CE 2797

MemoPart™ Snare
Instruction for Use

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SHSMA
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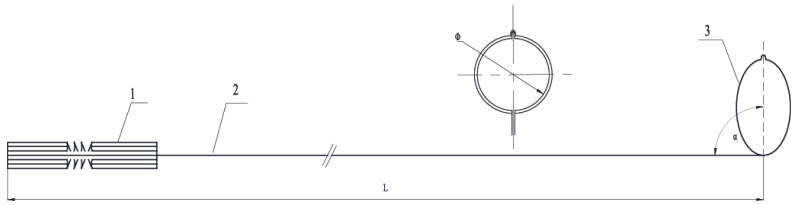
Read "Instruction for Use" carefully before use, Users should have the interventional treating practice or be guided by professionals

- Use before the last day of the expiration noted on the product packaging
- This device is sterilized using ethylene oxide and is for single use only. Do not reuse or resterilize. Attempts to resterilize the device may result in device malfunction, inadequate sterilization or patient harm.
- Do not use the device if the package is open or damaged.

1. Structure



1. Torsion handle 2. Snare rod 3. Snare loop

Fig.1 Structure of snare

*The snare rod is a PTFE sleeve with a nitinol wire.

*The snare loop is a wolfram-winded nitinol wire (version intended to be marketed; also named no steel sleeve snare).

2. Performance

The Snare consists of snare rod, snare loop and torsion handle, the raw materials of snare rod is Nitinol wire and PTFE sleeve, and the raw materials of snareloop is Gold plated tungsten wire and Nitinol wire, which shows an extended line shape when stretched and automatically restores to the original shape after the removal of the external force. Such performance guarantees the snare can be delivered into the heart defect parts through a smaller delivery sheath, and therefore it can be used for infants and young children.

3. Specification

The snare can pass through catheters with the inner diameter of greater than or equal to 0.9mm. The specifications of the snare depend on the diameter D of snare circle, which includes type of snare-15 and snare-20.

4. Intended purpose

The MemoPart™ Snare is designed for retrieval and manipulation of foreign bodies in coronary or peripheral vascular system, snaring guide wire in establishing track for closure of ventricular septal defect or patent ductus arteriosus.

4.1 Medical conditions or indications

When patient is with a foreign body remaining in coronary or peripheral blood vessel system, this device is indicated to perform retrieval and manipulation of the foreign body.When patient is with congenital ventricular septal defect (VSD) or patent ductus arteriosus (PDA) and requires conducting corresponding transcatheter closure, this device is indicated to snare guide wire to establish track.

4.2 Contraindication

◆ Conditions which are unfavorable for cardiac catheter examination, e.g. fever.
◆ Presence of thrombi in the chambers of the heart and hemorrhagic diseases such as active ulcer.
◆ The heart or vein is too narrow and severe pulmonary resistance hypertension.
◆ Recent infection is found or any type of severe infectious diseases being diagnosed within one month pre-operation.

5. Intended Patient Populations

This device is suitable for any patients who need retrieval and manipulation of foreign bodies located in the coronary or peripheral vascular system or who need transcatheter closure of VSD/PDA. The safety and efficacy of MemoPart™ snare in pregnant women or men intending to father children, nursing mothers and the immunocompromised patients have not been established.

6. Intended Users

The MemoPart™ snare should only be used by physicians who are trained in vascular interventional techniques. The physician should determine which patients are candidates for procedures that use this device. Before use, the operator should have a full understanding of the using instruction, warnings and precautions.

7. Warning

• Use within the disinfection effective period, and check the packaging before using. Do not use if the packaging is damaged.
• The device is for single use only. Due to design structure, there may be risks of breakage and cross contamination if reused.
• The product has been sterilized before leaving the factory, and the product packaging should be complete and unsealed under the required transport and storage conditions.
• The product is valid for three years. The disinfection effective period should be checked before using. Do not use the product if disinfection effective period is invalid.
• Patients who are allergic to nickel may have an allergic reaction to this device, especially those with a history of metal allergies.

8. Precautions

The distal end of the snare may shed off during the use process, which can be broken out with another snare; if it fails, then surgical method would be considered. Connection strength required in the existing standard, e.g. strict quality inspection, would definitely be avoided if violent operation is not used.

9. Adverse Events

Potential residual risks and undesirable side-effects associated with use of this product include, but not limited to, the following:
Stroke, Hematoma, Arrhythmia, Embolism, Infection, Bleeding, Vascular dissection, vascular occlusion, Allergic reaction, Compartment syndrome, Hemolytic reaction, vascular perforation and other vessel injury.
Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

10. Clinical Benefits to be expected

• It can relieve patients' discomfort by retrieving and manipulating foreign bodies located in the coronary and peripheral vascular system.
• It is as an auxiliary device to assist VSD/PDA occluders in accomplishing transcatheter closure of VSD/PDA and improving body functions of patients with congenital heart disease.

