ONE Snare®

English

Endovascular Snare System

INSTRUCTIONS FOR USE

DESCRIPTION:

The ONE Snare™ endovascular snare system consists of the snare, snare catheter, insertion tool and torque. The snare is constructed of nitinol cable and gold plated tungsten loop. The pre-formed snare loop can be introduced through catheters without risk of snare deformation because of the snare's super-elastic construction. The snare catheter is constructed of polyether block amide and contains a platinum/iridium radiopaque marker band.

INDICATION FOR USE:

The ONE Snare™ endovascular snare system is intended for use in the coronary and peripheral vascular system or hollow viscous to retrieve and manipulate foreign objects. Retrieval and manipulation procedures include indwelling venous catheter repositioning, indwelling venous catheter fibrin sheath stripping, and central venous access venipuncture procedure assistance.

CONTRAINDICATIONS:

1. This device is not intended for the removal of foreign objects entrapped by tissue growth.
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.

WARNINGS:

1. 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.
2. Do not use excessive force when manipulating the catheter through an introducer. Excessive force may damage the snare catheter.
3. This device has been sterilized utilizing ethylene oxide and is considered sterile if the package is not opened or damaged. Do not use a device that has been damaged or if the package is open or damaged.
4. For single patient use only. Do not reuse, reprocess or sterilize. 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 cross-infection 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.
5. After use this device may be a potential biohazard. Handle in a manner that will prevent accidental contamination.
6. Nitinol is a nickel titanium alloy. Possible reaction may occur for those patients who exhibit sensitivity to nickel.
7. Care should be observed when using this device for removal of a large fibrin sheath in order to minimize risk of pulmonary embolism.

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

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

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)

DIRECTIONS FOR USE:

Prepare the ONE 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 loop can be retracted into the distal end of the snare catheter.
4. Inspect the device by extending and retracting the snare loop through the distal end of the snare catheter 2-3 times, while carefully examining the snare catheter, radiopaque band 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 ONE Snare™ System:

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 (located on the proximal end of the snare, just distal to the torque device) distally until the loop of the snare is 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 asway 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 insertion tool 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 ONE Snare™ system, it is important to test product compatibility prior to use.
4. Gently push the snare shaft forward to completely open the loop. The loop is then slowly advanced forward, and 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 loop of the snare is closed to capture the foreign body. Note that attempting to close the loop by pulling the snare into the snare catheter will move the loop from its 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" (0.89 mm) 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 the snare loop 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 loop 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 loop. Remove the needle.
4. Close the snare over the guidewire by advancing the snare catheter.
5. Pull the guidewire into the inferior vena cava.

ONE Snare™ System contains:

(1) Snare, (1) Snare Catheter, (1) Insertion tool and (1) Torque Device.

Storage Conditions: Store in a cool, dry place.
Transportation Conditions: Avoid contact with high temperature and moisture during transportation.

Shelf Life: 5 years.

MERIT MEDICAL®

www.merit.com

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ONE Snare®

Chinese

血管内异物抓捕器

使 用 说 明 ：

产品描述：

简体中文

ONE Snare™ 血管内异物抓捕器由抓捕器、抓捕器导管、导入器及转矩装置组成。抓捕器由镍钛诺缆线、镀金钨环构成。预先定形的抓捕环可通过导管引入，因抓捕器的构造极具弹性，因此不存在抓捕器变形的风险。抓捕器导管由聚醚嵌段酰胺制成，带有铂／铱射线不透性标示带。

适用范围：

血管内异物抓捕器用于冠状动脉和外周血管系统或空腔性脏器以取出和控制异物。操作过程包括静脉留置导管复位，静脉留置导管纤维蛋白鞘剥脱以及辅助中心静脉穿刺术。

禁忌症：

1. 该装置不可用于移除因组织生长而卡住的异物。
2. 如存在室间隔缺损或持久性卵圆孔未闭，不应使用该装置进行纤维蛋白鞘剥脱。
3. 该装置不可用于移除植入的起搏器电极线。

