Summary of Safety and Clinical Performance (SSCP)

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the ONE Snare Endovascular Snare, ONE Snare Endovascular Microsnare, EMPOWER Single Loop Snare System, and Medtronic Retrieval Snare Kit System. These systems will be referred to hereafter under the term ONE Snare Family.

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

The English version of this SSCP document (SSCP0069) has been validated by the notified body (NB#2797). The following information is intended for users/healthcare professionals. A supplemental SSCP with information for patients was not established since the devices in the ONE Snare Family are not implantable devices for which patients are provided an implant card, nor are the devices intended to be used directly by patients.

1.0 Device identification and general information

1.0 Device trade name(s):

The device(s) and model numbers covered by this SSCP are presented in Table 1.

Table 1. Devices Included in this SSCP

Device Name	Product Numbers
ONE Snare Endovascular Snare System (petite and standard straight and 15-degree angled configurations) *	ONE500, ONE1000, ONE1500, ONE2000, ONE2500, ONE3000, ONE3500, ONE1001, ONE2501, ONE1501
ONE Snare Replacement Catheters	ONE4000, ONE6000
ONE Snare Microsnare System	ONE200, ONE201, ONE400, ONE401, ONE700, ONE701
EMPOWER Single-Loop Snare System	8784**
Medtronic Retrieval Snare Kit System	ONE1500-MDTCE

* Throughout this document, the device name refers to the specified product numbers unless otherwise noted. Where distinctions between the ONE Snare petite and standard systems and/or straight and 15-degree angled catheter configurations are appropriate, these systems and configurations are categorized individually.
** P/N 8784 is also an OEM part of Boston Scientific

1.1 Manufacturer Information

The name and address of the manufacturer of the ONE Snare Family are provided in Table 2.

Table 2. Manufacturer Information

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

Abbreviations: USA = United States of America

1.2 Manufacturer Single Registration Number (SRN)

The Single Registration Number (SRN) for the manufacturer is included in Table 3.

1.3 Basic UDI-DI

The basic Unique Device Identifier (UDI) with Device Identification (DI) key is provided in Table 3.

1.4 Medical Device Nomenclature Description / Text

The European Medical Device Nomenclature (EMDN) and Classificazione Nazionale dei Dispositivi medici (CND) codes and descriptors for the subject devices are listed in Table 3.

1.5 Risk Class of Device

The European Union (EU) device risk classification(s) for the ONE Snare Family are listed in Table 3.

Table 3. Device Identification Information

Device Name	EU Device Class	Product Number	Basic UDI-DI	Single Registration Number (SRN)	EMDN/CND Code	EMDN/CND Terms
ONE Snare Endovascular Snare System	Class III, Rule 7	ONE500, ONE1000, ONE1500, ONE2000, ONE2500, ONE3000, ONE3500, ONE1001, ONE2501, ONE1501	088445048822DX	US-MF-000001366	C019005	Retrieving Systems for Vascular Foreign Bodies
ONE Snare Replacement Catheters	Class III, Rule 7	ONE4000, ONE6000	088445048822DX	US-MF-000001366	C019005	Retrieving Systems for Vascular Foreign Bodies
ONE Snare Microsnare System	Class III, Rule 7	ONE200, ONE201, ONE400, ONE401, ONE700, ONE701	088445048822DX	US-MF-000001366	C019005	Retrieving Systems for Vascular Foreign Bodies
EMPOWER Single-Loop Snare System	Class III, Rule 7	8784*	088445048822DX	US-MF-000001366	C019005	Retrieving Systems for Vascular Foreign Bodies
Medtronic Retrieval Snare Kit System	Class III, Rule 7	ONE1500-MDTCE	088445048822DX	US-MF-000001366	C019005	Retrieving Systems for Vascular Foreign Bodies

* P/N 8784 is also an OEM part of Boston Scientific
Abbreviations: CND = Classificazione Nazionale dei Dispositivi medici; EMDN = European Medical Device Nomenclature; EU = European Union; SRN = Single Registration Number; UDI-DI = Unique Device Identifier with Device Identification

1.6 Year of EU Market Introduction

The year that the ONE Snare Family was first placed on the EU market is presented in Table 4.

1.7 Authorised Representative (if applicable)

The name of the authorized representative(s) and, if applicable, the SRN are provided in Table 4.

1.8 Notified Body

The Notified Body (NB) involved in the conformity assessment of the ONE Snare Family in accordance with Annex IX or Annex X of the Medical Device Regulation (MDR) and responsible for validating the SSCP is listed in Table 4.

1.9 NB Single Identification Number

The NB Single Identification Number is listed in Table 4.

Table 4. Authorized Representative and Notified Body Information

Device Name	Year Placed on EU Market	Authorized Representative		Notified Body (NB)	
		Name	SRN	Name	ID Number
ONE Snare Endovascular Snare System and Replacement Catheters (ONE500, ONE1000, ONE1500, ONE2000, ONE2500, ONE3000, ONE3500, ONE1001, ONE2501, ONE4000, ONE6000)	2012	Merit Medical Ireland Ltd.	IE-AR-000001011	BSI	2797
ONE Snare Endovascular Snare System with 15-degree angle (ONE1501)	-	Merit Medical Ireland, Ltd.	IE-AR-000001011	-	-
ONE Snare Microsnare System (ONE200, ONE201, ONE400, ONE401, ONE700, ONE701)	2014	Merit Medical Ireland, Ltd.	IE-AR-000001011	BSI	2797
EMPOWER Single-loop Snare System (8784)	2017	Merit Medical Ireland, Ltd.	IE-AR-000001011	BSI	2797
Medtronic Retrieval Snare Kit System (ONE1500-MDTCE)	-	Merit Medical Ireland, Ltd.	IE-AR-000001011	-	-

Abbreviations: BSI = British Standards Institution; EU = European Union; ID = identification; SRN = Single Registration Number

2.0 Intended Use of the Device

2.0 Intended Purpose

The labeled intended purpose for the ONE Snare Family device configurations are summarized in Table 5.

Table 5. ONE Snare Family: Intended Purpose

Product Configuration	Intended Purpose
ONE Snare Endovascular Snare System and Replacement Catheters (ONE500, ONE1000, ONE1500, ONE2000, ONE2500, ONE3000, ONE3500, ONE1001, ONE2501, ONE4000, ONE6000, ONE1501)	The ONE Snare® Endovascular Snare System is intended for use in the retrieval and manipulation of foreign objects in the cardiovascular system, excluding the neurovasculature.
ONE Snare Microsnare Kit (ONE200, ONE201, ONE400, ONE401, ONE700, ONE701)	The ONE Snare® Endovascular Microsnare System is intended for use in the retrieval and manipulation of foreign objects in the cardiovascular system, excluding the neurovasculature.
EMPOWER Single-loop Snare System (8784*c)	The EMPOWER™ Single-Loop Endovascular Snare System is intended for use in the retrieval and manipulation of foreign objects in the cardiovascular system, excluding the neurovasculature.

