This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an up-to-date summary of the main aspects of the safety and clinical performance of the EN Snare Endovascular System and EMPOWER Tri-Loop Snare System. These systems will be referred to hereafter under the term EN Snare System.

The SSCP is not intended to replace the Instructions for Use (IFU) as the main document to ensure the safe use of the EN Snare, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

The following information is intended for users/healthcare professionals. A supplemental SSCP with information for patients was not established since the EN Snare System is not an implantable device for which patients are provided an implant card, nor is the device intended to be used directly by patients.

The English version of this SSCP document (SSCP-0902-001) has been validated by the notified body (#2797).

1.0 Device identification and general information

1.1 Device trade name(s)

The device(s) and model numbers covered by this SSCP are presented in Table 1.1.1.

Table 1.1.1 Devices Included in this SSCP

Device Name and Description	Product Numbers
EN Snare Mini Snare 2–4 mm	EN1003004
EN Snare Mini Snare 4–8 mm	EN1003008
EN Snare Standard Snare 6–10 mm	EN2006010
EN Snare Standard Snare 9–15 mm	EN2006015
EN Snare Standard Snare 12–20 mm	EN2006020
EN Snare Standard Snare 18–30 mm	EN2007030
EN Snare Standard Snare 27–45 mm	EN2007045
EMPOWER Tri-Loop Snare System	8785

1.2 Manufacturer Name and Address

The name and address of the manufacturer of the EN Snare System are provided in Table 1.2.1.

Table 1.2.1 Manufacturer Information

Manufacturer Name	Address of Manufacturer
Merit Medical Systems, Inc.	1600 West Merit Parkway, South Jordan, Utah 84095, USA

1.3 Manufacturer Single Registration Number (SRN)

The Manufacturer Single Registration Number (SRN) for the manufacturer is included in Table 1.6.1.

1.4 Basic UDI-DI

The basic Unique Device Identifier (UDI) key is provided in Table 1.6.1.

1.5 Medical Device Nomenclature Description / Text

The Classificazione Nazionale dei Dispositivi medici (CND) code and descriptors for the subject device(s) are listed in Table 1.6.1.

1.6 Class of Device

The EU device risk classification(s) for the EN Snare System are listed in Table 1.6.1.

Table 1.6.1 Device Identification Information

Device Name and description	EU Device Class	Product Number	Basic UDI-DI	Single Registration Number (SRN)	CND Code	CND Terms
EN Snare Mini Snare 2–4 mm	III	EN1003004	088445048408DH	US-MF-000001366	C019005	VASCULAR FOREIGN BODIES, RETRIEVING SYSTEMS
EN Snare Mini Snare 4–8 mm	III	EN1003008	088445048408DH	US-MF-000001366	C019005	VASCULAR FOREIGN BODIES,

Device Name and description	EU Device Class	Product Number	Basic UDI-DI	Single Registration Number (SRN)	CND Code	CND Terms
						RETRIEVING SYSTEMS
EN Snare Standard Snare 6–10 mm	III	EN2006010	088445048408DH	US-MF-000001366	C019005	VASCULAR FOREIGN BODIES, RETRIEVING SYSTEMS
EN Snare Standard Snare 9–15 mm	III	EN2006015	088445048408DH	US-MF-000001366	C019005	VASCULAR FOREIGN BODIES, RETRIEVING SYSTEMS
EN Snare Standard Snare 12–20 mm	III	EN2006020	088445048408DH	US-MF-000001366	C019005	VASCULAR FOREIGN BODIES, RETRIEVING SYSTEMS
EN Snare Standard Snare 18–30 mm	III	EN2007030	088445048408DH	US-MF-000001366	C019005	VASCULAR FOREIGN BODIES, RETRIEVING SYSTEMS
EN Snare Standard Snare 27–45 mm	III	EN2007045	088445048408DH	US-MF-000001366	C019005	VASCULAR FOREIGN BODIES, RETRIEVING SYSTEMS
EMPOWER Tri-Loop Snare System	III	8785	088445048408DH	US-MF-000001366	C019005	VASCULAR FOREIGN BODIES, RETRIEVING SYSTEMS

1.7 Year of EU Market Introduction

The year that the EN Snare System received CE marking and was first placed on the EU market is presented in Table 1.9.1.

1.8 Authorised Representative (if applicable)

The name of the authorised representative(s) and, if applicable, the authorised representative(s) SRN are provided in Table 1.9.1.

1.9 Notified Body

The Notified Body (NB) involved in the conformity assessment of the EN Snare System in accordance with Annex IX or Annex X of the MDR (Regulation (EU) 2017/745) and responsible for validating the SSCP is listed in Table 1.9.1. The NB Single Identification Number is also provided in Table 1.9.1.

Table 1.9.1 Authorised Representative and Notified Body Information

Device Name	Year Placed on EU Market	Authorised Representative		Notified Body (NB)	
		Name	SRN	Name	ID Number
EN Snare Mini Snare 2–4 mm	2009	Merit Medical Ireland Ltd.	IE-AR-000001011	BSI	2797
EN Snare Mini Snare 4–8 mm	2009	Merit Medical Ireland Ltd.	IE-AR-000001011	BSI	2797
EN Snare Standard Snare 6–10 mm	2009	Merit Medical Ireland Ltd.	IE-AR-000001011	BSI	2797
EN Snare Standard Snare 9–15 mm	2009	Merit Medical Ireland Ltd.	IE-AR-000001011	BSI	2797
EN Snare Standard Snare 12–20 mm	2009	Merit Medical Ireland Ltd.	IE-AR-000001011	BSI	2797
EN Snare Standard Snare 18–30 mm	2009	Merit Medical Ireland Ltd.	IE-AR-000001011	BSI	2797
EN Snare Standard Snare 27–45 mm	2009	Merit Medical Ireland Ltd.	IE-AR-000001011	BSI	2797
EMPOWER Tri-Loop Snare System	2017	Merit Medical Ireland Ltd.	IE-AR-000001011	BSI	2797

2.0 Intended Use of the Device

2.1 Intended Purpose

The EN Snare® System is intended for use in the cardiovascular system to retrieve and manipulate foreign objects. Retrieval and manipulation procedures include indwelling venous catheter fibrin sheath stripping.

2.2 Indications and Target Populations

The EN Snare System is indicated for patients requiring the retrieval or manipulation of foreign bodies in the cardiovascular system. Device use and sizing are based upon patient vascular anatomy and clinician preference. The EN Snare System is utilized in adult patients in accordance with appropriate vessel sizing.

2.3 Contraindications and/or Limitations

Contraindications for the EN Snare System are listed below. Limitations on the use and sizing of the EN Snare System are dictated by patient vascular anatomy.

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

- This device should not be used for fibrin sheath stripping in the presence of septal defects or Patent Foramen Ovale (PFO).
- This device is not intended for removal of implanted pacing leads.
- This device is not intended for use in the neurovasculature.

3.0 Device Description

3.1 Description of the Device

The EN Snare System is a tri-looped snare comprised of stranded platinum (Pt) and nitinol (NiTi) coupled to a NiTi shaft wire. When combined with the delivery catheter or compatible guide catheter, the triple loop snare can be used for retrieval and manipulation of foreign bodies (including tissue/thrombus) within the cardiovascular system. Procedures are typically performed under fluoroscopic guidance. A radiopaque marker at the delivery catheter tip facilitates position of the snare adjacent to the target foreign body. The flexibility of the nitinol shape-memory loop material allows the pre-shaped snare configuration to be withdrawn into a catheter for delivery and then deployed in the desired vascular location vessels while minimizing the potential for vascular injury during device manipulation (Figure 3.1.1). Foreign-body capture is achieved by placing the nitinol snare loop(s) around the free end or edge of the object, and then pulling the snare loop(s) down around the object by advancing the delivery catheter while holding the snare in position (Figure 3.1.2). As the catheter is advanced over the snare, the object is pulled into or against the distal portion of the catheter. The tensile strength of the loop(s) is sufficient to retrieve or manipulate foreign objects without damaging the snare. Various loop sizes are available to accommodate different target vessel sizing. EN Snare System configurations are summarized in Table 3.1.1.

