Boston Scientific

# Interlock™

## Fibered IDC™ Occlusion System



Boston Scientific (Master Brand DFUTemplate 8in x 8in Global, 90106041AK), DFU, MB, Interlock, Global, 90961055-01A

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# Interlock™

## Fibered IDC™ Occlusion System

**℞ 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**

The Interlock Fibered IDC Occlusion System includes a coil (manufactured from platinum-tungsten alloy) that is mechanically attached to a coil delivery wire. This assembly is contained within an introducer sheath. The platinum coil contains synthetic fibers for greater thrombogenicity. The Interlock Fibered IDC Occlusion Coil is designed to be delivered under fluoroscopy with a 0.021 in (0.53 mm) inner diameter (I.D.) microcatheter (e.g. Renegade™ Microcatheter) with one or two radiopaque (RO) tip markers. The interlocking delivery wire design allows the coil to be advanced and retracted before final placement in the vessel, thus aiding in more controlled delivery including the ability to withdraw the coil prior to deployment.

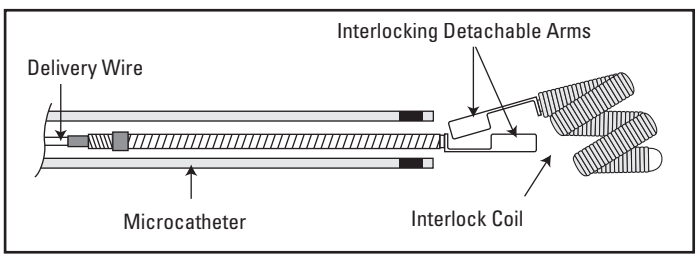


**Figure 1. Interlock Fibered IDC Occlusion System**

**Contents**

The Interlock Fibered IDC Occlusion System includes an embolic coil with interlocking delivery wire, introducer sheath, and rotating hemostatic valve (RHV).

**INTENDED USE/INDICATIONS FOR USE**

The Interlock Fibered IDC Occlusion System is a modified interlocking detachable coil indicated to obstruct or reduce rate of blood flow in the peripheral vasculature. This device is not intended for neurovascular use.

**CONTRAINDICATIONS**

None known.

**WARNINGS**

Do not advance the delivery wire once the coil has been placed. Perforation or damage of the vessel wall could occur.

**GENERAL PRECAUTIONS**

Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these and other instructions relevant to the procedure. Failure to do so may result in complications.

Do not apply excessive force while seating the introducer sheath in the microcatheter hub. Introducer sheath tip deformation and difficulty with coil delivery into the microcatheter could result.

Do not rotate the delivery wire more than one turn (360 degrees) during delivery of the Interlock Fibered IDC Occlusion Coil. Excessive rotation of the delivery wire may damage the Interlock Fibered IDC Occlusion Coil or may result in premature detachment of the interlocking arms within the microcatheter.

Do not advance the Interlock Fibered IDC Occlusion System if it becomes lodged within the microcatheter. Determine the cause of the resistance and replace the microcatheter and coil if necessary. See Interlock Fibered IDC Occlusion System Removal Procedure for further instructions.

Advance and retract the Interlock Fibered IDC Occlusion System smoothly, especially in tortuous anatomy. Replace the coil if unusual friction is noted within the microcatheter. If friction is noted in any successive coil, carefully examine both coil and microcatheter for possible damage. Replace both if necessary.

Do not retract the Interlock Fibered IDC Occlusion System too quickly or against resistance. Doing so may result in a stretched coil or damage to the interlocking mechanism.

Multiple embolization procedures may be required to achieve the desired occlusion of some vessels. To position another Interlock Fibered IDC Occlusion System, return to Steps 1-9 in Directions For Use.

Replace microcatheters periodically during delivery of multiple coils or if increased resistance is noted during coil delivery.

Axial compression or tension forces may be stored in the microcatheter shaft during Interlock Fibered IDC Occlusion Coil delivery, and coil release may lead to catheter tip movement. Verify repeatedly during the procedure that the distal shaft of the microcatheter is not under stress prior to Interlock Fibered IDC Occlusion Coil detachment by slightly repositioning the microcatheter, delivery wire, or entire assembly simultaneously.

Carefully remove the delivery wire after coil deployment so that the delivery arm does not catch on the valve in the RHV thumbscrew.