Product Configuration	Intended Purpose
Medtronic Retrieval Snare Kit System (ONE1500-MDTCE)	The Medtronic Retrieval Snare Kit System is intended for use in the retrieval and manipulation of foreign objects in the cardiovascular system, excluding the neurovasculature.

* P/N 8784 is also an OEM part of Boston Scientific

2.1 Indications for Use

The labeled indications for use for the ONE Snare Family device configurations are summarized in Table 5.

Table 6. ONE Snare Family: Indications for Use

Product Configuration	Indications for Use
ONE Snare Standard Endovascular Snare System and Replacement Catheters (ONE500, ONE1000, ONE1500, ONE2000, ONE2500, ONE3000, ONE3500, ONE1001, ONE2501, ONE4000, ONE6000, ONE1501)	The ONE Snare® Endovascular Snare System is indicated for use in patients who require retrieval or manipulation of foreign objects in the cardiovascular system.
ONE Snare Microsnare System (ONE200, ONE201, ONE400, ONE401, ONE700, ONE701)	The ONE Snare® Endovascular Microsnare System is indicated for use in patients who require retrieval or manipulation of foreign objects in the cardiovascular system.
EMPOWER Single-loop Snare System (8784)	The EMPOWER™ Single-Loop Endovascular Snare System is indicated for use in patients who require retrieval or manipulation of foreign objects in the cardiovascular system.
Medtronic Retrieval Snare Kit System (ONE1500-MDTCE)	The Medtronic Retrieval Snare Kit System is indicated for use in patients who require retrieval or manipulation of foreign objects in the cardiovascular system.

2.2 Intended Patient Population

The intended patient population for the devices in the ONE Snare Family are adult patients requiring retrieval or manipulation of foreign objects in the cardiovascular system, excluding the neurovasculature, where loop size is selected appropriately for the target vessel size.

2.3 Contraindications

The labeled contraindications for the ONE Snare Family device configurations are summarized in Table 7.

Table 7. ONE Snare Family: Contraindications

Product Configuration	Contraindications
ONE Snare Endovascular Snare System and Replacement Catheters (ONE500, ONE1000, ONE1500, ONE2000, ONE2500, ONE3000, ONE3500, ONE1001, ONE2501, ONE4000, ONE6000, ONE1501) ONE Snare Microsnare System (ONE200, ONE201, ONE400, ONE401, ONE700, ONE701) EMPOWER Single-loop Snare System (8784) Medtronic Retrieval Snare Kit System	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.

Product Configuration	Contraindications
(ONE1500-MDTCE)	

3.0 Device Description

The ONE Snare Family device configurations are summarized in Table 8.

Table 8. ONE Snare Family Configurations

Product	Configuration	Description/Product Image(s)
ONE Snare Endovascular Snare System	• Loop diameters: 5–35 mm • Catheter sizes: 4 Fr, 6 Fr • Snare lengths: 65 cm, 80 cm 120 cm • Straight catheter lengths: 48 cm, 100 cm • 15-degree angle catheter length: 65 cm	Single-loop snare constructed of a stranded (NiTi) and a gold-plated tungsten loop. Delivered and deployed from a polyether block amide (PEBAX) catheter with an embedded Pt/Ir marker band for precise positioning under fluoroscopic guidance. A catheter with a 15-degree angle located 1 cm from the distal tip is also available with the 15-mm loop diameter. Snare manipulation is achieved with the use of an external torque device. 
EMPOWER Single-loop Snare System	• Loop diameter: 15 mm • Catheter size: 6 Fr • Snare length: 150 cm • Catheter length: 130 cm	Single-loop snare constructed of a stranded (NiTi) and a gold-plated tungsten loop. Delivered and deployed from a polyether block amide (PEBAX) catheter with an embedded Pt/Ir marker band for precise positioning under fluoroscopic guidance. Snare manipulation is achieved with the use of an external torque device. 
ONE Snare Microsnare System	• Loop diameters: 2 mm, 4 mm, 7 mm • Catheter size:	Single-loop snare constructed of a stranded (NiTi) and a gold-plated tungsten loop. Delivered and deployed from a polyether block amide (PEBAX) catheter with an embedded Pt/Ir marker band for precise positioning under fluoroscopic guidance. Snare manipulation is achieved with the use of an external torque device.

Product	Configuration	Description/Product Image(s)
	2.3-3.0 Fr • Snare length: 175 cm, 200 cm • Catheter lengths: 150 cm, 175cm	 Left – standard ONE Snare (30mm head); Right – ONE Snare Microsnare (2 mm head)
Medtronic Retrieval Snare Kit System	• Loop diameter: 15 mm • Catheter size: 6 Fr • Snare length: 158.5 cm • Catheter length: 137 cm	Single-loop snare constructed of a stranded (NiTi) and a gold-plated tungsten loop. Delivered and deployed from a polyether block amide (PEBAX) catheter with an embedded Pt/Ir marker band for precise positioning under fluoroscopic guidance. Snare manipulation is achieved with the use of an external torque device. 

Abbreviations: cm = centimeters; Fr = French; mm = millimeter; NiTi = nitinol; PEBAX = polyether block amide; Pt = platinum; Pt/Ir = platinum-iridium

The full list of catalog code offerings is listed in Table 9.

