EN Snare®

INSTRUCTIONS FOR USE:

INDICATION FOR USE:
The EN Snare® Endovascular Snare and Catheter is intended for use in the cardiovascular system or hollow viscous to retrieve and manipulate foreign objects. Manipulation procedures include indwelling venous catheter repositioning, indwelling venous catheter fibrin sheath stripping, and central venous access venipuncture procedure assistance.

DESCRIPTION:
The EN Snare® system consists of three interlaced, cabled, super-elastic Nitinol, preformed loops. The super-elastic Nitinol construction enables the loops to be introduced through catheters without the risk of device deformation.

WARNINGS:
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.
4. 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.
5. Do not use excessive force when manipulating the catheter through an introducer. Excessive force may damage the catheter.
6. This device has been sterilized utilizing Ethylene Oxide and is considered sterile if the package is not opened or damaged. It is intended for Single Patient Use Only. Do not attempt to clean or re-sterilize the device. After use this device may be a potential biohazard. Handle in a manner that will prevent accidental contamination. Do not use a device that has been damaged or if the package is open or damaged.
7. Nitinol is a nickel titanium alloy. Possible reaction may occur for those patients who exhibit sensitivity to nickel.

℞ 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).

Prepare the EN 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 Introducer 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 loops can be retracted into the distal end of the Snare Catheter.
4. Test and inspect the device by extending and retracting the snare loops 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 EN Snare®:
If the Snare Catheter is already positioned within the vasculature, the provided Introducer (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 Introducer (located on the proximal end of the Snare, just distal to the Torque Device) distally until the loops of the Snare are enclosed within the tubing portion of the Introducer.
3. Insert the distal end of the Introducer into the hub of the indwelling Snare Catheter until resistance is felt. This will indicate the tip of the Introducer is properly aligned with the inner lumen.
4. Hold the Introducer as straight as possible, grasp the shaft of the Snare just proximal to the hub of the Introducer and advance the Snare until it is secure within the lumen of the Snare Catheter. The Introducer can be removed by first removing the Torque Device and pulling the Introducer off the proximal end of the Snare's 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 introducer 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 loops by pulling the device into the distal end of the Snare Introducer. Place the tapered end of the Snare Introducer into the proximal (hub) end of the Snare Catheter, guide catheter or sheath and advance the Snare forward maintaining constant contact between the Introducer and Snare Catheter hub.
   NOTE: When attempting to utilize guide catheters or sheaths not specifically manufactured for use with the EN Snare® System, it is important to test product compatibility prior to use.
4. Gently push the Snare shaft forward to completely open the loops. The loops are then slowly advanced forward, and may be rotated if desired, 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 loops of the device are closed to capture the foreign body. (Note that attempting to close the loops by pulling the Snare into the Snare Catheter will move the loops from their 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" 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 one of the Snare loops 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 loops 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 loops. Remove the needle.
4. Close the Snare over the guidewire by advancing the Snare Catheter.
5. Pull the guidewire into the desired location.

EN Snare® FOREIGN BODY RETRIEVAL DEVICE SYSTEM*

Description	Snare Diameter Range	Snare Length	Catheter Size	Catheter Length
Mini *EN* Snare System	2-4 MM	175 CM	3.2 F	150 CM
Mini *EN* Snare System	4-8 MM	175 CM	3.2 F	150 CM

Description	Snare Diameter Range	Snare Length	Catheter Size	Catheter Length
EN Snare System	6-10 MM	120 CM	6 F	100 CM
EN Snare System	9-15 MM	120 CM	6 F	100 CM
EN Snare System	12-20 MM	120 CM	6 F	100 CM
EN Snare System	18-30 MM	120 CM	7 F	100 CM
EN Snare System	27-45 MM	120 CM	7 F	100 CM

* Every *EN* Snare System contains: (1) Snare, (1) Snare Catheter, (1) Introducer and (1) Torque Device.

Shelf life: 3 years.

Storage Conditions: Room temperature, ventilation, dry, away from light.

Transportation Conditions: Do not expose to excessive heat or humidity during transportation.

MERIT MEDICAL®

Manufacturer
Merit Medical Systems, Inc. South Jordan, Utah 84095 U.S.A. 1-801-253-1600
U.S.A. Customer Service 1-800-356-3748
Authorized Representative
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www.merit.com

