COOK®
MEDICAL

MReye® Flipper® Detachable Embolization Coil

Instructions for Use

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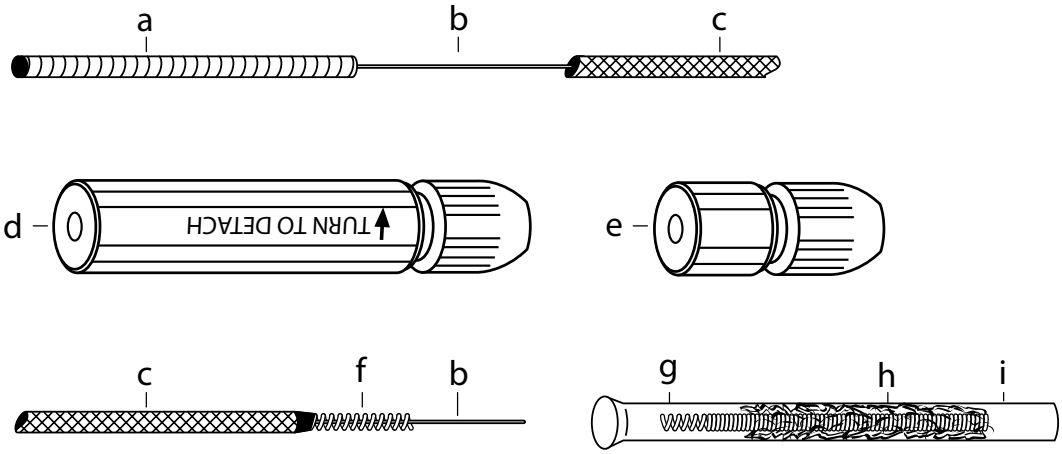
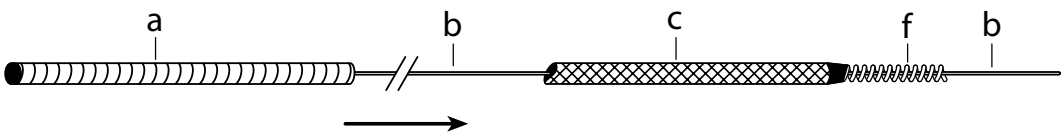
332-02EN



a) Handle of Straightening Mandril **1**
b) Straightening Mandril
c) Coil Delivery Wire
d) Pin Vise
e) Adapter for protection during shipment/storage only
f) Thread of Delivery Wire
g) Thread of Coil
h) Detachable Embolization Coil
i) Coil Loading Cartridge



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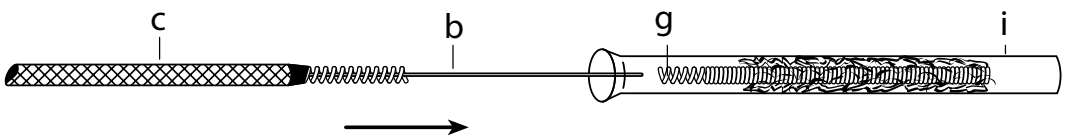

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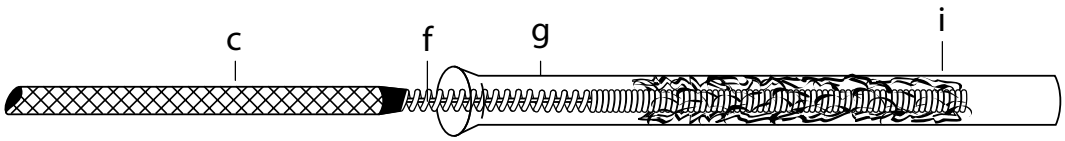

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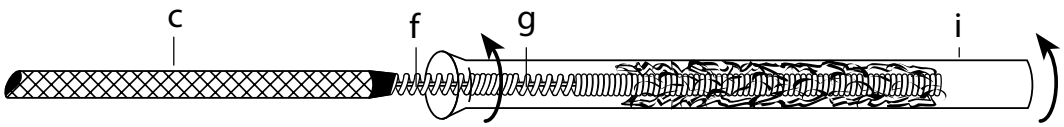

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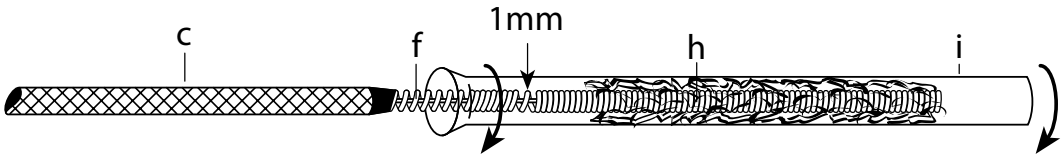

