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The symbols glossary is located electronically at www.argonmedical.com/symbols

Indication for Use

Single-Loop Snare Retrieval Kits and Triple-Loop Snare Retrieval Kits are intended for the percutaneous removal of retrievable inferior vena cava (IVC) filters that are no longer medically required, via jugular approach.

Device Description

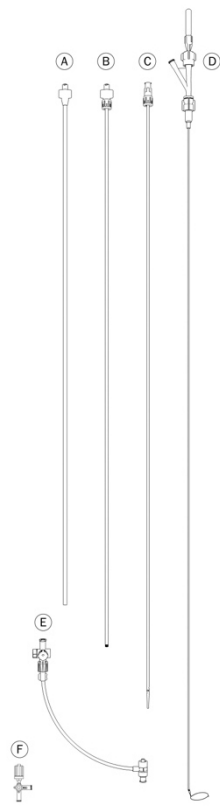
Single-Loop Snare Retrieval Kits and Triple-Loop Snare Retrieval Kits consist of a 9F inner sheath, 11F outer sheath, 8F dilator, hemostasis valve with sideport, stopcock, 20mm single-loop snare (fully expanded) or 30mm triple-loop snare (fully expanded), 7F snare catheter, Tuohy-Borst Y-port adapter, and torque handle. The snares have radiopaque loops and are preloaded in the snare catheter. The snare catheter, inner sheath, and outer sheath have a radiopaque marker band at the distal tip for enhanced fluoroscopic visualization. The maximum recommended infusion rate is 15mL/sec for power injection of undiluted contrast at body temperature through the dilator, outer sheath and stopcock.

This product does not contain natural rubber latex.

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

Contraindications for Use

None known



- A. 11F (ID) x 60cm Outer Sheath
- B. 9F (ID) x 64cm Inner Sheath
- C. 8F (OD) x 75cm Dilator
- D. 7F [2.4mm] (OD) x 76cm Snare Catheter with Tuohy-Borst Y-Port Adapter, 20mm x 93cm Single-Loop Snare or 30mm x 93cm Triple-Loop Snare with Torque Handle
- E. Hemostasis Valve with Sideport
- F. 3-Way Stopcock

Warnings

- Do not use the device or accessories after the expiration date.
- Contents are supplied sterile and are intended for single use only. Do not re-sterilize. Do not use if sterile barrier is damaged.
- Do not continue to use any component damaged during the procedure.
- Do not use excessive force when advancing, retracting, or manipulating kit components and accessories.
- Do not overtighten hub connections.
- Risks and benefits should be carefully assessed in pregnant patients as radiation from fluoroscopic imaging may endanger the fetus.
- Use fluoroscopic guidance when advancing, retracting, or manipulating kit components and accessories in the vasculature.
- Do not remove an IVC filter from patients with heightened risk of pulmonary embolism (PE).
- Do not attempt removal if collapsing the IVC filter will cause thrombus contained within the basket to embolize.
- Do not redeploy a removed IVC filter.
- The side port extension tube of this product contains Di(2-ethylhexyl) phthalate (DEHP) which has been shown to cause reproductive harm in male neonates, pregnant women carrying male fetuses, and peripubertal males. The following procedures have been identified as posing the greatest risk for DEHP exposure: exchange transfusion in neonates, total parenteral nutrition (TPN) in neonates (with lipids in polyvinylchloride (PVC) bag), multiple procedures in sick neonates (high cumulative exposure), heart transplantation or coronary artery bypass graft surgery (aggregate dose), and massive infusion of blood into trauma patient. It is recommended that DEHP-free medical products be considered when these procedures are to be performed on male neonates, pregnant women who are carrying male fetuses, and peripubertal males.

Single-Loop Snare Retrieval Kit – Triple-Loop Snare Retrieval Kit

Precautions

- For use by physicians trained in vascular diagnostic and interventional techniques only.
- Vascular access is necessary to allow retrieval of IVC filters.
- A patient may experience a negative reaction to angiography if the patient is allergic to contrast medium or has compromised renal function.
- Anatomical variances, including spinal deformations, may complicate the removal procedure.
- Avoid entangling a guidewire, sheath or catheter in an IVC filter.
- Consider removing a guidewire entrapped in an IVC filter prior to attempting IVC filter retrieval. An entrapped guidewire may prevent the IVC filter from collapsing sufficiently to fit within the inner or outer sheath.
- Avoid engaging the arms or legs of an IVC filter when using a snare to engage the IVC filter hook.
- If resistance is experienced during removal of a IVC filter, check the captured IVC filter and the retrieval sheath using fluoroscopy.
- It may not be possible to snare a IVC filter hook if it is embedded in the vessel wall.
- Follow all contraindications, warnings, cautions, precautions and instructions for all infusates, including contrast medium as specified by their manufacturer.

Potential Complications

Procedures requiring percutaneous interventional techniques should not be attempted by physicians unfamiliar with the potential complications. These events may be serious in nature and may require hospitalization or intervention to address the condition. Possible complications of Single-Loop Snare Retrieval Kit and Triple-Loop Snare Retrieval Kit usage include, but are not limited to the following:

- Thrombosis
- Pulmonary embolism
- Hematoma
- Perforation of vessels
- Infection
- Hemorrhage
- Cardiac arrhythmia
- Damage to the artery or vein
- Guidewire entrapment
- Caval thrombosis/occlusion
- Insertion site thrombosis
- Extravasation of contrast material at time of imaging
- Hematoma or nerve injury at the puncture site
- Restriction of blood flow
- Stenosis at implant site
- Stroke
- Blood loss
- Pain
- Death

NOTE: It is possible that complications such as those described in the “Warnings”, “Precautions”, or “Potential Complications” sections of this Instructions For Use will affect the recoverability of the device and result in the clinician’s decision to have the filter remain permanently implanted.

