Boston Scientific

VortX™ - 18
VortX™ Diamond - 18
Straight - 18
Figure 8 - 18
Multi-Loop - 18
Complex Helical - 18

Fibered Platinum Coil

Coil Pusher - 16

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Boston Scientific (Master Brand DFUTemplate 3in x 9in Global, 90106040AK), DFU, MB, Fibered Platinum Coil, Global, 90961453-01B

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℞ 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

Boston Scientific's 0.46 mm (0.018 in) Fibered Platinum Coils consist of platinum-tungsten alloy coils with synthetic fibers.

The coil is provided with an introducer with a retaining clip that secures both ends of the introducer during shipping and storage. The coil plunger is used to move the coil out of the introducer and into the microcatheter (see Figure 1).

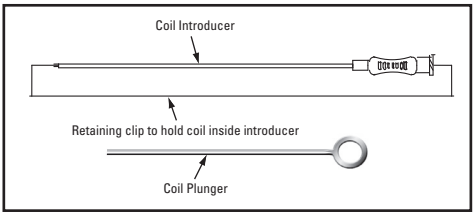

Figure 1. Coil Introducer, Retaining Clip and Plunger

The Coil Pusher-16 is a tapered, highly flexible coated device with a radiopaque tip marker in the distal end used in conjunction with the microcatheter to deliver and deploy 0.46 mm (0.018 in) pushable occlusion coils.

Contents

The 0.018 in Fibered Platinum Coils include an embolic coil with introducer and coil plunger.

The Coil Pusher-16 includes a coil pusher and torque device.

INTENDED USE/INDICATIONS FOR USE

Boston Scientific's 0.018 Fibered Platinum Coils are intended for arterial and venous embolizations in the peripheral vasculature.

The Coil Pusher-16 is intended to be used in conjunction with a microcatheter to deliver and deploy 0.018 pushable occlusion coils.

CONTRAINDICATIONS

None known.

WARNINGS

Recanalization has been observed with the usage of some coils. Angiographic follow-up is recommended to ensure continued occlusion.

Never advance the coil pusher after the coil has been deployed to avoid risk of damaging the vessel. If vessel damage occurs follow institutional protocols.

PRECAUTIONS

- Compatibility with microcatheters other than the Boston Scientific 0.53 mm (0.021 in) lumen I.D. microcatheters has not been established.
- Do not use microcatheters, coil pushers or coils that have been damaged in any way.
- The long-term effect of this product on extravascular tissues has not been established, so care should be taken to retain this device in the intravascular space.
- Check that all fittings are secure so that air is not introduced into the guiding or microcatheters during continuous flush.
- Verify that the distal shaft of the microcatheter is not under stress before coil deployment. Axial compression or tension forces may be stored in the microcatheter causing the tip to move during coil delivery.
- If resistance is encountered when withdrawing the coil pusher, draw back on the microcatheter simultaneously until the coil pusher can be removed without resistance.
- Do not advance the coil with force if the coil becomes lodged within the microcatheter. Determine the cause of resistance and replace the microcatheter and the coil when necessary.
- All injections should be delivered in a slow, controlled fashion to avoid a change in coil position.
- Replace the microcatheter if increased resistance is noted during coil delivery.

MAGNETIC RESONANCE IMAGING (MRI)

Non-clinical testing has demonstrated that the VortX™ - 18, VortX™ Diamond - 18, Straight - 18, Figure 8 - 18, Multi-Loop - 18, and Complex Helical - 18 Fibered Platinum Coils are MR Conditional. These products can be scanned safely under the following conditions:

- Static magnetic field of 1.5 Tesla or 3.0 Tesla
- Static magnetic field gradient < 25 T/m
- Product of static magnetic field and static magnetic field gradient < 50 T^2/m (extrapolated)
- Normal operating mode of the MR system and use of transmit/receive head coil and/or whole body transmit coils

The VortX - 18, VortX Diamond - 18, Straight - 18, Figure 8 - 18, Multi-Loop - 18, and Complex Helical - 18 Fibered Platinum Coils should not migrate in this MRI environment. Non-clinical testing at field strengths other than 1.5 Tesla or 3 Tesla has not been performed to evaluate coil migration or heating.