**MAGNETIC RESONANCE IMAGING (MRI)**

Non-clinical testing has demonstrated that the Interlock Fibered IDC Occlusion System is MR Conditional. It 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 Interlock Fibered IDC Occlusion System 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



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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 Interlock™ Fibered IDC™ Occlusion System. 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

Coil selection is a matter of physician preference and the clinical situation. The shape and diameter of the vessel to be occluded as well as proximity to branch vessels generally govern selection of the coil diameter and length. Coil diameter should approximate the vessel diameter. Selection of a coil diameter >1 mm larger than the vessel diameter may result in coil elongation and a non-compact placement with less effective reduction of blood flow. Selection of a coil diameter smaller than the vessel diameter may result in coil migration.

## HOW SUPPLIED

Do not use if package is opened or damaged.

Do not use if labeling is incomplete or illegible.

The Interlock Fibered IDC Occlusion System includes an embolic coil with interlocking delivery wire, introducer sheath, and rotating hemostatic valve (RHV).

**Handling and Storage**

Store in cool, dry, dark place.

## PRODUCT PREPARATION

Prior to use, ensure that sterile packaging is intact. Return the device if sterility appears to have been compromised.

Remove the Interlock Fibered IDC Occlusion System from its packaging and inspect for product damage. Ensure that the interlocking arms are interlocked within the introducer sheath. Do not advance the coil outside the introducer sheath. Do not use the Interlock Fibered IDC Occlusion System if it is damaged.

In order to achieve excellent performance of the Interlock Fibered IDC Occlusion System and reduce the risk of thromboembolic complications, it is critical that a continuous flow of appropriate flush solution be maintained between a) the microcatheter and guiding catheter, and b) the microcatheter and any intraluminal device. Continuous flushing:

- Reduces retrograde blood flow into the microcatheter and introducer sheath during coil delivery.
- Reduces contrast crystal formation and/or thrombosis on the delivery wire and in the guiding catheter and microcatheter lumens.
- Reduces premature coil thrombosis.

An example of a continuous flush setup is shown in Figure 2.

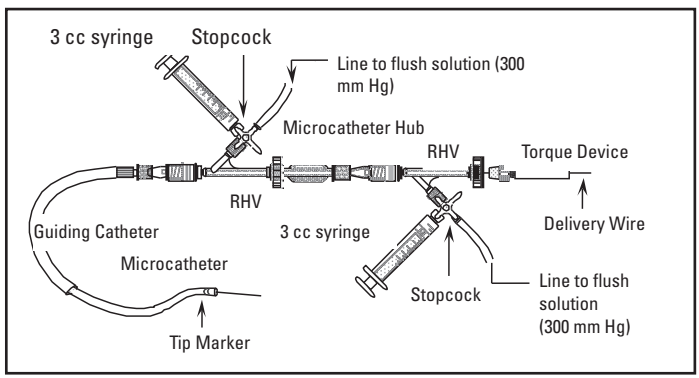


**Figure 2. Example of Continuous Flush Setup**

## DIRECTIONS FOR USE

1. Place the microcatheter in the area to be embolized per standard technique. Take care to position the microcatheter tip parallel with, not perpendicular to, the vessel wall to facilitate deposition of the coil.

2. Slowly withdraw the Interlock™ Fibered IDC™ Occlusion System from its dispenser coil and inspect assembly. Discard if there is any evidence of damage. Ensure that the Interlock Fibered IDC Occlusion System arms are interlocked inside the introducer sheath. Do not remove the Interlock Fibered IDC Occlusion System assembly from the introducer sheath.
3. Release the Interlock Fibered IDC Occlusion System inside its introducer sheath by gently pinching the sheath on both sides of the twist-lock mechanism and rotating proximal side counter-clockwise 2-3 rotations
(Figure 3 and 4).

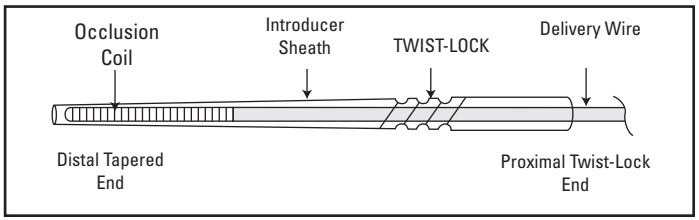


**Figure 3. Introducer Sheath with Twist-Lock Mechanism**

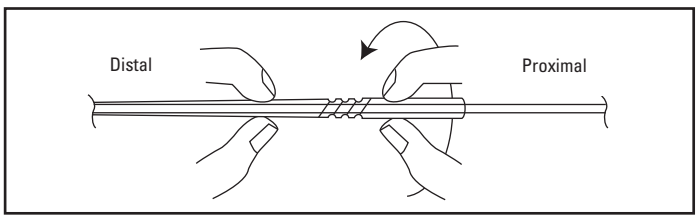


**Figure 4. Unlock via Counter-Clockwise Rotation**

4. Attach the included RHV to the proximal luer adapter on the hub of the microcatheter. Begin continuous flow of an appropriate flush solution. In general, one drop of flush solution every 1-3 seconds from a pressure bag containing the flush solution is recommended.
5. Open the thumbscrew of the RHV and carefully insert the Interlock Fibered IDC Occlusion System until the distal tip of the introducer sheath is firmly seated in the microcatheter hub.