Table 9. Product Codes and Device Configurations

Catalog Number	Description	Snare Diameter	Snare Length (cm)	Snare Collapsed Diameter in (mm)	Catheter Size	Catheter Length
ONE Snare Endovascular Snare System*						
ONE500	ONE Snare Standard Kit 5 mm	5 mm	120 cm	0.040 in (1.02 mm)	4 Fr	100 cm
ONE1000	ONE Snare Standard Kit 10 mm	10 mm	120 cm	0.040 in (1.02 mm)	4 Fr	100 cm
ONE1500	ONE Snare Standard Kit 15 mm	15 mm	120 cm	0.050 in (1.27 mm)	6 Fr	100 cm
ONE1501	ONE Snare Standard Kit 15 mm (15-degree curved tip)	15 mm	80 cm	0.040 in (1.02 mm)	4 Fr	65 cm
ONE2000	ONE Snare Standard Kit 20 mm	20 mm	120 cm	0.050 in (1.27 mm)	6 Fr	100 cm
ONE2500	ONE Snare Standard Kit 25 mm	25 mm	120 cm	0.050 in (1.27 mm)	6 Fr	100 cm

Catalog Number	Description	Snare Diameter	Snare Length (cm)	Snare Collapsed Diameter in (mm)	Catheter Size	Catheter Length
ONE3000	ONE Snare Standard Kit 30 mm	30 mm	120 cm	0.050 in (1.27 mm)	6 Fr	100 cm
ONE3500	ONE Snare Standard Kit 35 mm	35 mm	120 cm	0.050 in (1.27 mm)	6 Fr	100 cm
ONE1001	ONE Snare Petite Kit 10 mm	10 mm	65 cm	0.040 in (1.02 mm)	4 Fr	48 cm
ONE2501	ONE Snare Petite Kit 25 mm	25 mm	65 cm	0.050 in (1.27 mm)	6 Fr	48 cm
EMPOWER Single Loop Snare System (OEM)						
8784**	EMPOWER Single Loop Snare System	15 mm	150 cm	0.050 in (1.27 mm)	6 Fr	130 cm
Medtronic Retrieval Snare Kit System (OEM)						
ONE1500-MDTCE	Medtronic Retrieval Snare Kit System	15 mm	158.5 cm	0.050 in (1.27 mm)	6 Fr	137 cm
ONE Snare Replacement Catheters						
ONE4000	ONE Snare Standard Catheter, 100 cm, 4 Fr	–	–	–	4 Fr	100 cm
ONE6000	ONE Snare Standard Catheter, 100 cm, 6 Fr	–	–	–	6 Fr	100 cm
ONE Snare Microsnare System						
ONE200	ONE Snare Microsnare Kit 2 mm	2 mm	175 cm	0.019 in (0.48 mm)	2.3–3 Fr	150 cm
ONE201	ONE Snare Microsnare Kit 2 mm	2 mm	200 cm	0.019 in (0.48 mm)	2.3–3 Fr	175 cm
ONE400	ONE Snare Microsnare Kit 4 mm	4 mm	175 cm	0.019 in (0.48 mm)	2.3–3 Fr	150 cm
ONE401	ONE Snare Microsnare Kit 4 mm	4 mm	200 cm	0.019 in (0.48 mm)	2.3–3 Fr	175 cm
ONE700	ONE Snare Microsnare Kit 7 mm	7 mm	175 cm	0.019 in (0.48 mm)	2.3–3 Fr	150 cm
ONE701	ONE Snare Microsnare Kit 7 mm	7 mm	200 cm	0.019 in (0.48 mm)	2.3–3 Fr	175 cm

* Throughout this document, the device name refers to the specified product numbers unless otherwise noted. Where distinctions between the ONE Snare petite and standard systems and/or straight and 15-degree angled catheter configurations are appropriate, these systems and configurations are categorized individually.
** P/N 8784 is also an OEM part of Boston Scientific
Abbreviations: cm = centimeters; Fr = French; in = inches; mm = millimeters

3.0 Materials/Substances in Contact with Patient Tissues

A biocompatibility assessment has been completed for the ONE Snare Family, and biocompatibility testing was performed according to recommendations set forth in the ISO 10993 Biological Evaluation of Medical Devices series of standards. Table 10 lists the materials or substances in the ONE Snare Family that may be in patient contact, together with their tissue contact categorization.

Table 10. Materials in Contact with Patient Tissues

Product Component	Materials in Contact with Patient Tissues	Categorization
Snare	Black oxide nitinol wire (core wire)	Externally communicating Circulating blood contact Limited duration (≤ 24 hours)
	Nitinol wire, chromium doped, straight annealed (stranded cable)	

Product Component	Materials in Contact with Patient Tissues	Categorization
	Gold-plated Tungsten wire (gold wire)	
	PTFE, black colorant (shrink tubing)	
	Loctite 4304, Loctite 4014 (adhesives)	
Catheter	PEBAX 7233, $BaSO_4$, Tinuvin 783, Tinuvin 234, Irganox B1171, Irganox 1010, white colorant (outer tubing)	Externally communicating Circulating blood contact Limited duration (≤ 24 hours)
	Pt/Ir (90/10) (marker band)	
	PEBAX 3533, $BaSO_4$, Tinuvin 783, Tinuvin 234, Irganox B1171, Irganox 1010, white colorant (hub)	
	Polycarbonate (Luer)	

Abbreviations: BaSO4 = barium sulfate; PEBAX = polyether block amide (Arkema); Pt = platinum; Pt/Ir = platinum-iridium; PTFE = polytetrafluoroethylene

The devices in the ONE Snare Family are intended for single-use only and are provided sterile to the end user. The subject devices are not intended to be re-sterilized by the user. Merit utilizes ethylene oxide (EtO) sterilization for the ONE Snare Family.

The devices in the ONE Snare Family are single-use and the useful device lifetime of the device is contingent upon the duration of the medical procedure. Typically, intervention may last 10-30 minutes per device intended use for the retrieval and manipulation of foreign objects in the cardiovascular system. From a conservative standpoint, the total procedural time has been assumed to be an hour (60 minutes) in order to account for particularly difficult or challenging cases. This assumption is supported by data from ongoing PMCF (see Section 5.2).

3.1 Operating Principles

The devices in the ONE Snare Family are used by clinicians to manually snare, manipulate, or reposition foreign objects in the cardiovascular system. Snare loop size for retrieval and manipulation procedures is selected appropriately for the target vessel size.

Procedures are typically performed under fluoroscopic guidance. 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 vasculature while minimizing the potential for vascular injury during device manipulation (Figure 1). Foreign-body capture is achieved by placing the nitinol snare loop around the free end or edge of the object (Figure 1), and then pulling the snare loop down around the object by advancing the delivery catheter while holding the snare in position. 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 provides sufficient force to retrieve or manipulate foreign objects without damaging the snare.

