EMBOLD™ Fibered

Detachable Coil System

TABLE OF CONTENTS

℞ ONLY

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

REUSE WARNING

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.

DEVICE DESCRIPTION

EMBOLD Fibered Detachable Coil System includes a coil (manufactured from platinum-tungsten alloy) that is mechanically attached to a delivery wire. This assembly is contained within an introducer sheath. The platinum coil contains synthetic fibers for greater thrombogenicity. The EMBOLD Fibered Detachable Coil System is designed to be delivered under fluoroscopy through a microcatheter with an inner diameter (ID) of 0.021 in (0.53 mm) to 0.027 in (0.69 mm) (e.g., Direxion Microcatheter) with 1 or 2 radiopaque (RO) tip markers and length up to 155 cm. The delivery wire design allows the coil to be fully advanced, retracted, and deployed prior to final placement.

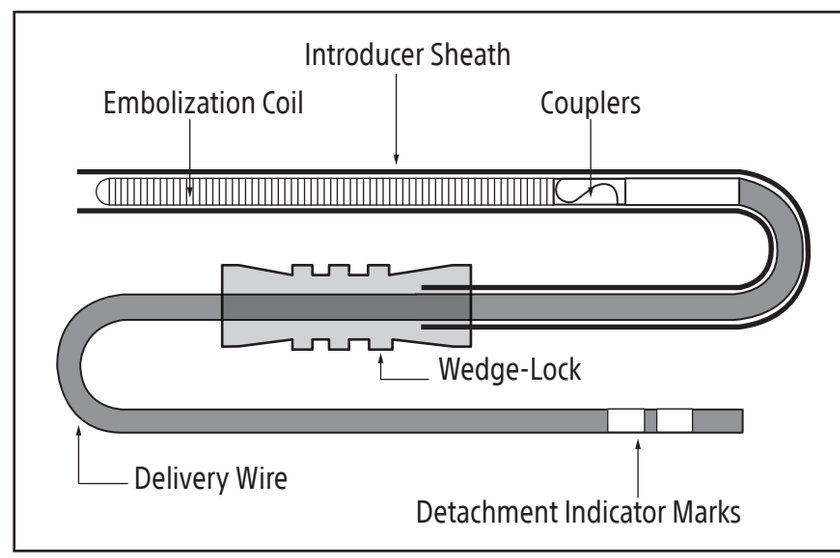

Figure 1. EMBOLD Fibered Detachable Coil System

BSC (MB eIFU Template 8.2677 x 11.6929 A4, 92524324D), eIFU, MB, EMBOLD Fibered, en, 51311096-01B

Contents

The EMBOLD Fibered Detachable Coil System includes an embolic coil attached to a delivery wire contained within an introducer sheath.

Operating Principle

The coil implant is a shaped metal wire with polymeric fiber bundles that is connected to a delivery system. The device is delivered through a microcatheter and the coil is detached by disconnecting the coil from the delivery system and is implanted into the target vasculature. After coil detachment, the delivery system is removed from the microcatheter.

Non-pyrogenic

This device meets pyrogen limit specifications.

User Information

The EMBOLD Fibered Detachable Coil System should only be used by physicians who are experienced in interventional vascular embolization procedures in the region intended to be embolized.

INTENDED USE/INDICATIONS FOR USE

The EMBOLD Fibered Detachable Coil System is indicated to obstruct or reduce rate of blood flow in the peripheral vasculature. This device is not intended for coronary or neurovascular use.

CONTRAINDICATIONS

There are no known contraindications.

WARNINGS

The following warning statements provide important information for safe use of EMBOLD Fibered Detachable Coil System. Observe all warnings and precautions noted throughout these and other instructions relevant to the procedure. Failure to do so may result in patient injury or product damage.

- Do not use the EMBOLD Fibered Detachable Coil System if it is damaged.
- To reduce the risk of thromboembolic complications, it is critical that a continuous flow of appropriate flush solution be maintained between a) the microcatheter and guide catheter, and b) the microcatheter and any intraluminal device.
- If undesirable movement of the coil can be seen under fluoroscopy after coil placement and before detachment, remove the coil and replace with another more appropriately sized EMBOLD Fibered Detachable Coil. Movement of the coil may indicate the coil could migrate once it is detached.
- Axial compression or tension forces may be stored in the microcatheter shaft during EMBOLD Fibered Detachable 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 detachment by slightly repositioning the microcatheter, delivery wire, or entire assembly simultaneously. Coil release without relieving stored forces may lead to catheter tip movement, which could cause vessel trauma.
- Due to the delicate nature of coils and the tortuosity that can be present in vasculature pathways, as well as various morphologies of vasculature, the coil may become stretched during delivery and repositioning. Stretching is a precursor to potential coil breakage. The coil should respond in approximately a 1:1 motion with the delivery system. If the coil does not move in a 1:1 motion, or if advancement after retraction or repositioning is significantly more challenging or impossible, this may be an indicator of coil stretching. If stretching is observed or suspected, carefully remove the coil and microcatheter from the vasculature simultaneously.
- Do not retract the EMBOLD Fibered Detachable Coil System too quickly or against resistance. Doing so may result in a stretched coil, premature detachment of the coil, or other damage to the coil or delivery system.
- The coil may detach prematurely if the detachment mechanism (located near the proximal end of the delivery wire) is activated before intended. Use caution when handling this portion of the delivery system prior to coil detachment. Follow all instructions when introducing and positioning the coil to avoid prematurely detaching the coil.

