Version: C

Effective date: 2025-02-25

V-HaloSnare® Peripheral Vascular Snare

Instruction for Use

(Please read this manual carefully before use, paying special attention to all warnings and precautions)

Shanghai EndoVas Medical Technology Co., Ltd.

V-HaloSnare® Peripheral Vascular Snare

Shanghai EndoVas Medical Technology Co., Ltd.

CE 2764

Instruction for use for Peripheral Vascular Snare

Please read the instruction carefully before using this product. If not operated correctly according to instructions, warnings, and precautions, it may result in serious surgical consequences or cause serious harm to patients.

Note: The product is for peripheral use only. Not for use in cardiology

【Product Components】

The Peripheral Vascular Snare consists of a snare, snare catheter, introducer, and torque handle. The snare is consisted mainly of raw materials of gold-plated tungsten wire, nickel-titanium alloyand PTFE; The snare catheter is consisted mainly of raw materials of HDPE containing barium sulfate、 HDPE、 Ta development loop; The introducer is consisted mainly of raw materials of HDPE, it guides the snare smoothly into the snare catheter. The torque serves to assist in the twisting of the catheter.

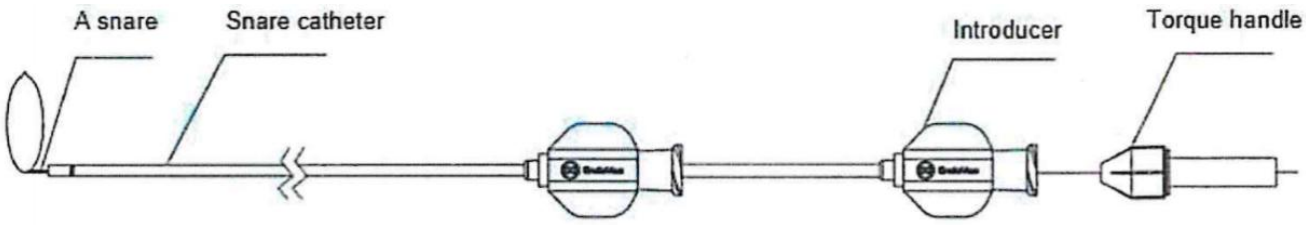

Figure1. Peripheral Vascular Snare

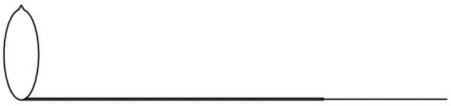

Figure 2. Snare

Figure 3. Snare catheter

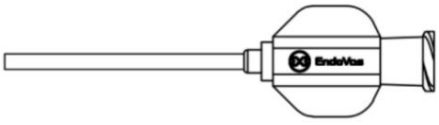

Figure 4. Introducer

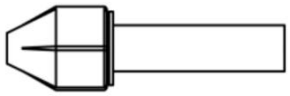

Figure 5. Torque handle

【Specification】

Product specification list is shown below:

Model	Loop Diameter D1(mm)	Loop width W(mm)	Snare Length L1(mm)	Catheter Specification	Catheter Length L3(mm)
G-15	15	18	1200	6	1050
G-20	20	23	1200	6	1050
G-25	25	28	1200	6	1050
G-30	30	33	1200	6	1050
S-15	15	18	800	6	650

【Intended Purpose】

The Peripheral Vascular Snare is intended for foreign body manipulation and retrieval.

【Intended User】

This product shall be used by skilled surgeon and trained nurses. The qualified surgeons trained on the operation of Peripheral Vascular Snare, experienced in surgical operation and fully understood the Instructions for use prior to operate.

【Indication】

The Peripheral Vascular Snare is intended for capturing and controlling foreign objects in peripheral blood vessels through a catheter. Peripheral blood vessels include but are not limited to the aorta, iliac artery, iliac vein, femoral artery, femoral vein, popliteal artery, popliteal vein, superior vena cava, inferior vena cava, etc.

【Patient target groups/patient population】

Patients with foreign objects in the peripheral blood vessels may require a retrieval device, including but not limited to filters, dislodged stents, balloons, guide wires, etc., as determined by the doctor.

【Contraindications】

- Cannot be used to remove foreign objects that have become embedded in body tissue.
- Cannot be used to remove foreign objects entangled in tissue growth.

