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) has been validated by the notified body. The following information is intended for users/healthcare professionals.

1 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 (Fr)	DISTAL FRENCH SIZE (Fr)	CATHETER USABLE LENGTH	CATHETER TIP SHAPE	CATHETER ID	MAX GUIDE WIRE	GUIDE CATH MIN ID
MDR-29MC29175ST	2.9 Fr	2.9 Fr	175 cm (69”)	Straight	0.027" (0.68 mm)	0.021" (0.53 mm)	0.042" (1.07 mm)
MDR-29MC29175SN	2.9 Fr	2.9 Fr	175 cm (69”)	Swan Neck	0.027" (0.68 mm)	0.021" (0.53 mm)	0.042" (1.07 mm)
MDR-29MC2917545	2.9 Fr	2.9 Fr	175 cm (69”)	45°	0.027" (0.68 mm)	0.021" (0.53 mm)	0.042" (1.07 mm)
MDR-29MC29165ST	2.9 Fr	2.9 Fr	165 cm (65”)	Straight	0.027" (0.68 mm)	0.021" (0.53 mm)	0.042" (1.07 mm)
MDR-29MC29165SN	2.9 Fr	2.9 Fr	165 cm (65”)	Swan Neck	0.027" (0.68 mm)	0.021" (0.53 mm)	0.042" (1.07 mm)
MDR-29MC2916545	2.9 Fr	2.9 Fr	165 cm (65”)	45°	0.027" (0.68 mm)	0.021" (0.53 mm)	0.042" (1.07 mm)
MDR-29MC29150ST	2.9 Fr	2.9 Fr	150 cm (59")	Straight	0.027" (0.68 mm)	0.021" (0.53 mm)	0.042" (1.07 mm)

CATALOG NUMBER†	PROXIMAL FRENCH SIZE (Fr)	DISTAL FRENCH SIZE (Fr)	CATHETER USABLE LENGTH	CATHETER TIP SHAPE	CATHETER ID	MAX GUIDE WIRE	GUIDE CATH MIN ID
MDR-29MC29150ST/A	2.9 Fr	2.9 Fr	150 cm (59")	Straight	0.027" (0.68 mm)	0.021" (0.53 mm)	0.042" (1.07 mm)
MDR-29MC29150SN	2.9 Fr	2.9 Fr	150 cm (59")	Swan Neck	0.027" (0.68 mm)	0.021" (0.53 mm)	0.042" (1.07 mm)
MDR-29MC29150SN/A	2.9 Fr	2.9 Fr	150 cm (59")	Swan Neck	0.027" (0.68 mm)	0.021" (0.53 mm)	0.042" (1.07 mm)
MDR-29MC2915045	2.9 Fr	2.9 Fr	150 cm (59")	45°	0.027" (0.68 mm)	0.021" (0.53 mm)	0.042" (1.07 mm)
MDR-29MC2915045/A	2.9 Fr	2.9 Fr	150 cm (59")	45°	0.027" (0.68 mm)	0.021" (0.53 mm)	0.042" (1.07 mm)
MDR-29MC29130ST	2.9 Fr	2.9 Fr	130 cm (51")	Straight	0.027" (0.68 mm)	0.021" (0.53 mm)	0.042" (1.07 mm)
MDR-29MC29130ST/A	2.9 Fr	2.9 Fr	130 cm (51")	Straight	0.027" (0.68 mm)	0.021" (0.53 mm)	0.042" (1.07 mm)
MDR-29MC29130SN	2.9 Fr	2.9 Fr	130 cm (51")	Swan Neck	0.027" (0.68 mm)	0.021" (0.53 mm)	0.042" (1.07 mm)
MDR-29MC29130SN/A	2.9 Fr	2.9 Fr	130 cm (51")	Swan Neck	0.027" (0.68 mm)	0.021" (0.53 mm)	0.042" (1.07 mm)
MDR-29MC2913045	2.9 Fr	2.9 Fr	130 cm (51")	45°	0.027" (0.68 mm)	0.021" (0.53 mm)	0.042" (1.07 mm)
MDR-29MC2913045/A	2.9 Fr	2.9 Fr	130 cm (51")	45°	0.027" (0.68 mm)	0.021" (0.53 mm)	0.042" (1.07 mm)
MDR-29MC29110ST	2.9 Fr	2.9 Fr	110 cm (43")	Straight	0.027" (0.68 mm)	0.021" (0.53 mm)	0.042" (1.07 mm)
MDR-29MC29110ST/A	2.9 Fr	2.9 Fr	110 cm (43")	Straight	0.027" (0.68 mm)	0.021" (0.53 mm)	0.042" (1.07 mm)
MDR-29MC29110SN	2.9 Fr	2.9 Fr	110 cm (43")	Swan Neck	0.027" (0.68 mm)	0.021" (0.53 mm)	0.042" (1.07 mm)
MDR-29MC29110SN/A	2.9 Fr	2.9 Fr	110 cm (43")	Swan Neck	0.027" (0.68 mm)	0.021" (0.53 mm)	0.042" (1.07 mm)
MDR-29MC2911045	2.9 Fr	2.9 Fr	110 cm (43")	45°	0.027" (0.68 mm)	0.021" (0.53 mm)	0.042" (1.07 mm)
MDR-29MC2911045/A	2.9 Fr	2.9 Fr	110 cm (43")	45°	0.027" (0.68 mm)	0.021" (0.53 mm)	0.042" (1.07 mm)
MDR-28MC28175ST	2.8 Fr	2.8 Fr	175 cm (69")	Straight	0.024" (0.63 mm)	0.021" (0.53 mm)	0.040" (1.02 mm)
MDR-28MC28175SN	2.8 Fr	2.8 Fr	175 cm (69")	Swan Neck	0.024" (0.63 mm)	0.021" (0.53 mm)	0.040" (1.02 mm)
MDR-28MC2817545	2.8 Fr	2.8 Fr	175 cm (69")	45°	0.024" (0.63 mm)	0.021" (0.53 mm)	0.040" (1.02 mm)
MDR-28MC28165ST	2.8 Fr	2.8 Fr	165 cm (65")	Straight	0.024" (0.63 mm)	0.021" (0.53 mm)	0.040" (1.02 mm)
MDR-28MC28165SN	2.8 Fr	2.8 Fr	165 cm (65")	Swan Neck	0.024" (0.63 mm)	0.021" (0.53 mm)	0.040" (1.02 mm)
MDR-28MC2816545	2.8 Fr	2.8 Fr	165 cm (65")	45°	0.024" (0.63 mm)	0.021" (0.53 mm)	0.040" (1.02 mm)

