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 Maestro microcatheter.

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

The English version of this SSCP document (SSCP-0143-325) has been validated by the Notified Body (NB). The following information is intended for users/healthcare professionals. Since the Maestro microcatheter is not a long-term implant device, a patient-directed SSCP is not required.

1.0 Device identification and general information

1.1 Device trade names

The devices and model numbers covered by this SSCP are presented in Table 1.

Table 1. Devices Included in this SSCP

CATALOG NUMBER	PROXIMAL FRENCH SIZE (F)	DISTAL FRENCH SIZE (F)	CATHETER USABLE LENGTH	CATHETER TIP SHAPE	CATHETER INSIDE DIAMETER	MAX GUIDE WIRE	GUIDE CATH MIN ID
Maestro Microcatheters							
MDR-29MC29150ST	2.9F	2.9F	150 cm (59")	Straight	0.027" (0.68 mm)	0.021" (0.53 mm)	0.042" (1.07 mm)
MDR-29MC29150SN	2.9F	2.9F	150 cm (59")	Swan Neck	0.027" (0.68 mm)	0.021" (0.53 mm)	0.042" (1.07 mm)
MDR-29MC2915045	2.9F	2.9F	150 cm (59")	45°	0.027" (0.68 mm)	0.021" (0.53 mm)	0.042" (1.07 mm)
MDR-29MC29130ST	2.9F	2.9F	130 cm (51")	Straight	0.027" (0.68 mm)	0.021" (0.53 mm)	0.042" (1.07 mm)
MDR-29MC29130SN	2.9F	2.9F	130 cm (51")	Swan Neck	0.027" (0.68 mm)	0.021" (0.53 mm)	0.042" (1.07 mm)
MDR-29MC2913045	2.9F	2.9F	130 cm (51")	45°	0.027" (0.68 mm)	0.021" (0.53 mm)	0.042" (1.07 mm)
MDR-29MC29110ST	2.9F	2.9F	110 cm (43")	Straight	0.027" (0.68 mm)	0.021" (0.53 mm)	0.042" (1.07 mm)
MDR-29MC29110SN	2.9F	2.9F	110 cm (43")	Swan Neck	0.027" (0.68 mm)	0.021" (0.53 mm)	0.042" (1.07 mm)

CATALOG NUMBER	PROXIMAL FRENCH SIZE (F)	DISTAL FRENCH SIZE (F)	CATHETER USABLE LENGTH	CATHETER TIP SHAPE	CATHETER INSIDE DIAMETER	MAX GUIDE WIRE	GUIDE CATH MIN ID
MDR-29MC2911045	2.9F	2.9F	110 cm (43")	45°	0.027" (0.68 mm)	0.021" (0.53 mm)	0.042" (1.07 mm)
MDR-28MC28150ST	2.8F	2.8F	150 cm (59")	Straight	0.024" (0.63 mm)	0.021" (0.53 mm)	0.040" (1.02 mm)
MDR-28MC28150SN	2.8F	2.8F	150 cm (59")	Swan Neck	0.024" (0.63 mm)	0.021" (0.53 mm)	0.040" (1.02 mm)
MDR-28MC2815045	2.8F	2.8F	150 cm (59")	45°	0.024" (0.63 mm)	0.021" (0.53 mm)	0.040" (1.02 mm)
MDR-28MC28130ST	2.8F	2.8F	130 cm (51")	Straight	0.024" (0.63 mm)	0.021" (0.53 mm)	0.040" (1.02 mm)
MDR-28MC28130SN	2.8F	2.8F	130 cm (51")	Swan Neck	0.024" (0.63 mm)	0.021" (0.53 mm)	0.040" (1.02 mm)
MDR-28MC2813045	2.8F	2.8F	130 cm (51")	45°	0.024" (0.63 mm)	0.021" (0.53 mm)	0.040" (1.02 mm)
MDR-28MC28110ST	2.8F	2.8F	110 cm (43")	Straight	0.024" (0.63 mm)	0.021" (0.53 mm)	0.040" (1.02 mm)
MDR-28MC28110SN	2.8F	2.8F	110 cm (43")	Swan Neck	0.024" (0.63 mm)	0.021" (0.53 mm)	0.040" (1.02 mm)
MDR-28MC2811045	2.8F	2.8F	110 cm (43")	45°	0.024" (0.63 mm)	0.021" (0.53 mm)	0.040" (1.02 mm)
MDR-28MC24150ST	2.8F	2.4F	150 cm (59")	Straight	0.020" (0.52 mm)	0.018" (0.46 mm)	0.040" (1.02 mm)
MDR-28MC24150SN	2.8F	2.4F	150 cm (59")	Swan Neck	0.020" (0.52 mm)	0.018" (0.46 mm)	0.040" (1.02 mm)
MDR-28MC2415045	2.8F	2.4F	150 cm (59")	45°	0.020" (0.52 mm)	0.018" (0.46 mm)	0.040" (1.02 mm)
MDR-28MC24130ST	2.8F	2.4F	130 cm (51")	Straight	0.020" (0.52 mm)	0.018" (0.46 mm)	0.040" (1.02 mm)
MDR-28MC24130SN	2.8F	2.4F	130 cm (51")	Swan Neck	0.020" (0.52 mm)	0.018" (0.46 mm)	0.040" (1.02 mm)
MDR-28MC2413045	2.8F	2.4F	130 cm (51")	45°	0.020" (0.52 mm)	0.018" (0.46 mm)	0.040" (1.02 mm)
MDR-28MC24110ST	2.8F	2.4F	110 cm (43")	Straight	0.020" (0.52 mm)	0.018" (0.46 mm)	0.040" (1.02 mm)
MDR-28MC24110SN	2.8F	2.4F	110 cm (43")	Swan Neck	0.020" (0.52 mm)	0.018" (0.46 mm)	0.040" (1.02 mm)
MDR-28MC2411045	2.8F	2.4F	110 cm (43")	45°	0.020" (0.52 mm)	0.018" (0.46 mm)	0.040" (1.02 mm)
MDR-28MC21150ST	2.8F	2.1F	150 cm (59")	Straight	0.018" (0.45 mm)	0.016" (0.41 mm)	0.040" (1.02 mm)

