EN Snare®

INSTRUCTIONS FOR USE

MERITMEDICAL®

English

EN Snare®

INSTRUCTIONS FOR USE

INDICATION FOR USE:
The *EN* Snare® Endovascular Snare System is intended for use in the cardiovascular system to retrieve and manipulate foreign objects. Retrieval and manipulation procedures include indwelling venous catheter fibrin sheath stripping.

DESCRIPTION:
The *EN* Snare® system consists of three interlaced, cabled, super-elastic Nitinol, preformed loops. The super-elastic Nitinol construction enables the loops to be introduced through catheters without the risk of device deformation.

WARNINGS:
1. This device is not intended for the removal of foreign objects entrapped by tissue growth. Excessive force used to remove entrapped foreign bodies may lead to device failure.
2. This device should not be used for fibrin sheath stripping in the presence of septal defects of Persistent Foramen Ovale.
3. This device is not intended for removal of implanted pacing leads.
4. 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.
5. Do not use excessive force when manipulating the catheter through an introducer, or when manipulating the snare device. Excessive force may lead to device failure.
6. This device has been sterilized utilizing Ethylene Oxide and is considered sterile if the package is not opened or damaged. It is intended for Single Patient Use Only. Do not attempt to clean or re-sterilize the device. After use this device may be a potential biohazard. Handle in a manner that will prevent accidental contamination. Do not use a device that has been damaged or if the package is open or damaged.
7. For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or crossinfection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
8. Nitinol is a nickel titanium alloy. Possible reaction may occur for those patients who exhibit sensitivity to nickel.

℞ Only: CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

Do not use if package is damaged and consult instructions for use.

Non-pyrogenic

PRECAUTION: Care should be observed when using this device for removal of a large fibrin sheath in order to minimize risk of pulmonary embolism.

POTENTIAL COMPLICATIONS:
1. Potential complications associated with foreign body retrieval devices in arterial vasculature include, but are not limited to:
   - Embolization
   - Stroke
   - Myocardial infarction (depending upon placement)
2. Potential complications associated with snare retrieval devices in venous vasculature include, but are not limited to:
   - Pulmonary embolism
3. Other potential complications associated with foreign body retrieval devices include, but are not limited to:
   - Vessel perforation
   - Device entrapment
   - Hemorrhage
   - Soft tissue injury
   - Arrhythmia
   - Vascular dissection

Catheter damage can occur when attempting fibrin sheath stripping on small French size diameter catheters. (See WARNINGS) Incidence of pulmonary embolism after fibrin sheath stripping may occur. (See PRECAUTION).

Prepare the *EN* Snare® System:
Select the appropriate Snare diameter range for the site in which the foreign body is located. The Snare diameter range should approximate the size of the vessel in which it will be used.
1. Remove the Snare and Snare Catheter from their hoop holders and inspect for any damage.
2. Remove the Insertion Tool and Torque Device from the proximal end of the snare shaft.
3. Load the Snare into the Snare Catheter by inserting the proximal end of the snare into the distal (non-hubbed) end of the Snare Catheter, until the proximal end of the Snare shaft exits the hub and the loops can be retracted into the distal end of the Snare Catheter.
4. Test and inspect the device by extending and retracting the snare loops through the distal end of the snare catheter 2-3 times, while carefully examining the Snare Catheter and the device for any damage or defects.
5. When appropriate, the system (Snare and Snare Catheter) can be advanced to the desired site as a single unit assembled as described above).

Alternative Preparation of the *EN* Snare®:
If the Snare Catheter is already positioned within the vasculature, the provided Insertion Tool (located on the proximal end of the Snare and just distal to the Torque Device) may be used to position the Snare in the indwelling Snare Catheter.
1. Remove the Snare from the protective holder and inspect for any damage.
2. Move the provided Insertion Tool distally until the loops of the Snare are enclosed within the tubing portion of the Insertion Tool.
3. Insert the distal end of the Insertion Tool into the hub of the indwelling Snare Catheter until resistance is felt. This will indicate the tip of the Insertion Tool is properly aligned with the inner lumen.
4. Hold the Insertion Tool as straight as possible, grasp the shaft of the Snare just proximal to the hub of the Insertion Tool and advance the Snare until it is secure within the lumen of the Snare Catheter. The insertion tool can be removed by grasping the blue tab and firmly peeling it away from the snare shaft.