CATALOG NUMBER†	PROXIMAL FRENCH SIZE (Fr)	DISTAL FRENCH SIZE (Fr)	CATHETER USABLE LENGTH	CATHETER TIP SHAPE	CATHETER ID	MAX GUIDE WIRE	GUIDE CATH MIN ID
MDR-28MC28150ST	2.8 Fr	2.8 Fr	150 cm (59")	Straight	0.024" (0.63 mm)	0.021" (0.53 mm)	0.040" (1.02 mm)
MDR-28MC28150ST/A	2.8 Fr	2.8 Fr	150 cm (59")	Straight	0.024" (0.63 mm)	0.021" (0.53 mm)	0.040" (1.02 mm)
MDR-28MC28150SN	2.8 Fr	2.8 Fr	150 cm (59")	Swan Neck	0.024" (0.63 mm)	0.021" (0.53 mm)	0.040" (1.02 mm)
MDR-28MC28150SN/A	2.8 Fr	2.8 Fr	150 cm (59")	Swan Neck	0.024" (0.63 mm)	0.021" (0.53 mm)	0.040" (1.02 mm)
MDR-28MC2815045	2.8 Fr	2.8 Fr	150 cm (59")	45°	0.024" (0.63 mm)	0.021" (0.53 mm)	0.040" (1.02 mm)
MDR-28MC2815045/A	2.8 Fr	2.8 Fr	150 cm (59")	45°	0.024" (0.63 mm)	0.021" (0.53 mm)	0.040" (1.02 mm)
MDR-28MC28130ST	2.8 Fr	2.8 Fr	130 cm (51")	Straight	0.024" (0.63 mm)	0.021" (0.53 mm)	0.040" (1.02 mm)
MDR-28MC28130ST/A	2.8 Fr	2.8 Fr	130 cm (51")	Straight	0.024" (0.63 mm)	0.021" (0.53 mm)	0.040" (1.02 mm)
MDR-28MC28130SN	2.8 Fr	2.8 Fr	130 cm (51")	Swan Neck	0.024" (0.63 mm)	0.021" (0.53 mm)	0.040" (1.02 mm)
MDR-28MC28130SN/A	2.8 Fr	2.8 Fr	130 cm (51")	Swan Neck	0.024" (0.63 mm)	0.021" (0.53 mm)	0.040" (1.02 mm)
MDR-28MC2813045	2.8 Fr	2.8 Fr	130 cm (51")	45°	0.024" (0.63 mm)	0.021" (0.53 mm)	0.040" (1.02 mm)
MDR-28MC2813045/A	2.8 Fr	2.8 Fr	130 cm (51")	45°	0.024" (0.63 mm)	0.021" (0.53 mm)	0.040" (1.02 mm)
MDR-28MC28110ST	2.8 Fr	2.8 Fr	110 cm (43")	Straight	0.024" (0.63 mm)	0.021" (0.53 mm)	0.040" (1.02 mm)
MDR-28MC28110ST/A	2.8 Fr	2.8 Fr	110 cm (43")	Straight	0.024" (0.63 mm)	0.021" (0.53 mm)	0.040" (1.02 mm)
MDR-28MC28110SN	2.8 Fr	2.8 Fr	110 cm (43")	Swan Neck	0.024" (0.63 mm)	0.021" (0.53 mm)	0.040" (1.02 mm)
MDR-28MC28110SN/A	2.8 Fr	2.8 Fr	110 cm (43")	Swan Neck	0.024" (0.63 mm)	0.021" (0.53 mm)	0.040" (1.02 mm)
MDR-28MC2811045	2.8 Fr	2.8 Fr	110 cm (43")	45°	0.024" (0.63 mm)	0.021" (0.53 mm)	0.040" (1.02 mm)
MDR-28MC2811045/A	2.8 Fr	2.8 Fr	110 cm (43")	45°	0.024" (0.63 mm)	0.021" (0.53 mm)	0.040" (1.02 mm)
MDR-28MC24175ST	2.8 Fr	2.4 Fr	175 cm (69”)	Straight	0.020" (0.52 mm)	0.018" (0.46 mm)	0.040" (1.02 mm)
MDR-28MC24175SN	2.8 Fr	2.4 Fr	175 cm (69”)	Swan Neck	0.020" (0.52 mm)	0.018" (0.46 mm)	0.040" (1.02 mm)
MDR-28MC2417545	2.8 Fr	2.4 Fr	175 cm (69”)	45°	0.020" (0.52 mm)	0.018" (0.46 mm)	0.040" (1.02 mm)
MDR-28MC24165ST	2.8 Fr	2.4 Fr	165 cm (65”)	Straight	0.020" (0.52 mm)	0.018" (0.46 mm)	0.040" (1.02 mm)
MDR-28MC24165SN	2.8 Fr	2.4 Fr	165 cm (65”)	Swan Neck	0.020" (0.52 mm)	0.018" (0.46 mm)	0.040" (1.02 mm)

