

MAGNE-CATH™
MAGENTIC SNARE CATHETER SYSTEM

Contents: One long (main) catheter and one short (mating) catheter. Contents are sterile.

Cautions:

- Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
- Read Instruction before use
- For single patient use only. Reuse of the device could cause infection and/or delivery malfunction. Do not resterilize.
- This device is known to pose hazards in all MR environments.
- Do not use excessive force when manipulating the device. Excessive force may damage the device or vessel.
- Only manipulate this device while under direct fluoroscopic guidance.

Product Description:

The MAGNE-CATH consists of two separate catheters; 1) a long (main) catheter with a preformed extended arm and; 2) a short (mating) catheter. Each catheter is visible under fluoroscopy and has a gold plated magnet at the distal tip for coupling. Both catheters are compatible with a 0.035" guidewire.

Indication for Use:

The Biopsy Sciences MAGNE-CATH is intended for use in the cardiovascular system and hollow viscous to retrieve and/or manipulate objects. Typical procedures include retrieval of foreign objects such as fractured catheters, and manipulation of wires and catheters during bifurcated stent graft placement.

Complications:

The following complications are generally associated with snare retrieval devices and may occur when using the MAGNE-CATH:

- Device entrapment or breakage
- Embolization
- Myocardial infarction
- Pulmonary embolism
- Stroke
- Vessel perforation

Contraindications:

- This device is not intended for removing foreign bodies that have become entrapped by tissue growth.
- This device is not intended for fibrin sheath stripping.
- This device is not intended for removal of implanted pacing leads.
- This device is not intended for use in patients with a pacemaker or defibrillator.

MAGNE-CATH (Figure 1)

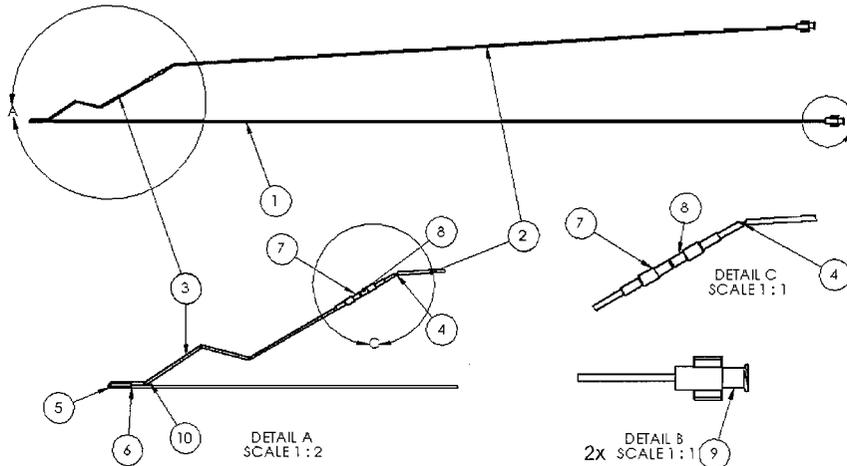


Illustration and Nomenclature:

1. Main Catheter
2. Mating Catheter
3. Extended Arm of the Main Catheter
4. Guidewire Opening of the Mating catheter
5. Main Catheter Lumen
6. Main Catheter distal end (Extended Arm/Main Catheter Joint)
7. Main Catheter Magnet