CATALOG NUMBER	PROXIMAL FRENCH SIZE (F)	DISTAL FRENCH SIZE (F)	CATHETER USABLE LENGTH	CATHETER TIP SHAPE	CATHETER INSIDE DIAMETER	MAX GUIDE WIRE	GUIDE CATH MIN ID
MDR-28MC21150SN	2.8F	2.1F	150 cm (59")	Swan Neck	0.018" (0.45 mm)	0.016" (0.41 mm)	0.040" (1.02 mm)
MDR-28MC2115045	2.8F	2.1F	150 cm (59")	45°	0.018" (0.45 mm)	0.016" (0.41 mm)	0.040" (1.02 mm)
MDR-28MC21130ST	2.8F	2.1F	130 cm (51")	Straight	0.018" (0.45 mm)	0.016" (0.41 mm)	0.040" (1.02 mm)
MDR-28MC21130SN	2.8F	2.1F	130 cm (51")	Swan Neck	0.018" (0.45 mm)	0.016" (0.41 mm)	0.040" (1.02 mm)
MDR-28MC2113045	2.8F	2.1F	130 cm (51")	45°	0.018" (0.45 mm)	0.016" (0.41 mm)	0.040" (1.02 mm)
MDR-28MC21110ST	2.8F	2.1F	110 cm (43")	Straight	0.018" (0.45 mm)	0.016" (0.41 mm)	0.040" (1.02 mm)
MDR-28MC21110SN	2.8F	2.1F	110 cm (43")	Swan Neck	0.018" (0.45 mm)	0.016" (0.41 mm)	0.040" (1.02 mm)
MDR-28MC2111045	2.8F	2.1F	110 cm (43”)	45°	0.018” (0.45 mm)	0.016” (0.41 mm)	0.040” (1.02 mm)

1.2 Manufacturer Information

The name and address of the manufacturer of the Maestro microcatheter 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 United States 84095

1.3 Manufacturer Single Registration Number (SRN)

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

1.4 Basic UDI-DI

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

1.5 Medical Device Nomenclature Description / Text

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

1.6 Risk Class of Device

The EU device risk classification for the Maestro microcatheter 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	CND Terms
Maestro Microcatheter	III	All	088445047256DB	US-MF-000001366	C0104020202	PERIPHERAL EMBOLISATION CATHETERS AND MICROCATHETERS

1.7 Year of EU Market Introduction

The year that the Maestro microcatheter was first placed on the EU market is presented in Table 4.

1.8 Authorised Representative

The name of the authorized representative and SRN are provided in Table 4.

1.9 Notified Body

The NB involved in the conformity assessment of the Maestro microcatheter 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.

1.10 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
Maestro Microcatheter	2009	Merit Medical Ireland Ltd.	IE-AR-000001011	BSI	2797

2.0 Intended Use of the Device

2.1 Intended Purpose

The Maestro microcatheter is intended for the peripheral vascular infusion of diagnostic, embolic, and/or therapeutic materials.

2.2 Indication and Intended Patient Groups

2.2.1 Indications

The Maestro microcatheter is indicated for use in patients requiring peripheral vascular infusion of diagnostic, embolic, and/or therapeutic materials for the treatment or diagnosis of disease and/or lesions,

preoperative intervention, or hemostasis as determined by clinician assessment.

2.2.2 Intended Patient Population

The Maestro microcatheter is intended for use in adult patients requiring controlled and selective infusion of diagnostic, embolic, or therapeutic materials into peripheral vasculature.

2.3 Contraindications

There are no known contraindications for the Maestro microcatheter.

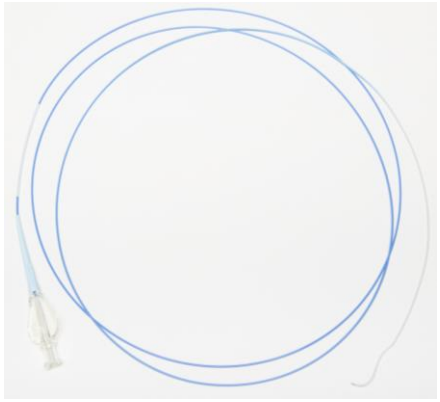
3.0 Device Description

3.1 Materials/Substances in Contact with Patient Tissues

The Maestro microcatheters are small diameter catheters that are designed to access small vessels or super selective anatomy. The microcatheters facilitate the infusion of diagnostic, embolic or therapeutic materials into the vasculature primarily for the purposes of vessel occlusion. Merit Medical Systems, Inc. currently markets 2.8/2.1, 2.8/2.4 Fr, 2.8/2.8 Fr, and 2.9/2.9 Fr Maestro microcatheters.