CATALOG NUMBER†	PROXIMAL FRENCH SIZE (Fr)	DISTAL FRENCH SIZE (Fr)	CATHETER USABLE LENGTH	CATHETER TIP SHAPE	CATHETER ID	MAX GUIDE WIRE	GUIDE CATH MIN ID
MDR-28MC2416545	2.8 Fr	2.4 Fr	165 cm (65”)	45°	0.020" (0.52 mm)	0.018" (0.46 mm)	0.040" (1.02 mm)
MDR-28MC24150ST	2.8 Fr	2.4 Fr	150 cm (59")	Straight	0.020" (0.52 mm)	0.018" (0.46 mm)	0.040" (1.02 mm)
MDR-28MC24150ST/A	2.8 Fr	2.4 Fr	150 cm (59")	Straight	0.020" (0.52 mm)	0.018" (0.46 mm)	0.040" (1.02 mm)
MDR-28MC24150SN	2.8 Fr	2.4 Fr	150 cm (59")	Swan Neck	0.020" (0.52 mm)	0.018" (0.46 mm)	0.040" (1.02 mm)
MDR-28MC24150SN/A	2.8 Fr	2.4 Fr	150 cm (59")	Swan Neck	0.020" (0.52 mm)	0.018" (0.46 mm)	0.040" (1.02 mm)
MDR-28MC2415045	2.8 Fr	2.4 Fr	150 cm (59")	45°	0.020" (0.52 mm)	0.018" (0.46 mm)	0.040" (1.02 mm)
MDR-28MC2415045/A	2.8 Fr	2.4 Fr	150 cm (59")	45°	0.020" (0.52 mm)	0.018" (0.46 mm)	0.040" (1.02 mm)
MDR-28MC24130ST	2.8 Fr	2.4 Fr	130 cm (51")	Straight	0.020" (0.52 mm)	0.018" (0.46 mm)	0.040" (1.02 mm)
MDR-28MC24130ST/A	2.8 Fr	2.4 Fr	130 cm (51")	Straight	0.020" (0.52 mm)	0.018" (0.46 mm)	0.040" (1.02 mm)
MDR-28MC24130SN	2.8 Fr	2.4 Fr	130 cm (51")	Swan Neck	0.020" (0.52 mm)	0.018" (0.46 mm)	0.040" (1.02 mm)
MDR-28MC24130SN/A	2.8 Fr	2.4 Fr	130 cm (51")	Swan Neck	0.020" (0.52 mm)	0.018" (0.46 mm)	0.040" (1.02 mm)
MDR-28MC2413045	2.8 Fr	2.4 Fr	130 cm (51")	45°	0.020" (0.52 mm)	0.018" (0.46 mm)	0.040" (1.02 mm)
MDR-28MC2413045/A	2.8 Fr	2.4 Fr	130 cm (51")	45°	0.020" (0.52 mm)	0.018" (0.46 mm)	0.040" (1.02 mm)
MDR-28MC24110ST	2.8 Fr	2.4 Fr	110 cm (43")	Straight	0.020" (0.52 mm)	0.018" (0.46 mm)	0.040" (1.02 mm)
MDR-28MC24110ST/A	2.8 Fr	2.4 Fr	110 cm (43")	Straight	0.020" (0.52 mm)	0.018" (0.46 mm)	0.040" (1.02 mm)
MDR-28MC24110SN	2.8 Fr	2.4 Fr	110 cm (43")	Swan Neck	0.020" (0.52 mm)	0.018" (0.46 mm)	0.040" (1.02 mm)
MDR-28MC24110SN/A	2.8 Fr	2.4 Fr	110 cm (43")	Swan Neck	0.020" (0.52 mm)	0.018" (0.46 mm)	0.040" (1.02 mm)
MDR-28MC2411045	2.8 Fr	2.4 Fr	110 cm (43")	45°	0.020" (0.52 mm)	0.018" (0.46 mm)	0.040" (1.02 mm)
MDR-28MC2411045/A	2.8 Fr	2.4 Fr	110 cm (43")	45°	0.020" (0.52 mm)	0.018" (0.46 mm)	0.040" (1.02 mm)
MDR-28MC21175ST	2.8 Fr	2.1 Fr	175 cm (69”)	Straight	0.018" (0.45 mm)	0.016” (0.41 mm)	0.040" (1.02 mm)
MDR-28MC21175SN	2.8 Fr	2.1 Fr	175 cm (69”)	Swan Neck	0.018" (0.45 mm)	0.016” (0.41 mm)	0.040" (1.02 mm)
MDR-28MC2117545	2.8 Fr	2.1 Fr	175 cm (69”)	45°	0.018" (0.45 mm)	0.016” (0.41 mm)	0.040" (1.02 mm)
MDR-28MC21165ST	2.8 Fr	2.1 Fr	165 cm (65”)	Straight	0.018" (0.45 mm)	0.016” (0.41 mm)	0.040" (1.02 mm)

