



Expro Elite Snare Instructions For Use



Contents:
One (1) Expro Elite Snare



It is important to read the instructions for use with careful attention to all cautions, notes, and warnings prior to using this product.



STERILE: This device is sterile unless packaging seal has been broken. If packaging seal is compromised, **DO NOT USE.** Return packaging contents to Vascular Solutions address on last page (FOR RETURNED GOODS). Sterilized using ethylene oxide gas.



This device is intended for **SINGLE USE ONLY.**
DO NOT RESTERILIZE AND/OR REUSE.



Product Order Code



Manufacture Identification Number



Expiration Date

English



Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Device Description:

The Snare consists of a moveable central core with a pre-formed loop on the end, which is housed in a .035 outer sheath. The loop can be advanced out of and retracted into the outer sheath by advancing or retracting the central core.

Indications For Use:

The Expro Elite Snare is intended for use in the cardiovascular system and hollow viscous to retrieve and/or manipulate objects using minimally invasive surgical procedures. Manipulation procedures include retrieval and/or repositioning of intravascular foreign objects such as coils, balloons, catheters and/or guidewires within the cardiovascular system.

Contraindications:

This device is not intended for removing foreign bodies that have become entrapped by tissue growth.

Storage:

Store the Expro Elite™ Snare in a cool, dark, dry area at a controlled room temperature.

Warnings:

This device is not intended for removing foreign bodies that have become entrapped by tissue growth. This device should not be used for fibrin sheath stripping in the presence of septal defects of Persistent Foramen Ovale. This device is not intended for removal of implanted pacing leads. Pull forces applied to catheters during fibrin sheath stripping may damage, stretch, or break indwelling catheters 6 French or smaller in diameter. Do not use excessive pull force when attempting fibrin sheath stripping of catheters 6 French or smaller in Diameter.

Precautions:

Caution should be observed when using this device for removal of a large fibrin sleeve in order to minimize risk of pulmonary embolism.

Adverse Reactions:

Testing has indicated that indwelling catheter damage could occur when attempting fibrin sheath stripping on small bore catheters (See Warnings.) One incident of pulmonary embolism after fibrin sheath stripping has been published (See Precaution.)

Preparations For Use:

Select the appropriate size Snare for the location in which the foreign body is located. In general, the Snare loop should approximate the size of the vessel in which it will be used.

Remove the Snare from the protective holder and inspect for any damage. Inspect device by extending and retracting the snare loop through the distal end of outer sheath 2-3 times, while carefully examining the sheath, radiopaque marker band and snare for defects or damage.

Snare Assisted Manipulation/Retrieval:

1. Retract the snare loop into the outer sheath.
2. Introduce the snare into the patient through a catheter that accommodates a .035 guidewire.
3. Position the snare proximal to the foreign body.
4. Advance the central core gently to completely open the loop. Slowly advance the Snare until the loop is around the proximal end of the foreign body. The Snare loop may be rotated by turning the central core to facilitate capture.
5. By advancing the Snare outer sheath, the loop of the Snare is closed to grab the foreign body. (Note that attempting to close the loop by pulling the Snare back within the outer sheath will move the loop from its position around the foreign body.)
6. To manipulate a foreign body, maintain tension between the central core and outer sheath to retain the hold on the foreign body, and move the Snare and outer sheath together to manipulate foreign body to the desired position.
7. To retrieve a foreign body, maintain tension between the central core and outer sheath and move the Snare and outer sheath together (proximally) to or into the guide catheter or sheath. The foreign body is then withdrawn through or together with the guiding catheter or vascular sheath. Withdrawal of large foreign bodies may require the insertion of larger sheaths, guiding catheters, or a cut down at the peripheral site.

Snare Assisted Removal of Fibrin Sheaths From Indwelling Catheters:

1. From a common femoral vein approach, advance the selected Snare to the inferior vena cava or right atrium.
2. Advance an .035 inch guidewire through the port (distal or venous port if more than one lumen) of the indwelling catheter and into the right atrium or inferior vena cava.
3. Encircle guidewire with the Snare loop.
4. Advance the Snare over the distal end of the catheter to a position proximal to the fibrin sheath.
5. Close the Snare around the catheter and continue applying light traction while gently pulling the Snare down (towards distal end of catheter) over the port(s).
6. Repeat steps 4 & 5 until the catheter is free of fibrin sheath.

Snare Assisted Venous Canalization:

1. Introduce the Snare at a patent venous access site and position in the vasculature at the desired venous access site.
2. Open Snare loop to provide a target to guide a puncture into the desired venous access site.
3. Introduce guidewire through needle and through Snare loop.
4. Close Snare over needle by advancing outer sheath.
5. Pull the guidewire into inferior vena cava.

DISCLAIMER OF WARRANTY

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