- Do not rotate the delivery wire more than 1 turn (360 degrees) during delivery of the EMBOLD Fibered Detachable Coil System. Excessive rotation of the delivery wire may damage the EMBOLD Fibered Detachable Coil System or may result in premature detachment of the coil.
- Do not advance the delivery wire once the coil has been detached. Vessel trauma could occur.

PRECAUTIONS

The following precaution statements provide important information for safe use of EMBOLD Fibered Detachable Coil System. Observe all warnings and precautions noted throughout these and other instructions relevant to the procedure. Failure to do so may result in patient injury or product damage.

- To ensure safe delivery, never make sudden movements, do not force in case of resistance, and operate gently and with caution.
- Ensure the microcatheter in use has the appropriate ID and length for the selected coil.
- 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 advance the EMBOLD Fibered Detachable Coil System if it becomes lodged within the microcatheter. Determine the cause of the resistance and replace the microcatheter and coil if necessary. See the "Operational Instructions – Full System Removal" section for further instructions.
- Advance and retract the EMBOLD Fibered Detachable Coil 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.
- If resistance is encountered or if the coil is not responding in a 1:1 motion while retracting the EMBOLD Fibered Detachable Coil System and the coil is at an acute angle relative to the microcatheter tip, it may be possible to avoid coil stretching by carefully pulling back the distal tip of the microcatheter slightly before continuing to retract the coil.
- No tools are required to detach the coil. Using a tool could result in damage to the inner wire causing the coil to be difficult or impossible to release.
- When in highly tortuous anatomy, increased resistance may be felt when retracting the inner wire and a greater retraction distance may be required to detach the coil.
- During verification of coil detachment, if coil retraction into the microcatheter is observed and the inner wire between the detachment indicator marks has been exposed, the implant may detach as soon as the coil detachment zone is advanced beyond the microcatheter tip. Ensure catheter tip position is satisfactory and is maintained during this step to reduce the potential for malpositioning of the proximal portion of the coil.
- Multiple embolization coils may be required to achieve the desired occlusion.
- Replace microcatheters periodically during delivery of multiple coils or if increased resistance is noted during coil delivery.

MAGNETIC RESONANCE IMAGING (MRI) SAFETY INFORMATION

MR Conditional	Non-clinical testing has demonstrated that the EMBOLD Fibered Detachable Coil is MR Conditional. A patient with the coil may safely undergo MRI imaging under the following conditions. Failure to follow these conditions may result in injury to the patient.
Name/Identification of the Device	EMBOLD Fibered Detachable Coil System
Nominal Value(s) of Static Magnetic Field [T]	1.5 T or 3.0 T
Maximum Spatial Field Gradient	40 T/m (4,000 gauss/cm)
Radiofrequency (RF) Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Integrated Whole-Body Transmit Coil
RF Receive Coil Type	Any
Operating Mode	Normal Operating Mode
Maximum Whole-Body Specific Absorption Rate (SAR)	2 W/kg (Normal Operating Mode)
Maximum Head SAR	3.2 W/kg (Normal Operating Mode)
Scan Duration	2 W/kg whole-body average SAR for 15 minutes of continuous RF (a sequence or back-to-back series/scan without breaks), followed by: • 15 minutes of cooling at 1.5 T, or • 5 minutes of cooling at 3.0 T.
MR Image Artifact	The presence of this implant(s) may produce an image artifact of up to 5 mm.
If information about a specific parameter is not included, there are no conditions associated with that parameter.	

ADVERSE EVENTS

Potential adverse events which may be associated with the use of a coil and/or the peripheral embolization procedure include, but are not limited to:

- Allergic reaction (device, contrast, medications)
- Arrhythmia
- Bleeding/hemorrhage
- Cerebrovascular accident (CVA)
- Death
- Embolism (air, plaque, thrombus, device, tissue, or other)
- Hematoma
- Infection/sepsis
- Ischemia
- Necrosis
- Need for additional intervention or surgery
- Nerve injury
- Pain/discomfort
- Post-embolization syndrome (PES)
- Recanalization
- Thrombus/thrombosis
- Transient ischemic attack (TIA)
- Vasospasm
- Vessel trauma (arteriovenous fistula, dissection, injury, perforation, pseudoaneurysm, rupture)

HOW SUPPLIED

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.

Device Details

Do not use if package is damaged or unintentionally opened before use.

Do not use if labeling is incomplete or illegible.

Handling and Storage

This product has no special handling or storage requirements.

OPERATIONAL INSTRUCTIONS

Additional Items For Safe Use

The following supplies are not provided and need to be available and prepped prior to use of the EMBOLD Fibered Detachable Coil System:

- Sterile heparinized saline
- Continuous flush equipment (e.g., pressurization bag and/or pressure cuff)
- Contrast medium
- Appropriate device(s) needed for gaining vascular access
- Appropriate size and length of each:
  - Guide catheter
  - Guide wire and/or micro guide wire
  - Microcatheter
- Rotating hemostatic valve(s) (RHV)
- Luer-lock syringe(s)
- Three-way stopcock(s)

Coil Size Selection

Coil selection is a matter of physician preference and the clinical situation. The shape and diameter of the vessel to be embolized 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.