CATALOG NUMBER†	PROXIMAL FRENCH SIZE (Fr)	DISTAL FRENCH SIZE (Fr)	CATHETER USABLE LENGTH	CATHETER TIP SHAPE	CATHETER ID	MAX GUIDE WIRE	GUIDE CATH MIN ID
MDR-28MC21165SN	2.8 Fr	2.1 Fr	165 cm (65”)	Swan Neck	0.018" (0.45 mm)	0.016” (0.41 mm)	0.040" (1.02 mm)
MDR-28MC2116545	2.8 Fr	2.1 Fr	165 cm (65”)	45°	0.018" (0.45 mm)	0.016” (0.41 mm)	0.040" (1.02 mm)
MDR-28MC21150ST	2.8 Fr	2.1 Fr	150 cm (59")	Straight	0.018" (0.45 mm)	0.016" (0.41 mm)	0.040" (1.02 mm)
MDR-28MC21150ST/A	2.8 Fr	2.1 Fr	150 cm (59")	Straight	0.018" (0.45 mm)	0.016" (0.41 mm)	0.040" (1.02 mm)
MDR-28MC21150SN	2.8 Fr	2.1 Fr	150 cm (59")	Swan Neck	0.018" (0.45 mm)	0.016" (0.41 mm)	0.040" (1.02 mm)
MDR-28MC21150SN/A	2.8 Fr	2.1 Fr	150 cm (59")	Swan Neck	0.018" (0.45 mm)	0.016" (0.41 mm)	0.040" (1.02 mm)
MDR-28MC2115045	2.8 Fr	2.1 Fr	150 cm (59")	45°	0.018" (0.45 mm)	0.016" (0.41 mm)	0.040" (1.02 mm)
MDR-28MC2115045/A	2.8 Fr	2.1 Fr	150 cm (59")	45°	0.018" (0.45 mm)	0.016" (0.41 mm)	0.040" (1.02 mm)
MDR-28MC21130ST	2.8 Fr	2.1 Fr	130 cm (51")	Straight	0.018" (0.45 mm)	0.016" (0.41 mm)	0.040" (1.02 mm)
MDR-28MC21130ST/A	2.8 Fr	2.1 Fr	130 cm (51")	Straight	0.018" (0.45 mm)	0.016" (0.41 mm)	0.040" (1.02 mm)
MDR-28MC21130SN	2.8 Fr	2.1 Fr	130 cm (51")	Swan Neck	0.018" (0.45 mm)	0.016" (0.41 mm)	0.040" (1.02 mm)
MDR-28MC21130SN/A	2.8 Fr	2.1 Fr	130 cm (51")	Swan Neck	0.018" (0.45 mm)	0.016" (0.41 mm)	0.040" (1.02 mm)
MDR-28MC2113045	2.8 Fr	2.1 Fr	130 cm (51")	45°	0.018" (0.45 mm)	0.016" (0.41 mm)	0.040" (1.02 mm)
MDR-28MC2113045/A	2.8 Fr	2.1 Fr	130 cm (51")	45°	0.018" (0.45 mm)	0.016" (0.41 mm)	0.040" (1.02 mm)
MDR-28MC21110ST	2.8 Fr	2.1 Fr	110 cm (43")	Straight	0.018" (0.45 mm)	0.016" (0.41 mm)	0.040" (1.02 mm)
MDR-28MC21110ST/A	2.8 Fr	2.1 Fr	110 cm (43")	Straight	0.018" (0.45 mm)	0.016" (0.41 mm)	0.040" (1.02 mm)
MDR-28MC21110SN	2.8 Fr	2.1 Fr	110 cm (43")	Swan Neck	0.018" (0.45 mm)	0.016" (0.41 mm)	0.040" (1.02 mm)
MDR-28MC21110SN/A	2.8 Fr	2.1 Fr	110 cm (43")	Swan Neck	0.018" (0.45 mm)	0.016" (0.41 mm)	0.040" (1.02 mm)
MDR-28MC2111045	2.8 Fr	2.1 Fr	110 cm (43”)	45°	0.018” (0.45 mm)	0.016” (0.41 mm)	0.040” (1.02 mm)
MDR-28MC2111045/A	2.8 Fr	2.1 Fr	110 cm (43”)	45°	0.018” (0.45 mm)	0.016” (0.41 mm)	0.040” (1.02 mm)