Figure 3.1.1. Snare Deployment in a Vessel

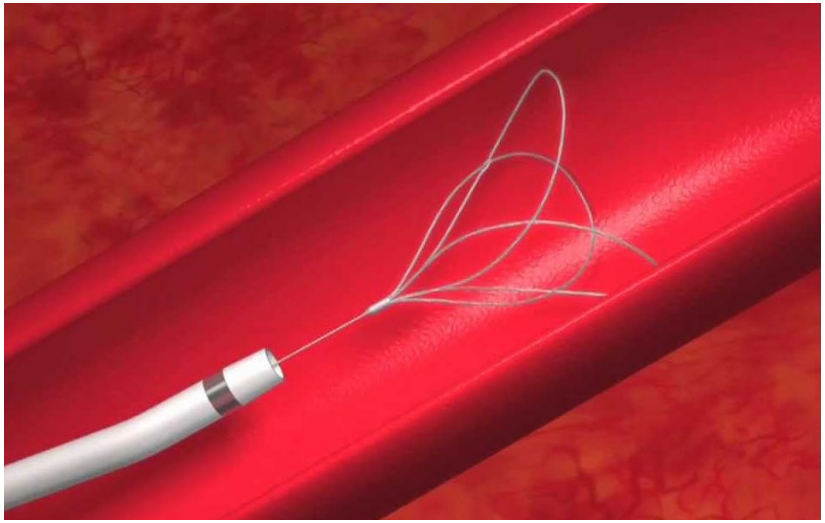
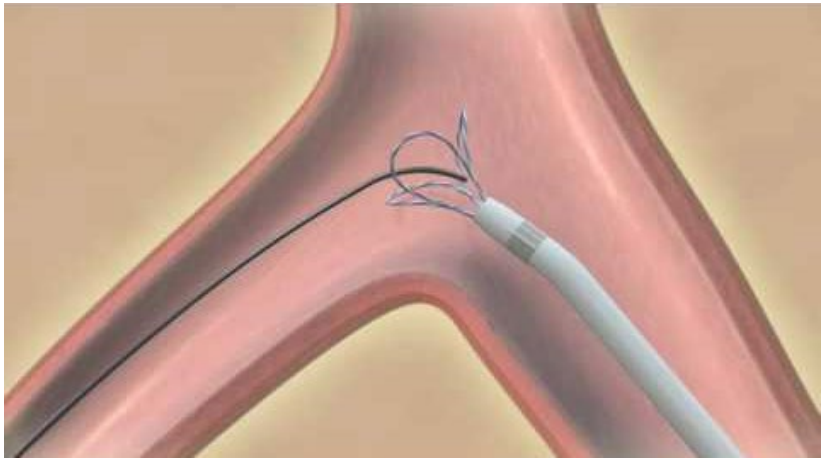


Figure 3.1.2. Snare Withdrawal to Achieve Device Capture



The devices and components in the EN Snare System are packaged as sterile, single-use devices. The catheter as well as the snare device, Insertion Tool, and torque device are loaded in polypropylene spiral dispensers. The components are then sealed in 2 separate Tyvek/Nylon pouches. Both

pouches are packaged with an IFU in a carton. Merit utilizes ethylene oxide (EtO) sterilization for the EN Snare System.

Table 3.1.1. EN Snare System Device Configurations

Catalog Number	Description	Snare Diameter	Snare Length (cm)	Snare Collapsed Diameter in (mm)	Catheter Size	Catheter Length
EN1003004	EN Snare Mini Snare 2–4 mm	2–4 mm	175 cm	0.028 in (0.71 mm)	3.2 Fr	150 cm
EN1003008	EN Snare Mini Snare 4–8 mm	4–8 mm	175 cm	0.028 in (0.71 mm)	3.2 Fr	150 cm
EN2006010	EN Snare Standard Snare 6–10 mm	6–10 mm	120 cm	0.045 in (1.14 mm)	6 Fr	100 cm
EN2006015	EN Snare Standard Snare 9–15 mm	9–15 mm4	120 cm	0.055 in (1.40 mm)	6 Fr	100 cm
EN2006020	EN Snare Standard Snare 12–20 mm	12–20 mm	120 cm	0.055 in (1.40 mm)	6 Fr	100 cm
EN2007030	EN Snare Standard Snare 18–30 mm	18–30 mm	120 cm	0.055 in (1.40 mm)	7 Fr	100 cm
EN2007045	EN Snare Standard Snare 27–45 mm	27–45 mm	120 cm	0.055 in (1.40 mm)	7 Fr	100 cm
668785-300	EN Snare Merit OEM Standard Snare	9-15 mm	150 cm	0.055 in (1.40 mm)	6 Fr	130 cm

A biocompatibility assessment has been completed for the EN Snare System, and biocompatibility testing was performed according to recommendations set forth in the ISO 10993 *Biological Evaluation of Medical Devices* series standards. The tissue contact categorizations for the EN Snare System are summarized in Table 3.1.2.

Table 3.1.2. Tissue Contact Categorization: EN Snare System

Device	Categorization
Snare	Externally communicating Circulating Blood Limited contact duration (≤ 24 hours)
Catheter	Externally communicating Circulating Blood Limited contact duration (≤ 24 hours)
Insertion Tool	No patient contact
Torque Device	No patient contact

The general operational steps associated with procedural use of the devices in the EN Snare System are summarized in Table 3.1.33.

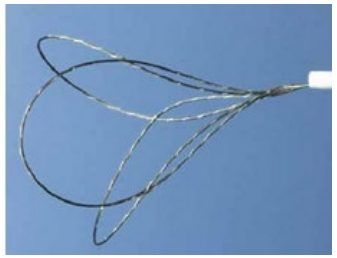
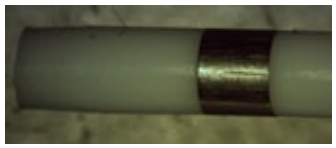
Table 3.1.3. Principles of Operation: EN Snare System

Procedure	Operational Steps
Snare Preparation and Delivery	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.
	Remove the Insertion Tool and torque device from the proximal end of the snare shaft, and insert 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. Advance the snare and snare catheter system to the desired site.
	In cases where a snare catheter is already positioned within the vasculature, advance the Insertion Tool toward the distal end of the snare until the snare loop(s) are captured within the Insertion Tool tubing. Insert the distal end of the Insertion Tool into the hub of the snare catheter until resistance is felt, and then back-load the snare into the catheter. The Insertion Tool can be removed by grasping the blue tab and peeling it away from the snare shaft.
Snare Deployment	Gently push the snare shaft forward to completely open the loop(s) of the snare. The snare is then either advanced around the proximal end of the foreign body or brought back around the distal end of the foreign body.
Object Retrieval	Advancing the snare catheter to close the loop(s) of the snare and capture the foreign body. Attempting to close the loop by pulling the snare into the snare catheter will move the position of the loop(s) with respect to the foreign body. Maintain tension on the snare catheter and move the snare and snare catheter assembly together proximally such that they are positioned at or within 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 peripheral access site cut-down.
Object Manipulation	Maintain tension on the snare catheter to retain the foreign body, and move the snare and snare catheter together to manipulate the foreign body to the desired position.
Fibrin Sheath Removal	Using a femoral venous approach, advance the snare into the inferior vena cava or right atrium. Advance an 0.035” guidewire through the indwelling catheter and into the inferior vena cava or right atrium. Position the snare loop(s) around the guidewire and advance the snare over the distal end of the catheter to a position proximal to the fibrin sheath. 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. Repeat until the catheter is free of fibrin sheath.

3.2 Previous Generation(s) or Variant(s)

The EN Snare System was acquired by Merit from Medical Device Technologies (MD Tech) in 2009. Following the acquisition, Merit began manufacturing the “Original” EN Snare System and obtained CE-marking and 510(k) clearance (K092343) in the third and fourth quarter of 2009, respectively. The fluoroethylene propylene (FEP) catheter and coaxial FEP introducer components of the Original EN Snare System were purchased from a supplier. In 2015, Merit assumed manufacturing for the entire EN Snare System, and a “Modified” device configuration was subsequently implemented. The Modified device includes a catheter comprised of a polyether block amide (PEBAX) outer and polytetrafluoroethylene (PTFE) inner, embedded marker band, and replacement of the introducer with a peel-away insertion tool. Please refer to the Table 3.2.1.

Table 3.2.1. Overview of Modifications to the EN Snare System

Component	EN Snare System (Modified)	EN Snare System (Original)	Comments
Snare			Snare unchanged
Torque Device			Torque device unchanged
Catheter	 Embedded markerband	 Swaged markertband	Pt/Ir marker band is embedded in the Modified EN Snare System
	 Hub with integral strain relief	 Hub without strain relief	Hub design modified to include integral strain relief in the Modified EN Snare System
	Materials: Shaft: PEBAX outer with PTFE inner Hub: PEBAX with polycarbonate luer	**Materials:** Shaft: Fluorinated ethylene propylene (FEP) Hub: High density polyethylene (HDPE)	PEBAX materials selected for improved catheter performance and manufacturability. Original EN Snare System catheter purchased from supplier. Modified EN Snare System catheter manufactured in-house by Merit Medical Systems.
Insertion Tool/Introducer		 Introducer: Coaxial configuration	Peel-away design avoids need for over-the-snare-wire withdrawal required for coaxial introducer design.