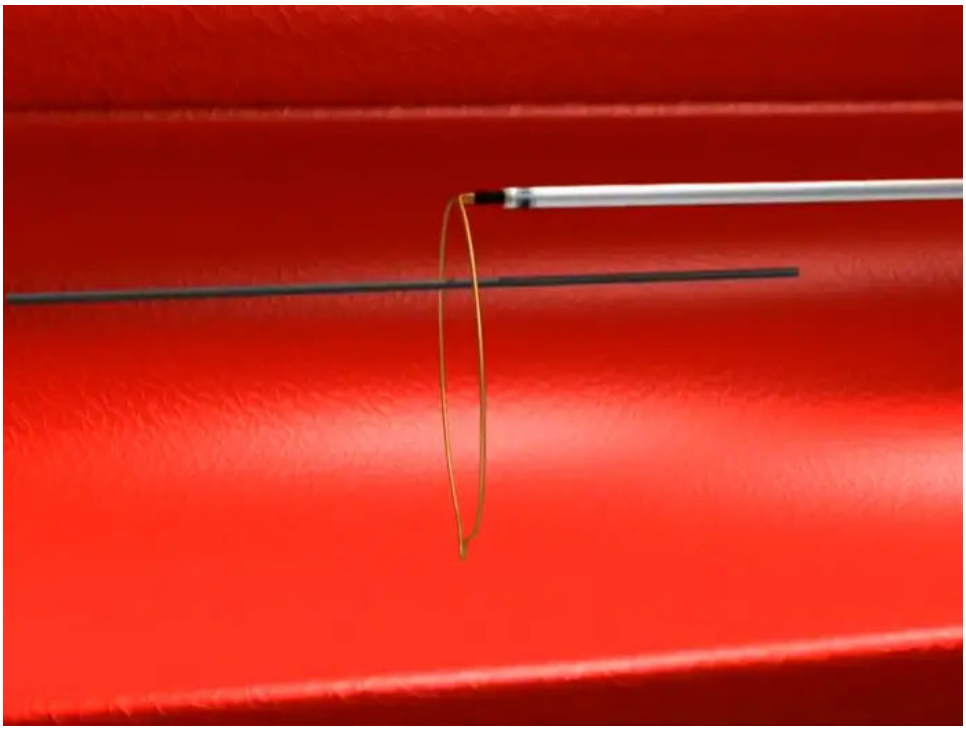

Figure 1. ONE Snare Loop Capture

3.2 Previous Generation(s) or Variant(s) (if applicable)

In 2009, Merit developed and introduced a single-loop snare design, the ONE Snare Endovascular System (ONE Snare System). The standard ONE Snare configurations have held CE-marking since September 2012. The ONE Snare Microsnare System was added to the ONE Snare Family in 2014 and expanded the standard and petite ONE Snare device configurations to include smaller loop diameters and delivery catheter sizes. The ONE Snare System with 15-degree catheter contains a catheter with a 15-degree angle located 1 cm from the distal tip, along with a 15-mm loop diameter. The EMPOWER Single-Loop Snare is an Original Equipment Manufacturer (OEM) configuration of the ONE Snare System supplied to Boston Scientific Corporation, Inc. The Medtronic Retrieval Snare Kit System is an OEM configuration of the ONE Snare System supplied to Medtronic.

The ONE Snare System has been developed as an incremental change to an existing technology. There are no novel procedure-related (e.g., mode of use, device-patient interface, interaction and control, or deployment methods) or device-related (e.g., medical purpose, design, mechanism of action, new/modified materials, site of application, components, or manufacturing process) dimensions of the device relative to those of the generic group of loop snares. There has been no evolution to the basic design (i.e., snare delivered by a catheter with distal marker band) of the ONE Snare System since it was introduced in 2009. Incremental changes in device configuration, including snare diameter, length, collapsed diameter, and angle as well as, accordingly, catheter size, length and angle, have been introduced to accommodate physician preference, which can be influenced by access site, vessel diameter, and size/shape of the foreign body. No such changes were undertaken to address a safety or performance concern.

3.3 Accessories

The accessories included with each device in the ONE Snare Family are the torque device (Figure 2 and Figure 3), and insertion tool (Figure 4 and Figure 5). Additional accessories associated with conventional percutaneous vascular access include, but are not limited to, access needle, introducer, dilator, guidewire, and contrast solution.

Figure 2. Torque Device: ONE Snare System

Figure 3. Torque Device: ONE Snare Microsnare System

Figure 4. Insertion Tool: ONE Snare System

Figure 5. Peel-away Feature of the Insertion Tool

4.0 Risks and Warnings

4.0 Residual Risks and Undesirable Effects

As identified in the IFU, there are potential adverse events (AEs) associated with the use of the devices in the ONE Snare Family. These are summarized in Table 11.

Table 11. Potential Adverse Events for the ONE Snare Family

Product Configuration	Potential Adverse Events
ONE Snare Endovascular Snare System ONE Snare Microsnare System EMPOWER Single-loop Snare System Medtronic Retrieval Snare Kit System	1. Potential complications associated with foreign object 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 object retrieval devices include, but are not limited to: • Vessel perforation • Device entrapment

A review of clinical literature on the subject device and benchmark competitor devices was conducted. Snare-related or snare procedure-related AEs identified in the literature for the subject device and benchmark competitor devices are shown in Table 12. All known and foreseeable hazards and associated risks have been identified and reduced as far as possible, and the residual risks are deemed acceptable.

Table 12. Adverse Events Reported in the Literature

Adverse Event	ONE Snare System n/N (%)	Device-Related	Procedure-Related	Benchmark Devices n/N (%)	Time Frame
Severe mitral regurgitation, worsening hypoxemia, and hypotension	1/1 (100%)[1]	X	X	-	Periprocedural
Atrioventricular block requiring permanent pacemaker	1/1 (100%)[2]		X	2/25 (8%)[3]	ONE Snare System: Postprocedural – in the hour following percutaneous closure of a ventricular septal defect