Equipment Required

The following equipment is required and not included in the Snare Retrieval Kit to remove an IVC filter:

- Guidewire ≤ 0.038” in diameter and 110cm minimum length
- Vascular access kit
- 8F, 10F, 12F or 14F dilator (optional)
- Contrast medium
- Syringes
- Items for intraoperative sterile technique
- Diagnostic catheter (optional)

Directions for Use

Pre-Procedure Preparation

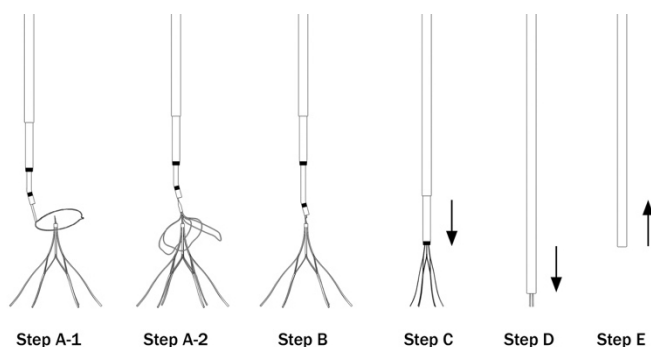
1. Remove all components from packaging using sterile technique.
2. Disassemble the outer sheath from the inner sheath.
3. Using heparinized saline or a suitable isotonic solution, flush the inner sheath, outer sheath, and dilator through their respective hubs, and flush the snare catheter through the Y-port on the Tuohy-Borst Y-port adapter.
Note: Remove the cap on the Y-port prior to flushing the snare catheter.
4. Pull back the torque handle to retract the snare loop into the snare catheter until it is completely inside the catheter.
5. Insert the inner sheath into the outer sheath and connect the gray luer nut to the blue hub, completing the sheath assembly.
6. Insert the dilator through the hemostasis valve on the inner sheath and connect the blue luer nut to the white valve.
7. Prepare and drape the patient for jugular access using standard aseptic technique.

Procedural Steps

8. Insert a guidewire distal to the IVC filter.
9. Pre-dilate the access site and vessel using a series of dilators up to 14F dilator (not included).
10. Insert the dilator and sheath assembly or insert a diagnostic catheter (not included in the kit) over the guidewire until the distal tip is caudal to the IVC filter.
 - a. If injecting contrast medium through the diagnostic catheter or dilator, remove the guidewire.
 - b. If injecting contrast medium through the sideport of the inner sheath, remove the guidewire and dilator, and remove the cap on the sideport and place on the hemostasis valve to avoid leakage.
 - c. If injecting contrast medium injection through the inner sheath, remove the guidewire and dilator, and remove the hemostasis valve and replace with the stopcock.
Note: The hemostasis valve is not designed for contrast medium injection. Contrast medium leaks can occur at the hub.
11. Conduct imaging to determine that the IVC filter, the retrieval route, and surrounding vasculature are free of thrombus. Undiluted contrast medium at body temperature (37°C) can be injected at 15mL/sec.
 - a. If a diagnostic catheter was used for imaging, reinsert the guidewire such that the distal tip protrudes from the diagnostic catheter. Then, remove the diagnostic catheter and insert the sheath assembly over the guidewire until the distal tip is cephalad to the IVC filter.
 - b. If the dilator was used for imaging, remove the dilator. Retract the sheath assembly until the distal tip is cephalad to the IVC filter.
 - c. If the inner sheath was used for imaging, retract the sheath assembly until the distal tip is cephalad to the IVC filter and re-attach the hemostasis valve.

12. While holding the sheath assembly in place, insert the snare catheter through the hemostasis valve on the inner sheath until the snare catheter protrudes out of the distal tip of the inner sheath.
13. Push the torque handle forward until the snare loop(s) fully expands beyond the distal tip of the snare catheter.
14. Under fluoroscopic guidance, advance the single-loop snare (Figure 1, Step A-1) or triple-loop snare (Figure 1, Step A-2) and snare catheter forward until the IVC filter retrieval hook is within the snare loop(s).

Figure 1: IVC Filter Retrieval Using the Single-Loop Snare Retrieval Kit or Triple-Loop Snare Retrieval Kit



15. Under fluoroscopic guidance, hold the snare steady and advance the snare catheter to close the snare loop(s) around the IVC filter hook (Figure 1, Step B).
16. Optional: Tighten the Tuohy-Borst Y-port adapter to temporarily hold the snare, if needed, then tighten the torque handle to secure the IVC filter hook against the distal tip of the snare.
Note: Always maintain tension on the snare to prevent disengagement of the snare loop(s) from the IVC filter hook.
17. Under fluoroscopic guidance, advance the inner sheath until the IVC filter is completely contained within the inner sheath or until significant resistance is felt (Figure 1, Step C).
18. If the IVC filter is not completely contained within the inner sheath, disengage the gray Luer nut of the inner sheath from the blue hub of the outer sheath, and advance the outer sheath, under fluoroscopy guidance, over the IVC filter until it is completely contained within the outer sheath (Figure 1, Step D).
19. Remove the inner sheath, outer sheath, snare, snare catheter, and IVC filter. (Figure 1, Step E).
Note: A follow-up image of the vessel is recommended. If the IVC filter is completely contained within the inner sheath, the inner sheath, snare, snare catheter, and IVC filter may be removed and imaging may be conducted through the outer sheath, using the stopcock to maintain hemostasis.
20. Re-establish hemostasis following hospital protocol.

Disposal

After use, this product may be a potential biohazard. Handle and dispose in accordance with applicable laws and regulations.

Storage

Store at controlled room temperature.