018-07
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SAVION DLVR™ SAVION FLX™

Guidewire with ICE™ Hydrophilic Coating

℞ ONLY

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

CAREFULLY READ AND UNDERSTAND ALL INSTRUCTIONS, INDICATIONS, WARNINGS, PRECAUTIONS AND DIRECTIONS FOR USE PRIOR TO USING ANY BOSTON SCIENTIFIC GUIDEWIRE. FAILURE TO DO SO MAY RESULT IN COMPLICATIONS.

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

Boston Scientific SAVION DLVR and SAVION FLX Guidewires with ICE Hydrophilic Coating are steerable guidewires available with a nominal diameter of 0.014 in (≤ 0.37 mm) and in nominal lengths of 182 cm, 185 cm, or 300 cm. All models are available with a shapeable Straight Tip or a preformed Angled Tip.

- **SAVION DLVR** Guidewire features a 3 cm radiopaque spring coil at the distal end of the core wire that is shapeable. A polymer sleeve, coated with ICE Hydrophilic Coating, jackets the tapered core wire between the spring coil and the proximal fluorinated polymer coating. Available tip flexibility/rail support profile:

  Maximum Support - floppy tip with maximum support.
- **SAVION FLX** Guidewire features a 30 cm radiopaque polymer sleeve, coated with ICE Hydrophilic Coating, jacketing the nitinol distal core wire. The distal 2 cm is shapeable. The proximal section of the guidewires is PTFE coated. Available tip flexibility/rail support profile:

  Moderate Support - intermediate tip with moderate support.

Boston Scientific Guidewires with Proximal Markers:

SAVION FLX Guidewires have brachial and femoral markers located on the proximal segment of the guidewire to aid in estimating the guidewire's position relative to the distal guide catheter tip. The proximal markers are compatible with brachial and femoral guide catheters that are at least 90 cm or 100 cm long, respectively.

Boston Scientific Extendable Guidewires:

The 182 cm SAVION DLVR and 185 cm SAVION FLX Guidewires have a modified proximal end that permits the attachment of the AddWire™ Extension Wire.

Joining the extension wire to the guidewire facilitates the exchange of interventional therapeutic devices while maintaining guidewire position in the intravascular anatomy. After the device exchange has been completed, the extension can be detached, and the guidewire can be used in its original capacity. **CAREFULLY READ INSTRUCTIONS PACKAGED WITH THE EXTENSION WIRE PRIOR TO USE.**

The 300 cm length SAVION DLVR and SAVION FLX Guidewires allow exchange of therapeutic devices without the use of an extension wire or exchange system.

Boston Scientific Guidewires with Hydrophilic Coating:

Refer to the product label for presence of a hydrophilic coating. When hydrated, a hydrophilic coating provides increased lubricity of the guidewire surface.

Figure 1. Tip Style

INTENDED USE/INDICATIONS FOR USE

Boston Scientific SAVION DLVR and SAVION FLX Guidewires are intended to facilitate the placement of balloon dilatation catheters or other interventional therapeutic devices during PTCA, PTA, or other intravascular interventional procedures. They are not intended for use in the cerebral vasculature.

CONTRAINDICATIONS

None known.

WARNINGS

Guidewires should be used only by physicians thoroughly trained in their intended use. Prior to the procedure, all equipment to be used for the procedure should be carefully examined to verify proper function and integrity. Surface irregularities, bends or kinks may decrease performance characteristics.

Use extreme caution and careful judgment in patients for whom anticoagulation is not indicated. Severe reaction may occur in response to contrast agents that cannot be adequately premedicated.

Follow the enclosed directions carefully. When the guidewire is in the body, it should be manipulated only under fluoroscopy. Do not attempt to move the wire without observing the resultant tip response.

Never advance the guidewire against resistance without first determining the reason for resistance under fluoroscopy. Do not rotate the guidewire if significant resistance is felt. Excessive force against resistance may result in separation of the guidewire tip, damage to the catheter or vessel damage.