Operational Instructions – Preparation

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 delivery of the coil.

   CAUTION: Ensure the microcatheter in use has the appropriate ID and length for the selected coil.

2. In order to achieve expected performance of the EMBOLD Fibered Detachable Coil 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 guide catheter, and b) the microcatheter and any intraluminal device. Securely attach an RHV to the proximal luer adapter on the hub of the microcatheter. Begin continuous flow of an appropriate flush solution. In general, 1 drop of flush solution every 1 second – 3 seconds (300 mm Hg) from a pressure bag containing the flush solution is recommended. An example of a continuous flush setup is shown in Figure 2.

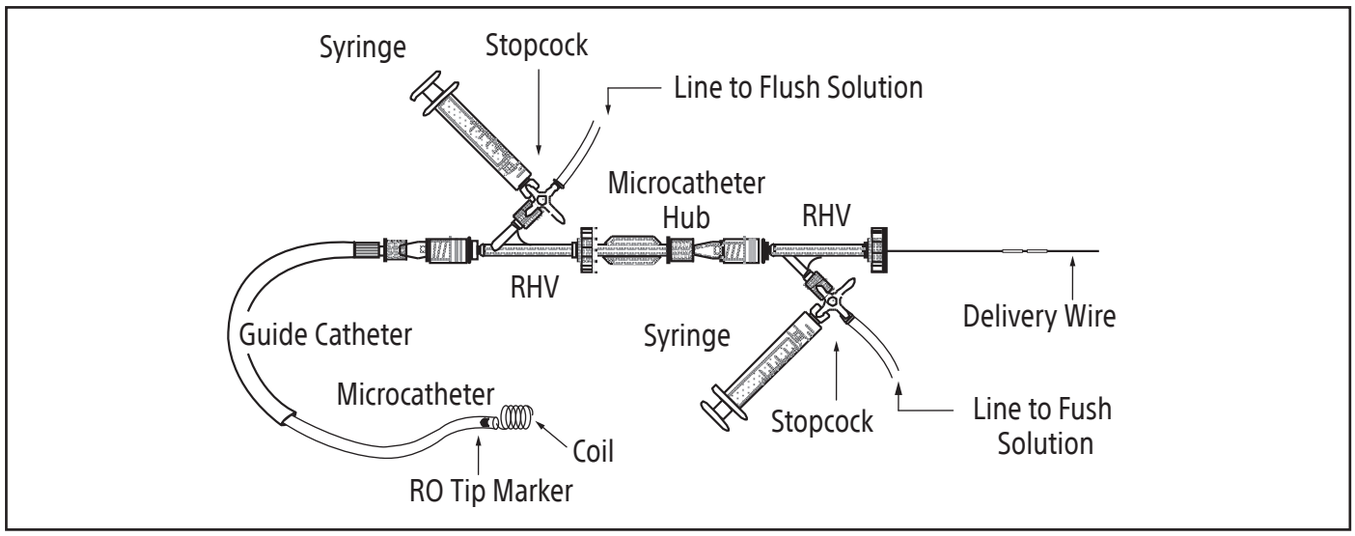

Figure 2. Example of continuous flush setup

3. Prior to use, ensure that sterile packaging is intact. Return the device if sterility appears to have been compromised.
4. Open the sterile pouch and transfer the dispenser coil into the sterile field using sterile technique.
5. Slowly withdraw the EMBOLD Fibered Detachable Coil System from its dispenser coil and inspect assembly. Do not use the EMBOLD Fibered Detachable Coil System if it is damaged. Do not advance or retract the EMBOLD Fibered Detachable Coil System from the introducer sheath.

NOTE: Wiping of the EMBOLD Fibered Detachable Coil System with a dry gauze or using alcohol, antiseptic solution, and other solvents to pre-treat the device may impact the performance of the lubricious coating.

Operational Instructions – Device Introduction

1. Open the thumbscrew of the RHV and carefully insert the EMBOLD Fibered Detachable Coil 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.

---

2. 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.
3. Unlock the EMBOLD Fibered Detachable Coil System from the introducer sheath by holding the introducer sheath just distal to the orange wedge-lock and pulling the wedge-lock proximally (Figure 3, Figure 4). Carefully remove the wedge-lock fully over the delivery wire.