Adverse Event	ONE Snare System n/N (%)	Device-Related	Procedure-Related	Benchmark Devices n/N (%)	Time Frame
					Benchmark Device: Not reported – complication measured at 30 days follow up
Hematoma	-		X	1/5 (20%)[4]	Not reported – framed as periprocedural
Thrombosis	-		X	1/23 (4.3%)[5]	Periprocedural
Heart failure and shock after failed defibrillator lead extraction leading to heart transplant	-		X	1/23 (4.3%)[5]	Postprocedural - extending up to 5 months
Death	-		X	1/23 (4.3%)[5] 1/25 (4%)[3] 1/30 (3.3%)[6]	Postprocedural – at 30 days follow up
Loss of right-sided pulse and affected distal perfusion requiring peritoneal dialysis for 3 days	-		X	1/2 (50%)[7]	Postprocedural – at 30 days follow up
Ischemic stroke	-		X	1/12 (8.3%)[8]	Postprocedural – at day 18
Snare rupture	-	X		1/4 (25%)[9]	Postprocedural - details not reported
Pericardial effusion requiring pericardiocentesis	-		X	1/25 (4%)[3]	Postprocedural – at 10 months follow up
Minor vascular complications	-		X	1/25 (4%)[3]	Not reported - follow-up extended to 30 days
Major vascular complications	-		X	6/30 (20%)[6]	Postprocedural – at 30 days follow up
Disabling stroke	-		X	1/30 (3.3%)[6]	Postprocedural – at 30 days follow up
Non-disabling stroke	-		X	2/30 (6.7%)[6]	Postprocedural – at 30 days follow up
Acute kidney injury stage 2/3			X	1/30 (3.3%)[6]	Postprocedural – at 30 days follow up
Secondary myocardial infarction	-		X	1/30 (3.3%)[6]	Postprocedural – at 30 days follow up
New pacemaker placement	-		X	2/30 (6.7%)[6]	Postprocedural – at 30 days follow up
Hemodynamic instability from laceration requiring vasopressors	-		X	2/30 (6.7%)[6]	Postprocedural – at 30 days follow up
Puncture site bleeding treated			X	1/1 (100%)[10]	Postprocedural – at

Adverse Event	ONE Snare System n/N (%)	Device-Related	Procedure-Related	Benchmark Devices n/N (%)	Time Frame
with balloon-assisted coil embolization					hour 2

4.1 Warnings and Precautions

The labeled warnings and precautions for the ONE Snare Family device configurations are summarized in Table 13.

Table 13. ONE Snare Family: Warnings & Precautions

Product Configuration	Labeling
ONE Snare Endovascular Snare System EMPOWER Single-loop Snare System Medtronic Retrieval Snare Kit System	**Warnings** • Excessive force used to remove entrapped foreign objects may lead to device failure. • 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. 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 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. • After use this device may be a potential biohazard. Handle in a manner that will prevent accidental contamination. Dispose of device in a manner consistent with standard protocols for biohazard waste disposal. • Nitinol is a nickel titanium alloy. Possible reaction may occur for those patients who exhibit sensitivity to nickel. • 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. • Use caution when retrieving foreign objects through the heart anatomy to avoid potential tissue/valve damage.
	Precautions • 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. • Attempting to close the loop by pulling the snare into the snare catheter will move the loop from its position around the foreign object. • Withdrawal of large foreign objects may require the insertion of larger sheaths, guiding catheters, or a cut-down at the peripheral site.
ONE Snare Microsnare System	**Warnings** • Excessive force used to remove entrapped foreign objects may lead to device failure. • 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

Product Configuration	Labeling
	not opened or damaged. 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 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. • After use this device may be a potential biohazard. Handle in a manner that will prevent accidental contamination. Dispose of device in a manner consistent with standard protocols for biohazard waste disposal. • Nitinol is a nickel titanium alloy. Possible reaction may occur for those patients who exhibit sensitivity to nickel. • 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. • Use caution when retrieving foreign objects through the heart anatomy to avoid potential tissue/valve damage.
	Precautions
	• When attempting to utilize guide catheters or sheaths not specifically manufactured for use with the ONE Snare™ Microsnare system, it is important to test product compatibility prior to use. • Attempting to close the loop by pulling the snare into the snare catheter will move the loop from its position around the foreign object. • Withdrawal of large foreign objects may require the insertion of larger sheaths, guiding catheters, or a cut-down at the peripheral site.

Abbreviations: EU = European Union

The general caution statement in the labeling for the devices in the ONE Snare Family is as follows:

- **Rx Only** Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

There is no MR compatibility information provided in the labeling for the ONE Snare Family.

4.2 Other Relevant Safety Aspects

There have been no Corrective Action Reports (CARs), field escalations, or product recalls for the ONE Snare Family.

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

5.0 Summary of Clinical Data for the Equivalent Device

The ONE Snare System is equivalent to the ONE Snare Microsnare System, the ONE Snare System with 15-degree catheter, the EMPOWER Single-Loop Snare System, and the Medtronic Retrieval Snare Kit System. Any identified differences with regard to clinical, technical, and biological characteristics were analyzed and none of these differences were determined to significantly affect clinical safety or performance. Therefore, clinical data provided in Section 5.2 is applicable to all equivalent device configurations.

5.1 Summary of Clinical Investigations of the Subject Device

Conformity of the ONE Snare Family was initially assessed and endorsed by the applicable Notified Body in 2012. No manufacturer-sponsored pre-market clinical investigations have been performed as part of the development of the devices in the ONE Snare Family.

5.2 Summary of Clinical Data from Other Sources

A review of relevant clinical literature published between January 01, 2009 and April 30, 2021 for device safety and performance was conducted. Table 14 and Table 15 summarize the literature included for the evaluation of the safety and performance of the ONE Snare Family. For evaluation of performance, cumulative success was defined as the combined rate of (1) complete snare-mediated foreign body/tissue retrieval/manipulation through the vascular/percutaneous sheath and (2) snare-mediated foreign body retrieval/manipulation from the original foreign body/tissue position with complete extraction requiring an adjunctive surgical approach. For evaluation of safety, AEs were also summarized from the clinical literature data as defined in the Society of Interventional Radiology (SIR) and the Society of Cardiovascular and Interventional Radiology (SCIVR) guidelines.[11,12]

Table 14. ONE Snare Family: Summary Study Characteristics

Author (Year) LOE Study Type	Primary Clinical Indication, Cardiovasculature	Device Application, Access	Patients, n/N (%)*	Devices Used (N)	Gender (M/F) Age (years)	Follow-up
Aregullin (2021)[13] LOE: C Case Report	Transcatheter Fontan completion procedure, central circulatory system (left pulmonary artery)	Exteriorize tip of V-18 Guidewire (access), Left internal jugular vein	1/1 (100%)	10-mm ONE Snare System (1)	M, 15 [a]	1 year
Filippone (2019)[14] LOE: C Case Report	Amplatzer septal occlude (ASO) embolization with lower abdominal aorta occlusion, Central circulatory system (inner lumen of the aorta, above the renal arteries up to the aortic valve plane)	ASO retrieval, Right femoral artery	1/1 (100%)	6-Fr 35-mm ONE Snare System (1)	F, NR	Hospital discharge
Fischer (2020)[15] LOE: C Case Report	Embolization of multipolar mapping catheter arm during electroanatomical mapping, peripheral vasculature (renal artery proximal to the branching level)	Retrieval of multipolar mapping catheter arm, Femoral artery	1/1 (100%)	ONE Snare System (1)	F, 76	Post-procedure
Goy (2014)[2] LOE: C Case Report	Ventricular septal defect (VSD) closure following aortic valve replacement, central circulatory system (pulmonary artery)	Establish arteriovenous wire loop (access), Right femoral vein	1/1 (100%)	6-Fr ONE Snare System (1)	F, 80	3 months
Naghi (2016)[16] LOE: C Case Report	Fracture and migration of pericardiocentesis drain, pericardial space [b]	Drain catheter retrieval, Subxiphoid soft-tissue tract	1/1 (100%)	4-Fr 10-mm ONE Snare System (1)	M, 34	30 days

