MULTI-SNARE® SET MULTI-SNARE® MICRO SET





Do not resterilize







(LATEX)









Consult instructions for use



only





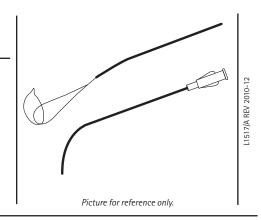
damaged







STERILE EO Sterilized using



Instructions for Use:

Contents of unopened, undamaged package are: STERILE • NONPYROGENIC

Disposable - This device is intended for one use only. Do not reuse or resterilize. Sterilized with Ethylene Oxide.

Caution:

Carefully read all instructions prior to use. Observe all warnings and cautions. Failure to do so may result in complications.

General Information and Warnings:

The product described here may be used only by specialist physicians who are familiar with the techniques used in diagnostic and interventional cardiology. These instructions for use and the information on the packaging should be read carefully before each use.

Federal Law (USA) restricts this device to use by a physician.

Warnings:

- Do not use the product if the packaging has been opened, or is damaged, if you are not sure that it is sterile, or if the expiry date has passed.
- Each product is packed separately, and is delivered in an EO sterilized and pyrogen-free condition. It is intended for single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization of medical devices intended for single use only may result in degraded performance or a loss of functionality. Reuse of single use only medical devices may result in exposure to viral, bacterial, fungal, or prionic pathogens.
- The product must be stored in a dry place. Do not expose the packaged products to direct sunlight.

Device Description:

The Multi-Snare® and the Multi-Snare® Micro are medical devices. They merely differ because of their dimensions. They are made out of a super elastic Nitinol wire, wrapped with a thin, radiopaque Platinum wire around the distal pre-formed loop. A PTFE tube is shrunk on the proximal shaft of this loop to ensure good torqueability. The super elastic characteristics and the shape memory effect of the Nitinol material allow the snare to be inserted through the B. Braun Interventional Systems Inc. snare catheter or through another catheter (check compatibility prior to use) to the region of interest without any risk of deformation.

Depending on the position of the snare catheter's tip the diameter of the loop is variable in a predetermined range (see label). Both Multi-Snare® and Multi-Snare® Micro are available as a set including the snare catheter. For better radiopacity a radiopague marker is located distally on the snare catheter shaft.

An insertion aid is provided to ease the guidance of the snare into the catheter. The provided torquer eases the handling of the product. The Multi-Snare® Micro is available with diameters of 2 and 4 mm and in the length of 175 cm, whereas the standard Multi-Snare® is offered from 5 to 30 mm in diameter and in the length of 125 cm. Please refer to the product label for exact dimensions, designs and compatibility with other devices.

Indications for Use:

The Multi-Snare® Set (and its components) is intended for:

- Retrieval and manipulation of foreign objects from the vascular system and hollow viscera.
- Assistance in creating loops where cross-over technique is applied.
- Reposition of indwelling venous catheters.
- Assistance in performing venipuncture to obtain access to central vein.

Contraindications

The snare may not be used

- For removal of foreign bodies that have become entrapped by tissue overgrowth
- For removal of implanted pacing leads

Possible Complications

- Air embolism
- Death
- Hematoma at the puncture site
- Infection
- Perforation of the vessel wall
- Pulmonary embolism because of "lost" fibrin sheath material, especially when the fibrin sheath is long and big

Directions for use

Selection of the snare, and preparation

The maximum snare diameter (see label) should not exceed the targeted vessel diameter. Remove the snare from the protective transport dispenser. Take care that the proximal end of the snare does not cross the mark on the connected insertion aid. Carefully inspect snare (and snare catheter) for any damages.

Note: It is recommended to use the B. Braun Interventional Systems Inc. Multi-Snare® or Multi-Snare® Micro together with the B. Braun Interventional Systems Inc. snare catheter.

Note: Prior to use thoroughly flush the snare catheter, and the Multi-Snare® / Multi-Snare® Micro with sterile heparinized saline solution. An additional systemic application of heparin is recommended.

Introduction

Disconnect the insertion aid from the transport dispenser, and connect it with the snare catheter or another suitable catheter.

Note: We advise you that the insertion aid was specially optimized for the compatibility with the B. Braun Interventional Systems Inc. snare catheter.

Insertion without guidewire

The snare catheter is inserted into the human body via an introducer sheath or a big vascular cannula with hemostatic valve.

Insert the snare using the insertion aid provided into the snare catheter which is already positioned in the vascular system, and place it proximally to the foreign body. For an eased manipulation and torqueability of the snare the provided torquer should be mounted at the proximal end of the Multi-Snare®.

In general it is recommended to insert first the snare catheter to the region of interest. It is also possible to introduce the snare catheter with the preloaded snare as a unit.

Insertion over a guidewire

Note: Check whether the guidewire or guiding catheter has the necessary diameter, and length to accommodate the snare. Position the indwelling guidewire as close as possible to the foreign body. Place the snare loop over the proximal end of the guidewire, and pull tight. Advance the snare into the guiding catheter or vascular cannula until the distal end of the snare catheter is positioned just proximal to the foreign body.

Manipulation/Extraction of foreign objects

- Push the snare shaft carefully forward to open the loop. The open loop is then slowly advanced forward and placed around the proximal end of the foreign body. The diameter of the snare can be adjusted within the determined limits by moving the snare catheter forward or backward.
- 2 By advancing the snare catheter, the snare loop is closed around the foreign body, and the foreign body is trapped.

WARNINGS: Pulling back the snare can change the position of the snare loop.

- 3 To manipulate a foreign body, maintain tension on the snare catheter to retain the hold on the foreign body. Move the snare, and the snare catheter as a unit, in order to manipulate the foreign body to the desired position.
- ◆ To remove the foreign body, maintain tension on the snare catheter, and pull the snare and the snare catheter as a unit to the tip of the guiding catheter or introducer sheath. The foreign body is then withdrawn through or together with the guiding catheter or introducer sheath. The withdrawal of larger foreign bodies may require the exchange with larger sheaths, or guiding catheters, or a comminution of the foreign body in the peripheral vascular system.

Snare Assisted Venous Canalization

- Introduce the snare at a patient venous access site, and position it at the new, desired venous access site in the vascular system.
- ② Open the snare loop. The opened loop functions as a target to guide the puncture at the desired venous access site.
- 3 Insert the guidewire through the cannula and the opened snare loop.
- 4 Pull the snare tight around the cannula by advancing the snare catheter.
- **⑤** Pull the guide wire into the inferior vena cava.

Disposal after Use

After use, medical products and accessories pose a potential biological hazard. For this reason, the products and their accessories should be handled and disposed of in accordance with recognized medical procedure, and in compliance with the relevant legal regulations and local ordinances.



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