Snare Assisted Retrieval and Manipulation Suggestions:
1. If present, remove the indwelling delivery catheter.
2. If a guidewire is in a patient at the location of a foreign body, advance a snare catheter over the guidewire to the desired location. Then remove the guidewire and advance the snare through the snare catheter. Alternatively, cinch one loop of the snare over the proximal end of the guidewire and advance the entire system (snare and snare catheter assembly) into a guide catheter or introducer sheath until the distal end of the snare catheter is positioned proximal to the foreign body.
3. If a guidewire is not present, pull the snare into the distal end of the snare catheter and advance through a guide catheter or introducer sheath until it is positioned proximal to the foreign body. Alternatively, collapse the snare loop by pulling the device into the distal end of the snare insertion tool. Place the tapered end of the snare insertion tool into the proximal (hub) end of the snare catheter, guide catheter or sheath and advance the snare forward maintaining constant contact between the insertion tool and snare catheter hub. NOTE: When attempting to utilize guide catheters or sheaths not specifically manufactured for use with the *EN* Snare® system, it is important to test product compatibility prior to use.
4. Gently push the Snare shaft forward to completely open the loops. The loops are then slowly advanced forward, and may be rotated if desired, around the proximal end of the foreign body. Alternatively, the Snare may be advanced beyond the target location and the loops brought back around the distal end of the foreign body.
5. By advancing the Snare Catheter, the loops of the device are closed to capture the foreign body. (Note that attempting to close the loops by pulling the Snare into the Snare Catheter will move the loops from their position around the foreign body.)
6. To manipulate a foreign body, maintain tension on the Snare Catheter to retain the hold on the foreign body, and move the Snare and Snare Catheter together to manipulate a foreign body to the desired position.
7. To retrieve a foreign body, maintain tension on the Snare Catheter and move the Snare and Snare Catheter assembly together proximally to, or into a guide catheter or sheath. The foreign body is then withdrawn through or together with the guiding catheter or introducer 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. Using standard technique, prepare a femoral vein approach, advance the selected Snare to the inferior vena cava or right atrium.
2. Advance a .035" guidewire through the end port (distal or venous port if more than one lumen) of the indwelling catheter and into the inferior vena cava or right atrium.
3. Position one of the Snare loops around the guidewire.
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 toward the distal end of the catheter over the end ports.
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 site.
2. Open the Snare loops to provide a target to guide an entry needle into the desired venous access site.
3. Introduce a guidewire through the needle and through the Snare loops. Remove the needle.
4. Close the Snare over the guidewire by advancing the Snare Catheter.
5. Pull the guidewire into the desired location.

EN Snare® FOREIGN BODY RETRIEVAL DEVICE SYSTEM*

Description	Snare Diameter Range	Snare Length	Catheter Size	Catheter Length
Mini *EN* Snare System	2-4 MM	175 CM	3.2 F	150 CM
Mini *EN* Snare System	4-8 MM	175 CM	3.2 F	150 CM

Description	Snare Diameter Range	Snare Length	Catheter Size	Catheter Length
EN Snare System	6-10 MM	120 CM	6 F	100 CM
EN Snare System	9-15 MM	120 CM	6 F	100 CM
EN Snare System	12-20 MM	120 CM	6 F	100 CM
EN Snare System	18-30 MM	120 CM	7 F	100 CM
EN Snare System	27-45 MM	120 CM	7 F	100 CM

* Every *EN* Snare System contains: (1) Snare, (1) Snare Catheter, (1) Insertion Tool and (1) Torque Device.

MERITMEDICAL®

CE 2797

www.merit.com

Manufacturer:
Merit Medical Systems, Inc.
1600 West Merit Parkway, South Jordan, Utah
84095 U.S.A. 1-801-253-1600
U.S.A Customer Service 1-800-356-3748

EC REP

Authorized Representative:
Merit Medical Ireland Ltd, Parkmore Business
Park West, Galway, Ireland
EC Customer Service +31 43 3588222

380098009_002 ID 2020-02-26