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Truepath™

Extension Wire

Rx ONLY

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

This device is supplied in sterile condition. All materials inside the sterile barrier pouch (the device, as well as the carrier tube and pouch liner) are sterile. The external surface of the sterile barrier pouch, as well as the product carton, should not be considered sterile.

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 reesterilization 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 reesterilization 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 TruePath Extension Wire is a flexible stainless steel tubular wire with a polyimide coupling located at the distal end. The extension is approximately 160 cm long and has a diameter of 0.014 inches along the stainless steel tubular wire and a diameter of 0.018 inches along the polyimide coupling. The Extension Wire is a non-patient contacting component.

Contents for (1) TruePath Extension Wire

- One (1) TruePath Extension Wire

INTENDED USE/INDICATIONS FOR USE

The TruePath Extension Wire is designed to extend the TruePath CTO Device so that a catheter can be exchanged for another catheter.

CONTRAINDICATIONS

None known.

PRECAUTIONS

- Use prior to 'Use By' date.
- Do not autoclave. Exposure to temperatures above 54°C (130°F) may damage the extension wire.
- If strong resistance is met during manipulation, discontinue the procedure and determine the cause of the resistance before proceeding. If the cause of the resistance cannot be determined, withdraw the entire system.
- If the polyimide tube at the distal end of the extension wire is damaged, do not use. Do not attempt to straighten a kinked polyimide tube. Replace the unit with an undamaged unit before proceeding.
- The Extension Wire is a non-patient contact component and should not be introduced into the support catheter.

HOW SUPPLIED

Sterile:

This product is sterilized with ethylene oxide gas. It is intended for single use only. Do not reesterilize. Non-pyrogenic.

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, dark, dry place.

Store product in outer carton.

Do not store devices where they are directly exposed to organic solvents or ionizing radiation.

DISPOSAL INSTRUCTIONS

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

OPERATIONAL INSTRUCTIONS

Inspection Prior to Use

Check pouch for "Use By" date. Do not use the product after the "Use By" date. Carefully inspect the sterile package before opening. If the integrity of the sterile package has been compromised prior to the product "Use By" date (e.g., damage of the package), contact your local Boston Scientific representative for return information. Do not use if any defects are noted.

Preparation

Step Action

1. Open the outer box and remove the pouch. Open the sterile pouch slowly and remove the dispensing tube containing the extension wire.
2. Carefully remove the distal end of the extension wire from the dispensing tube clip.
3. Place the proximal end of the TruePath CTO Device into the distal end of the extension wire. Note: the TruePath CTO Device motor housing must first be removed following the TruePath CTO Device Directions For Use.
4. Gently push the TruePath CTO Device until fully seated within the extension wire.
5. Verify proper engagement has occurred by gently pulling on the TruePath CTO Device and extension wire. If the TruePath CTO Device pulls out of the extension wire, repeat Step 4. If the TruePath CTO Device does not pull out of the extension wire, then proceed to Step 6.
6. Carefully remove the extension wire from the dispensing tube.
7. Exchange using standard procedures.

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 reesterilized 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

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Do not use if package is damaged.

Recyclable Package