Rizkallah (2016)[17] LOE: C Case Report	Central venous catheter (CVC) fracture and embolization to right atrium, central circulatory system (right atrium)	Catheter fragment retrieval, Right internal jugular vein	1/1 (100%)	6-Fr ONE Snare System (1)	M, 52	Post-procedure
Spilias (2019)[1] LOE: C Case Report	Migration of left atrial appendage (LAA) occlusion device, central circulatory system (mitral valve and left ventricle)	Retrieval of LAA occlusion device, Right common femoral artery and vein	1/1 (100%)	30-mm ONE Snare System‡ (1) 25-mm ONE Snare System (1)	M, 79	1 month
Suyama (2019)[18] LOE: C Case Series	Treatment of pancreatic fistula resulting from dislodged main pancreatic duct (MPD) tube, peripheral vasculature (jejunal lumen)	Replace original MPD tube, NR	2/2 (100%)	6-Fr 15-mm ONE Snare System (2)	Patient 1: M, 73 Patient 2: F, 74	Patient 1: 2 weeks Patient 2: 1 month
Yamada (2019)[19] LOE: C Case Report	Treatment of central venous occlusion with radiofrequency wire, central circulatory system (superior vena cava stump)	Capture radiofrequency wire (access), Right femoral vein	1/1 (100%)	10-mm ONE Snare System (1)	F, 41	14 months

Abbreviations: ASO = Amplatzer septal occluder; CVC = central venous catheter; F = females; Fr = French; LAA = left atrial appendage; LOE = levels of evidence; M = males; mm = millimeters; MPD = main pancreatic duct; NR = not reported; VSD = ventricular septal defect

* N = total number of patients treated, n = number of devices utilized

‡ Manufacturer reported as Medtronic, likely erroneously

[a] There are insufficient safety and performance data to support use of the subject devices in pediatric populations.

[b] Use in the pericardial space is considered off-label.

Table 15. ONE Snare Family: Safety and Performance Summary

Author (Year) LOE Study Type	Device	Fluoroscopy Time (min)	Procedure Time (min)	Primary Success n/N (%)	Secondary Success n/N (%)	Adverse Events n/N (%)	Other Notes
Aregullin (2021)[13] LOE: C Case Report	ONE Snare System	NR	NR	1/1 (100%)	NA	0/1 (0.00%)	Well-seated stents in intended position with good configuration confirmed at 3-month follow-up; normal quality of life, with unrestricted physical activity without shortness of breath at 1-year follow-up
Filippone (2019)[14] LOE: C Case Report	ONE Snare System	30	120	1/1 (100%)	NA	0/1 (0.00%)	Post-retrieval lower limb peripheral pulse confirmed
Fischer (2020)[15] LOE: C Case Report	ONE Snare System	25.03	293	1/1 (100%)	NA	0/1 (0.00%)	Simmons catheter (Performa, Merit Medical) used along with snare for retrieval; normal valve and renal function confirmed through follow-up echocardiography
Goy (2014)[2] LOE: C Case Report	ONE Snare System	NR	NR	1/1 (100%)	NA	1/1 (100%)*	Device identified as EN Snare in the article text, but description (“lasso”) and fluoroscopy images are consistent with the ONE Snare device; the patient developed an atrioventricular block in the hour following the procedure, and a permanent pacemaker was implanted; the event was determined to not be device-related; no residual shunt or valve dysfunction at 3-month follow-up
Naghi (2016)[16] LOE: C Case Report	ONE Snare System	NR	NR	0/1 (0.00%)	1/1 (100%)	0/1 (0.00%)	Drainage decreased over 2 weeks postop; drain and sheath removed on day 30. Regarding secondary success, the authors noted that the distal sheath segment, despite being successfully captured, could not be removed due to the caliber of the sheath in a folded configuration. Accordingly, the authors elected to increase the size of their pericardial sheath. Once this upsized sheath was in place, the folded 6-F sheath segment was snared, retracted, and removed from the pericardial space.

Author (Year) LOE Study Type	Device	Fluoroscopy Time (min)	Procedure Time (min)	Primary Success n/N (%)	Secondary Success n/N (%)	Adverse Events n/N (%)	Other Notes
Rizkallah (2016)[17] LOE: C Case Report	ONE Snare System	NR	NR	1/1 (100%)	NA	0/1 (0.00%)	No clinically significant sequelae
Spilias (2019)[1] LOE: C Case Report	ONE Snare System	NR	NR	0/1 (0.00%)	1/1 (100%)	1/1 (100%)	LAA occlusion device pulled partially into the MV using 30-mm snare, resulting in severe mitral regurgitation, worsening hypoxemia, and hypotension; device successfully extracted using 25-mm snare; no damage to aortic or mitral valves; patient discharged after 2 days, and no symptoms or bleeding issues at 1-month follow-up
Suyama (2019)[18] LOE: C Case Series	ONE Snare System	NR	NR	2/2 (100%)	NA	0/2 (0.00%)	Patient 1: Slightly elevated serum amylase levels 1 day after procedure; pancreatic juice from drain decreased over 2 weeks postop Patient 2: No symptoms following procedure; fluid collection disappeared 1 month postop
Yamada (2019)[19] LOE: C Case Report	ONE Snare System	NR	NR	1/1 (100%)	NA	0/1 (0.00%)	Chest and abdominal wall varicosities resolved at 6-month follow-up; patent bypass stents seen at 3-week and 14-month follow-up
Total				**10/10 (100%)** *Excl pediatric and off-label use: 8/8 (100%)[a,b]*		**2/10 (20.0%)** *Excl pediatric and off-label use: 2/8 (25.0%)[a,b]*	

Abbreviations: LAA = left atrial appendage; LOE = levels of evidence; min = minutes; MV = mitral valve; NR = not reported

[a] There are insufficient safety and performance data to support use of the subject devices in pediatric populations.

[b] Use in the pericardial space is considered off-label.