3.0 Tesla Temperature Information

Non-clinical testing of RF-induced heating was performed at 123 MHz in a 3.0 Tesla Magnetom Trio™ Device, Siemens Medical Solutions MR system, software version Numaris/4, syngo MR A30. The coils tested were in a location and orientation in the phantom that produced the worst case Radio Frequency (RF) heating. RF power was applied for 15 minutes with the conductivity of the phantom material about 0.24 S/m. The phantom average SAR calculated using calorimetry was 3.3 W/kg. Predicted in-vivo heating based on these non-clinical tests and computer simulation of the patient exposure to the electromagnetic fields in MRI yielded the following maximal in vivo rises:

For vessels in the body the calculated temperature rise was 2.8°C with an uncertainty upper bound temperature of 3.8°C for a whole body average SAR value of 2.0 W/kg and a continuous scan time of 15 minutes.

The actual in vivo rise is expected to be less than these values as the calculations did not include the cooling effects due to blood flow around the coil and blood perfusion in the tissue outside the coil.

1.5 Tesla Temperature Information

Non-clinical testing of RF-induced heating was performed at 64 MHz in a 1.5 Tesla Intera™ Medical Magnetic Resonance Imaging Apparatus Philips Medical Systems, software version Release 10.6.2.0, 2006-03-10 whole body coil MR scanner. The coils tested were in a location and orientation in the phantom that produced the worst case RF heating. RF power was applied for 15 minutes with the conductivity of the phantom material about 0.26 S/m. The phantom average SAR calculated using calorimetry was 3.6 W/kg. Predicted in-vivo heating based on these non-clinical tests and computer simulation of the patient exposure to the electromagnetic fields in MRI yielded to the following maximal in vivo rises:

For vessels in the body the calculated temperature rise was 5.2°C with an uncertainty upper bound temperature of 7.1°C for a whole body average SAR value of 2.0 W/kg and a continuous scan time of 15 minutes.

The actual in vivo rise is expected to be less than these values as the calculations did not include the cooling effects due to blood flow around the coil and blood perfusion in the tissue outside the coil.

Image Artifact Information

MR image at 1.5 and 3 Tesla may be performed immediately following the implantation of the VortX - 18, VortX Diamond - 18, Straight - 18, Figure 8 - 18, Multi-Loop - 18, and Complex Helical - 18 Fibered Platinum Coils. MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the coil. MR image artifact has been evaluated at 1.5 and 3 Tesla only.

The image artifact extended as much as 8 mm from the metal of the device when scanned in non-clinical testing using a Spin Echo sequence. With a Gradient Echo sequence, the image artifact extended as much as 10 mm beyond the metal of the device. Image tests were made in a 3.0 Siemens Magnetom Trio Device, software version Numaris/4. This testing was completed using ASTM F2119-07 test method.

ADVERSE EVENTS

The complications that may result from a peripheral embolization procedure include, but are not limited to:

- Complications related to catheterization (e.g., hematoma at the site of entry, vessel injury, etc.)
- Death
- Emboli

- Foreign body reactions necessitating medical intervention
- Hemorrhage
- Infection necessitating medical intervention
- Ischemia
- Pain
- Recanalization
- Temporary neurological deficit
- Tissue necrosis
- Undesirable clot formation of the vasculature
- Vasospasm

COIL SIZE SELECTION

Correct coil size selection increases occlusion effectiveness and patient safety. Occlusion effectiveness is dependent upon coil compaction, coil mass, and physical obstruction of the vessel, which is a direct consequence of proper selection of coil size in relation to vessel diameter. Selection of a coil larger than the vessel may result in a non-compact placement with less effective reduction of blood flow. Selection of a coil smaller than the vessel may result in coil migration.

To choose the appropriate coil size, examine pre-treatment angiograms. The use of digital subtraction fluoroscopic road mapping may serve as a valuable aid in properly assessing vessel diameter and corresponding coil size.

PREPARATIONS FOR USE

Coils are designed to be delivered under fluoroscopy using a Boston Scientific 0.53 mm (0.021 in) lumen I.D. microcatheter with a radiopaque tip marker and a Boston Scientific Coil Pusher (see Figure 2). The Coil Pusher is used to push the coil through the microcatheter. Coils come loaded in an introducer for easy transfer into the microcatheter.