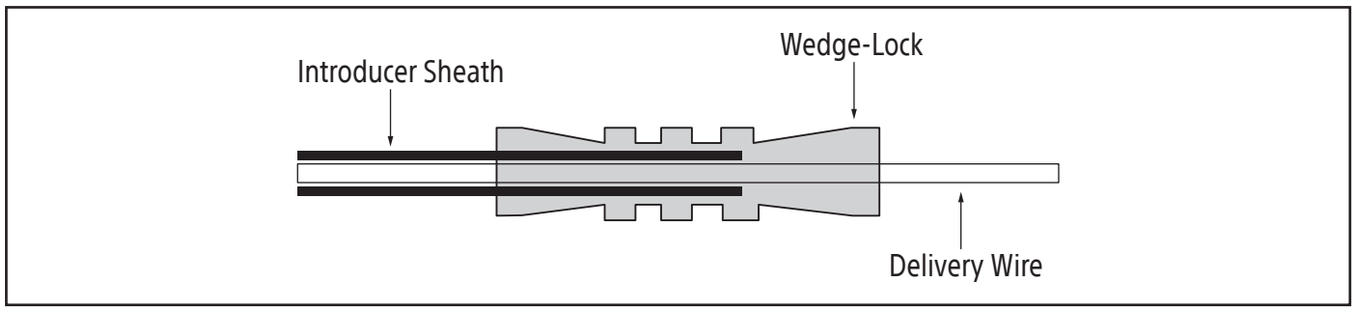

Figure 3. Introducer sheath with wedge-lock mechanism

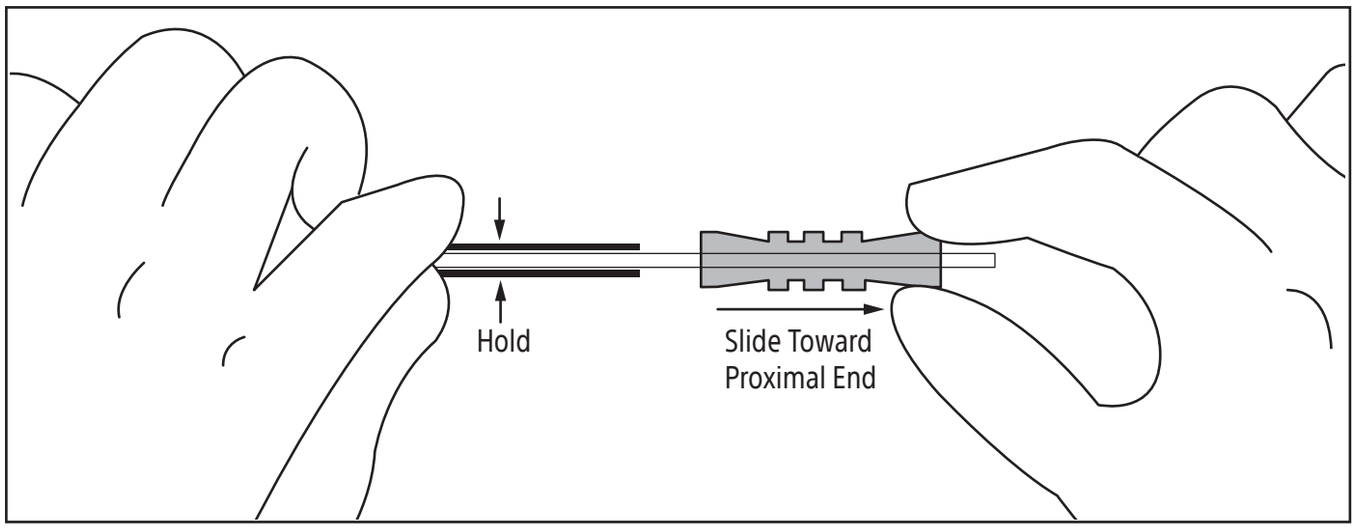

Figure 4. Unlock by sliding wedge-lock towards proximal end

4. Transfer the EMBOLD Fibered Detachable Coil and delivery wire from the introducer sheath into the microcatheter by advancing the delivery wire in a smooth, continuous manner using 1 cm – 2 cm strokes. Ensure that the introducer sheath remains firmly seated in the microcatheter hub to prevent coil or delivery wire damage.

CAUTION: Do not advance the EMBOLD Fibered Detachable Coil System if it becomes lodged within the microcatheter. Determine the cause of the resistance and replace the microcatheter and coil if necessary. See the "Operational Instructions – Full System Removal" section for further instructions.

---

5. When the proximal end of the delivery wire is within approximately 10 cm of the proximal end of the introducer sheath or when the coil reaches the distal end of the microcatheter (whichever occurs first), pause advancement and loosen the RHV thumbscrew. Gently withdraw the introducer sheath from the microcatheter and fully remove it from the delivery wire. Maintain in-line pressure of the continuous flush to prevent retrograde flow once the introducer sheath is removed.

Operational Instructions – Coil Positioning

1. Continue to advance the EMBOLD Fibered Detachable Coil System under fluoroscopy and position it carefully at the target site.
2. If coil repositioning is necessary, gently retract and re-advance the device under fluoroscopy until coil position is satisfactory. If repositioning is difficult or impossible, remove and discard the EMBOLD Fibered Detachable Coil System. See the "Operational Instructions – Full System Removal" section for further instructions.
3. Once satisfactory coil positioning has been achieved, maneuver the EMBOLD Fibered Detachable Coil System under fluoroscopy until the coil detachment zone is completely beyond the microcatheter RO tip marker (Figure 5). This ensures that the microcatheter will not interfere with coupler separation during coil detachment.

