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ENTRY KIT

For Use with Greenfield® Titanium Vena Cava Filter

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 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

Caution: Carefully read the Instructions for Use for the Greenfield Titanium Vena Cava Filter prior to use of this product.

This Entry Kit has been designed to aid in the insertion of the Greenfield Titanium Vena Cava Filter using either percutaneous or surgical technique.

Contents

Each Entry Kit Includes:

- One (1) 18 Gauge Entry Needle
- One (1) 0.038 in / 0.97 mm Amplatz™ Super Stiff Wire (180 cm length, 7 cm floppy tip)
- One (1) 8F / 2.7 mm Vascular Dilator
- One (1) 10F / 3.3 mm Vascular Dilator
- One (1) 12F / 4.0 mm Vascular Dilator

INTENDED USE/ INDICATIONS FOR USE

This Entry Kit is intended to be used only with the Greenfield Titanium Vena Cava Filter.

CONTRAINDICATIONS

None known specifically related to Entry Kit. See Instructions for Use for the Greenfield Titanium Vena Cava Filter for contraindications associated with the Greenfield Titanium Vena Cava Filter prior to use of the Entry Kit.

WARNINGS

- None known specifically related to Entry Kit. See Instructions for Use for the Greenfield Titanium Vena Cava Filter for warnings associated with the Greenfield Titanium Vena Cava Filter prior to use of the Entry Kit.

PRECAUTIONS

None known specifically related to Entry Kit. See Instructions for Use for the Greenfield Titanium Vena Cava Filter for precautions associated with the Greenfield Titanium Vena Cava Filter prior to use of the Entry Kit.

ADVERSE EVENTS

- Hematoma
- Vessel trauma
- Pseudoaneurysm

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. Rotate inventory so that products are used prior to the sterilization expiration date on package label.

OPERATIONAL INSTRUCTIONS

1. Enter Vessel Using Percutaneous or Cutdown Technique

A. Percutaneous Technique

Infiltrate the area with local anesthesia. Attach the 18 gauge entry needle to a 10 ml (cc) syringe (not included). Enter the vein using single-wall puncture technique.

B. Cutdown Technique

After infiltrating the area with local anesthetic, surgically expose the vein. Attach the 18 gauge entry needle to a 10 ml (cc) syringe and make a venipuncture in the exposed vein, or, make a small venotomy in the exposed section of the vein, large enough for the tip of the guidewire.

2. Insert/Advance Guidewire

CAUTION: To avoid insertion difficulties or tissue injury, never advance the guidewire without the use of fluoroscopic guidance.

Insert the 0.038 in / 0.97 mm / 180 cm Amplatz Super Stiff guidewire.

If percutaneous technique is used, remove the syringe from the needle and insert the 0.038 in / 0.97 mm guidewire through the needle. Leave the needle in place until the guidewire has been positioned, and then remove the needle.

If surgical cutdown is performed using venipuncture, remove the syringe from the needle and insert the 0.038 in / 0.97 mm guidewire through the needle. Leave the needle in place until the guidewire has been positioned, and then remove the needle. If performing venotomy, insert the 0.038 in / 0.97 mm guidewire through the venotomy.

Advance the guidewire to a position well beyond the renal veins, i.e., above the intended implant site.

3. Sequential Dilatation

If percutaneous technique is used, make a 3-4 mm skin incision with a #11 blade along the guidewire before sheath/dilator insertion.

In some cases, sequential dilatation with the 8, 10 and 12F / 2.7, 3.3 and 4.0 mm vascular dilators, may be necessary prior to insertion of the 12F / 4.0 mm sheath/dilator.

4. Insertion of Greenfield Titanium Vena Cava Filter

CAUTION: Carefully read the Instructions for Use for the Greenfield Titanium Vena Cava Filter prior to its use. The Instructions for Use are packaged with each filter system.

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**

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