



EMBO-COIL™

Embolization Coils

CAUTION: U.S federal law restricts this device to sale by or on the order of a veterinarian

CAUTION: This product is intended for veterinary use only. It is not for human use

DEVICE DESCRIPTION

Embo-Coil™ embolization coils are made of stainless steel with attached synthetic fibers to promote thrombogenicity. Fully formed coil diameters range from 3mm to 8 mm. The Embo-Coil™ is supplied preloaded in a delivery tube. The Embo-Coil™ is delivered to the target vessel by advancing it into a suitable Infiniti Medical delivery catheter and using a floppy tipped guide wire to advance the product.

INTENDED USE

Embo-Coil™ embolization coils are intended to be used in the attenuation of intra hepatic shunts. The product is intended for use by veterinarians experienced in shunt attenuation procedures and familiar with the standard usage of vascular access sheaths, angiographic catheters, guide wires, and the Vet Stent®- Cava.

CONTRAINDICATIONS

Embo-Coil™ embolization coils should not be used in situations that could result in portal hypertension or acute shunt thrombosis.

WARNINGS

- Positioning Embo-Coil™ embolization coils should be done with care. Coils should be placed such that they are entirely constrained by the Vet Stent® - Cava to prevent migration and non-target embolization.
- Periodic portal and central venous pressures should be measured and portograms performed in between successive coil placements to avoid acute shunt thrombosis or the development of portal hypertension.
- Embo-Coil™ embolization coils are recommended for use only with Infiniti Medical catheters. Compatibility with other brands cannot be assured. Side hole catheters must be avoided as the Embo-Coil™ embolization coil may become stuck or deploy prematurely.
- If excessive resistance is encountered while pushing the coil through the delivery catheter discontinue pushing. The catheter and coil may be removed in unison.

PRECAUTIONS

- Perform a venogram prior to embolization to determine correct catheter position.
- Prior to introduction of the embolization coil, flush the angiographic catheter with saline.

PRODUCT RECOMMENDATIONS

- Embo-Coil™ embolization coils are intended to be used with Infiniti Medical 4 Fr Cobra or Berenstein catheters.
- Embo-Coil™ embolization coils are intended to be used with Infiniti Medical .035" Bassett wires.

INSTRUCTIONS FOR USE

1. Perform a venogram prior to embolization to determine optimal catheter position and coil size.
2. Flush delivery catheter with saline prior to loading coil.
3. Firmly grasp the loading cartridge between thumb and forefinger. Introduce the metal end of the loading cartridge into the base of the catheter hub.
4. Maintaining position of the cartridge, advance the stiff portion of the wire into the loading cannula. Push the coil into the first 20 to 30 centimeters of the angiographic catheter.
5. Remove the wire guide and loading cartridge.
6. With the flexible tip of the wire guide, advance the embolization coil to the tip of the catheter. Verify position of the angiographic catheter prior to deployment.
7. Deploy the coil by advancing the wire guide past the tip of the catheter.
8. Perform final venogram to confirm coil position within target vessel.

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.

Infiniti Medical, LLC
525 Middlefield Road, Suite 150
Menlo Park, CA 94025
Tel: (650) 327-5000