The Maestro microcatheter device configuration is summarized in Table 5.

Table 5. Microcatheter Configurations

Product	Configuration	Description/Product Image(s)
Maestro	• One (1) straight 45°or swan neck Microcatheter with hydrophilic coating	The Maestro Microcatheter is available in 2.9/2.9, 2.8/2.8, 2.8/2.4 and 2.8/2.1Fr (proximal / distal) sizes and 110cm, 130cm and 150cm lengths. The distal tip of the microcatheter is offered in straight or pre-shaped 45 degree and swan neck configurations. The proximal end of the catheter consists of a molded winged hub with a tapered strain relief. The outer surface of the distal 80cm of the microcatheter shaft is coated with a hydrophilic coating designed to facilitate the introduction of the catheter into the vasculature. The microcatheter incorporates a radiopaque marker at the distal tip to facilitate fluoroscopic visualization. **Figure 1. Maestro Microcatheter** 

A biocompatibility assessment has been completed for the Maestro microcatheter, 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 microcatheter are summarized in Table 6.

Table 6. Tissue Contact Categorization: Maestro Microcatheter

Device	Categorization
Maestro Microcatheter	EC, CB, L

Abbreviations: CB = circulating blood contact, EC = externally communicating, L = limited duration (≤ 24 hours)

3.2 Operating Principals

The placement of the microcatheter is facilitated using an appropriate guidewire and a guiding catheter. A hemostatic valve is recommended to be used in conjunction with the guiding catheter to provide a fluid-tight seal around the microcatheter. The guidewire is inserted into the microcatheter, and the assembly is advanced through the guiding catheter. Once the position of the microcatheter has been confirmed, the guidewire is withdrawn and the microcatheter is used to infuse diagnostic, embolic, or therapeutic materials.

3.3 Previous Generations or Variants

The current Maestro Microcatheter variations are the same as the previous generations of Maestro Microcatheters, with the exception of the patient population callout and Indications for Use.

Attribute	Previous Generations Maestro Microcatheter	Current Maestro Microcatheter Initial MDR Submission	Comments
Indications	The Maestro microcatheter is intended for general intravascular use, including peripheral and coronary vasculature. Once the subselective region has been accessed, the microcatheter can be used for the controlled and selective infusion of diagnostic, embolic or therapeutic materials into vessels. The catheter should not be used in the cerebral vessels.	The Maestro microcatheter is indicated for use in patients requiring peripheral vascular infusion of diagnostic, embolic, and / or therapeutic materials for the treatment or diagnosis of disease and / or lesions, preoperative intervention, or hemostasis as determined by clinician assessment.	Merit revised the Indications for Use to remove Coronary from the Indications statement and to call out the clinical condition.
Patient Population	The Maestro microcatheter is intended for use in adult patients requiring controlled and selective infusion of diagnostic, embolic, or therapeutic materials into peripheral vasculature.	The Maestro microcatheter is intended for use in adult patients requiring controlled and selective infusion of diagnostic, embolic, or therapeutic materials into peripheral vasculature.	Merit added an identifier to call out that the Maestro Microcatheter is intended for use in Adult patients.

3.4 Accessories

The accessories listed in Table 7 are not supplied with the product but are required supplies for its use. Other devices and products which are intended to be used in combination with the device are listed below and in the device IFU.

Table 7. Additional Accessories and Products Not Included with the Device But Referenced in IFU