Component	EN Snare System (Modified)	EN Snare System (Original)	Comments
	Insertion Tool: Peel-away configuration		
	Materials: Tubing: Polypropylene Hub: Purple polypropylene	**Materials:** Tubing: Fluorinated ethylene propylene (FEP) Hub: High density polyethylene (HDPE)	Polypropylene materials selected for improved performance and manufacturability. Original EN Snare System Introducer purchased from supplier. Modified EN Snare System Insertion Tool manufactured in-house by Merit Medical Systems.

Abbreviations: FEP = fluorinated ethylene propylene, HDPE = high density polyethylene, PEBAX = polyether block amide, PTFE = polytetrafluoroethylene

3.3 Accessories

The accessories utilized with the EN Snare System are the Torque Device, introducer (Original EN Snare System), and Insertion Tool (Modified EN Snare System). Additional accessories associated with conventional percutaneous vascular access include, but are not limited to, access needle, introducer, dilator, guidewire, and contrast solution.

Table 3.3.1 Accessory Devices

Device Generation	Accessory Description
Original and Modified EN Snare System	**Torque Device:** Easy-to-grip torque device supports snare torqueability 
Original EN Snare System	**Introducer:** facilitates insertion of the snare into the snare catheter. 
Modified EN Snare System	**Insertion Tool:** facilitates insertion of the snare into the snare catheter. Peel-away design avoids need for over-the-snare-wire withdrawal required for coaxial introducer design. 

3.4 Description of Other Devices Used in Combination

In addition to the accessories listed above (Table 3.4.1), the EN Snare System is used in combination with devices including, but are not limited to, catheters and sheaths.

4.0 Risks and Warnings

4.1 Residual Risks and Undesirable Effects

Description of risks

The Merit Risk Management process is conducted in accordance with EN ISO 14971:2019. Risk assessment processes are utilized to analyse risks associated with the use of Merit devices, including possible misuses of a device. This ensures that all foreseeable potential failure modes and associated risks have been considered and addressed in the device design and/or production quality system. The process involves the following key aspects:

- Identifying potential failure modes, and their likely causes and effects
- Evaluating the probability of occurrence, degree of severity and relative detectability of each failure
- Identifying controls and preventive measures

In accordance all possible risk control measures have been implemented and verified and the EN Snare System has met all applicable regulations and standards. Through the clinical evaluation process, information relative to the clinical state-of-the-art and potential adverse events are identified based on a review of the pertinent clinical evidence.

The intended clinical benefits of endovascular snares include retrieval or manipulation of foreign bodies in the cardiovascular system, and avoidance of the morbidity and mortality associated with open surgical procedures.

Articles published between January 1, 2002 and July 31, 2020 were reviewed. Based on the literature, endovascular snares have been successfully used in the retrieval and repositioning of objects,[3,4] and fibrin stripping of indwelling dialysis catheters.[5] The performance outcomes identified by Wolf et al. (2008)[6] identified primary and secondary success rates with respect to endovascular snares. Primary success is associated with complete snare-mediated intervention whereas secondary success is characterized by the use of adjunctive surgical approaches (e.g., cut-down, forceps) to achieve successful intervention.[6] For purposes of the clinical evaluation, cumulative success will be quantified for the subject devices and the comparable benchmark loop snares. Cumulative success, which is a procedural endpoint, is defined as follows:

- Cumulative Success: Combined rate of (1) complete snare-mediated foreign body/tissue retrieval/repositioning through the

vascular/percutaneous sheath AND (2) snare-mediated foreign body retrieval/repositioning from the original foreign body/tissue position with complete extraction requiring an adjunctive surgical approach.

Primary and secondary success rates from the clinical literature are very high. Overall, primary success rates were 78.7% for the EN Snare System and 79.1% for the benchmark loop (i.e., gooseneck) snares. Secondary success rates were higher, exceeding 90%, for both EN Snare and the gooseneck snares. The potential complications/adverse events related to the subject device as identified in the Instructions For Use (IFUs) are summarized in Table 4.1.1. In addition, the snare/procedure-related major and minor adverse events identified in the Literature, and the corresponding risk assessment harms are presented in Table 4.1.2.

Table 4.1.1. EN Snare System: Potential Complications

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 • Hemorrhage • Soft tissue injury • Arrhythmia • Vascular dissection

Table 4.1.2. Adverse Events: Clinical Literature Data

Snare-Related Adverse Events	**Harms Category**
Major Complications	
Pulmonary embolism	Foreign Body Vascular
Foreign body embolization	
Groin hematoma	Hemorrhage, Soft Tissue Injury
IVC damage with extravasation	Hemorrhage, Soft Tissue Injury
Minor Complications	

Snare-Related Adverse Events	Harms Category
Intermittent ectopy (arrhythmia)	Cardiac Event
Lead dislodgement	Procedure Delay
Foreign body fragmentation	Foreign Body Vascular
Venous access site complication	Hemorrhage, Soft Tissue Injury

The EN Snare System is indicated for the retrieval and manipulation of foreign bodies, and therefore serve as a percutaneous adjunct to a variety of procedures. When used in accordance with the IFUs, the risks associated with the use of subject devices are low and outweighed by the clinical benefits associated with use.

The reported procedural adverse events (AEs) were low, as presented in Table 4.1.3. There were 2 deaths reported in the literature associated with 1 case of intracranial hemorrhage 8 days postop and 1 instance of ventricular fibrillation secondary to aortic dissection. In both cases, the identified adverse events were a result of the interventional procedure or the intravascular foreign body (IFB), and not specifically associated with the use of the snare device. Additional AEs including cardiac tamponade, difficulty advancing sheath, hemopericardium, pain during retrieval, respiratory complications, retained foreign body, sternal wound dehiscence, and wound pain were all unrelated to the use of the snare. Overall snare procedure-related AE rates associated with different clinical application categories for the EN Snare System are shown in Table 4.1.4. Of the snare procedure-related adverse events, there were 6 major (0.6%) and 21 minor (2.1%) events for the EN Snare System. There were no AEs associated with a snare-related failure. Based on the clinical literature data, the EN Snare System exhibits acceptable safety and performance in patients requiring retrieval/manipulation of IFBs (including fibrous tissue/thrombus). There were no reports of unintended Central Venous Catheter (CVC) damage as a result of snare-mediated catheter stripping procedures.

Table 4.1.3. Adverse Events Reported in the Literature

Adverse Event	EN Snare System	Loop Snares
Major Complications		
Foreign body embolization [c]	4/1001 (0.4) [c]	-
Pulmonary embolism [c]	2/1001 (0.2) [c]	-
Retained foreign body [b]	2/1001 (0.2) [b]	-
Aortic dissection [a,b]	1/1001 (0.1) [a,b]	-
Cardiac tamponade [b]	1/1001 (0.1) [b]	-
Groin hematoma	1/1001 (0.1)	-
Intracranial hemorrhage [a,b]	1/1001 (0.1) [a,b]	-

Adverse Event	EN Snare System	Loop Snares
Respiratory complications [b]	-	1/48 (2.1) [b]
Vessel damage with extravasation	1/1001 (0.1)	-
Total	**13/1001 (1.3)**	**1/48 (2.1)**
Snare-related	**0/1001 (0.0)**	**0/48 (0.0)**
Snare procedure-related	**6/1001 (0.6)**	**0/48 (0.0)**
Minor Complications		
Venous access site complication	15/1001 (1.5)	-
Foreign body fragmentation	4/1001 (0.4)	-
Caval perforation (asymptomatic) [b]	1/1001 (0.1) [b]	-
Difficulty advancing sheath [b]	1/1001 (0.1) [b]	-
Hemopericardium [b]	-	1/48 (2.1) [b]
Intermittent ectopy	1/1001 (0.1)	-
Lead dislodgement	1/1001 (0.1)	-
Pain during retrieval [b]	1/1001 (0.1) [b]	-
Sternal wound dehiscence [b]	1/1001 (0.1) [b]	-
Wound pain [b]	1/1001 (0.1) [b]	-
Total	**26/1001 (2.6)**	**1/48 (2.1)**
Snare-related	**0/1001 (0.0)**	**0/48 (0)**
Snare procedure-related	**21/1001 (2.1)**	**0/48 (0)**

Abbreviations: n = adverse events, N = patients
[a] Resulted in patient death, [b] Not snare/procedure-related, [c] Not snare/procedure-related in 1 of the identified cases

Table 4.1.4. Snare Procedure-Related Adverse Event Rates by Clinical Application Category