**Caution:** Do not apply excessive force while seating the introducer sheath in the microcatheter hub. Introducer sheath tip deformation and difficulty with coil delivery into the microcatheter could result.

6. Tighten the RHV thumbscrew just enough to prevent retrograde flow but not so tight as to pinch the introducer sheath and inhibit forward movement of the delivery wire. Maintain in-line pressure of the continuous flush to prevent retrograde flow once the sheath is removed.
7. Transfer the Interlock Fibered IDC Occlusion Coil and delivery wire from the introducer sheath into the microcatheter by advancing the delivery wire in a smooth, continuous manner. **Ensure that the introducer sheath remains firmly seated in the microcatheter hub to prevent premature deployment.**
8. Gently withdraw and remove the introducer sheath from the microcatheter once the proximal end of the delivery wire is within 10 cm of the proximal end of the sheath. **Do not discard the sheath in case it is necessary to remove the Interlock Fibered IDC Occlusion System prior to deployment.**
9. **Coil Delivery**

2-RO marker microcatheter: Maneuver the Interlock Fibered IDC Occlusion System under fluoroscopy until the delivery wire's radiopaque marker is approximately 1 cm proximal to the microcatheter's proximal radiopaque marker (Figure 5). This positions the interlocking arms approximately 1 cm proximal to the microcatheter tip. Do not advance the delivery wire further until ready to release the coil to prevent premature deployment.

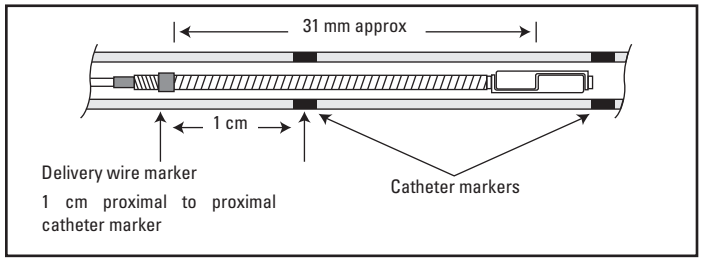


**Figure 5. Advancing Interlock Fibered IDC Occlusion System to Pre-Release Position (2-RO marker microcatheter)**

If Interlock Fibered IDC Occlusion System repositioning is necessary, gently retract the Interlock Fibered IDC Occlusion System under fluoroscopy. If repositioning is difficult or impossible, remove and discard the Interlock Fibered IDC Occlusion System. (See Interlock Fibered IDC Occlusion System Removal Procedure for further instructions.)

To deploy the coil, slowly advance the delivery wire under fluoroscopy until its marker aligns with, **but does not pass,** the microcatheter's proximal marker. When the two markers converge, the interlocking arms are outside the microcatheter body where they will disengage (Figure 6).

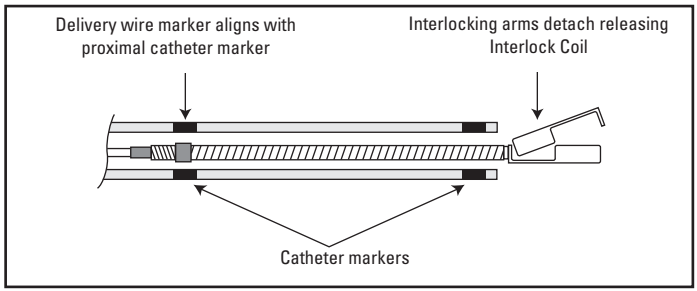


**Figure 6. Delivering Interlock Fibered IDC Occlusion Coil (2-RO marker microcatheter)**

1-RO marker microcatheter: Maneuver the Interlock Fibered IDC Occlusion System under fluoroscopy until the coil detachment zone is approximately 1 cm proximal to the microcatheter radiopaque tip marker (Figure 7). This positions the interlocking arms approximately 1 cm proximal to the microcatheter tip.

