Choose an optimally fibered, fully retractable¹ coil.

Offering an optimal balance between retractability and fiber thrombogenicity, Retracta[®] allows you to reposition, pack, and detach with precision.

Retracta®

It's easy to use from package to placement.

Retracta coils are used right out of the package with minimal effort and preparation. You don't have to attach extra devices to make our embolization products work or spend extra time getting them ready to work. The Retracta wire conforms to the catheter shape to make navigation easy. The detachment zone is easy to visualize under fluoroscopy, and the coil can be detached when you are ready.

Reposition, pack, and detach with precision.

Retracta is designed to give you greater control over the placement of the coil. The fully retractable feature allows you to reposition the coil if necessary. The soft platinum allows you to pack the coil into a tight occluding mass while the fiber increases thrombogenicity.

Choose an 0.035" catheter compatible detachable coil.

In addition to the 0.035 inch diameter end hole compatibility of the device, the flexible 20 cm tapered section of the delivery wire allows Retracta to take the shape of the catheter, enabling smooth navigation even around tight curves.

0.035" catheter end hole compatibility



Retracta

DETACHABLE EMBOLIZATION COIL

Features

- The Retracta Detachable Embolization Coil is intended for arterial and venous embolization in the peripheral vasculature.
- Retracta is a platinum coil with spaced synthetic fibers and is attached to a delivery wire.
- The Retracta system allows the coil to be fully advanced and completely repositioned before the coil is finally deployed.
- The coil delivery system provides safe delivery of embolization coils when correct positioning is especially critical.
- Retracta is fibered to promote thrombogenicity.
- Retracta is made of soft platinum for tight packing.
- Retracta has a helical shape for continuous wall apposition.
- Retracta features an enhanced radiopaque junction for accurate deployment.
- Optional contrast test injection can confirm placement and occlusion.
- It is MR conditional at 3 T.
- Retracta is available in a variety of sizes: diameters from 4-20 mm (even numbers); lengths of 7 and 14 cm, and for a 0.035 inch diameter platform.

Verify fluoroscopic visualization of the detachment zone.

The 8 mm detachment or junction zone, where the Inconel® covered nitinol delivery wire and platinum coil are screwed together, is visible under fluoroscopy and acts as a marker for accurate deployment. The radiopaque junction zone is located where the color transitions between the darker platinum coil and the lighter Inconel covered nitinol mandril. Since the junction should be positioned just inside the catheter tip prior to deployment, the catheter tip also acts as a marker.

Use a detachable coil whose delivery wire conforms to the catheter shape.

Retracta's delivery wire has a flexible 20 cm distal tapered length (Figure 1) to allow the catheter to retain its shape (Figure 2). Delivery friction and retraction friction are minimized without compromising pushability.² The flexible taper helps to keep the catheter tip in its desired position to avoid tip deflection.

Perform an optional contrast test injection to confirm coil placement.

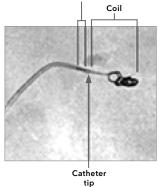
A unique feature of Retracta is its ability to allow the physician to check that coil placement is satisfactory. Once the coil has been placed, contrast medium can be injected through a Tuohy-Borst Sidearm Adaptor to confirm placement. If the coil placement is not satisfactory, the coil can be fully retracted and repositioned. Contrast can be injected again to confirm placement. The coil can then be detached from the wire.

Inconel is a registered trademark of Huntington Alloys Corporation.

2. Data on file based on delivery friction, retraction friction, tensile, and torque testing compliant with applicable Good Laboratory Practices (GLP) requirements. Catheter tip

Junction zone

Coil



Junction

zone

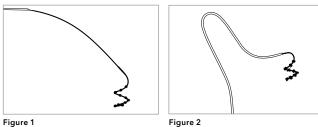


Figure 1

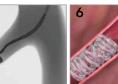


The coil is initially positioned too close to the parent vessel or bifurcation











The coil is repositioned more distally.

The contrast test injection confirms accurate coil positioning.

The coil is detached from the wire.

The contrast test injection confirms that the











Increase occlusive capacity with fiber.

Published animal studies,^{3,4} which were randomized and blinded, are among the first to provide strong evidence supporting what clinicians have long observed: that fibers enhance thrombogenicity. The studies provide strong evidence that incorporating nylon fibers in metallic embolization coils significantly shortens the speed to acute occlusion, significantly reduces the number of devices needed, and significantly reduces the radiation dose delivered when compared to bare-metal coils.

Use Retracta in combination with highly fibered pushable coils.

Using pushable and detachable coils in combination helps you meet both the clinical goal of occlusion and the economic goal of containing costs. This combination approach is useful in procedures where precise control and a high level of thrombogenicity are desired. For safe and precise placement, use the Retracta for the first and last coils and pack tightly in between with highly fibered pushable coils to increase thrombogenicity. Fewer coils are needed to achieve occlusion if the coils are fibered.^{3,4}

Fibered pushable coils that may be used in conjunction with Retracta include:

- Nester Embolization Coils
- Tornado Embolization Coils

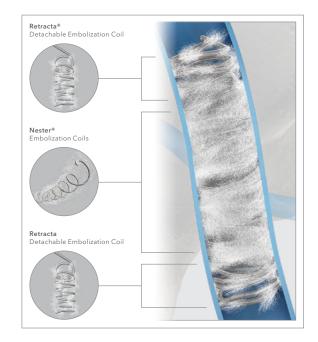
See the Retracta Detachable Embolization Coil in action.

Visit the Retracta product page on the <u>cookmedical.com</u> website to see more detailed information on Retracta.