<table>
<tr><th>Component</th><th>Comment</th></tr>
<tr><td>Syringe</td><td>To be used with heparinized saline solution to wet the microcatheter surface to activate the hydrophilic coating and to flush the lumen of the microcatheter to purge air from inside the microcatheter.</td></tr>
<tr><td>Access Needle</td><td>An Access Needle is first used to enter the vasculature using the Seldinger technique. The needle is placed through the skin into the desired vessel.</td></tr>
<tr><td>Guidewire</td><td>A guidewire is then threaded through the needle into the vessel, and the needle is removed.</td></tr>
<tr><td>Dilator</td><td>Dilator(s) are used to enlarge the skin and vessel entrance for the catheter sheath introducer.</td></tr>
<tr><td>Catheter Sheath Introducer</td><td>A Catheter Sheath Introducer is then placed over the guidewire and dilators into the vessel, and the guidewire and dilators are removed.</td></tr>
<tr><td>Guiding Catheter</td><td>Can be placed through the catheter sheath introducer to provide a passage through which the microcatheter or microcatheter/guidewire combination can be advanced into select locations in the vasculature.</td></tr>
<tr><td>Guidewire</td><td>A guidewire may be used to advance the microcatheter into the vasculature and as microcatheter support.</td></tr>
<tr><td>Therapeutic Material</td><td>Therapeutic materials are used to block the flow of blood to a specific region of tissue.
<table>
<tr><th>Microcatheter OD</th><th>Microcatheter ID</th><th>Maximum Guide Wire OD</th><th>Minimum Guiding Catheter ID</th></tr>
<tr><td>2.8F / 2.1F</td><td>0.018” (0.46 mm)</td><td>0.016” (0.41 mm)</td><td>0.040” (1.02 mm)</td></tr>
<tr><td>2.8F / 2.4F</td><td>0.020” (0.52 mm)</td><td>0.018” (0.46 mm)</td><td>0.040” (1.02 mm)</td></tr>
<tr><td>2.8F / 2.8F</td><td>0.024” (0.62 mm)</td><td>0.021” (0.53 mm)</td><td>0.040” (1.02 mm)</td></tr>
<tr><td>2.9F / 2.9F</td><td>0.027” (0.69 mm)</td><td>0.021” (0.53 mm)</td><td>0.042” (1.07 mm)</td></tr>
</table>
Embolics
<table>
<tr><th>Microcatheter OD</th><th>Maximum Particle Size</th><th>Maximum Spherical Size</th><th>Maximum Coil Size</th></tr>
<tr><td>2.8F / 2.1F</td><td>≤ 500 µm Emboli</td><td>≤ 700 µm Microspheres</td><td>≤ 0.016" (0.41 mm)</td></tr>
<tr><td>2.8F / 2.4F</td><td>≤ 700 µm Emboli</td><td>≤ 700 µm Microspheres</td><td>≤ 0.018” (0.46 mm)</td></tr>
<tr><td>2.8F / 2.8F</td><td>≤ 700 µm Emboli</td><td>≤ 700 µm Microspheres</td><td>≤ 0.018” (0.46 mm)</td></tr>
<tr><td>2.9F / 2.9F</td><td>≤ 1000 µm Emboli</td><td>≤ 900 µm Microspheres</td><td>N/A*</td></tr>
</table>
*Coils should not be used in the 2.9F/2.9F Maestro Microcatheters</td></tr>
</table>

4.0 Risks and Warnings

4.1 Residual Risks and Undesirable Effects

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

All possible risk control measures have been implemented and verified and the Maestro microcatheter 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 (AEs) are identified based on a review of the pertinent clinical evidence.

Intended clinical benefits: The Maestro Microcatheter exhibits an indirect clinical benefit to patients as it facilitates infusion of diagnostic, embolic, or therapeutic materials into vessels.

Articles published between February 1st, 2016 to January 31st, 2021 were reviewed. Based on the literature, microcatheters have been successfully used to facilitate the controlled and selective infusion of diagnostic, embolic, or therapeutic materials into vessels. Microcatheters are beneficial in that they facilitate diagnostic and therapeutic interventional procedures. For the clinical evaluation, the performance outcomes were defined as follows:

- Procedural Success: Catheterization of the proper vessel and achievement of subsequent administration of diagnostic, embolic, or therapeutic materials into vessels.

Procedural Success rates from the clinical literature are very high. Overall, Procedural Success was 98% for the Maestro Microcatheter and 97% for the benchmark devices.

The potential complications/AEs related to the subject device as identified in the IFUs are summarized in Table 8. In addition, the device/procedure-related events identified in the literature, and the corresponding risk assessment harms are presented in Table 9.

Table 8. Microcatheter: Potential Complications

Configuration	Adverse Events/Hazards
Maestro	Dissection Embolism Foreign body in patient Hemorrhage Infection Inflammatory reaction Perforation Thrombus formation Vasoconstriction

Table 9. Adverse Events: Maestro Clinical Literature Data

Complications from the Literature	Patients, n/N (%)*	Device-Related	Procedure-Related	IFU Complications	Harms
Groin hematoma	9/1951 (0.46%)	-	X	Hemorrhage	Hemorrhage
Pseudoaneurysm of common femoral artery	1/1951 (0.05%)	-	X	Hemorrhage	Hemorrhage
Inguinal hematoma	6/1951 (0.31%)	-	X	Hemorrhage	Hemorrhage

* Barral et al. (2021) was included for both Pursue and Maestro population counts

The Maestro microcatheter has been used with a high level of safety during endovascular procedures in patients. Device- or procedure-related adverse events reported in the clinical literature for the Maestro Microcatheter and comparable benchmark guide catheters including their rate of incidence and time of occurrence are shown in Table 10 and Table 11. Note that the groin hematomas and pseudoaneurysm were all determined to be un-related to the Maestro Microcatheter and all AEs from the benchmark competitor studies were procedure related.

Table 10. Adverse Events from Maestro Microcatheter Studies

Device- or Procedure-Related Adverse Event	Maestro Microcatheter Studies, n/N (%)*	Timing of Adverse Event		
		Acute (≤ 30 days)	> 30 days	Not Reported
Groin hematoma	9/1951 (0.46%)	2	0	7
Pseudoaneurysm of common femoral artery	1/1951 (0.05%)	0	0	1
Inguinal hematoma	6/1951 (0.31%)	0	0	6

* Barral et al. (2021) was included for both Pursue and Maestro population counts