- Cannot be used to remove fibrous sheaths.
- Cannot be used in patients who do not tolerate contrast media.
- Cannot be used to remove implanted pacing wires.

【Warnings】

- The product must be used within the valid life.
- Before use, the product and packaging should be inspected, if the packaging is damaged or the product is damaged, it should not be used further. If the package is damaged or the product is damaged, it should not be used further and should be replaced or returned to the manufacturer in a timely manner.
- Read the instructions carefully before use and follow the intended use.
- It should be used by a specially trained physician or team.
- Excessive force exerted during the capture and control of foreign objects may result in damage to the snare, and there is a risk of detachment of the gold plating of the snare's ferrule. There is a risk of the gold plating on the trap's ferrule coming off.
- Do not reuse and do not use for secondary sterilization. Reusing the devices may lead to cross - infection, device malfunction, and compromised patient safety due to potential damage and inadequate sterilization.
- Dispose of the product and packaging after use in accordance with the policy.
- This device contains a nickel-titanium alloy and may cause allergic reactions in patients who are allergic to nickel ions. This device contains a nickel-titanium alloy. Patients should be informed about the materials contained in the device and the potential for allergy/hypersensitivity to these materials.
- Failure to use a visual guide when advancing, withdrawing, or manipulating a Peripheral Vascular Snare in the cardiovascular system may result in foreign body displacement or damage to the peripheral vascular system.

【Clinical side effects/Possible complications/Undesirable effects】

Potential complications that may exist with the use of the product in arterial vessels include, but are not limited to:

- Embolism
- Stroke
- Myocardial infarction

Potential complications that may exist with the use of the product in venous vessels include, but are not limited to:

- Pulmonary embolism

Other potential complications of using the product include, but are not limited to:

- Vascular injury
- Vascular perforation
- Instrument residue

【Main performance criteria】

- Sealing strength is ≥2.25N per test strip.
- There should be no leakage of liquid from the conduit seat (luer fitting) or connecting assembly or from other parts of the conduit; air should not enter the conduit seat (luer fitting) assembly during continuous suction.
- Smoothly passes through all parts of the vascular simulation.
- Should be sterile. (Use ethylene oxide sterilised bioculture indicator).

【Summary of the product's safety criteria】

The snare is made of nitinol alloy materials, which has excellent biocompatibility. This ensures that it causes minimal adverse reactions when in contact with the body's tissues and blood, reducing the risk of inflammation, allergic responses, and thrombosis. It features a smooth - surfaced, gentle curve of the snare helps prevent damage to the vascular endothelium during insertion and manipulation, minimizing the risk of vessel perforation or dissection. In addition, the snare wire is designed to be flexible yet strong, with good tensile strength to avoid breakage during use, which could lead to retained fragments in the body.

【Accessories not included but necessary for use】

There are no accessories for Peripheral Vascular Snare.

【Devices related to the surgical technique】

- Catheter sheath
- Guidewire
- Imaging device

【Application steps】

- Preoperative Preparation

1. The snare system should be used in conjunction with an appropriately sized catheter sheath to grasp the foreign body in the target vessel. The inner diameter of the catheter sheath should be > 2.1 mm, and the

inner diameter of the target vessel should be close to the diameter of the catcher sleeve.

2. Remove the catcher, introducer sleeve, torque and catcher catheter from the coil and inspect for damage.

3. Flush the catheter with saline before use.

4. Recover the catcher ferrule into the guide sleeve (between the proximal end of the catcher and the torque), verifying that the catcher ferrule is located at the distal (non-rule) end of the guide cannula.

5. With the distal end of the guide sleeve aligned with the proximal (luer) end of the catcher tubing, insert the catcher ferrule into the tubing.

6. Torque to the catcher, taking care that the fixing position does not press against the polymer covering on the proximal end of the catcher.

7. Release and retrieve the snare collar 2-3 times at the distal end of the catcher tubing while carefully inspecting the snare collar, catcher tubing for carefully inspect the trap collar and catcher tubing for damage.

- Optional Procedures

1. If the snare catheter has been placed in the vessel, the catcher can be inserted into the catheter through the introducer cannula. If the catheter If a guide wire is present in the catheter, remove the guide wire before continuing to use the catcher.