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EN Snare®

异物抓捕器

使 用 说 明：

适用范围：
该产品适用于心血管系统的异物取出和操作。操作程序包括留置静脉导管的重新定位、留置静脉导管纤维蛋白鞘剥离，以及辅助中心静脉穿刺手术。

产品描述：
EN Snare® 由三个交错、缆线状超弹性镍钛合金预成型环圈组成。超弹性镍钛合金构造使环圈能通过导管引入时没有器械变形的风险。

警告：
1. 本器械不适用于清除因组织生长产生的异物。
2. 本器械不应用于存在持久性卵圆孔室间隔缺陷的纤维蛋白鞘剥离。
3. 本器械不能用于植入的起搏器电极线的取出。
4. 在纤维蛋白鞘剥离过程中对导管施加拉力可能会导致损坏、拉伸或破坏直径为 6 F 或更小的留置导管。在使用直径为 6 F 或更小的留置导管尝试进行纤维蛋白鞘剥离时，请勿使用过大拉力。
5. 在通过导入器操作导管时，请勿用力过大。用力过大可能会损坏导管。
6. 本器械已用环氧乙烷灭菌，如果包装未打开或损坏，则可认为是无菌的。它仅适用于单个病人使用。请勿尝试清洁或对器械重新灭菌。本器械在使用后可能有潜在生物危害。处理方式要预防意外污染。如果器械已损坏，或者包装已打开或损坏，请勿使用。
7. 镍钛诺 (Nitinol) 是一种镍钛合金。对镍表现为过敏的患者可能会发生过敏反应。

仅凭处方销售：注意：美国联邦限制本器械仅能由医师或遵医嘱销售。

注意事项：在使用本器械清除大纤维蛋白鞘时应谨慎，以将肺栓塞的风险降到最低。

潜在并发症：
1. 动脉血管中与异物取出器械相关的潜在并发症包括，但不限于：
   - 栓塞
   - 中风
   - 心肌梗死（与放置情况有关）
2. 静脉血管中与抓捕器异物取出器械相关的潜在并发症包括，但不限于：
   - 肺栓塞
3. 其他与异物取出器械相关的潜在并发症包括，但不限于：
   - 血管穿孔
   - 器械卡压

在使用小 French 直径导管尝试进行纤维蛋白鞘剥离时，可能会发生导管损坏。（参见警告）在纤维蛋白鞘剥离后，可能会发生肺栓塞。（参见注意事项）。

准备 EN Snare® 系统：

选择与异物所处部位相应的抓捕器直径范围。抓捕器直径范围应与其将进入的血管大小相近。

1. 从环套包装中取出抓捕器和抓捕器导管，并检查是否有任何损坏。
2. 将导入器和转矩装置从抓捕器轴近端取下。
3. 将抓捕器轴近端插入抓捕器导管远端（非导管头）将抓捕器加载到抓捕器导管中，直到抓捕器轴近端露出导管头，并且环圈能够缩进抓捕器导管远端。
4. 通过将抓捕器圈伸出和缩进抓捕器导管远端 2-3 次对器械进和测试并检查，同时仔细检查抓捕器导管、不透 光标记带和器械是否有任何损坏或缺陷。
5. 如果合适，系统（抓捕器和抓捕器导管）可按上述方法组装，作为一个整体装置推到所要的部位。

EN Snare® 的另外一种准备方法：
如果抓捕器导管已在血管内定位，配套的的导入器（位于抓捕器近端，靠近转矩器械远端）可用来将抓捕器送入抓捕器导管内定位。
1. 从保护性包装中取出抓捕器，并检查是否有任何损坏。
2. 向远端移动配套的导入器（位于抓捕器近端，靠近转矩器械的远端），直到抓捕器环圈被导入器的导管部分包住。
3. 将导入器远端插入留置抓捕器导管的导管头中，直到感觉到有阻力。这表明导入器头部刚好与管腔对正。
4. 尽可能笔直地握住导入器，在导引器近端处抓住抓捕器轴并向前推动抓捕器，直到其可靠地进入抓捕器导管腔内。要取下导入器，首先取下转矩器械，然后将导入器从抓捕器轴近端拉出。

抓捕器辅助异物取出和操作建议：
1. 如果存在，取出留置传送导管。
2. 如果导丝在患者体内的异物部位，通过导丝将抓捕器导管向前推进到所要的位置。然后，取出导丝并将抓捕器推入抓捕器导管。或者，将抓捕器的一个环箍套在导丝近端，然后向前移动整个系统（抓捕器和抓捕器导管组件）推入导引导管或引入鞘，直到抓捕器导管远端与异物位置接近
3. 如果不存在导丝，将抓捕器推入抓捕器导管远端并向前推动穿过导引导管或导管鞘，直到它位于异物近端。或者，将器械拉入到抓捕器导入器远端收拢抓捕器环圈。将抓捕器导引器锥形端放入抓捕器导管近端、Hub头端）、导引导管或者导管鞘中，并向前推动抓捕器，保持导入器和抓捕器导管头之间一直接触。