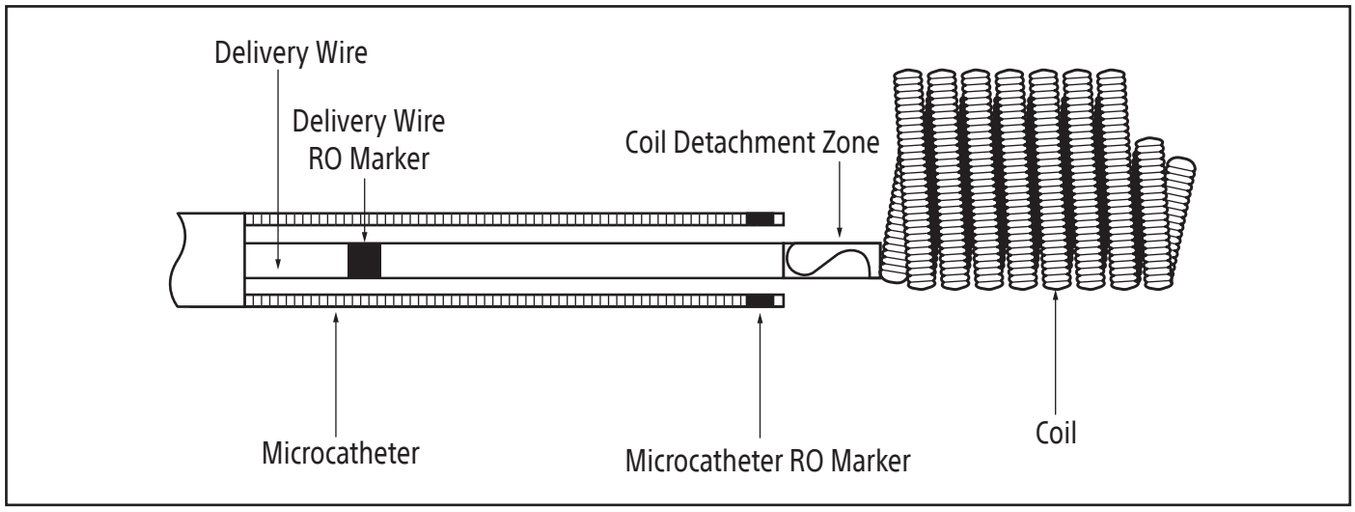

Figure 5. Pre-Detachment Positioning of EMBOLD Fibered Detachable Coil

If using a 2-RO marker microcatheter, the proximal microcatheter RO marker may also be used to indicate when the coil has fully exited the microcatheter. This may be beneficial if the distal tip of the microcatheter is obscured. Advance until the delivery wire RO marker is just past the proximal microcatheter RO marker (Figure 6). This ensures that the microcatheter will not interfere with coupler separation during coil detachment.

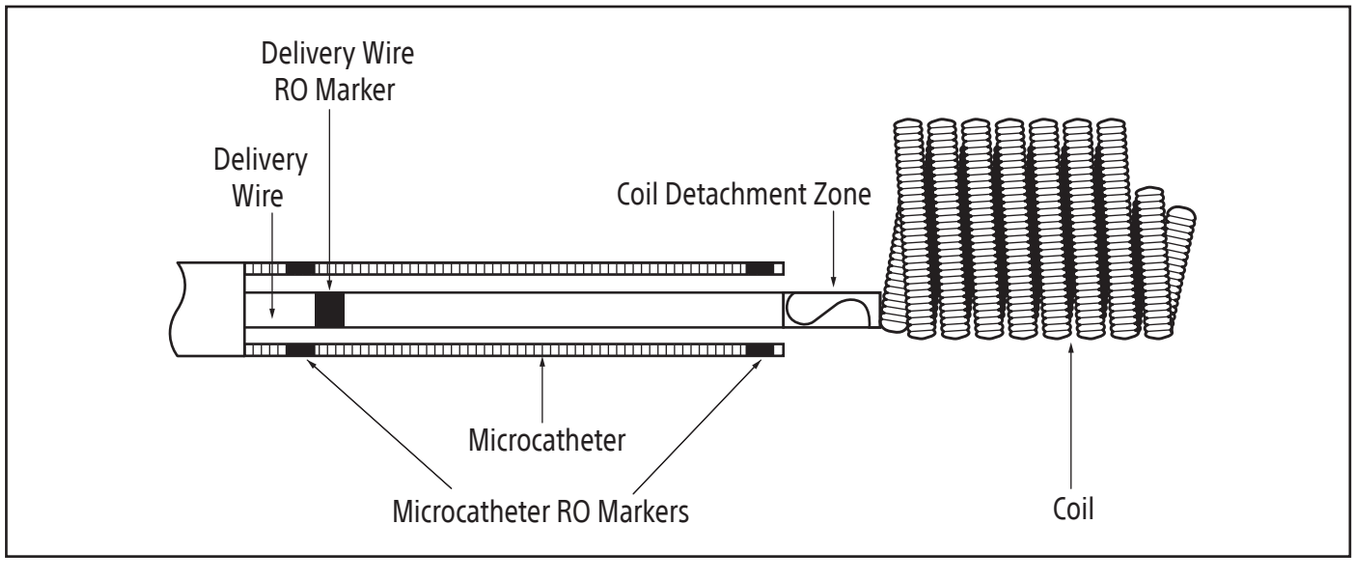

Figure 6. Pre-Detachment Positioning of EMBOLD Fibered Detachable Coil (2-RO marker microcatheter)

4. Verify the final positioning of the coil to confirm no additional adjustments are required.

WARNING: Axial compression or tension forces may be stored in the microcatheter shaft during EMBOLD Fibered Detachable 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 detachment by slightly repositioning the microcatheter, delivery wire, or entire assembly simultaneously. Coil release without relieving stored forces may lead to catheter tip movement, which could cause vessel trauma.