Clinical Application	EN Snare System AEs, n/N (%)		Loop Snares AEs, n/N (%)s	
	Major	Minor	Major	Minor
RETRIEVAL	**6/980 (0.6)**	**20/980(2.0)**	**0/48 (0)**	**0/48 (0)**
Retrieval: Peripheral	**5/924(0.5)**	**19/924 (2.1)**	**0/34 (0)**	**0/34 (0)**
Cardiac Occluder Retrieval	0/5 (0)[1-4]	0/5 (0)[1-4]	0/1 (0)[4]	0/1 (0)[4]
Central Venous Catheter Retrieval	0/3 (0)[5-7]	0/3 (0)[5-7]	0/2 (0)[6,7]	0/2 (0)[6,7]
Central Venous Catheter Fibrin Sheath Stripping	0/66 (0)[8,9]	0/66 (0)[8,9]	-	

Clinical Application	EN Snare System AEs, n/N (%)		Loop Snares AEs, n/N (%)s	
	Major	**Minor**	**Major**	**Minor**
IVCF Retrieval	5/844 (0.59)[10-17]	19/844 (2.3)[10-17]	0/30 (0)[14]	0/30 (0)[14]
Stent Retrieval	0/2 (0)[18,19]	0/2 (0)[18,19]	-	-
Tissue/Thrombus Retrieval/Removal	0/1 (0)[20]	0/1 (0)[20]	-	-
Other Cardiovascular Retrieval	0/3 (0)[21-23]	0/3 (0)[21-23]	0/1 (0)[22]	0/1 (0)[22]
Retrieval: Cardiac	**1/56(1.8)**	**1/56 (1.8)**	**0/14 (0)**	**0/14 (0)**
Cardiac Occluder Retrieval	0/1 (0)[24]	0/1 (0) [24]	-	-
Central Venous Catheter Retrieval	0/33 (0)[25-32]	0/33 (0)[25-32]	0/5 (0)[29-32]	0/5 (0)[29-32]
IVCF Retrieval	1/5 (40.0)[13,17,33-35]	1/5 (20.0)[17,33-35]	0/4 (0)[16,34]	0/4 (0)[16,34]
Stent Retrieval	0/2 (0)[36,37]	0/2 (0)[36,37]	0/1 (0)[36]	0/1 (0)[36]
Tissue/Thrombus Retrieval/Removal	0/2 (0)[38,39]	0/2 (0)[38,39]	-	-
Other Cardiovascular Retrieval	0/13 (0)[40-50]	0/13 (0)[40-50]	0/4 (0)[45,46,49]	0/4 (0)[45,46,49]
MANIPULATION	**0/21 (0)**	**1/21 (4.8)**	**-**	**-**
Manipulation: Peripheral	**0/5 (0)**	**0/5 (0)**	**-**	**-**
Occluder Placement	0/1 (0)[51]	0/1 (0)[51]	-	-
Central Venous Catheter Repositioning	0/1 (0)[52]	0/1 (0)[52]	-	-
Other Cardiovascular Manipulation	0/3 (0)[53-55]	0/3 (0)[53-55]	-	-
Manipulation: Cardiac	**0/16 (0)**	**1/16 (6.3)**	**-**	**-**
Occluder Placement	0/2 (0)[56,57]	0/2 (0)[56,57]		
Other Cardiovascular Manipulation	0/14 (0)[58-60]	1/14 (7.1)[58-60]	-	-
TOTAL	**6/1001 (0.6)**	**21/1001 (2.1)**	**0/48 (0)**	**0/48 (0)**

Abbreviations: AE = adverse event, n = adverse events, N = procedures

4.2 Warnings and Precautions

The labeled warnings and precautions for the EN Snare System are summarized in Table 4.2.1.

Table 4.2.1. Warnings and Precautions

Category	Labeling Statements
Warnings	• Excessive force used to remove entrapped foreign bodies may lead to device failure. • 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. • Do not use excessive force when manipulating the catheter through an introducer, or when manipulating the snare device. Excessive force may lead to device failure. • 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. • For single patient use only. Do not reuse, reprocess or resterilize. 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 crossinfection, 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. • Nitinol is a nickel titanium alloy. Possible reaction may occur for those patients who exhibit sensitivity to nickel. • After use, dispose of device in a manner consistent with standard protocols for biohazard waste disposal. • There are insufficient safety and performance data to support use of the device in pediatric populations. • In the EU, any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the applicable Member State.
Precautions	Care should be observed when using this device for removal of a large fibrin sheath in order to minimize risk of pulmonary embolism.

4.3 Other Relevant Safety Aspects

There have been no field safety corrective actions or field notifications for the EN Snare System.

5.0 Summary of Clinical Evaluation and Postmarket Clinical Follow-up (PMCF)

5.1 Summary of Clinical Data for the Equivalent Device

Conformity of the EN Snare System has been established through an equivalence demonstration per the following:

- Modified EN Snare System (subject device) and the established Original EN Snare System (equivalent comparator)
- Any identified differences with regard to clinical, technical, and biological characteristics were analyzed and none significantly affected clinical safety or performance. In accordance with MEDDEV 2.7/1 Rev 4, the clinical, technical, and biological equivalence of the above-listed

subject and equivalent comparator device were established through this analysis.

The clinical data for the EN Snare System as presented in Table 5.3.1 and Table 5.3.2 (Section 5.3) represent both the Original and Modified device configurations.

5.2 Summary of Clinical Investigations of the Subject Device

Not applicable, as clinical evaluation based on published literature. There were no clinical investigations of the EN Snare System prior to CE marking.

5.3 Summary of Clinical Data from Other Sources

The devices in the EN Snare System have been used effectively for retrieval and manipulation of foreign bodies (including tissue/thrombus) in the cardiovascular system. Clinical data supporting the safety and performance of the EN Snare System have been derived from the following sources:

- A postmarket clinical follow-up (PMCF) study implemented in 2020.
- A comprehensive literature review using the Embase®, MEDLINE, and PubMed databases for the period from January 1, 2002 to July 31, 2020. Literature search strategies were designed to identify articles relevant to the devices in the EN Snare System. Both favorable and unfavorable references were identified and summarized.

As documented in the PMCF report (PMCFER-QRMT0046-001), clinician surveys were received comprising 42 patient cases with the EN Snare System. Case information is summarized in Table 5.3.1 and Figure 5.3.1. Of the documented clinical use cases, 47.6% (20/42) were associated with foreign-body retrieval and 52.4% (22/42) were reported as foreign-body manipulation. Fibrin sheath/catheter stripping was reported in 55.0% (11/20) of the retrieval cases. Technical success was achieved in 100% of the reported cases and there were no AEs identified by the clinician respondents.

Table 5.3.1. EN Snare Case Use Summary: PMCF Data

Clinical Application	Procedures	Snare Size	Primary Success n/N (%)	Secondary Success n/N (%)	Cumulative Success n/N (%)	Adverse Events n/N (%)
Retrieval	**20**	**4-8 mm (2), 6-10 mm (3), 12-20 mm (4), 18-30 mm (11)**	**20/20 (100)**	**0/20 (0)**	**20/20 (100)**	**0/20 (0)**
Fibrin catheter stripping	11	18-30 mm (11)	11/11 (100)	0-11 (0)	11/11 (100)	0/11 (0)
IVCF retrieval	5	4-8 mm (1), 12-20 mm (4)	5/5 (100)	0/5 (0)	5/5 (100)	0/5 (0)
Retrieval - unspecified	4	4-8 mm (1), 6-10 mm (3)	4/4 (100)	0/4 (0)	4/4 (100)	0/4 (0)
Manipulation	**22**	**4-8 mm (21)**	**22/22 (100)**	**0/22 (0)**	**22/22 (100)**	**0/22 (0)**

Clinical Application	Procedures	Snare Size	Primary Success n/N (%)	Secondary Success n/N (%)	Cumulative Success n/N (%)	Adverse Events n/N (%)
Manipulation - unspecified	20	4-8 mm (20)	20/20 (100)	0/20 (0)	20/20 (100)	0/20 (0)
Guidewire capture – body floss	1	NR	1/1 (100)	0/1 (0)	1/1 (100)	0/1 (0)
Aortic stent graft placement	1	4-8 mm (1)	1/1 (100)	0/1 (0)	1/1 (100)	0/1 (0)
Total	**42**	**4-8 mm (23), 6-10 mm (3), 12-20 mm (4), 18-30 mm (11)**	**42/42 (100)**	**0/42 (0)**	**42/42 (100)**	**0/42 (0)**