Table 11. Adverse Events from Benchmark Competitor Studies

Device- or Procedure-Related Adverse Event	Benchmark Competitor Studies n/N (%)	Timing of Adverse Event		
		Acute (≤ 30 days)	> 30 days	Not Reported
Abscess	1/2312 (0.043%)	0	0	1
Access site complications	11/2312 (0.48%)	11	0	0
Access site hematoma without pseudoaneurysm	7/2312 (0.30%)	7	0	0
Access site pain without neurological deficits	1/2312 (0.043%)	1	0	0
Arterial dissection	3/2312 (0.13%)	0	0	3
Ecchymosis	8/2312 (0.35%)	0	0	8
Groin pain without hematoma	1/2312 (0.043%)	1	0	0
Inguinal bruise / hematoma	19/2312 (0.82%)	0	0	19
Local hematoma	3/2312 (0.13%)	0	0	3
Lower extremity deep vein thrombosis	2/2312 (0.087%)	2	0	0
Portal thrombosis	12/2312 (0.52%)	0	0	12
Symptomatic focal radial artery occlusion	4/2312 (0.17%)	4	0	0

Safety data for the Maestro microcatheter from the clinical literature and for comparable benchmark guide catheters are summarized in Table 12. The cumulative device-related AE rate for the Maestro microcatheter is 0% (0/1910). The overall cumulative device-related AE rate for the comparable benchmark microcatheters is 0% (0/2312).

Table 12. Comparative Adverse Event Rates: Maestro Microcatheter

Attribute	Subject Device	Benchmark Devices
Device-Related AE Rate	0% (0/1910)	0% (0/2312)

This assessment accounts for various factors related to the risks associated with the Maestro microcatheter. Given that the complication rates are low and generally transient in nature, patients are assumed to accept the risks associated with guide catheters based on the probable benefits.

In summary, the safety of the subject device has been substantiated via objective evidence from clinical literature data. The results of the clinical risk/safety analysis demonstrate that the subject devices meet the established acceptance criteria with respect to safety measures exhibit an acceptable overall safety profile. No new safety concerns specific to the subject device were identified in this evaluation, and the rates reported in the literature are consistent with available data for state-of-the-art alternative treatments

4.2 Warnings and Precautions

The labeled warnings and precautions for the Maestro microcatheter device configurations are summarized in Table 13.

Table 13. Maestro Microcatheter: Warnings & Precautions

Product Configuration	Labeling
Maestro Microcatheter	**Warnings**
	• Due to contractual agreements, the Maestro Microcatheter is not for neurovascular use at or above the common carotid artery or at or above the vertebral artery. • There is insufficient clinical data to support the use in the coronary or cerebral vasculature. • Sterile if package is unopened and undamaged. • 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, dispose of product and packaging in accordance with hospital, administrative, and/or local government policy. • Do not use a power injector to infuse agents other than contrast media, as the microcatheter may become blocked. The safety setting of injection pressure must not exceed the maximum dynamic injection pressure of 5515 kPa (800 psi). Exceeding injection pressure beyond the maximum injection pressure may cause microcatheter rupture possibly resulting in patient injury. If flow through the microcatheter becomes restricted, do not attempt to clear the microcatheter lumen by infusion. Identify and resolve the cause of the blockage or replace the microcatheter with a new microcatheter before resuming infusion. (See Instructions for Using a Power Injector) • Make sure that the guiding catheter does not slip out of the vessel. If the guiding catheter should leave the vessel when the microcatheter and/or the guide wire is moved, this may result in the damage of the microcatheter system. • Microcatheter advancement beyond the end of the guide wire may result in vessel trauma. • 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
	• **RX only** Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. • Ensure embolic material compatibility with microcatheter prior to use. • Always monitor infusion rates when using the microcatheter • When injecting contrast for angiography, ensure that the microcatheter is not kinked or occluded. • The microcatheter has a lubricious hydrophilic coating on the outside of the catheter. It must be kept hydrated prior to removal from its carrier and during the actual procedure in order to be lubricious. This can be accomplished by attaching the Y-connector to a continuous saline drip. • Prior to a procedure, all equipment to be used for the procedure should be

Product Configuration	Labeling
	carefully examined to verify proper function and integrity. • Inspect the microcatheter prior to use for any bends or kinks. Any microcatheter damage may decrease the desired performance characteristics. • Exercise care in handling of the microcatheter during a procedure to reduce the possibility of accidental breakage, bending or kinking. • When the microcatheter is in the body, it should be manipulated only under fluoroscopy. Do not attempt to move the microcatheter without observing the resultant tip response. • Exchange microcatheters frequently during lengthy procedures that require extensive manipulation or multiple guide wire exchanges. • Never advance or withdraw an intravascular device against resistance until the cause of the resistance is determined by fluoroscopy. Movement of the microcatheter or guide wire against resistance may result in separation of the microcatheter or guide wire, damage to the microcatheter, or vessel perforation. • Because the microcatheter may be advanced into narrow sub selective vasculature, repeatedly assure that the microcatheter has not been advanced so far as to interfere with its removal. • Excessive tightening of a hemostatic valve onto the microcatheter shaft may result in damage to the catheter. • Read and follow the manufacturer's IFU for diagnostic, embolic, or therapeutic agents to be used with this microcatheter. • Use prior to the "use before" date. • Store at controlled room temperature. • Syringe accuracy is +/- 5%.

4.3 Other Relevant Safety Aspects

The Corrective and Preventive Action (CAPA) process for the subject devices is conducted under GPS 999.092. In accordance with the procedure, a risk assessment is conducted to evaluate the significance of the risk of the issue and its associated impact. If the CAPA requires escalation, the appropriate management representatives are required to review and assess the escalation based on their scope of responsibility.