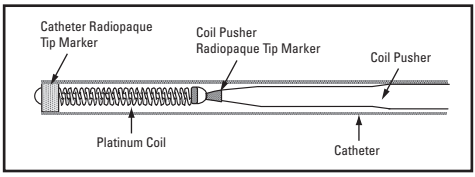

Figure 2. Coil Delivery Set-Up

CONTINUOUS FLUSH SET-UP

In order to reduce the risk of complications, a continuous flow of appropriate flush solution should be maintained between a) the microcatheter and guiding catheter, and b) the microcatheter and any intraluminal device. Continuous flushing also reduces retrograde flow of blood into the microcatheter during coil delivery and reduces the potential for contrast crystal formation and/or clotting on both the guidewire and inside the microcatheter lumen.

1. Attach a rotating hemostatic valve (RHV) to the hub of the guiding catheter. Attach a stopcock to the side arm of the RHV and then connect a line for continuous flush of appropriate solution.
2. Attach a second RHV to the hub of the microcatheter. Attach a stopcock to the side arm of the RHV and then connect a line for continuous flushing of appropriate solution.

Caution: Check that all fittings are secure so that air is not introduced into the guiding or microcatheters during continuous flush.

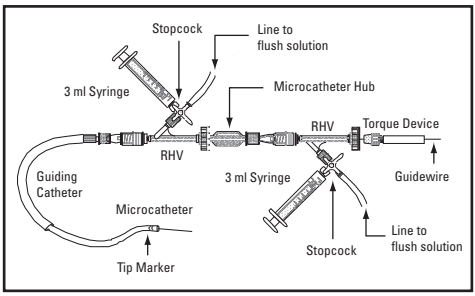

Figure 3. Example of Continuous Flush Set-up

DIRECTIONS FOR USE

Caution: Verify that the distal shaft of the microcatheter is not under stress before coil deployment. Axial compression or tension forces may be stored in the microcatheter causing the tip to move during coil delivery.

1. Position the microcatheter within the vasculature using standard technique according to the Directions for Use provided with the microcatheter. If a guidewire has been used to facilitate the placement of the microcatheter, remove it after placement of the microcatheter.

Note: The use of high quality, digital subtraction fluoroscopic road mapping helps to monitor the microcatheter position.

2. Remove the retaining clip from the coil introducer (see Figure 1) and discard. Attach a 3 ml saline-filled syringe with luer lock to the introducer hub. Gently infuse the introducer with saline to reduce friction and aid in coil introduction.
3. Insert the coil introducer with pre-loaded coil through the RHV and seat into the hub of the attached microcatheter.
4. Using the coil plunger provided, slowly advance the coil completely through the introducer, and into the microcatheter lumen.

   If the coil does not easily advance into the microcatheter, rotate the introducer approximately one half turn while maintaining contact with the microcatheter hub. Continue advancing the coil into the microcatheter with the coil plunger.
5. Once the coil has entered the microcatheter lumen, remove the introducer and the coil plunger.
6. Insert the proximal end of the coil pusher into the microcatheter lumen and advance the coil approximately one quarter of microcatheter's total length. Remove coil pusher.

Caution: If resistance is encountered when withdrawing the coil pusher, draw back on the microcatheter simultaneously until the coil pusher can be removed without resistance.

7. Verify under fluoroscopy that the distal tip of the microcatheter has remained at the desired location.

   Thread the distal (floppy) end of the coil pusher into the microcatheter lumen and continue to advance the coil into the desired position while monitoring via fluoroscopy.

Caution: Do not advance the coil with force if the coil becomes lodged within the microcatheter.Determine the cause of resistance and replace the microcatheter and the coil when necessary.

8. Remove coil pusher after the coil has been deployed.

Warning: Never advance the coil pusher after the coil has been deployed to avoid risk of damaging vessel. If vessel damage occurs follow institutional protocols.

9. Inject contrast medium and assess coil placement and vessel occlusion.

Caution: All injections should be delivered in a slow, controlled fashion to avoid a change in coil position.

10. Deploy additional coils by repeating steps 2–9.

    Multiple embolization procedures may be required to achieve the desired occlusion of some vessels.

Caution: Replace the microcatheter if increased resistance is noted during coil delivery.

HOW SUPPLIED

Boston Scientific products are sterile and non-pyrogenic in unopened, undamaged packaging. Packaging is designed to maintain sterility unless the primary product pouch has been opened or damaged.

A "Use by" date is listed on the package label.

Do not use if the package is opened or damaged.

Do not use if labeling is incomplete or illegible.

Handling and Storage

Store in a dry place at room temperature.

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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