---

5. Tighten the RHV thumbscrew on the delivery system to prevent inadvertent coil movement during coil detachment.

Operational Instructions – Coil Detachment

1. When ready for coil detachment, grasp the white detachment indicator marks located near the proximal end of the delivery wire (Figure 7).

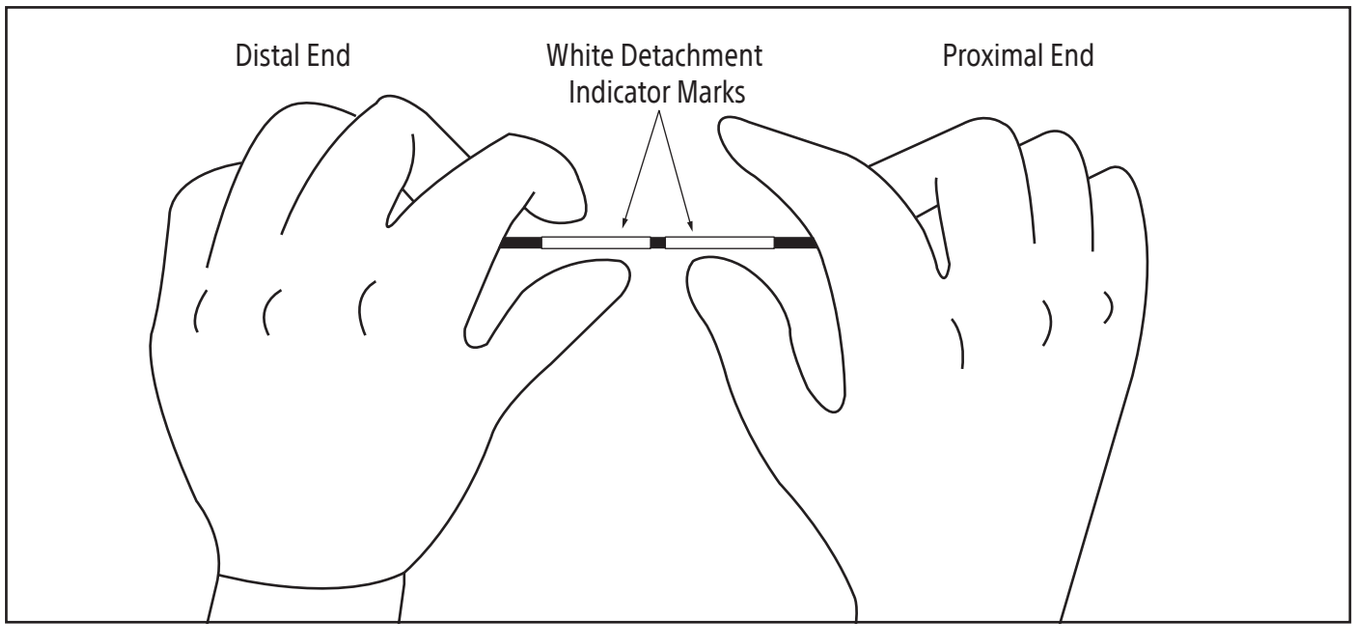

Figure 7. Coil detachment preparation

2. While holding the distal mark steady, slowly bend the proximal mark until the delivery wire snaps between the 2 markings (Figure 8).

