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Stingray™

Extension Wire

Rx 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 re sterilize. Reuse, reprocessing or re sterilization 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 re sterilization 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 Stingray Extension Wire is a stainless steel wire with a connector at the distal end. The extension wire has a nominal diameter of 0.014 in (0.36 mm) and is 145 cm in length. The shaft is coated with PTFE (polytetrafluoroethylene). It is exclusively compatible with the extendable Stingray Guidewires. The guide pin on the proximal end of the extendable guidewire is inserted into the center lumen of the connector of the extension wire. Once the guide pin is inserted, the extension wire is rotated in a clockwise direction (with respect to the guidewire).

Contents

Quantity	Material
1	Stingray Extension Wire

INTENDED USE / INDICATIONS FOR USE

The attachment of the Stingray Extension Wire to the extendable guidewire creates a guidewire that can be used to exchange a catheter without removing the guidewire from the vessel. When the exchange is complete, the guidewire extension can be detached and the original guidewire can again be used in a conventional manner.

CONTRAINDICATIONS

None known.

WARNINGS

- Only physicians thoroughly trained in interventional procedures should use the extension wire.

PRECAUTIONS

- Use prior to the Expiration Date.
- The extension wire is exclusively compatible with the extendable Stingray guidewires.

- Do not rotate or manipulate the extended guidewire once it is attached. This may cause the extension wire to detach from the guidewire.
- Do not force the proximal end of the guidewire into the connector on the extension wire. Attachment is achieved by rotating and not by pushing.
- The extension wire should be handled with care. Prior to use and during the procedure, inspect the packaging and extension wire for bends, kinks, or other damage. Discontinue use if the extension wire becomes damaged.
- Do not attempt to straighten an extension wire that has been kinked.
- Catheter exchange should only be done under fluoroscopic observation.

ADVERSE EVENTS

- None known

HOW SUPPLIED

Do not use if package is opened or damaged.
Do not use if labeling is incomplete or illegible.

Handling and Storage

Store in a cool, dry, dark place.

OPERATIONAL INSTRUCTIONS

Supplies

- No additional supplies necessary

Product Preparation

- Remove the extension wire from the sterile packaging.
- After removing the extension wire from the holder tube, inspect to make sure it is not damaged.

Product Operation

- Remove the torque device (if applicable) from the end of the extendable guidewire.
- Maintain position of the extendable guidewire and confirm its position in the vessel by fluoroscopy.
- Insert the guide pin on the proximal end of the extendable guidewire into the distal end of the extension wire. Once the guide pin is inserted, rotate the extension wire in a clockwise direction (with respect to the guidewire) until the two wires are pulled together securely.
- Check for secure attachment by pulling on both wires.
- Withdraw the catheter to be exchanged, over the extended wire, while maintaining wire position in the vessel.
- Inspect the extended wire to make sure it has not been damaged. Confirm the position of the extendable guidewire in the vessel by fluoroscopy. Prepare the catheter to be exchanged according to the manufacturer's *Directions For Use*. Advance the new catheter over the extended wire while maintaining position of the extendable guidewire and guiding catheter.

NOTE: Keep the system as straight as possible to facilitate the exchange.

NOTE: Do not torque or manipulate the guidewire extension. This may cause the connector to unscrew and may lead to detachment of the wires.

- Detach the guidewire extension by rotating the extension wire in a counterclockwise direction (with respect to the guidewire) until the guidewire is released.
- Once the extension wire is detached, the extendable guidewire may be torqued and manipulated per standard techniques.
- The same extension wire may be used for additional exchanges provided that sterility is maintained.

- Upon completion of the use of the extension wire, discard according to hospital standards and national legal requirements.

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 re sterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

EC REP **EU Authorized Representative**

Boston Scientific Limited
Ballybrit Business Park
Galway
IRELAND

AUS **Australian Sponsor Address**

Boston Scientific (Australia) Pty Ltd
PO Box 332
BOTANY
NSW 1455
Australia
Free Phone 1800 676 133
Free Fax 1800 836 666

ARG **Argentina Local Contact**

Para obtener información de contacto de Boston Scientific Argentina SA, por favor, acceda al link www.bostonscientific.com/arg

BRA **Brazil Local Contact**

Para informações de contato da Boston Scientific do Brasil Ltda, por favor, acesse o link www.bostonscientific.com/bra

 **Legal Manufacturer**

Manufactured for:
Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
USA
USA Customer Service 888-272-1001

 **Do not use if package is damaged.**

 **Recyclable Package**

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