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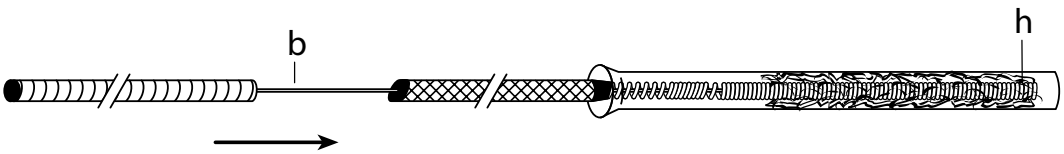

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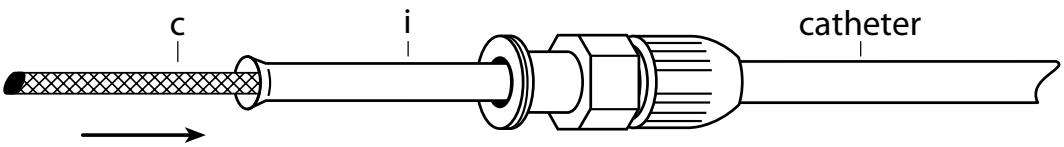

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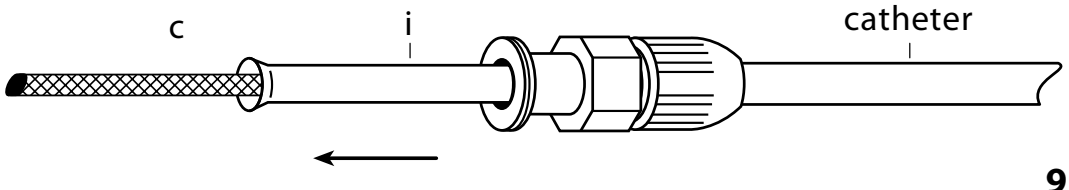
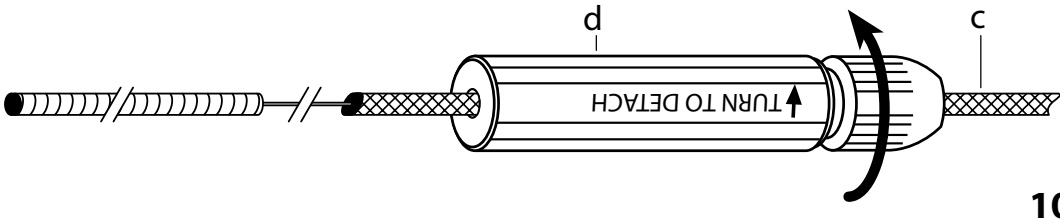
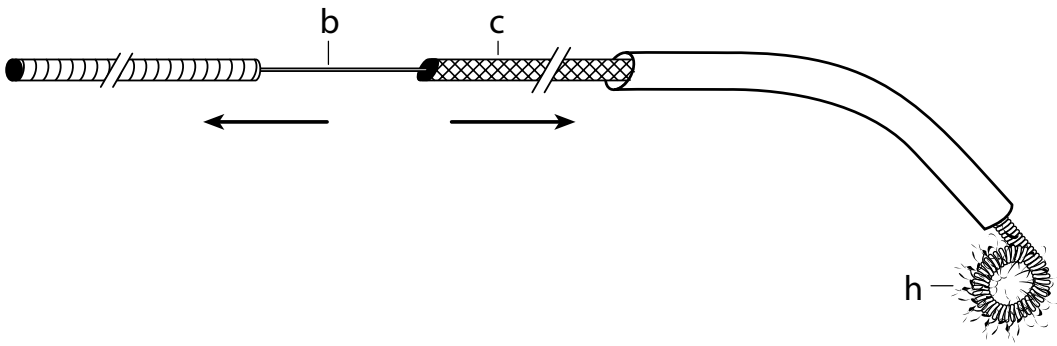