- 1. Watch the <u>Retracta animation</u> to learn how to use the Retracta Detachable Embolization Coil.
- 2. In this <u>Retracta live case video</u>, a physician effortlessly deploys multiple Retracta coils in a live venous embolization case. Watch his hands and live fluoroscopic images while listening to his commentary.
- 3. The <u>Retracta Deployment Tips video</u> provides helpful notes on the preparation and use of Retracta.
- Fiber on the Retracta coil helps achieve occlusion. Listen to the <u>Fiber Study video</u> where a physician is interviewed about an animal study where the impact of fiber was tested.

- Trerotola SO, Pressler GA, Premanandan C. Nylon fibered versus non-fibered embolization coils: comparison in a swine model. J Vasc Interv Radiol. 2019;30(6):949-955.
- White SB, Wissing ER, Van Alstine WG, Trerotola SO. Comparison of fibered versus nonfibered coils for venous embolization in an ovine model. J Vasc Interv Radiol. 2023;34(5):888-895.













| Order Number | Reference Part Number | Recommended Catheter ID/End Hole Diameter inch | Extended Embolus Length cm | Coiled Embolus Diameter mm | Approximate Number of Loops |
|-----------------|---------------------------|---|----------------------------------|---|-----------------------------------|
| 0.035 inch | Diameter Detachable Coils | | | | |
| G34187 | MWCER-35-7-4 | 0.035 | 7 | 4 | 5.6 |
| G34188 | MWCER-35-7-6 | 0.035 | 7 | 6 | 3.7 |
| G34189 | MWCER-35-7-8 | 0.035 | 7 | 8 | 2.8 |
| G34190 | MWCER-35-7-10 | 0.035 | 7 | 10 | 2.2 |
| G34191 | MWCER-35-7-12 | 0.035 | 7 | 12 | 1.9 |
| G34197 | MWCER-35-14-6 | 0.035 | 14 | 6 | 7.4 |
| G34198 | MWCER-35-14-8 | 0.035 | 14 | 8 | 5.6 |
| G34199 | MWCER-35-14-10 | 0.035 | 14 | 10 | 4.5 |
| G34200 | MWCER-35-14-12 | 0.035 | 14 | 12 | 3.7 |
| G34201 | MWCER-35-14-14 | 0.035 | 14 | 14 | 3.2 |
| G34202 | MWCER-35-14-16 | 0.035 | 14 | 16 | 2.8 |
| G34203 | MWCER-35-14-18 | 0.035 | 14 | 18 | 2.5 |
| G34204 | MWCER-35-14-20 | 0.035 | 14 | 20 | 2.2 |
| Order Number | Reference Part Number | Accepts Catheter Fr | | Accepts Instrumentation Diameter inch | |

| Tuohy-Borst Sidearm Adapter (Optional Accessory for Contrast Injection) | | | | | | |
|---|----------|-----|-------------|--|--|--|
| G06299 | PTBYC-RA | ≤ 9 | 0.014–0.018 | | | |
| | | | | | | |

Some products or part numbers may not be available in all markets. Contact your local Cook representative or Customer Support & Distribution for details.

Retracta[™] Detachable Embolization Coil

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

INTENDED USE: The Retracta Detachable Embolization Coil is intended for arterial and venous embolization in the peripheral vasculature.

CONTRAINDICATIONS: None known

WARNINGS: Positioning of embolization coils should be done with particular care. Coils should not be left too close to the inlets of arteries and should be intermeshed with previously placed coils if possible. A minimal but sufficient arterial blood flow should remain to hold the coils against the previously placed coils until a solid dot ensures permanent fixation. The purpose of these suggestions is to minimize the possibility of loose coils becoming dislodged and obstructing a normal and essential arterial channel. The Retracta Detachable Embolization Coil is not recommended for use with polyurethane 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: Perform an angiogram prior to embolization to determine correct catheter position. • Prior to introduction of the embolus coil, flush the angiographic

catheter with saline. This product is intended for use by physicians trained and experienced in arterial and venous vessel embolization techniques. Standard techniques for placement of vascular access sheaths, angiographic catheters, and wire guides should be employed. See instructions for use for full product information.

AB_T_MWCER_REV2

Customer Service

EU Website: cookmedical.eu

EDI: cookmedical.eu/edi Distributors: +353 61239240, ssc.distributors@cookmedical.com Austria: +43 179567121, oe.orders@cookmedical.com Belgium: +32 27001702, be.orders@cookmedical.com Denmark: +45 38487607, da.orders@cookmedical.com Finland: +358 972519996, fi.orders@cookmedical.com France: +33 171230269, fr.orders@cookmedical.com Germany: +49 6950072804, de.orders@cookmedical.com Hungary: +36 17779199, hu.orders@cookmedical.com Iceland: +354 800 7615, is.orders@cookmedical.com Ireland: +353 61239252, ie.orders@cookmedical.com Italy: +39 0269682853, it.orders@cookmedical.com Netherlands: +31 202013367, nl.orders@cookmedical.com Norway: +47 23162968, no.orders@cookmedical.com Spain: +34 912702691, es.orders@cookmedical.com Sweden: +46 858769468, se.orders@cookmedical.com Switzerland - French: +41 448009609, fr.orders@cookmedical.com Switzerland - Italian: +41 448009609, it.orders@cookmedical.com Switzerland - German: +41 448009609, de.orders@cookmedical.com United Kingdom: +44 2073654183, uk.orders@cookmedical.com

COOK• medical USA Website: cookmedical.com EDI: cookmedical.com/edi.do

Americas:

Phone: +1 812.339.2235, 800.457.4500, Fax: 800.554.8335 E-mail: customersupport@cookmedical.com

Australia:

Phone: +61 734346000, 1800777222, Fax: +61 734346001, 1800077283 E-mail: cau.custserv@cookmedical.com

AI-ESC-IR-OHNS-PI-RH-SUR-A4