警告：

1. 纤维蛋白鞘剥脱过程对导管所使用的拉力可能损坏、拉升或弄破留置导管（直径等于或小于 6 French）。当尝试对导管（直径等于或小于 6 French）进行纤维蛋白鞘剥脱时，请勿太过用力。
2. 当通过导入器控制导管时，请勿太过用力。
   太过用力可能损坏抓捕器导管。
3. 该装置已采用环氧乙烷灭菌，如果产品包装未打开或无破损，则视为无菌。已破损的装置，或如果包装已打开或破损，请勿使用。
4. 只供一位患者使用。请勿重复使用、重新处理或重新灭菌。重复使用、重新处理或再次灭菌可能破坏装置的结构完整性，及／或导致装置故障，从而可能导致患者受伤、患病或死亡。重复使用、重新处理或重新灭菌也可能构成装置污染风险，及／或导致患者感染或交叉感染，包括但不限于在患者间传播传染病。装置污染可能导致患者受伤、患病或死亡。
5. 使用后，该装置可能具有潜在的生物危害。应采用将能防止意外污染的方式处理。
6. 镍钛诺是一种镍钛合金。对镍过敏的患者可能出现一些潜在反应。
7. 使用该装置移除较大纤维蛋白鞘时应小心谨慎，以减少肺栓塞风险。

℞ only: 警示 — 联邦（美国） 法律限定本装置仅可由医师或凭医嘱销售。

潜在并发症：

1. 与在动脉血管系统中的异物取出装置相关的潜在并发症包括但不限于：
- 栓塞
- 中风
- 心肌梗死（取决于放置位置）

2. 与在静脉血管系统中的抓捕器取出装置相关的潜在并发症包括但不限于：
- 肺栓塞

3. 与异物取出装置相关的其他潜在并发症包括但不限于：
- 血管穿孔
- 装置卡住

当尝试在具有较小尺寸直径的导管上进行纤维蛋白鞘剥脱时，可能损坏导管。
（参见警告）

进行纤维蛋白鞘剥脱后，可能出现肺栓塞。
（参见警告）

使用说明：

准备 ONE Snare™ 系统：

为异物所在的部位选择合适的抓捕器直径范围。抓捕器直径范围应接近于将在其中使用抓捕器的血管的大小。
1. 从套箍固定架取下抓捕器和抓捕器导管，检查是否有任何破损。
2. 从抓捕器轴的近端取下导入器和转矩装置装置。
3. 通过将抓捕器器的近端插入抓捕器导管的远端（非导管座端），将抓捕器组装到抓捕器导管，直到抓捕器的近端离开导管座，且抓捕环可缩回至抓捕器器导管的远端。
4. 展开和缩回穿过抓捕器导管远端的抓捕环 2 至 3 次，以检查装置，同时仔细检查抓捕器导管、射线不透性带和装置是否有任何破损或缺陷。
5. 适当时，按上述方法组装后，可将系统（抓捕器与抓捕器导管）作为一个整体，推进至所需位置。

ONE Snare™ 系统的其他准备方案：

如抓捕器导管已放置于脉管系统内，则可使用厂家提供的插导入器（位于抓捕器近端，转矩装置的远端）将抓捕器放置于留置抓捕器导管内。
1. 从保护固定架取下抓捕器，检查是否有任何破损。
2. 向远侧移动所提供的导入器（位于抓捕器近端，转矩装置的远端），直到抓捕器的抓捕环装入导入器的管身部分。
3. 将导入器的远端插入留置抓捕器导管的导管座，直到感觉受阻。这将表明导入器的尖端与内管腔适当对齐。
4. 尽可能笔直地握住导入器，抓住正处于导入器底座近端的抓捕器轴，往前推进抓捕器直到它在抓捕器导管的管腔内固定。先取下扭控器，而后将导入器拉至抓捕器器轴近端，将其取下。

