ARGON
MEDICAL DEVICES

Halo™ Single-Loop Snare Kit

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

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Intended Use/Purpose
This kit is intended for foreign body manipulation and retrieval.

Device Description:
The Single-Loop Snare Kit consist of a snare, snare catheter, introducer, and torque handle. The snare is constructed of a nitinol cable and gold-plated tungsten loop. The snare can be inserted through a snare catheter without risk of deformation because of the snare's super-elastic construction. The snare catheter contains a platinum-iridium radiopaque marker band. The device is not made with natural rubber latex.

Indication for Use:
The Single-Loop Snare Kit is intended for use in the cardiovascular system or hollow viscus to retrieve and manipulate foreign objects.

Contraindications:
- This device should not be used for fibrin sheath stripping in the presence of septal defects or patent foramen ovale.
- This device is not intended for removal of implanted pacing leads.

Warnings:
- Do not use the device after the expiration date.
- The device is provided sterile. Do not use if the sterile barrier is broken (i.e., the device is damaged, or the package is opened or damaged prior to use).
- The device is for single-use only. Do not reuse, reprocess, or re-sterilize.
- Failure to use fluoroscopic guidance when advancing, retracting, or manipulating kit components in the vasculature may lead to foreign body dislodgement or damage to surrounding vasculature.
- Do not use excessive force when advancing, manipulating, or retracting kit components.
- This device contains nitinol, an alloy of nickel and titanium. Persons with allergic reactions to these metals may suffer an allergic reaction to this device. Patients should be counseled on the materials contained in the device, as well as potential for allergy/hypersensitivity to these materials.

Precautions:
- For use by physicians trained in vascular diagnostic and interventional techniques only.

Potential Complications:
Potential complications associated with snare retrieval devices in arterial vasculature include, but are not limited to:
- Embolization
- Stroke
- Myocardial infarction

Potential complications associated with snare retrieval devices in venous vasculature include, but are not limited to:
- Pulmonary embolism

Other potential complications associated with foreign body retrieval devices include, but are not limited to:
- Vessel injury
- Vessel perforation
- Device entrapment

Pre-Procedure Preparation
External Snare Assembly:
Select the appropriate snare diameter that approximates the vessel size in which the foreign body is located.

1a. Remove the snare and snare catheter from their packaging hoops and inspect for damage.
2a. Flush the catheter prior to use.
3a. Remove the introducer and torque handle from the proximal end of the snare shaft.
4a. Load the snare into the snare catheter by inserting the proximal end of the snare shaft into the distal end (non-hubbed end) of the snare catheter, until the proximal end of the snare shaft exits the hub of the snare catheter and the snare loop is retracted into the distal end of the snare catheter.
5a. Extend and retract the snare loop through the distal end of the snare catheter 2-3 times, while carefully inspecting the device for any damage.

Alternate Snare Assembly:
If the snare catheter is already positioned within the vasculature, the provided introducer may be used to insert the snare in the snare catheter. If the snare catheter is positioned over a guidewire, remove the guidewire before proceeding.

1b. Remove the snare, with introducer, from the packaging hoop and inspect for damage.
2b. Move the introducer distally until the snare loop is enclosed within the tube of the introducer.
3b. Insert the distal end of the introducer into the hub of the snare catheter until resistance is felt (i.e., the introducer is properly aligned with the inner lumen of the snare catheter).
4b. Hold the introducer straight and grasp the snare shaft just proximal to the hub of the introducer, then advance the snare until the snare loop is secure within the lumen of the snare catheter.
5b. Remove the introducer by gripping the tab and pulling away from the snare shaft.

Directions for Use
Snare Assisted Manipulation and Retrieval:

1. If the external snare assembly was used, retract the snare loop into the snare catheter and advance the assembly into the guide catheter or sheath until the distal end of the snare catheter is just proximal to the foreign body. Alternatively, if a guidewire is present, cinch one loop of the snare over the proximal end of the guidewire and advance the snare and snare catheter into the guide catheter or sheath until the distal end of the snare catheter is just proximal to the foreign body.
2. If the alternate snare assembly was used, advance the snare through the snare catheter until the snare is just proximal to the distal end of the snare catheter.
3. Advance the snare distally to expose the snare loop. Then slowly advance the snare loop around the foreign body.
4. Hold the snare stationary and advance the snare catheter distally to close the snare loop around the foreign body.
5. To manipulate the foreign body, maintain tension on the snare catheter to maintain a hold on the foreign body, and move the snare and snare catheter together to the desired foreign body position.
6. To retrieve the foreign body, maintain tension on the snare catheter and move the snare and snare catheter together, proximally, to or into the guide catheter or sheath. Then, withdraw the foreign body through or together with the guide catheter or sheath. Withdrawal of large foreign bodies may require the insertion of larger guide catheters or sheaths, or a cut down at the peripheral site.

Disposal
- After use, handle and dispose in accordance with hospitals policies and procedures concerning biohazard materials and waste.

Storage Conditions:
- Store at controlled room temperature.