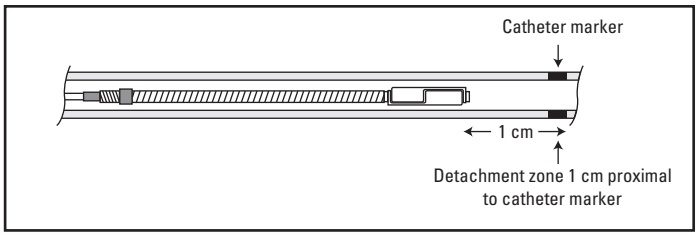


**Figure 7. Advancing Interlock™ Fibered IDC™ Occlusion System to Pre-Release Position (1-RO marker microcatheter)**

If Interlock Fibered IDC Occlusion System repositioning is necessary, gently retract the Interlock Fibered IDC Occlusion System under fluoroscopy. If repositioning is difficult or impossible, remove and discard the Interlock Fibered IDC Occlusion System. (See Interlock Fibered IDC Occlusion System Removal Procedure for further instructions.)

To deploy the coil, slowly advance the delivery wire under fluoroscopy until interlocking arms pass microcatheter's tip marker (Figure 8).

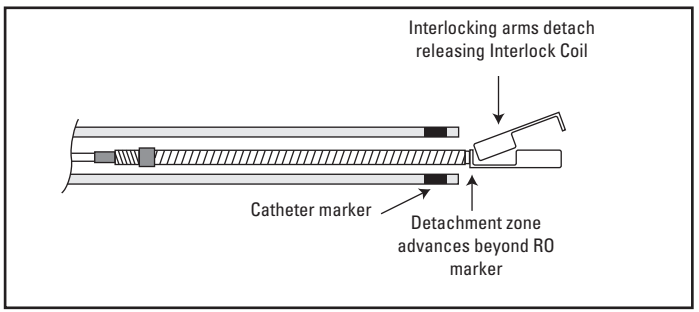


**Figure 8. Delivering Interlock Fibered IDC Occlusion Coil (1-RO marker microcatheter)**

**WARNING**

Do not advance the delivery wire once the coil has been placed. Perforation or damage of the vessel wall could occur.

**Precautions**

Multiple embolization procedures may be required to achieve the desired occlusion of some vessels. To position another Interlock Fibered IDC Occlusion System, return to Steps 1-9 in Directions for Use.

Replace microcatheters periodically during delivery of multiple coils or if increased resistance is noted during coil delivery.

Axial compression or tension forces may be stored in the microcatheter shaft during Interlock Fibered IDC Occlusion Coil delivery, and coil release may lead to catheter tip movement. Verify repeatedly during the procedure that the distal shaft of the microcatheter is not under stress prior to Interlock Fibered IDC Occlusion Coil detachment by slightly repositioning the microcatheter, delivery wire, or entire assembly simultaneously.

Carefully remove the delivery wire after coil deployment so that the delivery arm does not catch on the valve in the RHV thumbscrew.

**INTERLOCK FIBERED IDC OCCLUSION SYSTEM REMOVAL PROCEDURE**

An Interlock Fibered IDC Occlusion System must be removed if the coil is determined to be the incorrect size. If resistance is noted and repositioning is difficult, remove and discard. Make sure that the introducer sheath twist-lock mechanism is disengaged to facilitate threading of the sheath over the delivery wire (Figure 4).

1. Gently begin to retract the Interlock Fibered IDC Occlusion System under fluoroscopy. If resistance is encountered, retract the microcatheter and delivery wire simultaneously to facilitate movement.
2. Once the Interlock Fibered IDC Occlusion System is withdrawn to approximately the mid-shaft point in the microcatheter, gently thread the distal end of the introducer sheath over the proximal end of the delivery wire.
3. Open the thumbscrew of the RHV and carefully advance the introducer sheath until it is firmly seated in the proximal luer adapter of the microcatheter.
4. Tighten the RHV thumbscrew just enough to prevent retrograde flow but not so tight as to inhibit backward movement of the delivery wire through the microcatheter.
5. Holding the introducer sheath in place, gently withdraw the Interlock Fibered IDC Occlusion System until the interlocking arms and distal coil tip are visible inside the sheath.
6. Lock the Interlock Fibered IDC Occlusion System into position by gently pinching the introducer sheath on both sides of the twist-lock mechanism and rotating the proximal side clockwise (Figure 9).

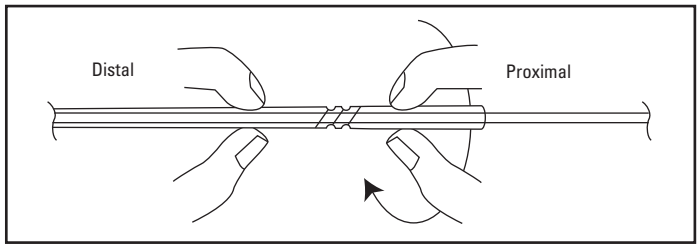


**Figure 9. Lock via clockwise rotation**

7. Withdraw the introducer sheath/delivery wire assembly from the microcatheter/RHV assembly.

**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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