抓捕器辅助取出与操作建议：

1. 如存在留置输送导管，则将其移除。
2. 如患者体内的导丝位于异物处，则沿导丝推进抓捕器导管以到达所需位置。然后移除导丝，将抓捕器推进，穿过抓捕器导管。或者，确保抓捕器的抓捕环穿过导丝近端，将整个系统（抓捕器与抓捕器导管组件）推进至导引导管或导管鞘中，直到抓捕器导管的远端位于靠近异物的位置。
3. 若没有导丝，则将抓捕器拉进抓捕器导管的远端，并推进以穿过导引导管或导鞘，直到它位于靠近异物的位置。
   或者，也可将装置拉进抓捕器导入器的远端以收缩抓捕环。将抓捕器导入器的锥形端置于抓捕器导管、导引导管或导管鞘的近端（导管座），并向前推进抓捕器，使导入器与抓捕器导管导管座始终保持接触状态。注意： 当尝试使用并非为用于与 ONE Snare™ 系统配合使用而专门制造的导引导管或导管鞘时，在使用前测试产品的兼容性至关重要。
4. 轻轻地向前推动抓捕器轴以完全打开抓捕环。然后抓捕环将会被缓慢向前推动，环绕异物的近端。或者，还可将抓捕器推进至目标位置以远，然后将环绕异物远端的抓捕环向回拉。
5. 通过推进抓捕器导管，关闭抓捕器的抓捕环以圈住异物。注意，尝试通过将抓捕器拉进抓捕器导管的方式闭合抓捕环，将导致抓捕环偏离其环绕异物的位置。
6. 为了控制异物，保持对抓捕器导管的拉力，以抓住异物不放，同时一并移动抓捕器与抓捕器导管，从而控制异物，将其移至所需位置。
7. 为了取出异物，保持抓捕器导管上的张力，并向近侧将抓捕器与抓捕器导管组件一并移至或移入导引导管或导管鞘。然后，异物将通过导管或导管鞘取出，或连同导引导管或导管鞘一起取出。取出较大异物可能需要插入较大的导管鞘、导引导管或在周围部位进行切除。

抓捕器辅助移除留置导管的纤维蛋白鞘：

1. 使用标准技术，建立股静脉通路，将所选抓捕器推进下腔静脉或右心房。
2. 推进 0.035" (0.89 mm) 的导丝，使其穿过留置导管的末端接口（如果管腔多于一个，则为远端或静脉接口），并进入下腔静脉或右心房。
3. 将抓捕环置于环绕导丝四周。
4. 将抓捕器推过导管的远端，到达靠近纤维蛋白鞘的位置。
5. 闭合环绕导管的抓捕器，继续施加轻微拉力，将抓捕器器朝导管远端向下拉至末端接口。
6. 重复步骤 4 和 5，直到导管脱离血纤维蛋白外鞘。

抓捕器辅助静脉开通术：

1. 在已开通的静脉通道部位引入抓捕器器，并将其置于脉管系统的理想部位。
2. 打开抓捕环以提供目标，引导注射针扎入目标静脉通道部位。
3. 引入导丝，穿过针和抓捕环。移除针。
4. 通过推进抓捕器导管，闭合导丝上方的抓捕器。
5. 将导丝拉入下腔静脉。

ONE Snare™ 系统包括：

(1) 个抓捕器、(1) 个抓捕器导管、(1) 个导入器及 (1) 个转矩装置。

储存条件：存储于阴凉干燥处。

运输条件：运输过程中应不暴露在高温或高湿下。

产品名称：血管内异物抓捕器
生产日期和失效日期：见产品标签
有效期：5 年
注册证编号：国械注进20173036911
产品技术要求编号：国械注进20173036911
中国境内代理人及售后服务单位名称：麦瑞通医疗器械（北京）有限公司
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ONE500, ONE1000, ONE1500, ONE2000, ONE2500, ONE3000, ONE3500, ONE1001,ONE2501, ONE4000, ONE6000
说明书编制或修订日期：2024年8月
结构及组成：血管内异物抓捕器，由抓捕器、抓捕器导管、导入器和转矩装置四个组件组成。抓捕器由镍钛合金缆线和镀金钨环组成; 导管由聚醚嵌段酰胺 Pebax 7233 SA01管道构成，远端有铂／铱不透射线的标记带。环氧乙烷灭菌，一次性使用。

MERIT MEDICAL®

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