c
i
catheter

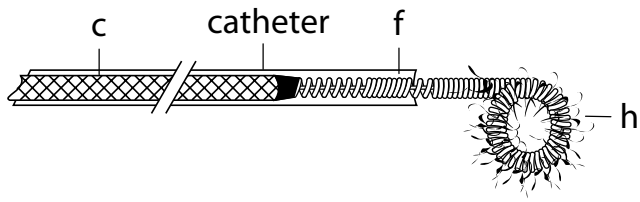
9


d
c
TURN TO DETACH

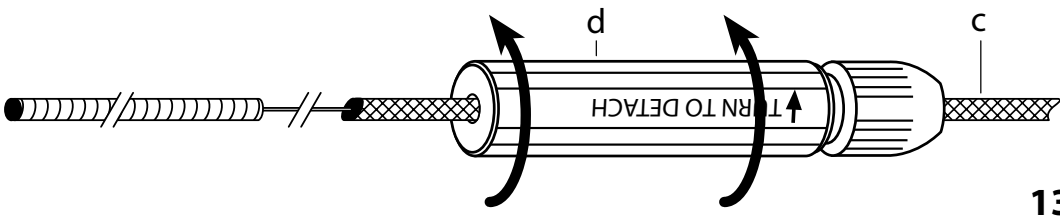
10


b
c
h

11


c
catheter
f
h

12


d
c
TURN TO DETACH

13

MREYE® FLIPPER® DETACHABLE EMBOLIZATION COIL AND DELIVERY SYSTEM

CAUTION: U.S. federal law restricts this device to sale by or on the order of a physician (or a properly licensed practitioner).

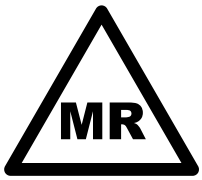
DEVICE DESCRIPTION

MReye Flipper Detachable Embolization Coils are made of Inconel® with synthetic fibers. The delivery system consists of a PTFE-coated stainless steel delivery wire, a straightening mandril and a pin vise handle for detachment. The MReye Flipper Detachable Embolization Coil is designed to be delivered under fluoroscopy to the target vessel.

INTENDED USE

MReye Flipper Detachable Embolization Coils are intended for arterial and venous embolization in the peripheral vasculature.

MRI SAFETY INFORMATION



Through nonclinical testing, embolization coils manufactured of Inconel have been shown to be MR conditional at static magnetic field strengths of 3.0 Tesla or less, a maximum spatial gradient of 330 gauss/cm, and a maximum whole-body-averaged specific absorption rate (SAR) of 2.0 W/kg for 20 minutes of MRI.

Embolization coils manufactured of Inconel will not migrate in this MRI environment. Nonclinical testing has not been performed to rule out the possibility of device migration at static magnetic field strengths higher than 3.0 Tesla and a maximum spatial gradient higher than 330 gauss/cm.

In this testing, embolization coils manufactured of Inconel produced a temperature rise of ≤ 0.6 °C at a maximum whole-body-averaged specific absorption rate (SAR) of 2.0 W/kg for 20 minutes of MRI. The effect of heating in the MRI environment for other conditions, multiple coils or overlapping coils is unknown.

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the embolization coils manufactured of Inconel.

CONTRAINDICATIONS

None known

WARNINGS

- Do not remove the coil from the cartridge.
- Do not rotate the delivery wire counter-clockwise during insertion; rotation might detach the coil inadvertently.
- After the detachable coil delivery system with the coil has been introduced into the catheter, it is important that the coil does not exit the catheter tip until the mandril has been pulled back. Otherwise, the catheter may become dislocated in the vessel.
- These coils are not recommended for use with polyurethane or polyvinylchloride catheters or catheters with sideports. If a catheter with sideports is used, the embolus may lodge in the sideport or pass inadvertently through it. Use of a polyurethane catheter may also result in lodging of the embolus within the catheter.

PRECAUTIONS

- This product is intended for use by physicians trained and experienced in diagnostic and interventional techniques. Standard techniques for placement of vascular access sheaths, angiographic catheters and wire guides should be employed.
- Manipulation of products requires fluoroscopic control.
- Perform an angiogram prior to embolization to determine correct catheter position.
- The angiographic catheter must be flushed with saline prior to introduction of the detachable coil.
- It is important to follow the loading procedure carefully in order to avoid complications during attachment and detachment of the coil.
- Ensure that the straightening mandril is at the tip of the coil during advancement through the catheter; if it is not, the coil might start coiling up inside the catheter, which may complicate detachment.
- If, at any time during the procedure (advancement or detachment), resistance is felt, do not attempt to use force to overcome the problem; remove and replace the whole system if necessary.

PRODUCT RECOMMENDATIONS

In order to obtain stability during coil introduction, a 5 French or larger, non-tapered (NT) end hole multipurpose catheter without sideports (i.e., HNB(R)5.0 -NT) is recommended. The catheter must have a minimum inner diameter of .041 inches.