Figure 5.3.1. EN Snare Size Distribution: PMCF Data

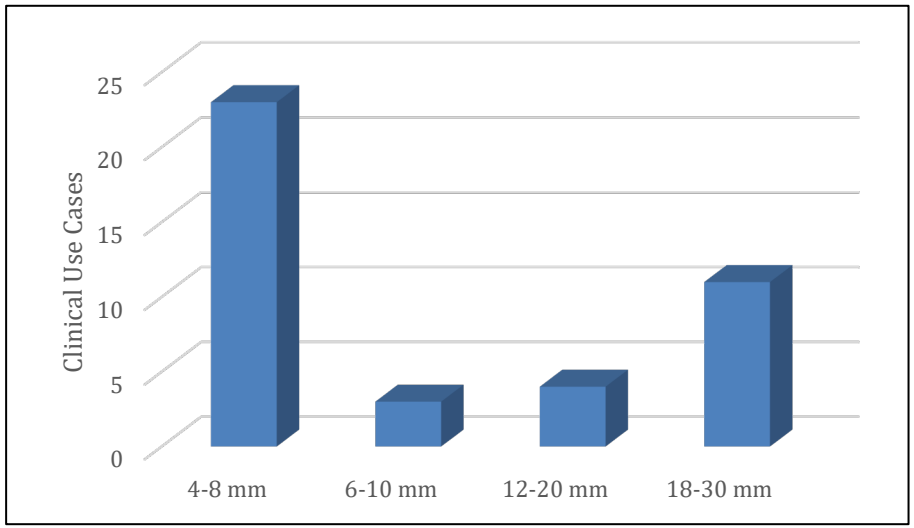


Table 5.3.2 provides a summary of EN Snare System performance data derived from the safety and performance (S&P) clinical literature data as well as the PMCF data. These data are compared to benchmark loop snare performance data from the literature. As indicated by the data, the success rates for EN Snare System are consistent with those reported for competitive snare devices. The data presented only pertains to device use in accordance with the EN Snare System instructions for use. Non-indicated uses of the EN Snare System and benchmark devices have been excluded from the summary data in Table 5.3..

The success rates for the EN Snare System and benchmark loop snares are high and exceed 80% in all cases except cardiac retrievals for the

benchmark devices. For the overall retrieval applications (peripheral and cardiac), the cumulative success rate for the benchmark loop snares is higher than the subject device (*P*=0.034), but the estimated difference is only 4.1%. There is no statistically significant difference in the success rates for snare manipulation procedures (*P*=0.456). The overall total success rate for the benchmark loop snares (89.7%) was statistically significantly higher than the corresponding rate for the EN Snare System (85.5%) (*P*=0.029). Consistent with the other comparisons though, the estimated difference was less than 10%. In conclusion, the subject device satisfies the established acceptance criteria for performance.

Table 5.3.2. Comparative Cumulative Success Rate

Clinical Application	Cumulative Success Rate, n/N (%)		Estimated Difference [95% CI]	P-value p1-p2 ≠ 0	Post-hoc Analysis $\Delta_{0.80}$[61]	*P*-value p1-p2 > 0, p1-p2 < 0
	EN Snare System	Benchmark Loop Snares				
RETRIEVAL	**856/1008 (84.9)**	**407/457 (89.1)**	**-4.1% [-7.7%,-0.5%]**	***P*=0.034‡**	**5.2%**	***P*=0.019‡**
Peripheral	785/932 (84.2)	398/443 (89.8)	-5.6% [-9.3%,-2.0%]	*P*=0.005‡	5.2%	*P*=0.003‡
Cardiac	51/56 (91.1)	9/14 (64.3)	26.8% [-0.6%,53.0%]	*P*=0.022†	38.3%†	-
Unspecified§	20/20 (100)§	-	-	-	-	-
MANIPULATION	**43/43 (100)**	**35/36 (97.2)**	**2.8% [-2.6%,8.1%]**	***P*=.456**	**7.6%**	**-**
Peripheral	5/5 (100)	18/19 (94.7)	5.3% [-4.8%,15.3%]	*P*=1.000†	14.4%†	-
Cardiac	16/16 (100)	17/17 (100)	0 [-,-]	*P*=1.000	-	-
Unspecified§	22/22 (100)§	-	-	-	-	-
Total Peripheral§	**790/937 (84.3)§**	**416/462 (90.0)**	**-5.7% [-9.3%,-2.1%]**	***P*=0.004‡**	**5.2%**	***P*=0.002‡**
Total Cardiac§	**67/72 (93.1)§**	**26/31 (83.9)§**	**9.2% [-5.0%,23.4%]**	***P*=0.163†**	**20.3%†**	**-**
TOTAL	**899/1051 (85.5)**	**442/493 (89.7)**	**-4.1% [-7.5%,-0.7%]**	***P*=0.029‡**	**4.9%**	***P*=0.015‡**

Abbreviations: CI = confidence interval

† Insufficient clinical data ($\Delta_{0.80}$>10%), ‡ Statistically significant, § PMCF data are not segregated into peripheral and cardiac

Safety data for the EN Snare System and benchmark loop snares are summarized in Table 5.3.3. These data are derived from the safety and performance (S&P) clinical literature data and postmarket clinical follow-up (PMCF) data. These data are compared to benchmark loop snare safety data from the literature. In all cases, non-indicated uses of the subject and benchmark devices have been excluded from the summary data in Table 5.3.3.

The EN Snare System exhibits very low major and minor AE rates, and these rates compare favorably with those reported for other benchmark snares in the literature. The overall major AE rates for the EN Snare System and benchmark loop snares are 0.6% and 0.2%, respectively. The overall minor AE rate for the EN Snare System is 2.0%, whereas the minor AE rate for the benchmark loop snares is 1.6%. There are no statistically significant differences between the overall major AE rate (*P*=0.441) or minor AE rate (*P*=0.691) for the EN Snare System and the benchmark loop snares. Based

on the post-hoc analysis, there is sufficient clinical evidence to make reliable statistical conclusions regarding the total overall major and minor AE rates (i.e., $\Delta_{0.80} \leq 10\%$). In both cases, the subject device satisfies the established acceptance criteria for safety.

Table 5.3.3. Snare-Related Adverse Events: EN Snare System

Clinical Application	Adverse Event Rate, n/N (%)		Estimated Difference [95% CI]	*P*-value p1-p2≠0	Post-hoc Analysis $\Delta_{0.80}$[61]
	EN Snare System	Loop Snares			
Major Adverse Events					
RETRIEVAL	**6/1000 (0.6)**	**1/457 (0.2)**	**0.4% [-0.3%,1.0%]**	***P*=0.445**	**0.9%**
Peripheral	5/924 (0.5)	1/443 (0.2)	0.3% [-0.3%,1.0%]	*P*=0.670	0.9%
Cardiac	1/56 (1.8)	0/14 (0)	1.8% [-1.7%, 5.3%]	*P*=1.000	5.0%
Unspecified§	0/20 (0)§				
MANIPULATION	**0/43 (0)**	**0/36 (0)**	**0 [-,-]**	***P*=1.000**	-
Peripheral	0/5 (0)	0/19 (0	0 [-,-]	*P*=1.000	-
Cardiac	0/16 (0)	0/17 (0	0 [-,-]	*P*=1.000	-
Unspecified§	0/22 (0)§				
Total Peripheral	**5/929 (0.5)§**	**1/462 (0.2)**	**0.3% [-0.3%,1.0%]**	***P*=0.670**	**0.9%**
Total Cardiac	**1/72 (1.4)§**	**0/31 (0)**	**1.4% [-1.3%,4.1%]**	***P*=1.000**	**3.9%**
TOTAL MAJOR	**6/1043 (0.6)**	**1/493 (0.2)**	**0.4% [-0.2%,1.0%]**	***P*=0.441**	**0.9%**
Minor Adverse Events					
RETRIEVAL	**20/1000 (2.0)**	**6/457 (1.3)**	**0.7% [-0.6%,2.0%]**	***P*=0.403**	**1.9%**
Peripheral	19/924 (2.1)	5/443 (1.1)	0.9% [-0.4%, 2.3%]	*P*=0.275	2.2%
Cardiac	1/56 (1.8)	0/14 (0)	1.8% [-1.7%,5.3%]	*P*=1.000	5.0%
Unspecified§	0/20 (0)§				
MANIIPULATION	**1/43 (2.3)**	**3/36 (8.3)**	**-6.0% [-16.1%,4.1%]**	***P*=0.326**	**14.4%†**
Peripheral	0/5 (0)	2/19 (10.5)	-10.5% [-24.3%,3.3%]	*P*=1.000	22.8%†
Cardiac	1/16 (6.3)	1/17 (5.9)	0.4% [-15.9%,16.7%]	*P*=1.000	27.0%†
Unspecified§	0/22 (0)§				
Total Peripheral§	**19/929 (2.0)§**	**7/462 (1.5)**	**0.5% [-0.9%,2.0%]**	***P*=0.675**	**2.4%**
Total Cardiac§	**2/72 (2.8)§**	**1/31 (3.2)**	**-0.4% [-7.7%,6.8%]**	***P*=1.000**	**10.4%†**
TOTAL MINOR	**21/1043 (2.0)**	**8/493 (1.6)**	**0.4% [-1.0%,1.8%]**	***P*=0.691**	**2.0%**