Merit has created 2 Corrective Action Reports (CARs) during the reporting period for this report. Of these CARs both have been closed out. There have been no product recalls/Field Safety Corrective Actions for the subject devices during the reporting period and during its entire time on the market.

Table 14. Corrective Action Report Summary

CAR#	Status	Date Opened	Date Closed	Details
17-01295	Closed	Fall 2017	April 2018	It was found that too much coating solution was being applied. This was corrected by a change in an internal machine withdraw rate. The correction was implemented Jan 20, 2018 and RGAs for this failure mode continued through April 2018.
19-02198	Closed	July 7, 2019	June 9, 2020	Upon investigation a problem with the hydrophilic coating was discovered. This problem only manifests when the Maestro is used inside of the small guide catheters predominately used in China. The CAR is on-going with corrective adjustments

CAR#	Status	Date Opened	Date Closed	Details
				already made to the coating process under effectiveness evaluation.

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

5.1 Summary of Clinical Data for the Equivalent Device

Not applicable, as clinical evaluation based on published literature for the subject device only.

5.2 Summary of Clinical Investigations of the Subject Device

Not applicable, as clinical evaluation was based on published literature. There were no clinical investigations of the Maestro microcatheter related to CE marking.

5.3 Summary of Clinical Data from Other Sources

Scientific Literature Review

The Maestro microcatheter has been used effectively for many years. Clinical data supporting the safety and performance of the Maestro microcatheter have been derived from the following sources:

- A comprehensive literature review using the Embase®, MEDLINE, and PubMed databases for the period from February 1st, 2016 to January 31st, 2021. Literature search strategies were designed to identify articles relevant to the devices in the Maestro microcatheter. Both favorable and unfavorable references were identified and summarized.

As detailed in the clinical literature data, the reported procedural success rate for the Maestro microcatheter is high. Based on the comparative analysis, the lower bound limit (LBL) of the 1-sided 95% confidence interval for p1-p2 is greater than -0.10 (-10%). The subject device meets the established acceptance criteria for Procedural Success.

Table 15. Comparative Cumulative Success Rates for the Maestro Microcatheter

Performance Measure	Subject Devices, n/N (%)	Benchmark Competitors, n/N (%)	Estimated Difference [95% LBL]	LBL > -δ
Procedural Success	2812/2859 (98%)	1143/1173 (97%)	0.9% (0.06%)	PASS

The Maestro microcatheter has been used with a high level of safety during endovascular procedures in patients. Safety data for the Maestro microcatheter from the clinical literature and for comparable benchmark microcatheters are summarized in Table 16. The cumulative AE rate for the Maestro microcatheter is 0% (0/1910). The overall cumulative AE rate for the comparable benchmark catheters is 01% (0/2312).

Table 16. Comparative Safety for the Maestro Microcatheter

Safety Measure	Subject Devices, n/N (%)	Benchmark Competitors, n/N (%)	Estimated Difference [95% UBL]	UBL < δ
Device-Related Adverse Events	0/1910 (0%)	0/2312 (0%)	0% (0%)	PASS

Abbreviations: CI = confidence interval

Post-Market Surveillance

Post-market surveillance (PMS) occurs continuously, with reviews occurring at regular, defined intervals to track and identify trends in device complaints. Reportable complaints are complaints that, upon evaluation of the available information, meet the reporting criteria established by a national regulatory authority for all countries/regions applicable to device(s) of the complaint. There have been no reportable events for the reporting period of February 2016 to January 2021 for the Maestro microcatheter.

The frequencies of complaints, reportable complaints, and their associated reported complications (complaint type) did not present any new risks or unanticipated frequency of risks associated with use of the Maestro microcatheter. The on-market experience reinforces that potential risks have been reduced as far as possible, that the potential benefits of the device outweigh the overall and individual potential risks, and that the potential risks remain acceptable.

5.4 Overall Summary of Clinical Performance and Safety

The clinical data demonstrate that the risks associated with the Maestro microcatheter are acceptable when weighed against the clinical benefits to the patient. All microcatheter procedures have a risk of complications and/or failure, and the risks for an individual are an unpredictable combination of patient, the primary interventional procedure, and device-related interactions. The subject devices are intended to facilitate the controlled and selective infusion of diagnostic, embolic, or therapeutic materials into vessels. The subject devices were deemed consistent with the state-of-the-art benchmark devices for safety and performance in this patient population. The Maestro microcatheter is well established, having demonstrated acceptable safety and performance profile since the catheters were first commercialized in 2016. Based on design verification/validation testing results, safety and performance outcomes in the literature and PMS data, there are no known uncertainties regarding safety and performance of the subject device or the intended use. The known risks are well documented, and the risk of occurrence is low and not associated with any safety or performance signals.

The clinical indications identified in the IFU for the Maestro microcatheter are supported by the clinical evidence presented in the Clinical Evaluation Report (CER). Furthermore, the IFU contains correct and sufficient information to reduce the risk of user error as well as information on residual risks and their management as supported by clinical evidence (e.g., handling and use instructions, description of risks, warnings, precautions, cautions, indications and contraindications, and instructions for managing foreseeable unwanted situations). The overall clinical benefits to the patient of the Maestro microcatheter substantially outweigh any residual risks associated with its clinical use. The risk/benefit assessment for the Maestro microcatheter is summarized in Table 17.