INSTRUCTIONS FOR USE

Loading Procedure

1. Remove the adapter (**e**), which is used for protection during shipment/ storage. (**Fig. 1**) Carefully remove the coil delivery wire from the spiral holder to avoid kinking the straightening mandril.
2. Advance the handle of the straightening mandril (**a**) until it meets the coil delivery wire (**c**). (**Fig. 2**)
3. Introduce the straightening mandril (**b**) into the flared end of the coil-loading cartridge (**i**) and into the center of the thread part of the coil (**g**). (**Fig. 3**)
4. Advance the coil-loading cartridge (**i**) until the thread of the coil (**g**) meets the thread of the delivery wire (**f**). (**Fig. 4**)
5. Turn the coil-loading cartridge (**i**) clockwise to join the thread of the coil (**g**) with the thread of the delivery wire (**f**). Continue the clockwise rotation of the coil-loading cartridge (**i**) to engage the thread of the coil (**g**) until the coil and the delivery system are almost completely joined. (**Fig. 5**)
6. To prepare the device and check the detachment mechanism, turn the coil-loading cartridge (**i**) counter-clockwise to leave a gap of 1 mm between the thread of the delivery wire (**f**) and the coil (**h**). (**Fig. 6**)
7. To keep the detachable embolization coil (**h**) straight, advance the straightening mandril (**b**) in small increments until it reaches the tip of the coil. (**Fig. 7**) Stop once resistance is met.

Coil Deployment

NOTE: Before performing the following steps, ensure that the loading procedure described above has been successfully completed.

1. It is recommended that the non-tapered (NT) end hole multipurpose catheter without sideports be advanced through a Check-Flo® introducer sheath. A minimum catheter inner diameter of .041 inches is required.
2. Perform an angiogram to confirm vessel anatomy.
3. Introduce the coil-loading cartridge (**i**) into the hub of the catheter. Make sure the straightening mandril remains at the tip of the coil. Advance the coil delivery system through the coil-loading cartridge into the catheter. Take care not to kink the coil delivery wire upon advancement. (**Fig. 8**)

   WARNING: Do not rotate the coil delivery wire (**c**) during insertion through the catheter, as inadvertent detachment of the embolization coil within the catheter may occur.
4. Withdraw the cartridge (**i**) over the delivery wire (**c**). (**Fig. 9**)

5. Place the pin vise (**d**) on the proximal portion of the coil delivery wire (**c**) and lock the pin vise in place. (**Fig. 10**) Under fluoroscopic control, advance the coil delivery wire in order to place the coil at the tip of the catheter.
6. With the catheter in place, maintain position of the straightening mandril (**b**) at the tip of the coil. Subsequently withdraw the straightening mandril (**b**) and correspondingly advance the delivery wire (**c**) to protrude 1 or 2 loops into the vessel. (**Fig. 11**)

   WARNING: Do not expose the screw threads beyond the distal tip of the catheter. (**Fig. 12**) This prevents kinking of this portion of the device. Kinking will make detachment from the delivery wire difficult.
7. If the detachable embolization coil (**h**) position is unsatisfactory, pull the coil back into the catheter. Due to clot formation on the coil fibers, prolonged exposure to the blood system may make coil retrieval difficult. It is recommended to exchange to a new embolization coil before continuing with the procedure.

   WARNING: If difficulties occur when detaching the embolization coil, or if resistance is felt when withdrawing the delivery wire, stop and evaluate the position of the coil, delivery wire and catheter tip. If the problem persists, remove the catheter and the delivery wire with the coil simultaneously and replace the whole system.
8. With the desired coil position obtained, keep the catheter in place and gently turn the pin vise (**d**) counter-clockwise to detach the delivery wire (**c**) from the coil. (**Fig. 13**)
9. Gentle traction on the delivery wire will determine whether detachment has occurred. Using fluoroscopy to confirm that the coil has been detached, remove the delivery system.
10. Remove the delivery wire. If the proximal screw-thread of the coil has not exited the tip of the catheter, it should be pushed out using a floppy-tipped wire guide. Do not use the screw-thread of the delivery wire, as entanglement may occur. Insert further embolization coils as required.
11. The delivery wire may be used for multiple coil placements within a single procedure. Inspect the delivery wire prior to re-use to ensure that it has not been damaged during its initial use.

HOW SUPPLIED

Supplied sterilized by ethylene oxide gas in peel-open packages. Intended for one-time use. Sterile if package is unopened or undamaged. Do not use the product if there is doubt as to whether the product is sterile. Store in a dark, dry, cool place. Avoid extended exposure to light. Upon removal from package, inspect the product to ensure no damage has occurred.

REFERENCES

These instructions for use are based on experience from physicians and (or) their published literature. Refer to your local Cook sales representative for information on available literature.

Manufacturer
WILLIAM COOK EUROPE ApS
Sandet 6, DK-4632
Bjaeverskov, DENMARK

www.cookmedical.com

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