Abbreviations: cm = centimeter; Fr = French; ID = inner diameter; mm = millimeter

† 110cm, 130cm and 150cm catheters include configurations with Grilamid hub (base product code) and Trogamid hub (base code with /A), 165cm and 175cm catheters are only configured with the Trogamid hub.

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.	Merit Medical Systems, Inc. 1600 West Merit Parkway South Jordan, Utah 84095 USA

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 Classificazione Nazionale dei Dispositivi medici (CND) code(s) and descriptors for the subject devices are listed in Table 3.

1.6 Risk Class of Device

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

Abbreviations: CND = Classificazione Nazionale Dispositivi medici; EMDN = European Medical Device Nomenclature; EU = European Union; SRN = Single Registration Number; UDI -DI = Unique Device Identification – Device Identification

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 the SRN are provided in Table 4.

1.9 Notified Body

The Notified Body (NB) involved in the conformity assessment of the Maestro microcatheter in accordance with Annex IX or Annex X of the 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

Abbreviations: EU = European Union; NB = Notified Body; SRN = Single Registration Number

2 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 Indications and Intended Patient Groups

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.

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 Intended Clinical Benefits

The Maestro microcatheter exhibits an indirect clinical benefit to patients as they facilitate infusion of diagnostic, embolic, or therapeutic materials into vessels.

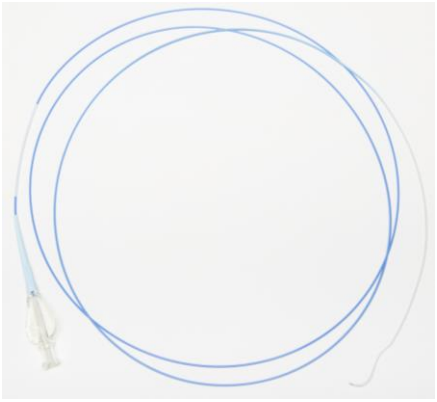
2.4 Contraindications:

There are no known contradictions for the Maestro microcatheter.

3 Device Description

The Maestro Microcatheters are small diameter catheters that are designed to access small vessels or superselective 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 French (Fr), 2.8/2.4 Fr, 2.8/2.8 Fr, and 2.9/2.9 Fr Maestro Microcatheters. The product configurations are summarized in Table 5.

Table 5. Maestro Microcatheter Configurations

Product	Configuration	Description/Product Images
Maestro Microcatheter	• One (1) straight, 45°or swan neck Microcatheter with hydrophilic coating	The Maestro Microcatheter is available in 2.9/2.9 Fr, 2.8/2.8 Fr, 2.8/2.4 Fr, and 2.8/2.1 Fr (proximal / distal) sizes and 110 cm, 130 cm, 150 cm, 165 cm and 175 cm 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 80 cm 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. 

Abbreviations: cm = centimeter; Fr = French

3.1 Materials/Substances in Contact with Patient Tissues

The materials of construction for the Maestro microcatheter components are summarized in Table 6. The materials of construction of the Maestro microcatheter do not include components requiring specific consideration, such as medicinal substances or non-viable animal or human tissues, and such components are not utilized during manufacturing.