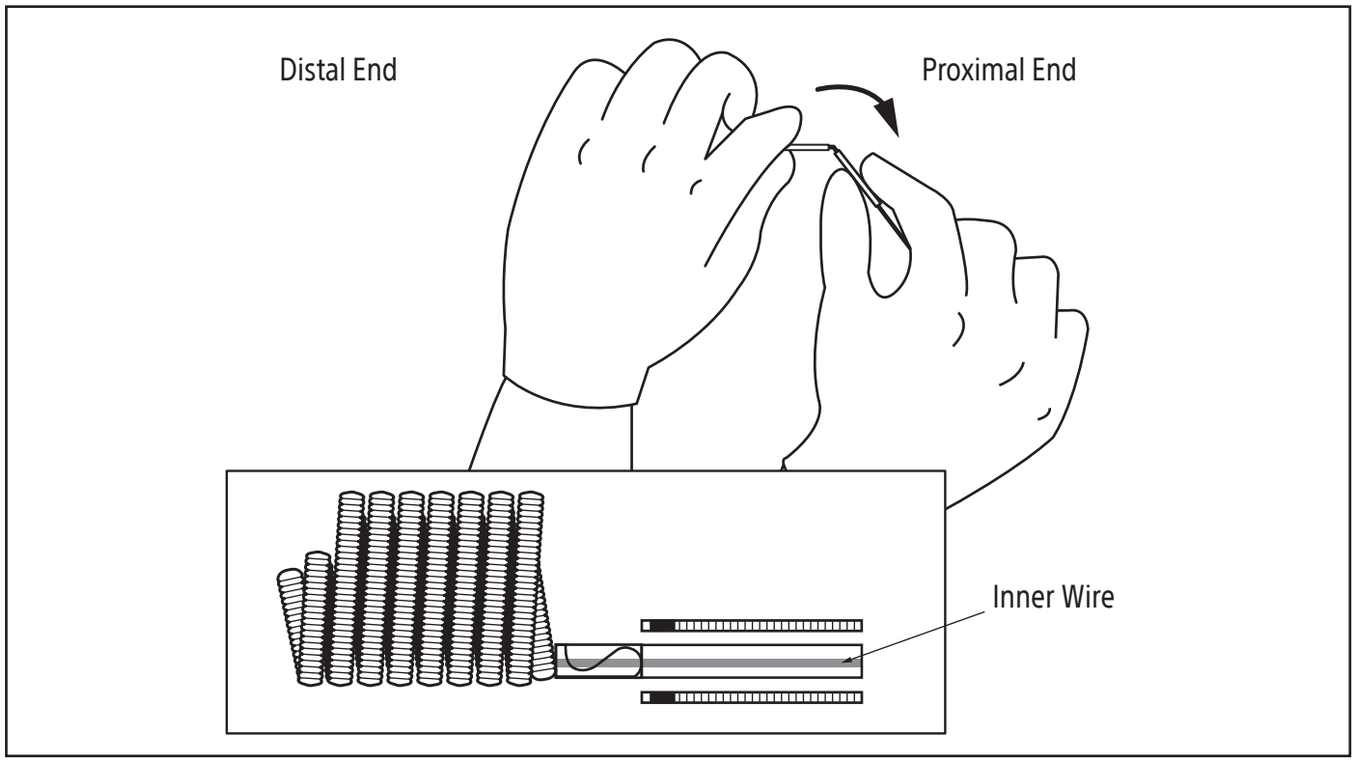

Figure 8. Coil detachment initiation

3. Retract only the proximal segment of the delivery wire until at least 1 cm of the inner wire is exposed to complete the coil detachment (Figure 9).

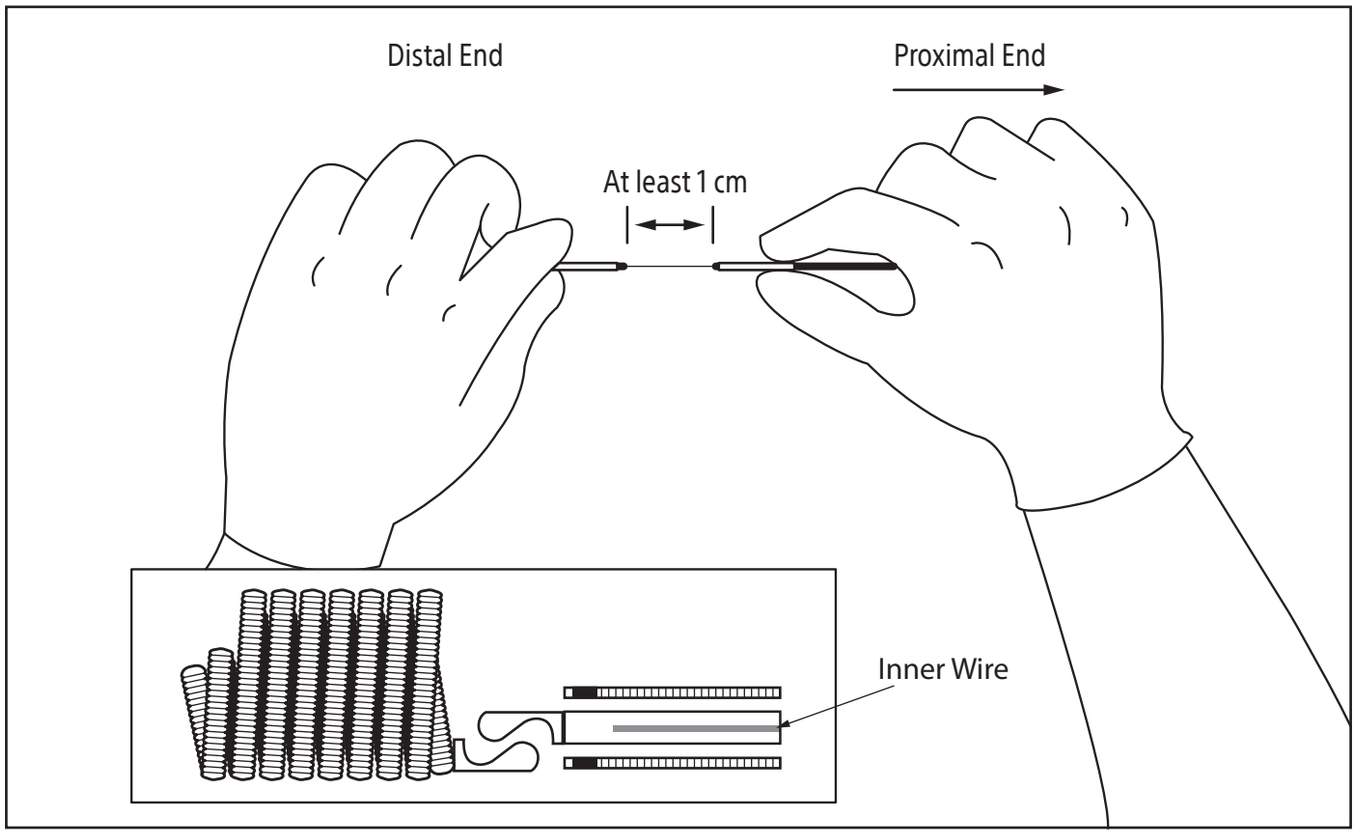

Figure 9. Inner wire retraction to complete coil detachment

CAUTION: When in highly tortuous anatomy, increased resistance may be felt when retracting the inner wire and a greater retraction distance may be required to detach the coil.