† Insufficient clinical data ($\Delta_{0.80}$>10%), § PMCF data are not segregated into peripheral and cardiac

5.4 Overall Summary of Clinical Performance and Safety

The EN Snare System has been commercially available since 2009 and is indicated for the percutaneous retrieval and manipulation of vascular foreign bodies (including tissue/thrombus). Retrieval and manipulation procedures include indwelling venous catheter fibrin sheath stripping. All percutaneous/endovascular snares have a risk of complications and/or failure, and the risks for an individual are an unpredictable combination of patient, the primary surgical/interventional procedure, and device-related interactions. The technology associated with the EN Snare System is well established, and high cumulative retrieval success rates and low adverse event/complications rates have been demonstrated for the EN Snare System. None of the complications were unexpected for endovascular snares, and all the identified adverse events are addressed in the product IFU. Furthermore, there is high potential for long-term complications associated with untreated intravascular foreign bodies. Based on design verification/validation testing, safety and performance outcomes in the literature, and post market surveillance data, there are no known uncertainties regarding safety and performance of the EN Snare System and there are no identified undesirable side effects associated with its use. Therefore, the risks associated with the use of the EN Snare System are low and outweighed by the clinical benefits, when used in accordance with the IFUs. The risk/benefit assessment for the EN Snare System is summarized in Table 5.4.1.

Table 5.4.1. Summary of Benefit/Risk Assessment[62,63]

Factor	Notes	Assessment
Uncertainty		
Quality of the study design	• How robust were the data?	EN Snare System: 61 articles
Quality of the study conduct	• How was the trial designed, conducted, and analyzed?	Data consist primarily of case reports and case series
	• Are there missing data?	No
Robustness of the study results analysis	• Are the study results repeatable?	N/A – case reports and case series
	• Is this study a first of a kind?	No
	• Are there other studies that achieved similar results?	Yes
Generalizability of the results	• Can the results of the study be applied to the population generally, or are they more intended for discrete, specific groups?	Yes
Characterization of the disease/condition	• How does the disease/condition affect the patients that have it?	Increased risk of death/serious complications
	• Is the condition treatable?	Yes
	• How does the condition progress?	60–71% incidence of death/serious complications in untreated foreign body cases.[64] In stable patients with retained cardiopulmonary foreign bodies, 81% remained asymptomatic at 845 day mean follow-up.[65] Fibrin

Factor	Notes	Assessment
		sheath formation around the intravenous segment of long-term hemodialysis access catheters is one of the most common causes of catheter failure.[66,67] Thrombotic occlusion of CVCs resulting from fibrin build-up has been reported to occur at rates ranging from 3% to 79%.[68]
Patient tolerance for risk, and perspective on benefit:	• Did the sponsor present data regarding how patients tolerate the risks posed by the device? • Are the risks identifiable and definable?	N/A Yes; see Section 6.0
Disease severity	• Is the disease so severe that patients will tolerate a higher amount of risk for a smaller benefit?	60–71% incidence of death/serious complications in untreated cases.[64] In stable asymptomatic patients, conservative therapy is viable.[65] Thrombotic occlusion of CVCs resulting from fibrin build-up has been reported to occur at rates ranging from 3% to 79%.[68]
Disease chronicity	• Is the disease/condition chronic? • How long do patients with the disease/condition live? • If chronic, is the illness easily managed with less invasive or difficult therapies?	Only if untreated 60–71% incidence of death/serious complications in untreated cases[64] In asymptomatic patients, watchful waiting may be an appropriate strategy[65]
Patient-centric assessment	• How much do patients value this treatment?	High – successful retrieval avoids morbidity and mortality associated with the alternatives of more invasive surgical retrieval or a retained foreign body in symptomatic patients.
	• Are patients willing to accept the risk of this treatment to achieve the benefit?	Yes
	• Does the treatment improve overall quality of life?	Yes
	• How well are patients able to understand the benefits and risks of the treatment?	In cases of planned intervention for unstable foreign bodies, patients are able to understand that the benefits of intervention far outweigh the risks.[64] Not applicable in cases of unplanned intervention during a procedure.
Availability of alternative treatments or diagnostics	• What other therapies are available for this condition?	Conservative therapy/monitoring, stone baskets, intravascular forceps, biopsy forceps, surgical retrieval
	• How effective are the alternative treatments?	Conservative treatment viable in stable asymptomatic patients; 81% of patients remain asymptomatic at 845 day mean follow-up.[65] The use of other treatments such as stone baskets, intravascular forceps, and biopsy forceps have been reported, but guidance can be difficult,[64] there is an increased risk of vessel damage or perforation,[64] and they pose size limitations.[69] Surgical retrieval is typically reserved for cases where percutaneous approaches have failed.[70]

Factor	Notes	Assessment
	• How does their effectiveness vary by subpopulation?	N/A
	• How well-tolerated are the alternative therapies?	Stone baskets are effective for foreign body retrieval, but can be difficult to guide[64] Intravascular forceps present and increased risk of vascular damage/perforation as compared to snares[64]
	• How does their tolerance vary by subpopulation?	N/A
	• What risks are presented by any available alternative treatments?	60–71% incidence of death/serious complications in untreated cases[64] Stone baskets are effective for foreign body retrieval, but can be difficult to guide[64] Intravascular forceps present and increased risk of vascular damage/perforation as compared to snares[64]
Risk mitigation	• Could you identify ways to mitigate the risks (such as using product labeling, establishing education programs, providing add-on therapy, etc.)?	Well established technology that is compatible with standard interventional techniques; no additional labeling or clinician training have been identified to further mitigate risks
	• What is the type of intervention proposed?	N/A
Postmarket data	• Are there other devices with similar indications on the market? Are the probabilities for effectiveness and rates of harmful events from those devices similar to what is expected for the device under review?	Yes; see Section 6.0
	• Is postmarket data available that change the risk/benefit evaluation from what was available when the previous devices were evaluated?	No
	• Is there reason to consider evaluation of any of the following elements further in the postmarket setting, due to the risk/benefit evaluation as described above? ○ Longer-term device performance. ○ Effectiveness of training programs or provider preferences in use of device. ○ Subgroups (e.g., pediatrics, women). ○ Rare adverse events.	None of the additional postmarket elements are considered applicable to the subject device. Snares are utilized on a transient basis, therefore long-term device performance is not applicable. Additionally, snares are well-established interventional devices, and additional training/use cases are not deemed necessary. No safety/performance issues related to patient subgroups or rare adverse events have been identified.
	• Is there reason to expect a significant difference between real-world performance of the device and the performance found in pre-market experience with the device?	No; data presented is derived from real-world case studies and case series.

Factor	Notes	Assessment
	• Is there data that otherwise would be provided to support approval, which could be deferred to the postmarket setting?	N/A
	• Is there off-label use, or on-label use that is different than originally expected?	No
Novel technology addressing unmet medical need	• How well is the medical need this device addresses being met by currently available therapies?	Highly effective
	• How desirable is this device to patients?	Highly desirable as compared to surgical intervention
Summary of the Benefit(s)	**Summary of the Risk(s)**	**Summary of Other Factors**
EN Snare System		
Successful retrieval avoids morbidity and mortality associated with the alternatives of more invasive surgical retrieval or a retained foreign body in symptomatic patients EN Snare System: Cumulative Success: 85.5% * Loop Snares: Cumulative Success: 89.7% * * Significant difference (*P*=0.029) but estimated difference < 10%	Complication occur as a low rate and they are generally transient in nature EN Snare System: Major AE Rate: 0.6% * Minor AE Rate: 2.0% ** Complaint Rate (PMS): 0.086% Loop Snares: Major AE Rate: 0.2% * Minor AE Rate: 1.6% ** * No significant difference (*P*=0.441) ** No significant difference (*P*=0.691)	Conservative treatment can be a viable approach in stable asymptomatic patients,[65] but reports of death/serious complications have been reports in 60–71% of untreated cases[64] Well established technology that is compatible with standard interventional techniques

5.5 Planned Postmarket Clinical Follow-up (PMCF)

The need to conduct PMCF activities is subject to annual review as part of the Post Market Surveillance (PMS) process and also based on emerging data. All data are subject to a risk review from which a determination is made regarding the requirements for PMCF.