Clinical data from post-market clinical follow-up (PMCF) was also collected and evaluated, including physician feedback and patient specific surveys. Data from physician feedback has not been included in the clinical benefit/performance or risks/safety analyses, given that it provides such a low-quality form of evidence.

Regarding physician feedback, clinicians were requested to provide feedback about patient cases in which the ONE Snare Endovascular Snare System was used. A minimum of 65 data points were required and a total of 66 were collected. Resulting performance and safety summary data are shown in Table 16.

Table 16. Summary Performance and Safety Measures for PMCF Data, Physician Feedback

Total Procedures	Cumulative Success n/N (%)	Adverse Events n/N (%)
66 [a]	66/66 (100%)	1/66 (1.52%)

[a] ONE Snare procedures = 57, ONE Snare Microsnare procedures = 9

Regarding patient specific surveys, health care professionals were recruited and screened to participate as survey respondents taking into consideration direct experience with the device, membership within the clinical community associated with the use or specialization of the device, product usage, account volume, absence of product bias, and availability of professional / clinical resources (staff). A minimum of 223 product evaluation surveys were required. A total of 226 data points were collected. Of the 226 cases, 3 were used for Fibrin Sheath Stripping which is being considered foreign body manipulation. There were also 17 cases of reported use within the pediatric patient population, including adolescent (14) and infant (3) patients. Per IFU warning, there is currently insufficient data to support the use of the ONE Snare device within the pediatric population. Resulting safety and performance summary data are shown in Table 17.

Table 17. Summary Performance and Safety Measures for PMCF Data, Patient Specific Surveys

Total Procedures	Cumulative Success n/N (%)	Adverse Events n/N (%)
226 [a]	202/209 (96.7%) [b]	1/209 (0.479%) [b]

[a] ONE Snare procedures = 209, ONE Snare Microsnare procedures = 17

[b] There are insufficient safety and performance data to support use of the subject devices in pediatric populations.

The PMCF data details the average device lifetime within a procedure of 30.6 minutes with a standard deviation of 21.5 minutes. This result is in alignment with the device lifetime as documented in Section 3.0.

5.3 Overall Summary of Clinical Performance and Safety

Table 18 provides a summary of cumulative success rates for the ONE Snare Family derived from clinical literature and PMCF data, with exclusions applied. These data are compared to performance data for benchmark competitor devices. Based on the combined clinical data presented in Table 18, the cumulative success rate for the ONE Snare Family is 96.8% and the cumulative success rate for benchmark competitor devices is 93.4%. There is no statistically significant difference between the ONE Snare Family and benchmark competitor devices for cumulative success rate (P>0.05). Furthermore, a post-hoc analysis revealed that the difference in cumulative success rates between the ONE Snare Family (p1) and benchmark competitors (p2) is greater than -

0.15 (i.e., p1 – p2 > -0.15), confirming that the performance outcomes of the subject devices are comparable or better than those of benchmark competitor devices.

Table 18. Comparative Performance for ONE Snare Family

Performance Outcome	ONE Snare Family, n/N (%)	Benchmark Competitors, n/N (%)	Estimated Difference [95% CI]	*P*-value p1-p2 ≠ 0	Post-hoc Analysis $\Delta_{0.80}^{20}$, Estimated Difference [95% LBL]	*LBL* > -0.15
Cumulative Success Rate	210/217 (96.8%)	171/183 (93.4%)	3.33% (-0.957%, 7.62%)	*P*=0.128	3.33% (-0.267%)[a]	*P*=0.000[a]

Abbreviations: CI = confidence interval, LBL=lower bound limit, PMCF = Postmarket Clinical Follow-Up

‡ Statistically significant (*P*<0.05)

[a] Post-hoc analysis was performed even though the null hypothesis for the double-sided test was not rejected.

Table 19 provides a summary of minor and major adverse event rates for the ONE Snare Family derived from clinical literature and PMCF data, with exclusions applied. These data are compared to safety data for benchmark competitor devices. The device- and procedure-related adverse event rate for the ONE Snare Family is 1.38%. The device- and procedure-related adverse event rates for benchmark competitor devices is 13.1%. There was a statistically significant difference between the subject devices and benchmark competitor devices for adverse event rates (*P*=0.000), such that the adverse event rate for the subject devices was less than the adverse event rate for benchmark competitor devices. Furthermore, a post-hoc analysis revealed that the difference in adverse event rates between the ONE Snare Family (p1) and benchmark competitors (p2) is less than 0.10 (i.e., p1 – p2 < 0.10), confirming that the safety outcomes of the subject devices are comparable or better than those of benchmark competitor devices.

Table 19. Comparative Safety for ONE Snare Family

Safety Outcome	ONE Snare Family, n/N (%)	Benchmark Competitors, n/N (%)	Estimated Difference [95% CI]	*P*-value p1-p2 ≠ 0	Post-hoc Analysis $\Delta_{0.80}^{20}$, Estimated Difference [95% UBL]	*UBL* <.10
Adverse Event Rate	3/217 (1.38%)	24/183 (13.1%)	-11.7% (-16.9%, -6.60%)	*P*=0.000	-11.7 (-7.43%)	*P*=0.000

Abbreviations: CI = confidence interval; PMCF = Postmarket Clinical Follow-Up; UBL=upper bound limit

Data to support the safety and performance of the ONE Snare System have been analyzed and provide evidence to support all the safety and performance outcomes. Based upon a review of the clinical data, the overall benefits to patients of using the device for its intended purpose outweigh the overall risks. The risk/benefit assessment for the ONE Snare Family is summarized in Table 20.