Table 17. Summary of Benefit/Risk Assessment[1,2]

Factor	Notes	Assessment
Uncertainty		
Quality of the study design	• How robust were the data?	26 (LOE: 0 A1, 2 A2, 13 B1, 6 B2, 5 C)
Quality of the study conduct	• How was/were the study/studies designed, conducted, and analyzed?	Data consists of prospective, retrospective, and small case series
	• Are there missing data?	No
Robustness of the study results analysis	• Are the results from the study/studies repeatable?	Yes, the methods employed for the randomized prospective studies are well documented, and therefore assumed to be repeatable
	• 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 resulting from progressions of primary disease.
	• Is the condition treatable?	Yes
	• How does the condition progress?	Tumors and cancers continue to divide and grow. This can be induced by environmental factors or as a result of DNA replication errors. [3] Atherosclerosis is a major risk factor for many different conditions involving the flow of blood. Atherosclerosis progresses as the body's medium and large arteries become thickened due to a buildup of fatty substances, such as cholesterol.[4]
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 8
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
Disease chronicity	• Is the disease/condition chronic?	Only if untreated
	• How long do patients with the disease/condition live?	The 5-year relative survival rate for all cancers is 70% among whites and 63% among blacks. Improvement in survival is based on advances in treatment and diagnosis.60 All patients with PAD have an increased cardiovascular morbidity and mortality e.g. a fourfold risk of myocardial infarction or at least a two-fold increase of ischemic stroke.61 Mortality rates in asymptomatic patients within 5 years are 19% increase and in symptomatic patients to up to 24%.62
	• If chronic, is the illness easily managed with less invasive or difficult therapies?	N/A

Factor	Notes	Assessment
Patient-centric assessment	• How much do patients value this treatment?	High – endovascular access avoids morbidity and mortality associated with the alternatives of more invasive open surgery 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?	N/A – the Microcatheter is used as an accessory tool during a procedure
Availability of alternative treatments or diagnostics	• What other therapies are available for this condition?	Lifestyle changes, medication, open surgery, endovascular procedures
	• How effective are the alternative treatments?	Conservative treatment is viable in stable asymptomatic patients
	• How does their effectiveness vary by subpopulation?	N/A
	• How well-tolerated are the alternative therapies?	The decision between open or endovascular repair for any disease is made based on patient co-morbidities, life-expectancy, urgency, and local operator expertise
	• How does their tolerance vary by subpopulation?	N/A
	• What risks are presented by any available alternative treatments?	Death/serious complications in untreated cases
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
	• Is post-market 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 post-market 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 post-market elements are considered applicable to the subject device. Microcatheters are utilized on a transient basis, therefore long-term device performance is not applicable. Additionally, Microcatheters are well-established 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 post-market 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 open surgery intervention

5.5 Postmarket Clinical Follow-up (PMCF)

The need to conduct PMCF activities is subject to annual review as part of the 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 Maestro microcatheter is detailed in PMCFP-QRMT0040-002. PMCF activities planned for the device include survey of health care professionals. An evaluation form will be circulated to health care professionals that use the Pursue microcatheter to collect cases or data point. A minimum of 149 data points represented separate patient cases will be collected.

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 Maestro microcatheter.
- 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 devices.
- 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

Microcatheters are used in general intravascular procedures. They can be used for the controlled and selective infusion of diagnostic media, embolic agents, or therapeutic materials into vessels. They are most commonly used in selective diagnostic and interventional procedures.[5] Delivery of embolic materials, and endovascular treatment are two such interventional procedures where microcatheters are used. Arterial embolization is a procedure where the blood supply to a tumor or abnormal tissue is blocked. It is used to treat certain types of liver cancers, kidney cancers, uterine fibroids, and aneurysms.[6] Tumors and cancers are due to mutations that are inherited, induced by environmental factors or as a result of DNA replication errors.[3] Uterine fibroids are one such tumor. They are benign clonal tumors that arise from the smooth-

muscle cells of the human uterus. They are clinically seen in 25% of women, yet surgical specimens suggest they are in as many as 77% of women.[7] Vascular aneurysms are rare vascular disorders with rates as low as 0.01% - 0.2%.[8] Vascular aneurysms are often caused by weakened artery walls that expand and may rupture if left untreated.

Listed below are some examples of conditions for which the Merit microcatheters may be used:

1. Delivery of embolic materials to tumors that have blood vessels feeding the tumor.
2. Endovascular treatment of a variety of vascular disease processes including but not limited to those noted below:
    - Benign and malignant tumors:
        - Multiple types and locations in the body, such as liver (hepatocellular carcinoma (HCC)), metastases from hyper vascular tumors, renal, prostate and uterine artery tumors
    - Vascular hemorrhage
        - Upper and lower gastrointestinal, gastroduodenal artery, and pseudoaneurysm
    - Vascular aneurysm
    - Vascular hemangioma
    - Pulmonary and bronchial arteriovenous fistulae treatment
    - Arteriovenous malformations (AVM)
    - Arteriovenous fistula (AVF)
    - Hepatoma
    - Uterine artery fibroids
    - Benign prostatic hypertrophy
    - Varicocele