The plan for ongoing PMCF for the EN Snare System is detailed in PMCFP-QRMT0046-001. The analysis will include consideration the following:

- Assessment of any safety or performance issues identified in the product feedback evaluation forms to determine what impact if any was contributed by the EN Snare System.
- As part of the annual update, safety and performance data collected from the PMCF activity and the clinical literature will be analyzed and compared to the safety and performance clinical literature data for the benchmark loop snares.
- Assessment if any safety or performance issues identified in the product feedback evaluation forms constitutes a previously unidentified residual risk.

6.0 Diagnostic or Therapeutic Alternatives

6.1 Review of Medical Condition

With the increasing frequency of endovascular interventions, there is a corresponding increase in the incidence of lost or embolized foreign bodies.[64] These intravascular foreign bodies (IFBs) are typically iatrogenic in origin and commonly consist of devices such as coils and occluders, or fragments of guidewires, catheters/sheaths, inferior vena cava filters (IVCFs), cardiac valves, or pacing leads.[64] Fracture of central venous catheters (CVCs) (e.g., Port-A-Caths, peripherally inserted central catheters [PICCs]) also presents a source of IFBs that occurs in approximately 1% of patients.[71] Clavicle pinch-off occurs in approximately 1% of CVCs,[72,73] and approximately 40% of these cases result in catheter fracture.[72] The conditions leading to CVC pinch-off and fracture are associated with the anatomical proximity of the subclavian vein and the sternoclavicular and first costosternal articulations.[74] Coronary stent displacement and migration is the most commonly reported instance necessitating foreign body retrieval because of the high number of cases performed.[75] Coronary stent embolization has been reported to occur at a rate of 0.9% per patients and 0.49% per stent.[64] These rates are higher for manually crimped stents as compared to premounted balloon expandable stents.[64] Patient survival rates are 100% in most reported cases series of IFB retrieval, whereas the incidence of death or serious complications range from 60% to 71% in untreated cases.[64] Complications associated with untreated IFBs include thrombophlebitis, sepsis, arrhythmia, myocardial injury, bacterial endocarditis, vessel occlusions, ischemia, and cardiac perforation.[64]

Egglin et al. (1995) found that more than one retrieval system/technique was required for successfully remove IFBs in 25% of cases.[76] With the introduction of the Amplatz Goose Neck Snare design, retrieval procedures have become easier and more efficient with the need for only single-sided access.[77] In their review of 135 publications between 2000 and 2012, Schechter et al. (2013) identified 19 case series with 5 or more patients and 115 case reports.[70] In the case series reports comprising 574 IFBs, they found that 94% of endovascular retrievals were successful, and an additional 1.6% of retrieval cases were successful using a combined open/endovascular approach.[70] Only 3.7% of IFBs could not be retrieved using minimally-invasive approaches.[70] Unsuccessful retrieval rates were higher (14.4%) in the case reports, and 32% of these reports involved symptomatic patient presentation.[70] Complication rates of 3.7%[70] to 4.2%[78] are associated with IFB retrieval, and include cardiac arrhythmia, pulmonary embolism, valve damage, groin hematoma, hemoptysis, and device fracture.[70,78]

In addition to IFBs, retrieval of thrombotic emboli and/or tissue is another area that involves the use of surgical or endovascular interventional techniques. These clinical conditions include pulmonary embolism,[79] ischemic neurovascular thromboembolism,[80] and fibrotic occlusion of CVCs.[67] Although thrombolytic therapy is commonly the first-line treatment for embolic events, these techniques are not successful in some cases and may be contraindicated in some patients.[79,80] For these patients, a variety of mechanical thrombectomy techniques and tools have been utilized. In the case of acute stroke therapy, mechanical thrombectomy has extended the time window for effective intervention.[81] In many instances, mechanical

embolectomy is combined with active aspiration to retrieve clot fragments and minimize the chance of embolic debris migration to distal vessels.[80,81] The treatments options and interventions utilized to address these various medical conditions are addressed in the following section.

6.2 Alternative Treatment Options and Interventions

Conservative Management

Although retrieval of IFBs is associated with good survival and low complication rates,[64] there are instances where conservative management is the preferred course of treatment. These include cases where IFB retrieval would result in adverse impacts on other implanted devices[21] or require extensive surgical intervention for extraction.[65] For devices such as inferior vena cava filters (IVCFs), only 47–50 % of filter fragments may be accessible to percutaneous retrieval tools.[65] Adopting a conservative approach has been shown to be a viable approach provided that the retained IFBs are stable and asymptomatic.[65] In a case series including 19 patients with 35 retained cardiopulmonary IFBs, 81% of the patients remained asymptomatic at a mean follow-up of 845 days.[65]

Surgical Retrieval

Open approaches to IFB retrieval are required in some instances, and the literature reports include sternotomy with cardiopulmonary bypass, thoracotomy, laparotomy, and laparoscopy.[70] As identified by Schechter et al. (2013) in their literature review, open retrieval approaches may be required for patients in whom multiple percutaneous retrieval attempts have failed.[70]

Endovascular Retrieval

A variety of endovascular tools including stone baskets, intravascular forceps (e.g., biliary or biopsy), guidewires, balloon catheters, and biliary or myocardial biopsy forceps have been utilized for IFB retrieval.[64,69,70] Stone baskets were originally designed to remove ureteral and biliary stones, and they are comprised of expandable wire loops contained within an outer delivery sheath.[69] They can be particularly useful in larger diameter vessels, but they can be difficult to guide.[64] Intravascular forceps have side-opening jaws and are available in sizes ranging from 3–12 Fr.[64] These devices are advantageous over snares as they do not require the IFB to present a free edge, but they also pose an increased risk of vessel damage or perforation.[64] The larger diameter and rigidity of intravascular forceps often limits their utility for IFB retrieval.[69]

Snares are used in various clinical settings where there is a need for a device to retrieve and manipulate foreign objects.[78,82] These include anatomical regions such as the cardiovascular system (e.g., coronary, central venous, peripheral vessels), hollow organs, and extra-cranial neurovasculature. Other authors have reported on the use of snares in endovascular fibrin stripping of indwelling dialysis catheters[66] and assisted vascular access.[83] Loop snares are most effective when the foreign fragment or target object presents a free end for ensnarement.[82] One or more of the loops of the

snare is positioned in the vessel so that the fragment is present in the loop, and the catheter sheath is advanced toward the loop, trapping the device within the closed loop. The catheter/ loop system with the snared device fragment are then removed as a single unit through the insertion site.

6.3 Professional Guidelines and Recommendations

Clinical practice guidelines and consensus statements issued by the following professional societies were reviewed to inform on the management IFBs and tissue/thrombus retrieval:

- 2006 SIR Guidelines for the Use of Retrievable and Convertible Vena Cava Filters[84]
- 2003 SIR Clinical Practice Guidelines[85]
- 2008 European Society of Cardiology (ESC) Guidelines on the Diagnosis and Management of Acute Pulmonary Embolism[79]
- 2018 ACR Appropriateness Criteria for the Management of Venous Thromboembolism and Interior Vena Cava Filters[86]
- 2018 Kidney Disease Outcome Quality Initiative (KDOQI) Clinical Practice Guidelines for Vascular Access[87]

The published guidelines reflect the judgment of acknowledged experts in the field who, based on their experience and on a detailed examination of the available literature, provide guidance to the general medical community on endovascular procedures relevant to foreign body and thrombus/tissue retrieval. These guidelines inform on appropriate and relevant safety and performance measures for the target therapy and alternative therapies. Although the guidelines may describe the clinical use of various devices, the application of such devices may or may not be within the labeled indications for use provided by the manufacturer. Therefore, the guidelines represent current clinical practice and not necessarily intended device use.