Table 20. Summary of Benefit/Risk Assessment[21,22]

Factor	Notes	Assessment
Uncertainty		
Quality of the study design	• How robust were the data?	9 articles (LOE: 9 C)
Quality of the study conduct	• How was/were the study/studies 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 results from the study/studies repeatable?	N/A – case reports and case series
	• Is/Are this/these study/studies first-of-a-kind?	No
	• Are there other studies that achieved similar results?	Yes
Generalizability of the results	• Can the results of the study/studies 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?	In stable patients with retained cardiopulmonary foreign bodies, 81% remained asymptomatic at 845 day mean follow-up[23]
Patient tolerance for risk, and perspective on benefit:	• Is there data regarding how patients tolerate the risks posed by the device?	N/A
	• Are the risks identifiable and definable?	Yes; see Table 11 and Table 12
Disease severity	• Is the disease so severe that patients will tolerate a higher amount of risk for a smaller benefit?	In stable asymptomatic patients, conservative therapy is viable[23]
Disease chronicity	• Is the disease/condition chronic?	Only if untreated
	• How long do patients with the disease/condition live?	60–71% incidence of death/serious complications in untreated cases[24]
	• If chronic, is the illness easily managed with less invasive or difficult therapies?	In asymptomatic patients, watchful waiting may be an appropriate strategy[23]
Patient-centric assessment	• How much do patients value this treatment?	High – facilitates a minimally invasive endovascular approach in patients requiring retrieval and/or manipulation of foreign objects in the cardiovascular system, excluding the neurovasculature.
	• 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?	N/A – unplanned intervention during a procedure When patients elect to undergo such therapy, they undergo informed consent
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

Factor	Notes	Assessment
		845 day mean follow-up[23]
	• 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[24] Intravascular forceps present increased risk of vascular damage/perforation as compared to snares[24]
	• 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[24] Stone baskets are effective for foreign body retrieval, but can be difficult to guide[24] Intravascular forceps present and increased risk of vascular damage/perforation as compared to snares[24]
Risk mitigation	• Could you identify ways to mitigate the risks (such as using product labeling, establishing education programs, providing add-on therapy, etc.)? • What is the type of intervention proposed?	Well established technology that is compatible with standard interventional techniques; no additional labeling or clinician training have been identified to further mitigate risks 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 Table 18 and Table 19
	• 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 AEs.	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 AEs 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 are derived from real-world case studies and case series
	• Is there data that otherwise would be provided to support approval, which could be deferred to the postmarket setting?	N/A

Factor	Notes	Assessment
	• 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**
ONE Snare Family		
The intended clinical benefit of the ONE Snare Family is to facilitate a minimally invasive endovascular approach in patients requiring retrieval and/or manipulation of foreign objects in the cardiovascular system, excluding the neurovasculature. ONE Snare Family Cumulative Success: 96.8% * Benchmark Competitor Devices Cumulative Success: 93.4% ** * Cumulative success rate for subject device not significantly different than benchmark competitor devices (*P*>0.05). The reported rates excluded pediatric populations, for which there is insufficient data to support performance.	Complications occur at a low rate and they are generally transient in nature. ONE Snare Family AE Rate: 1.38% * Complaint Rate (PMS): 0.044% Benchmark Competitor Devices AE Rate: 13.1% * * A significant difference in total overall major AE rates for subject devices and comparable benchmark devices (*P*=0.000), such that the AE rate for the subject devices is less than the AE rate for benchmark competitor devices. The reported rates excluded pediatric populations, for which there is insufficient data to support safety.	Conservative treatment can be a viable approach in stable asymptomatic patients,[23] but reports of death/serious complications have been reported in 60–71% of untreated cases.[24] Snares are well established technology that are compatible with standard interventional techniques.

Abbreviations: AE = adverse events; LOE = levels of evidence; N/A = not available; PMS = Postmarket Surveillance

5.4 Planned Postmarket Clinical Follow-up (PMCF)

Consideration has been made regarding Postmarket Clinical Follow-Up (PMCF). Merit actively monitors all after-market field data. Ongoing PMCF activities have included clinician surveys requesting feedback and patient specific surveys relevant to the performance and safety criteria about patient cases in which the ONE Snare Endovascular Snare System is used. Further details on planned and ongoing PMCF activities are provided in documents PMCFP-QRMT0047-001 and RR-QRMT0047-001.

6.0 Diagnostic or Therapeutic Alternatives

Snares are used in various clinical settings where there is a need for a device to retrieve and manipulate foreign objects.[25,26] These include coronary and peripheral vasculature. Loop snares are most effective when the foreign fragment or target object presents a free end for ensnarement.[26]

Alternative endovascular tools to snares include stone baskets, intravascular forceps, guidewires, balloon catheters, and biliary/myocardial biopsy forceps have been utilized for intravascular foreign body (IFB)

retrieval.[24,27] Stone baskets can be particularly useful in larger diameter vessels, but they can be difficult to guide.[24] Intravascular forceps have side-opening jaws and are available in sizes ranging from 3–12 Fr.[24] 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.[24]

Open approaches to IFB retrieval are required in some instances, and the literature reports include sternotomy with cardiopulmonary bypass, thoracotomy, laparotomy, and laparoscopy.[27] As identified by Schechter et al. (2013)[27] in their literature review, open retrieval approaches may be required for patients in whom multiple percutaneous retrieval attempts have failed.

7.0 Suggested Profile and Training for Users

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

8.0 Applicable Harmonized Standards and Common Specifications

The following harmonized standards and guidance documents were applied or considered during the clinical evaluation, including input processes such as design and development and output processes such as PMCF plans and reports, of the One Snare Family. Harmonized standards relevant to other processes, such as the quality management (EN ISO 13485:2016) and risk management (EN ISO 14971:2019) systems, are addressed in the GSPR document (GSPR0083 Rev. 002). ISO 14155:2020 has not been applied or considered during the clinical evaluation, as no clinical investigations have been undertaken to assess the safety or performance of the ONE Snare Family. All standards have been applied in full unless otherwise noted below:

- ISO 10555-1:2013/AMD 1:2017, Intravascular catheters – Sterile and single-use catheters – Part 1: General Requirements – Amendment 1 (Full*)
- ISO 11070:2014/A1:2018, Sterile single-use intravascular introducers, dilators and guidewires (Full*)
- EN ISO 80369-7:2021 (CEN; ISO 80369-7:2021, EQV), Small bore connectors for liquids and gases in healthcare applications – Part 7: Connectors for intravascular or hypodermic applications (Full*)
- IEC 62366-1:2015/A1:2020, Medical Devices – Application of usability engineering to medical devices (Partial**)
- ISO 11135:2014, Sterilization of healthcare products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices (Full*)
- ISO 10993-1:2018, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process (Full*)

** Per MDR 2017/745 Articles 8 & 9, full compliance is claimed for compliance with all requirements or the relevant part of the standard*
*** Partial compliant to ISO62366-1 Annex C - Product released to manufacture pre 2015 and as such only IEC 62366-1:2015+AMD1:2020 Annex C applies*

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9.0 Revision History

SSCP Revision	ECN Number	Date Issued	Change Description	SSCP Author	Revision Validated by the Notified Body	Date of Notified Body Approval
001	ECN154390	24-Aug-2022	Initial SSCP for the ONE Snare Family	Sara VanWyk, MPH, CCRP, RAC-Devices, MWC	☒ Yes Validation language: English ☐ No	10-Aug-2022