注：在尝试使用非专为与 EN Snare® 配合使用而生产的导引导管或鞘时，使用之前进行产品兼容性测试，这一点很重要。

4. 轻轻地向前推进抓捕器轴以完全打开环圈。然后，缓慢向前推动环圈，并且如有需要可在异物近端周围旋转。或者，可以将抓捕器推过目标位置并使环圈回到异物远端周围。
5. 通过向前推动抓捕器导管，关闭器械环圈以捕捉异物。（请注意，通过将抓捕器拉入抓捕器导管尝试关闭环圈将会把环圈从其在异物周围的位置移开）。
6. 要操作异物，保持抓捕器导管上的张力以保持夹紧异物，并同时移动抓捕器和抓捕器导管以将异物移到所要的位置。
7. 要取出异物，保持抓捕器导管上的张力，并同时将抓捕器和抓捕器导管组件向近端移动到或移入导引导管或鞘中。然后，通过或与导引导管或导管鞘一起取出异物。取出大异物可能需要插入更大的鞘、导引导管或在外周处进行切断。

抓捕器辅助从留置导管取出纤维蛋白鞘：
1. 使用标准技术，准备股静脉穿刺，将所选的抓捕器向下腔静脉或右心房推动。
2. 向前推动 .035 英寸导丝穿过留置导管的末端端口（如果有多个腔，远端或静脉端口）并向下腔静脉或右心房推动。
3. 将抓捕器环箍之一放在导丝周围。
4. 将抓捕器推至导管的远端接近纤维素蛋白鞘的位置。
5. 将抓捕器收拢进导管，并继续使用轻的牵引力，同时轻轻地将抓捕器沿导管远端拉至导管的末端端口。
6. 重复第 4 步和第 5 步，直到导管不含纤维蛋白鞘。

抓捕器辅助静脉造管术：
1. 将抓捕器插入病人的静脉穿刺部位并定位在血管中需要的部闪位。
2. 打开抓捕器环圈为引导注射针进入所要的静脉穿刺部位提供目标。
3. 将导丝穿过穿刺针及抓捕器环圈。取出穿刺针。
4. 通过向前推动抓捕器导管将套在导丝上的抓捕器收拢。
5. 将导丝拉入所要的位置。

EN Snare® 异物抓捕器

说明	抓捕器 直径范围	抓捕器 长度	导管 尺寸	导管 长度
微型EN Snare 系统	2-4 毫米	175 厘米	3.2 F	150 厘米
微型EN Snare 系统	4-8 毫米	175 厘米	3.2 F	150 厘米

说明	抓捕器 直径范围	抓捕器 长度	导管 尺寸	导管 长度
EN Snare 系统	6-10 毫米	120 厘米	6 F	100 厘米
EN Snare 系统	9-15 毫米	120 厘米	6 F	100 厘米
EN Snare 系统	12-20 毫米	120 厘米	6 F	100 厘米
EN Snare 系统	18-30 毫米	120 厘米	7 F	100 厘米
EN Snare 系统	27-45 毫米	120 厘米	7 F	100 厘米

* 每个 EN Snare 系统含有：(1) 个抓捕器、(1) 个抓捕器导管、(1) 个导入器和 (1) 个转矩器械。

有效期：3年
生产日期和失效日期：见产品标签
储存条件： 室温，通风，干燥，避光；
运输条件：运输过程中，避免接触高温潮湿；

适用型号:

型号 Model (working diameter)	抓捕器系统描述snare System Description	可接受 工作直径 (mm) Acceptable working diameter	抓捕器长度(cm) Snare Length	主体最大外径(in) Shaft Diameter	导管/导入器尺寸 (French)/ mm Catheter Size
EN1003004（2-4mm）	迷你 Mini	3-5	175	.018	3.2 (1.06mm)
EN1003008（4-8mm）	迷你 Mini	6-10	175	.018	3.2 (1.06mm)
EN2006010（6-10mm）	标准Standard	8-12	120	.026	6 (1.99mm)
EN2006015（9-15mm）	标准Standard	13 - 17	120	.026	6 (1.99mm)
EN2006020（12-20mm）	标准Standard	17 - 23	120	.026	6 (1.99mm)
EN2007030（18-30mm）	标准Standard	27- 33	120	.026	7(2.33mm)
EN2007045（27-45mm）	标准Standard	42-48	120	.026	7(2.33mm)

注册证编号：国械注进20193030284
产品技术要求编号： 国械注进20193030284
产品名称：异物抓捕器
型号、规格：EN1003004, EN1003008, EN2006010, EN2006015, EN2006020, EN2007030, EN2007045
结构及组成：该产品由圈套器、导管、导入器和转矩装置组成。环氧乙烷灭菌，一次性使用。货架有效期3年。
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
中国境内代理人及售后服务单位住所： 北京市朝阳区东大桥路9号楼2单元801室内B01、B02及B03单元
中国境内代理人及售后服务单位电话：010-85610788
中国境内代理人及售后服务单位传真：010-85616981
说明书编制或修订日期：2023年08月

MERIT MEDICAL®

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