Treatment Options and Interventions

There are several tests used by clinicians to diagnose vascular diseases. These tests help assess the current state of the vasculature. Diagnosing includes Magnetic Resonance Imaging (MRI), Computed Tomography (CT), and catheter angiogram. MRI is a non-invasive imaging technology that produces 3-D detailed images of anatomical areas of the body. The main principle of MRI is the excitement and detection of protons found in the water of living tissues.[9] The proton excitement is created using powerful magnets which force the protons to align with that specific magnetic field, then a current is applied causing the protons to spin out of their equilibrium. Once the current is deactivated a sensor detects the energy released as the

protons realign with the magnetic field.[9] Magnetic resonance angiography (MRA) is a technique used for the visualization and diagnosis of stenosis, including its anatomic location.[10] CT is another non-invasive imaging technique that generates cross-sectional images of the body. A CT scanner works by creating a narrow x-ray beam that rotates around the patient.[11] The Computed Tomographic Angiography (CTA) technique allows for the visualization of smaller and distal vessels, as well as larger vasculature.[12] Catheter Angiograms (CA) are the gold standard due to its superior resolution and ability to isolate small caliber vascular anomalies as well as provide therapeutic options.[16,13] CA should be used in instances in which noninvasive imaging is inconclusive or not able to be performed.[13-15] When the vasculature becomes too narrow or tortuous, microcatheters are used due to their increased trackability through vessels providing a state-of-the-art treatment option.

Once the presence of vascular disease has been established, different treatment strategies are available depending on the severity of the condition. The goal of the treatment is to reduce symptoms and improve prognosis.[16] Since many risk factors are associated with lifestyle, lifestyle modifications such as avoiding tobacco, maintaining regular exercise and a healthy diet are common recommendations for patients with vascular disease. If it is determined that pharmacological management is needed, medications are used to relieve symptoms and to treat risk factors such as high cholesterol, high blood pressure, irregular heartbeat and low blood flow.[17] Vascular aneurysms are physical abnormalities often caused by weakened artery walls that expand and may eventually rupture if left untreated. In these cases treatment options include monitoring and medication for smaller aneurysms and surgery or endovascular repair for larger aneurysms. Surgery involves removing the impacted portion of the artery and replacing it with a different vein from the patient or a graft. Endovascular repair is another option that may be used to fill the aneurysm with embolic materials delivered using a microcatheter. This causes the aneurysm to clot, preventing it from expanding or rupturing. Arteriovenous malformations (AVMs) and arteriovenous fistulae (AVFs) are abnormal passageways between arteries and veins. Alternate treatment options include radiosurgery, which focuses beams of radiation at the abnormal passageways, and surgery, where the AVM or AVF is removed. Microcatheters are used for non-surgical endovascular embolization, where embolic materials are delivered to the AVM or AVF to prevent blood flow between the arteries and veins. This option is less invasive than surgery and can be used to treat AVMs or AVFs that are inoperable, providing a state-of-the-art treatment option.

Treatments for tumors and cancer vary widely and depend on the type. They include (but are not limited to) prevention (diet, exercise, avoiding tobacco usage, etc.), early detection, surgical options to remove tumors, medication options and radiation options. Early detection is crucial for controlling the growth of cells. In 60% of patients cancer is not diagnosed and treated before metastasis occurs.[18] Surgical options are available to remove the entire mass, or to debulk it. Surgery works best for solid tumors that are contained in one area to reduce pain or pressure.[6] In situations where surgery is not an option microcatheters can be used to embolize the blood vessels feeding tumors. They can also be used to deliver drugs to the specific location of the tumor, allowing localized drug delivery versus blanket treatments.

Clinical practice guidelines and consensus statements issued by the following professional societies inform on the management of the controlled and selective infusion of diagnostic, embolic, or therapeutic materials into vessels:

- Society of Interventional Radiology Quality Improvement Standards for Percutaneous Transcatheter Embolization[19]
- Management of Patients with Peripheral Artery Disease (Compilation of 2005 and 2011 ACCF/AHA Guideline Recommendations) A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines[20]
- The Management of Uterine Leiomyomas (Society of Obstetricians and Gynaecologists of Canada)[21]
- Hepatocellular Carcinoma: ESMO (European Society for Medical Oncology) Clinical Practice Guidelines for Diagnosis, Treatment and Follow-up[22]

Based on the available diagnostic or therapeutic options as well as the recommendations from these guidelines and consensus statements, microcatheters offer a state-of-the art option that can provide selective therapeutic treatment and tumor embolization.

7.0 Suggested Profile and Training for Users

Placement and access of the Maestro microcatheter are only intended to be used by physicians trained in percutaneous intravascular techniques and procedures.

8.0 Applicable Harmonized Standards and Common Specifications

The following harmonized standards and guidance documents were applied or considered during the design and development of the Maestro microcatheter. All of these standards have been applied in full

- ISO 10993-1: 2018 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- ISO 594-2: 1998 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock fittings
- EN 10555-1: 2013 Intravascular Catheters - Sterile And Single-Use Catheters Part 1: Angiographic Catheters
- ISO 11135: 2014 Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices

9.0 References

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10.0 Revision History

SSCP Revision	ECN Number	Date Issued DD/MM/YYYY	Change Description	Revision Validated by the Notified Body
001	ECN 152278	Jul 2021	Initial release	☐ Yes Validation language: English ☒ No
002	ECN 167935	27/10/2023	SSCP update for the Maestro Microcatheter	☒ Yes Validation language: English ☐ No