Table 6. Maestro Microcatheter Device Materials

Product Family	Component		Material	Categorization by Nature of Body Contact and Duration
Maestro Microcatheter	Hub-original		Grilamid	EC, CB, L
	Hub-updated		Trogamid	EC, CB, L
	Strain Relief		Vestamid	NC
	Catheter Shaft	Inner Layer	Polytetrafluoroethylene (PTFE)	EC, CB, L
		Outer Layer	Pebax	EC, CB, L
		Braid	Nylon	EC, CB, L
		Marker Band	Platinum/Iridium	EC, CB, L
	Hydrophilic coating		Bottom layer: Polyvinyl Pyrrolidone, Photosensitive sulfonate sodium Surface layer: Polyethylene pyrrolidone copolymer, Polyacrylamide copolymer	EC, CB, L

Abbreviations: CB = circulating blood contact; EC = externally communicating; L = limited duration (≤ 24 hours); NC = no patient contact

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 Maestro microcatheter are summarized in Table 7.

Table 7. 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), NC = no patient contact

3.2 Operating Principles

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 Maestro microcatheter's hub material has changed from Grilamid to Trogamid in order to make the Maestro microcatheter suitable for use in a wider range of embolic procedures. In addition, the 165 cm and 175 cm lengths have been added to the Maestro microcatheter.

Table 8. History of Generations/Variants – Maestro Microcatheter

Generations	Change/Difference	Reason for Change/Difference	Date of Implementation	Basic UDI-DI
Regulation (EU) 2017/745 (MDR)				
Maestro with Grilamid Hub	Hub changed to Trogamid	New Trogamid hub material is chemically compatible with DSMO, lipiodol, chemo drugs, glues, and ethanol, making the Maestro microcatheter suitable for use in a wider range of embolization procedures.	Pending certification	088445047256DB
Maestro Microcatheter at 110 cm, 130 cm, 150 cm lengths	Added 165 cm, and 175 cm lengths	Provides easier radial artery access	Pending certification	088445047256DB

Generations	Change/Difference	Reason for Change/Difference	Date of Implementation	Basic UDI-DI

Abbreviations: MDD = Medical Device Directive; MDR = Medical Device Regulation; UDI-DI = Unique Device Identification – Device Identification

3.4 Accessories

The accessories listed in Table 9 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 9. 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>
</table></td></tr>
</table>

<table>
<tr><th>Component</th><th>Comment</th></tr>
<tr><td></td><td>
<table>
<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>

3.5 Devices Used in Combination

There are no other devices or products that are intended to be used in combination with the Maestro microcatheter.

4 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 analyze 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 (SOA) and potential adverse events (AEs) are identified based on a review of the pertinent clinical evidence. This assessment accounts for the various risk factors 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 peripheral vascular infusion of diagnostic, embolic, and/or therapeutic materials based on the probable benefits.

The potential complications/AEs related to the subject device as identified in the IFUs are summarized in Table 10. There were no device/procedure-related events identified in the literature from 2246 patients treated with Maestro microcatheters. All AEs that were reported in the literature were determined to be not device-related as they are known risks associated with routine interventional procedures, treatment with embolic agents, and underlying patient condition.

Table 10. Maestro Microcatheter: Potential Complications

Potential Complications
• Dissection • Embolism • Foreign body in patient • Hemorrhage • Infection • Inflammatory reaction • Perforation • Thrombus formation • Vasoconstriction

In summary, the safety of the subject devices has been substantiated via objective evidence from post-market clinical follow-up data and clinical literature data. The results of the clinical risk/safety analysis demonstrate that the subject device meets the established acceptance criteria with respect to safety and exhibits 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 11.

Table 11. 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.

Product Configuration	Labeling
	• 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 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%.

Abbreviations: EU = European Union; IFU = Instructions for Use; kPa = kilopascal; psi = pounds per square inch; USA = Unites States of America

4.3 Other Relevant Safety Aspects

The Corrective and Preventive Action (CAPA) process for the subject devices is conducted under QSP0219. 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 (Table 12).

Table 12. Corrective Action Report Summary

CAPA Number	CAPA Title	CAPA Originate Date	CAPA Description	CAPA Status
Maestro				
19-02198	N/A	07-July-2019	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 ongoing with corrective adjustments already made to the coating process under effectiveness evaluation.	Closed
22-03359	N/A	11-Feb-2022	During the manufacturing process there were a few incidents in a 12 month time frame where two work orders were mixed during the processing. The corrective actions for this issue was increased signage in the manufacturing area to show which work orders are currently being worked on, barriers to help keep work orders separate during production, and implementing forms production fills out to help track what is being worked on and what stage in the process it is at.	Closed

Abbreviations: CAPA = Corrective and Preventive Action; CAR = Corrective Action Report; N/A = not applicable

Merit has conducted 1 field escalation/product recall during the period of this report (Table 13).