---

4. Confirm under fluoroscopy that the coil has detached from the delivery wire by pulling back slowly on the delivery system and verifying there is no coil movement.

CAUTION: If coil retraction into the microcatheter is observed and the inner wire between the detachment indicator marks has been exposed, the implant may detach as soon as the coil detachment zone is advanced beyond the microcatheter tip. Ensure catheter tip position is satisfactory and is maintained during this step to reduce the potential for malpositioning of the proximal portion of the coil.

Operational Instructions – Delivery Wire Removal

1. Loosen the RHV thumbscrew and carefully remove the delivery wire after coil detachment.

WARNING: Do not advance the delivery wire once the coil has been detached. Vessel trauma could occur.

---

2. Dispose of device according to the instructions in the Disposal section.
3. Evaluate occlusion under fluoroscopy. Multiple embolization procedures may be required to achieve the desired occlusion of some vessels. Repeat the Operational Instructions section for each additional EMBOLD Fibered Detachable Coil System.

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

Operational Instructions – Full System Removal

The EMBOLD Fibered Detachable Coil System must be removed if the coil is determined to be the incorrect size or is otherwise determined to be unsuitable.

1. Gently begin to retract the EMBOLD Fibered Detachable Coil System under fluoroscopy. If resistance is encountered, carefully retract and remove the microcatheter and delivery wire simultaneously.
2. Once the EMBOLD Fibered Detachable Coil System is withdrawn to approximately halfway out of the microcatheter, gently thread the distal tip of the introducer sheath over the proximal end of the delivery wire.

NOTE: If product configuration does not allow for resheathing, retract and remove the system without utilizing the introducer sheath.

---

3. Open the thumbscrew of the RHV and carefully advance the introducer sheath until it is firmly seated in the hub of the microcatheter. Ensure that the delivery wire is accessible at the proximal end of the introducer sheath.
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 EMBOLD Fibered Detachable Coil System until the coil is fully within the introducer sheath.
6. Loosen the RHV thumbscrew and remove the introducer sheath from the microcatheter hub and RHV assembly.

Disposal

To minimize the risk of infection or microbial hazards after use, dispose device and packaging as follows:

After use, device and packaging may contain biohazardous substances. Any device and packaging that came into contact with biohazardous substances should be treated and disposed of as biohazardous waste or be treated and disposed of in accordance with any applicable hospital, administrative, and/or local government regulations. Use of a biohazardous container with biological hazard symbol is recommended. Untreated biohazardous waste should not be disposed of in the municipal waste system.

Post-Procedure

Assess patient for hematoma and/or other signs of bleeding at the puncture site.

Any serious incident that occurs in relation to this device should be reported to the manufacturer and relevant local regulatory authority.

Implant Card Instructions

Record the institution name, patient details, and implant date. Add a peel-off label from product packaging. Provide to patient. See Instructions for Use for more information.

INFORMATION TO BRIEF THE PATIENT

The physician should consider the following points while counseling patients on the use of the EMBOLD Fibered Detachable Coil System in association with the interventional procedure:

- Discuss the risks and benefits, including review of potential adverse events listed in this document, both for the EMBOLD Fibered Detachable Coil System and for other interventional treatments likely to be employed.
- Discuss patient allergies; in particular, the risk for patients who may be allergic or with known sensitivity to contrast/contrast-containing substances.
- Discuss post-procedure instructions, including any follow-up appointments, lifestyle changes, medications, and home-care or rehabilitation guidelines.
- Provide the patient with the completed implant card to carry and advise the patient that additional information, including MRI conditions, may be available on the Boston Scientific website (www.bostonscientific.com/patientlabeling).
- Instruct the patient to present the implant card to their Healthcare Professionals (doctors, dentist, technicians) so they can take the necessary precautions.
- Inform the patient that the EMBOLD Fibered Detachable Coil System is a permanent implantable. The materials of the device are nonbiodegradable and are intended to last for the lifetime of the patient.

WARRANTY

For device warranty information, visit (www.bostonscientific.com/warranty).

BSC (MB eIFU Template 8.2677 x 11.6929 A4, 92524324D), eIFU, MB, EMBOLD Fibered, en, 51311096-01B

REF Catalog Number

IFU-bsci.com Consult instructions for use.

Contents

EC REP Authorized Representative in the European Community

Manufacturer

LOT Lot Number

Recyclable Package

Use By

AUS Australian Sponsor Address

ARG Argentina Local Contact

Single use. Do not re-use.

Do Not Resterilize

Do not use if package is damaged.

Date of Manufacture

UDI Unique Device Identifier

ID Microcatheter ID Compatibility

Single sterile barrier system

STERILE EO Sterilized using ethylene oxide.

Non-Pyrogenic

MR Conditional

Health care center or doctor

Patient identification

Date

EC REP Authorized Representative in the European Community

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

Manufacturer

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752 USA
USA Customer Service +1-888-272-1001

www.bostonscientific.com

Do not use if package is damaged.

Recyclable Package

51311096-01

2022-01
< en >