Exercise care in handling of the guidewire during a procedure to reduce the possibility of accidental breakage, bending, kinking or coil separation. Resulting guidewire fractures might require additional percutaneous intervention or surgery.

The hydrophilic coating of these guidewires increases the possibility of vessel wall perforation compared to non-hydrophilic coatings. Maintain diligent control of the distal tip at all times during an intervention to avoid vessel dissections and perforations.

Care should be taken when advancing a guidewire after stent deployment. A guidewire may exit between stent struts when recrossing a stent that is not fully apposed to the vessel wall. Subsequent advancement of any device over the guidewire could cause entanglement between the guidewire and the stent.

PRECAUTIONS

Do not use a guidewire that has been damaged.

Use the device prior to the "Use By" date noted on the package.

This product is non-pyrogenic.

Sharp insertion tools may compromise the integrity of the polymer coating. To avoid guidewire damage and possible shearing of plastic, do not withdraw or manipulate the wire through a metal needle cannula.

Do not attempt to straighten a wire that has been kinked or bent. Do not advance a kinked guidewire into a balloon catheter or guide catheter as this may increase the potential of wire breakage.

Carefully check and match therapeutic device compatibility to the wire prior to use.

Abrasion of the hydrophilic coating may be caused by a tight catheter. It is advisable to stop using that catheter.

Remove the guidewire carefully from the carrier tube to reduce the possibility of damage to the distal tip. Refer to **PREPARATIONS FOR USE** section.

Boston Scientific Guidewires are designed to be compatible exclusively with the AddWire Extension Wire for interventional device exchange. Do not use another extension or exchange system. Carefully check and match the compatibility of the guidewire diameter with the interventional device prior to use.

Excessive tightening of the torque device onto the wire may result in abrasion of the coating on the wire.

ADVERSE EVENTS

Potential adverse events which may result from the use of the device include but are not limited to:

- Abrupt closure
- Allergic reaction (to contrast, device or other)
- Angina or unstable angina
- Arrhythmias
- Bleeding/Hemorrhage
- Cardiac tamponade/pericardial effusion
- Death
- Embolization (plaque, thrombus, device, tissue, or other)
- Hematoma
- Infection/Sepsis
- Myocardial infarction or ischemia
- Pain at the access site
- Pseudoaneurysm
- Renal insufficiency or renal failure
- Stroke/cerebral vascular accident (CVA)/transient ischemic attack (TIA)
- Thrombosis/Thrombus
- Vasospasm
- Vessel trauma (dissection, perforation, rupture or injury)

Some of the above potential adverse events may require additional urgent intervention or surgery.

HOW SUPPLIED

Handling And Storage

Store in a cool, dry, dark place. Do not use if package is opened or damaged. Do not use if labeling is incomplete or illegible.

PREPARATION FOR USE

1. Prepare the interventional device according to the manufacturer's instructions. Be sure to flush the interventional device lumen with heparinized saline before introducing the guidewire.
2. Flush the dispenser tube with saline by injecting into the hub end of the dispenser. This hydrates the hydrophilic segment of the guidewire before removing the guidewire from the dispenser tube.
3. Carefully remove the proximal end of guidewire from the dispenser. Repeat the injection of saline into the dispenser if the guidewire cannot be removed easily and attempt to remove the guidewire again. Do not reinsert the guidewire into the dispenser tube once it has been removed.

   Note: Do not pull the distal tip to remove the guidewire from the dispenser tube, as removal in such manner may damage the guidewire tip.
4. Inspect the wire prior to use to verify that it is undamaged.
5. If desired, the guidewire tip may be carefully shaped according to standard tip shaping practices. Do not use a shaping instrument with a sharp edge.

   Note: If the surface of the hydrophilic-coated wire becomes dry, wetting the surface with saline will restore the lubricity. Be sure to thoroughly hydrate the guidewire before introduction into an interventional device.