2. Remove the catheter from the coil and inspect for damage.

3. Push the guide sleeve toward the distal end until the catcher ferrule is placed inside the guide sleeve.

4. Insert the distal end of the guide sleeve into the luer fitting of the catcher conduit until resistance is felt, at which point the guide sleeve is aligned with the inner lumen of the conduit. The guide sleeve is aligned with the inner lumen of the catcher tubing.

5. Keeping the guide sleeve straight, slowly advance the catcher into the inner lumen of the catheter, removing the guide sleeve if necessary. If it is necessary to remove the guide sleeve at this time, remove the torque before removing the guide sleeve.

- Snare-assisted maneuvering/retrieval

1. To move the indwelling balloon or delivery catheter, it may be necessary to replace or extend the indwelling guide wire to facilitate balloon movement and increase the size of the indwelling catheter to accommodate the grapple. If an indwelling balloon or delivery catheter needs to be moved, it may be necessary to replace or extend the indwelling guide wire to facilitate balloon movement and increase the size of the indwelling catheter to accommodate the grapple.

2. If the guide wire is left in the foreign body area of the patient's body, advance the catheter or sheath by holding the proximal end of the catcher wire until the distal end of the catheter catheter is in place. the distal end of the catheter is close to the foreign body.

3. if no guide wire is present, pull the catcher into the distal end of the catheter and advance it until it is in close proximity to the foreign body.

4. gently advance the catcher wire until the trap is fully open and slowly advance the trap to capture the proximal end of the foreign body, with a cap of 10 trap releases. The maximum number of trap releases is 10 times.

5. Push in on the catcher tube and the ferrule closes to capture the foreign object. (Note that pulling the catcher inside the catcher tube to close the trap will cause the trap to close. (Note that pulling the catcher inside the catcher tube to close the ferrule will displace the ferrule at the foreign object location.)

6. To move the foreign object, maintain tension on the catcher tubing to hold the object while moving the catcher and tubing to bring the object to the designated location. To move the foreign object, maintain tension on the catcher tubing to hold the object while moving the catcher and tubing.

7. To grasp a foreign body, maintain catheter tension to hold the foreign body while moving the catcher and catheter into the introducer tube or vascular sheath. The foreign body is then taken into the introducer tube or vascular sheath. The foreign body is then brought into the introducer catheter or vascular sheath. The removal of larger foreign bodies requires placement of a larger vascular sheath or introducer. A larger vascular sheath or introducer catheter or some peripheral reduction is required for removal of larger foreign bodies.

【Shelf life and storage condition】

- This product is sterilized by ethylene oxide and is valid for three years.
- Manufacture date and expiration date refer to label.
- Avoid sunlight and store at room temperature in a dry place.
- Storage temperature: 10℃~30℃; Storage humidity: 10%~60% .

【Packaging】

- The product is supplied in a sterile state.
- Product components are fixed and protected in coil and packaged in single layer Tyvek® dialysis bags for sealing.

【Sterilization】

This product is sterilized by ethylene oxide and shall not undergo secondary sterilization. The sterilization method of this product is ethylene oxide sterilization, Tyvek® bag is recognized in the industry suitable for ethylene oxide sterilization packaging materials. The Tyvek® bag is suitable to ethylene oxide sterilization

method.

【Post sale service】

Contact with our company if there are any questions.

【Declaration】

The peripheral vascular snare is for single use and should not be reused. The Company shall not be responsible for any damage to the product or failure of the procedure due to reuse, improper selection of product specifications, operational errors, or any other human-caused accidents.

Shanghai EndoVas Medical Technology Co., Ltd.

Building 3, No.356, Zhengbo Road, Pilot Free Trade Zone Lingang Special Area, Shanghai, China

pearl.ding@endovasmedical.com

+86 13774226625

EC REP

Lotus NL B.V.

Koningin Julianaplein 10, le Verd, 2595AA, The Hague, Netherlands

+31644168999

Explanation of Symbols and Abbreviations Used on Product Labels

	Manufacturer
	Date of manufacture
	No secondary sterilization
	Do not re-use
	Batch code
	Consult instructions for use
	Use-by date
	Do not use if package is damaged
	Medical Device
	Sterilized using ethylene oxide
QTY：1	Quantity
	Keep Dry
	Avoid Sunshine
	Notified Body, and product meet the basic requirements of MDR 2017/745