11. Summary of Safety and Clinical Performance (SSCP)

The summary of safety and performance for the device is available on the website of EUDAMED: https://ec.europa.eu/tools/eudamed.
Basic UDI-DI: 69330523XZ0006KB

12. Materials recommended for use with this device

◆ Catheter, e.g. guiding catheter
◆ Sheath
◆ 20 ml luer-lock syringe

13. Directions for Use

The operator selects 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)Check the product packaging and take out the product from the package.
(2)Remove the snare from dispenser with a careful inspecting for any damage.
(3)Press the snare into the snare catheter and advance the system (snare catheter

and snare) into the established guiding catheter.
NOTE: Test compatibility between snare catheter and guiding catheter before use.
(4)Advance the distal end of the system (snare catheter and snare) until it is close to the proximal end of the foreign body. Keep the snare catheter still and gently push the snare rod forward to completely open the snare loop.
(5)The loop is then slowly advanced forward until there is overlap between snare loop and foreign body. If necessary, the snare can be rotated slightly.
(6)By advancing the snare catheter forward, the loop of the snare will be closed to capture the foreign body.
Note: Attempting close the loop by pulling the snare loop into the snare catheter may result in dislocation of the foreign body and damage to the vascular tissue.
(7)To manipulate the 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.
(8)To retrieve the foreign body, maintain tension on the snare catheter and according to the type of foreign body, choose to advance the guiding catheter forward to retract the foreign body or pull the system (snare catheter and snare) into the guiding catheter and gently pull the foreign body out from the femoral vein puncture site.
For example: when retrieving an inferior vena cava filter, it is recommended to choose an advanced guide catheter to retract the system (snare catheter and snare).
When used in capturing guide wire and establishing arteriovenous track in transcatheter closure of ventricular septal defect (VSD).
(1)Apply regional or general anesthesia to the patient.
(2)Transcatheter closure of VSD: Puncture the right femoral vein and right femoral artery (puncture the right internal jugular vein in the case of muscular VSD). Perform the right heart catheterization and place a MPA2 catheter in the pulmonary artery or vena cava (preparing for the delivery of the snare).
Transcatheter closure of PDA: Puncture the right femoral vein and right femoral artery. Perform the right heart catheterization and place a MPA2 catheter in the pulmonary artery or vena cava (preparing for the delivery of the snare).
(3)Transcatheter closure of VSD: Send a pigtail catheter and perform left heart catheterization, left ventriculography, and ascending aortography in sequence to determine the location and size of the VSD and the situation of aortic regurgitation. Conduct intravenous heparin injection.
Transcatheter closure of PDA: Send a pigtail catheter and perform angiography of the descending aortic arch, left or right anterior oblique angiography to determine the location and size of the PDA and the situation of aortic regurgitation. Conduct intravenous heparin injection.
(4)Transcatheter closure of VSD: From the right femoral artery, use a right coronary catheter or other catheter (such as a trimmed pigtail catheter) along with a super-hard exchange guide wire to explore the left ventricular opening of the VSD. After the super-stiff exchange guide wire was passed through the VSD into the right ventricle, withdraw the super-stiff exchange guide wire and introduce a long hydrophilic guide wire into the pulmonary artery or vena cava.
Transcatheter closure of PDA: From the right femoral artery, use a right coronary catheter or other catheter (such as a trimmed pigtail catheter) along with a super-hard exchange guide wire to pass through descending aorta and reach the opening of PDA. Then withdraw the super-stiff exchange guide wire and introduce a long hydrophilic guide wire into the pulmonary artery.
(5)Compress the snare loop and send the snare into the established MPA2 catheter. Deliver the snare from the right femoral vein to pulmonary artery (pulmonary artery or vena cava in VSD closure) through MPA2 catheter.
(6)Advance the distal end of the MPA2 catheter forward until it is close to the distal end of hydrophilic guide wire. Keep the snare catheter still and gently push the snare rod forward to completely open the snare loop.
(7)The loop is then slowly advanced forward until there is overlap between snare loop and hydrophilic guide wire. If necessary, the snare can be rotated slightly.
(8)By advancing the MPA2 catheter forward, the loop of the snare will be closed to capture the hydrophilic guide wire.
(9)To retrieve the hydrophilic guide wire, maintain tension on MPA2 catheter and gently pull the hydrophilic guide wire out from the femoral vein puncture site. The arteriovenous track between femoral vein and femoral artery is successfully established.

14. Disposal

Treat all disposable devices appropriately according to the local requirements for medical device waste disposal.

15. Storage and Expiry Date

15.1 The product is stored in a dry place without ultraviolet radiation and should be stored in a well-ventilated room with a relative humidity of no more than 80% relative and no corrosive gas.
15.2 The product is sterilized by ethylene oxide and is valid for three years.
15.3 The product is for single use only. Do not use if the packaging is damaged.

16. Symbol Definitions

SYMBOL	EXPLANATION OF SYMBOL
	MANUFACTURER
	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	DATE OF MANUFACTURE
	USE-BY DATE
	BATCH CODE
	CATALOGUE NUMBER
	SERIAL NUMBER
	STERILIZED USING ETHYLENE OXIDE
	DOUBLE STERILE BARRIER SYSTEM AND STERILIZED USING ETHYLENE OXIDE
	DOUBLE STERILE BARRIER SYSTEM WITH PROTECTIVE PACKAGING OUTSIDE
	DO NOT RESTERILIZE
	DO NOT RE-USE
	DO NOT USE IF PACKAGE IS DAMAGED
	CONSULT INSTRUCTIONS FOR USE
	MEDICAL DEVICE
	UNIQUE DEVICE IDENTIFIER
	KEEP DRY
	KEEP AWAY FROM SUNLIGHT
CE 2797	CE MARKING AND IDENTIFICATION NUMBER OF NOTIFIED BODY
The color of EO Sterilization indicator on the package bag turns yellow after EO sterilization.	

17. DISCLAIMER OFWARRANTY AND LIMITATION OF REMEDY

Descriptions or specifications in Shanghai Shape Memory Alloy Co., Ltd. printed matter, including this publication, are meant solely to generally describe the product at the time of manufacture and do not constitute any express warranties. Shanghai Shape Memory Alloy Co., Ltd will not be responsible for any direct, incidental, or consequential damages resulting from the abnormal use of the product.

Note: The exact same pdf version e-IFU can also be found on the website: https:// en.scientechmed.com/. When the manufacturer's instruction for use is updated, it will be uploaded timely. For it is difficult to trace to every end user to inform the change, so we advise the customer to browse and check it regularly.