DIRECTIONS FOR USE

Over-the-Wire Systems

1. Prior to inserting the guidewire into an interventional device, flush the device with heparinized saline. This will prime the device and provide smooth movement of the guidewire within the catheter.
2. Insert a guidewire insertion tool through the lumen hub of the interventional device.
3. Carefully insert the distal tip of the guidewire through the insertion tool into the interventional device and advance the wire until the wire tip is just proximal to the device tip.

4. Remove the insertion tool by withdrawing it over the proximal end of the guidewire.
5. The interventional device/guidewire system may now be inserted through the hemostatic valve and into the guide catheter. Advance the system through the guide catheter until it is just proximal to the distal tip of the guide catheter.
6. Create a seal around the interventional device by tightening the hemostatic valve. Ensure that guidewire movement is still possible.
7. If desired, attach a torque device to the guidewire.
8. Advance the guidewire out of the interventional device and into the vasculature beyond the lesion to be treated using accepted techniques while securing the interventional device in place. Do not move the guidewire without observing the response under fluoroscopy.
9. Secure the guidewire in place while tracking the interventional device over the wire and across the lesion.
10. If a different tip shape or guidewire is required, carefully withdraw and remove the guidewire while observing guidewire movement under fluoroscopy.
11. Reshape the guidewire tip according to accepted techniques or prepare the next guidewire to be used, and insert the guidewire according to Over-the-Wire Systems, Steps 1 through 9, above.

Single Operator Exchange System or "Bare Wire Technique"

1. Open the hemostatic valve and the flush line of the manifold. Insert a guidewire insertion tool through the valve and into the guide catheter.
2. Carefully insert the distal tip of the guidewire through the insertion tool and into the guide catheter.
3. Remove the insertion tool and continue to advance the guidewire. Tighten the hemostatic valve knurled knob so that the valve seals around the guidewire, but does not inhibit intentional wire movement. Close the flush line on the manifold.

Note: If using Boston Scientific's SAVION FLX™ Guidewire with Proximal Markers, advance the guidewire to appropriate proximal marker. Use the most distal marker as a distance approximation when using a 90 cm brachial guide catheter and the most proximal marker as the distance approximation when using a 100 cm femoral guide catheter. When the appropriate proximal marker is aligned with the knurled knob of the hemostatic valve, the guidewire tip is just proximal to the guide catheter distal tip.

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4. If desired, attach a torque device to the guidewire.
5. Advance the guidewire out of the guide catheter and into the vasculature beyond the lesion to be treated using accepted techniques. Do not move the guidewire without observing the response under fluoroscopy.
6. If a different tip shape or guidewire is required, carefully withdraw and remove the guidewire according to accepted techniques while observing guidewire movement under fluoroscopy.
7. Reshape the guidewire tip according to accepted techniques or prepare the next guidewire to be used, and insert the guidewire according to Single Operator Exchange System or "Bare Wire Technique," Steps 2 through 6, above.
8. Remove the torque device and secure the guidewire while tracking interventional devices over the wire and into the lesion.

Interventional Device Exchange Over-the-Wire Systems

1. Follow the directions regarding the preparation and use of Boston Scientific Guidewires provided above.
2. If using a Boston Scientific Exchange Length (300 cm) Guidewire, proceed to Step 3. If using a Boston Scientific Extendable Guidewire, extend the guidewire using the AddWire™ Extension Wire according to the instructions packaged with the Extension Wire.
3. To perform an exchange, maintain the position of the guidewire and carefully withdraw the interventional device over the guidewire.
4. Prepare the second interventional device as described by the manufacturer's instructions and load it onto the guidewire. Advance the interventional device over the Exchange Length Wire and across the lesion.

Interventional Device Exchange Single Operator Exchange System or "Bare Wire Technique"

1. To perform an exchange, maintain the position of the guidewire and carefully withdraw the interventional device over the guidewire.
2. Prepare the second interventional device as described by the manufacturer's instructions and load it onto the guidewire. Advance the interventional device over the wire and across the lesion.

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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