Table 13. Field Escalations and Recalls Summary

Escalation/Recall Identifier	CAPA Number (if applicable)	Date	Issue Description	Product Status/Disposition
172504-09/23/22-006R	N/A	23-Sep-22	Voluntarily recall of the Merit Maestro Microcatheter due to a typographical error in a	Closed

Escalation/Recall Identifier	CAPA Number (if applicable)	Date	Issue Description	Product Status/Disposition
			registration document. The error does not affect clinical use and no product complaints related to the error have been received to date. This issue does not affect the safety or performance of the device, when used as intended. Meanwhile, Merit has initiated internal and external processes and taken preventative actions to prevent similar errors from happening again. This is a recall for products in China only.	

Abbreviations: CAPA = Corrective and Preventive Action; N/A = not applicable

This recall summary indicates proper response to significant field events. These device failures are already known to Merit as evidenced in risk analysis documentation. Recalls for this product continue to be monitored with corrective actions assigned as part of Merit's continuous improvement efforts through its Quality System.

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

5.1 Summary of Clinical Data for the Equivalent Device

To adequately support safety and performance with sufficient clinical data for the 165 cm and 175 cm Maestro Microcatheter configurations, equivalence was established between the 165 cm and 175 cm Maestro Microcatheter configurations with new hub material and the existing configurations of the Merit Maestro Microcatheter (equivalent comparator).

The clinical, technical, and biological characteristics were analyzed between the subject devices and equivalent comparators and no differences are anticipated to significantly affect clinical safety or performance. In accordance with MEDDEV 2.7/1 Rev 4 Appendix A1, MDCG 2020-5, and MDR, Annex XIV, Part A, Section 3, the clinical, technical, and biological equivalence of the above-listed subject and equivalent comparator devices has been established through this analysis. Therefore, clinical data collected in this evaluation pertaining to the equivalent devices may be used to support the safety and performance of the subject devices. All clinical data for the equivalent and subject devices is listed in Section 5.3.

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

5.3.1 Systematic Literature Review

A comprehensive and systematic review of the peer-reviewed literature relevant to the clinical safety and performance of the Maestro microcatheter was conducted for the time period from 01-February-2021 to 30-September-2023. Historical literature from previous clinical evaluations were also included. Based on the suitability and data contribution appraisal, 37 articles were identified as pivotal data for on-label usage of the device and selected for inclusion in the clinical evaluation. Baseline study information pertaining to the pivotal clinical literature data for the Maestro microcatheter are presented in Table 14 and clinical safety and performance results are summarized in Table 15.

Table 14. Maestro Microcatheter: Summary Study Characteristics

Author (Year) LOE Study Type	Primary Clinical Indication	Microcatheter Application, Access	Patients, n/N (%)[a]	Devices Used (N)	Gender (M/F) Age (years)	Follow-up
Acharya et al. (2022)[1] LOE: B2 Prospective study	PA chemoembolization for patients with BPH	Application: chemoembolization with gelatin spherical particles Access: femoral artery (n = 1) and radial artery (n = 49)	50/50 (100)	Maestro (50)	50/0 CBCT with Automatic vessel Detection Software group: 65.3 ± 7.0 years Conventional 2D Fluoroscopy group: 66.4 ± 7.1 years	3 months

Author (Year) LOE Study Type	Primary Clinical Indication	Microcatheter Application, Access	Patients, n/N (%)[a]	Devices Used (N)	Gender (M/F) Age (years)	Follow-up
Becker et al. (2021)[2] LOE: B2 Retrospective study	DEB-TACE	Right common femoral artery	32/32 (100)	Maestro	26/6 67 ± 8.9 years	3 months
Becker et al (2021)[3] LOE: B2 Retrospective study	Hepatic artery TACE	Application: Chemoembolization with doxorubicin-loaded DEBs Access: right common femoral artery	52/52 (100)	Maestro	45/7 67 ± 11.3 years	NR
Becker & Hinrichs (2022)[4] LOE: C Case report	TAE	Application: Balloon-assisted renal TAE Access: Right femoral artery	1/1 (100)	Maestro (1)	1/0 65 years	NR
Bilhim et al. (2019)[5] LOE: A2 Prospective study	cPAE	Femoral artery	43/89 (48)	Maestro	cPAE (subject device): 43/0 67.3 ± 8.02 years bPAE (no subject device): 46/0 65.8 ± 7.93 years	6 months
Boeken (2021)[6] LOE: B1 Prospective study	PAE in patients with BPH	Radial or Femoral artery	215/215 (100)	Maestro	215/0 66 ± 8.7 years (range: 45–93)	1 year