Table 6.3.1. Standard of Care Guidelines and Recommendations for the Management of Medical Condition

Recommendation	Grade/Strength of Recommendation	Level of Evidence/GRADE
2008 ESC Guidelines on the Diagnosis and Management of Acute Pulmonary Embolism[79]		
Catheter embolectomy or fragmentation of proximal pulmonary arterial clots may be considered as an alternative to surgical treatment in high-risk patients when thrombolysis is absolutely contraindicated or has failed.	IIb	C
2018 KDOQI Clinical Practice Guidelines for Vascular Access[87]		
Statements: Mechanical management of CVC dysfunction (22.6) KDOQI considers it reasonable that the decision to perform fibrin sheath disruption during CVC exchange for CVC dysfunction, be based on the operator's discretion and best clinical judgment.		Expert Opinion*

Recommendation	Grade/Strength of Recommendation	Level of Evidence/GRADE
(22.7) There is inadequate evidence for KDOQI to make a recommendation on the efficacy of or method of fibrin sheath disruption based on CVC patency outcomes.		Expert Opinion*
(22.8) KDOQI considers it reasonable that CVC removal followed by replacement at a different site should be the last resort after conservative, medical, and other mechanical (e.g. angioplasty, CVC exchange) strategies have all failed to treat CVC dysfunction.		Expert Opinion*
2018 ACR Appropriateness Criteria for the Management of VTE and IVCFs[86]		
Variant 9: Indwelling retrievable inferior vena cava filter with failed first retrieval attempt: Reattempt Retrieval with Advanced Techniques: Once the decision to retrieve a filter has been made, technical success of retrieval is high. Retrieval techniques have evolved in recent years. Advanced techniques using snares, guidewires, and angioplasty balloons have been used when routine techniques fail. Lasers may be used to retrieve embedded filters. While advanced retrieval techniques enjoy high success and somewhat low complication rates (98.2% and 1.7%, respectively, in one study), complication rates are nevertheless higher when advanced techniques are required. If a first retrieval attempt is unsuccessful, referral to a center that specializes in advanced retrieval techniques will often result in successful removal.		Usually Appropriate

Abbreviation: CVC = central venous catheter

* Expert opinion statement that allows for the use of "the clinician's discretion and best clinical judgment" means that there is currently no rigorous evidence to recommend a therapy, device, or strategy over another.

Endovascular management of IFBs and tissue/thrombus retrieval requires clinical skill and familiarity with the full range of available interventional tools and techniques. High technical and clinical success rates along with low complication rates are generally observed for snare-mediated procedures. Snares provide a safe and effective means of percutaneous intervention for IFB and tissue/thrombus retrieval.

7.0 Suggested profile and training for users

Placement of the devices in the EN Snare System should be performed by trained healthcare professionals. Clinician specialties typically include interventional radiologists and interventional cardiologists.

8.0 Applicable Harmonized Standards and Common Specifications

All applied common specifications (CS), international standards harmonized under the medical device directives and/or the MDR, relevant adopted monographs of the European pharmacopoeia (MDR, Article 8 (2)), and other relevant standards, as applicable, are summarized in Table 8.1.

Table 8.1. Standard Conformance Summary

Standards Title	Merit Compliance Date/Version	Merit Compliance to State of the Art (Full/Partial/No, per applicable standard sections)	Justification for No or Partial Compliance
Labelling			
Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)	**EN ISO 15223-1:2016**	Full	N/A
Terminology, Symbols and Information Provided with Medical Devices; Information Supplied by the Manufacturer with Medical Devices	**EN 1041:2008+A1:2013**	Full	N/A
General Standards – Sterilization			
Sterilization of Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization	**EN ISO 11135:2014 & EN ISO 11135:2014/A1:2019**	Full	N/A
Product Adoption and process equivalency for ethylene oxide sterilization	**AAMI TIR28:2016**	Full	N/A
Classification of Air Cleanliness, Clean rooms & Associated Controlled Environments. Part 1: Classification of air cleanliness	**EN ISO 14644-1:2015**	Full	N/A
Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration	**EN ISO14644-2:2015**	Full	N/A
Sterilization of medical devices -- Microbiological methods -- Part 1: Determination of a population of microorganisms on products	**EN ISO 11737-1:2018**	Full	N/A
Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide sterilization residuals	**EN ISO 10993-7:2008 & EN ISO 10993-7:2008 /AC:2009**	Full	N/A
Bacterial Endotoxins Test	**ANSI/AAMI ST72:2019**	Full	N/A
General Standards – Quality Systems			
Quality Systems – Medical Devices – Quality Management Systems. Requirements for Regulatory Purposes	**EN ISO 13485:2016**	Full	N/A
Risk Management			
Medical Devices - Application of Risk Management to Medical Devices	**EN ISO 14971:2019**	Full	N/A

Standards Title	Merit Compliance Date/Version	Merit Compliance to State of the Art (Full/Partial/No, per applicable standard sections)	Justification for No or Partial Compliance
Biological Safety			
Biological Evaluation of Medical Devices – Part 1: Evaluation and testing	**ISO 10993-1:2018**	Full	N/A
Biological evaluation of medical devices -- Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	**ISO 10993-3:2014**	Full	N/A
Biological evaluation of medical devices -- Part 4: Selection of tests for interactions with blood	**ISO 10993-4:2017**	Full	N/A
Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity	**ISO 10993-5:2009**	Full	N/A
Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization	**ISO 10993-10: 2010**	Full	N/A
Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity	**ISO 10993-11:2017**	Full	N/A
Biological Evaluation of Medical Devices – Part 12: Sample preparation and reference materials	**ISO 10993-12:2012**	Full	N/A
Biological evaluation of medical devices — Part 19: Physico-chemical, morphological and topographical characterization of materials	**ISO 10993-18:2020**	Full	N/A
Standard Guide for Biocompatibility of Medical Device Packaging Materials	**ISO 10993-19:2020**	Full	N/A
Clinical Evaluation			
Clinical evaluation: Guide for manufacturers and notified bodies	**MEDDEV 2.7/1 Rev4**	Full	N/A
Design Control – Catheter			
Intravascular catheters — Sterile and single-use catheters — Part 1: General requirements	**ISO 10555-1:2013 & ISO 10555-1:2013/Amd 1:2017**	Full	Sections not tested: 4.9 Flowrate; 4.10 Power injection; 4.11 Side holes. All are N/A for a snare catheter.
Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications	**ISO 80369-7:2016**	Full	N/A
Design Control - Snare			
Sterile Single-Use Intravascular Catheter Introducers	**ISO 11070:2014/A1:2018**	Full	Section 4 “General Requirements” and

Standards Title	Merit Compliance Date/Version	Merit Compliance to State of the Art (Full/Partial/No, per applicable standard sections)	Justification for No or Partial Compliance
			Section 8 "Additional requirements for guidewires" are only applicable.
Usability			
Medical Devices – Application of usability engineering to medical devices	**IEC 62366-1:2015** & **IEC 62366-1:2015/COR1:2016**	Partial	Compliant to ISO62366-1:2015 Annex C. Product released to manufacture pre 2015 and as such only ISO62366-1:2015 Annex C applies.
Packaging			
Packaging for Terminally Sterilized Medical Devices. Part 1: Requirements for materials, sterile barrier systems, and packaging systems.	**EN ISO 11607-1:2020**	Full	N/A
Packaging for Terminally Sterilized Medical Devices. Part 2: Validation requirements for forming, sealing and assembly processes	**EN ISO 11607-2:2020**	Full	N/A
Packaging -- Complete, filled transport packages and unit loads -- Conditioning for testing	**EN ISO 2233:2001**	Full	N/A
Standard Practice for Performance Testing of Shipping Containers and Systems - ASTM D4169 - 16	**ASTM D4169 - 16**	Full	N/A
Standard Test Method for Detecting Gross Leaks in Medical Packaging by Internal Pressurization (Bubble Test) - ASTM F 2096-11 (2019)	**ASTM F2096 – 11 (2019)**	Full	N/A
Standard Test Method for Detecting Seal Leaks in porous Medical Packaging by Dye Penetration - ASTM F 1929	**ASTM F1929 - 15**	Full	N/A
Standard Test Method for Seal Strength of Flexible Barrier Materials - ASTM F88	**ASTM F88 / F88M - 15**	Full	N/A
Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices - ASTM F1980	**ASTM F1980 - 16**	Full	N/A
Post Market Clinical Follow-Up			
Post Market Clinical Follow-up studies	**MEDDEV 2.12/2 Rev2**	Full	N/A
Vigilance			
Guidelines on a Medical Devices Vigilance System	**MEDDEV 2.12/1 Rev8**	Full	N/A

9.0 Revision History

SSCP revision #	Date issued	Change description	Revision validated by the Notified Body
SSCP0902 Rev 001	ECN141747	Initial Release of SSCP	☐ Yes Validation language: English ☐ No (only applicable for class IIa or some IIb implantable devices for which the SSCP is not yet sampled for validation by the NB)
SSCP0902 Rev 002	ECN151705	• Inclusion of SRN for manufacturer and European Authorised Representative. • Assignment of single part number for EMPOWER snare system. • Clarification of use in adult population and inclusion of warning with regard to pediatric use.	☒ Yes Validation language: English ☐ No (only applicable for class IIa or some IIb implantable devices for which the SSCP is not yet sampled for validation by the NB)

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