Author (Year) LOE Study Type	Primary Clinical Indication	Microcatheter Application, Access	Patients, n/N (%)[a]	Devices Used (N)	Gender (M/F) Age (years)	Follow-up
Chen et al. (2019)[7] LOE: B1 Retrospective study	DEB-TACE	NR	131/102 [a] (108)	Maestro	84/18 59.05 ± 11.46 years	Median: 220 days
Chen et al. (2021)[8] LOE: B1 Retrospective study	DEB-TACE and cTACE	Femoral artery	335/335 (100)	Maestro	DEB-TACE: 145/26 54.9 ± 11.8 years cTACE: 146/18 55.4 ± 13.2 years	Median: 11.0 months (range: 1.0 – 37.0 months)
Cheng et al. (2020)[9] LOE: C Prospective study	PAE	Right and left femoral artery	13/13 (100)[a]	Maestro	13/0[b] 83 ± 5 years	Median: 10 weeks (range: 4-30 weeks)
Cheung et al. (2023)[10] LOE: C Retrospective study	TAE	Application: Hepatic pseudoaneurysm embolization Access: NR	1/5 (20)	Maestro (1)	1/0 92 years	12 months
Córdova et al. (2022)[11] LOE: C Case report	Embolization of AVMs	Application: Renal artery AVM embolization Access: Common femoral artery	1/1 (100)	Maestro (1)	0/1 62 years	NR
Hakimé et al. (2021)[12] LOE: B1 Retrospective study	PAE in patients with BPH	Left common femoral artery or left radial artery	165/165 (100)	Maestro	165/0 68 ± 8.4 years (range: 45 -89 years)	12 months

Author (Year) LOE Study Type	Primary Clinical Indication	Microcatheter Application, Access	Patients, n/N (%)[a]	Devices Used (N)	Gender (M/F) Age (years)	Follow-up
Lam et al. (2021)[13] LOE: C Retrospective study	UAE in patients with uterine fibroids	NR	26/26 (100)	Maestro	0/26 NR	3 months
Liu et al. (2020)[14] LOE: B1 Retrospective study	TACE in patients with HCC	Femoral artery	180/180 (100)	Maestro	155/25 54.3 ± 9.3 years	NR
Lyu et al (2023)[15] LOE: B2 Retrospective study	TACE for renal angiomyolipoma	Application: Chemoembolization with bleomycin–lipiodol emulsion beads (cTACE group) and bleomycin-loaded CSMs (CSM TACE group) Access: NR	54/54 (100) cTACE: 37/54 CSM TACE: 17/54	Maestro	cTACE: 9/28; 39 (34-48) years CSM TACE: 3/14; 49 (33-56) years	3 months
Ma et al. (2019)[16] LOE: B1 Retrospective study	DEB-TACE and cTACE in patients with HCC	Femoral artery	192/192 (100)	Maestro	DEB-TACE: 78/16 55.0 ± 12.9 years cTACE: 87/11 54.7 ± 13.4 years	11.4 months (range: 1.0-37.0 months)

Author (Year) LOE Study Type	Primary Clinical Indication	Microcatheter Application, Access	Patients, n/N (%)[a]	Devices Used (N)	Gender (M/F) Age (years)	Follow-up
Meine et al (2021)[17] LOE: C Retrospective study	SIRT in patients with HCC	Application: Administration of ^{99}mTc-HSA (Pretherapeutic SIRT) and Y90 microspheres (SIRT) Access: right common femoral artery	Pretherapeutic SIRT: 22/22 (100) SIRT: 22/22 (100)	Maestro (44)	17/5 70 ± 9 years	NR
Nakhaei (2020)[18] LOE: B1 Retrospective, single-center study	Uterine fibroids	Application: UAE Access: radial and femoral artery	91/182 (50)	Maestro (91)	0/91 46.2 ± 4.9 years	3 to 6 months
Peng et al. (2020)[19] LOE: B1 Prospective study	DEB-TACE in patients with liver cancer	NR	367/367 (100)	Maestro	286/81 59.95 ± 11.60 years	171 days (range: 38-404 days)
Pisco et al. (2018)[20] LOE: C Prospective study	PA chemoembolization in patients with prostate cancer	Right femoral artery	20/20 (100)	Maestro	20/0 67.5 ± 6.4 years	18 months
Spink et al. (2017)[21] LOE: B2 Retrospective study	BAE for hemoptysis	Via distal aortic arch	70/70 (100)	Maestro	32/38 34-71.5 years	NR
Sun et al. (2018)[22] LOE: B1 Retrospective study	DEB-TACE	NR	408/408[a] (127)	Maestro	NR[c]	3 days

Author (Year) LOE Study Type	Primary Clinical Indication	Microcatheter Application, Access	Patients, n/N (%)[a]	Devices Used (N)	Gender (M/F) Age (years)	Follow-up
Torres et al. (2017)[23] LOE: B1 Prospective study	PAE	Right femoral artery	137/137 (100)	Maestro	137/0 66.1 ± 8.4 years (range: 47–86 years)	18 months
Vanstapel et al. (2021)[24] LOE: C Retrospective study	BAE	Application: embolization Access: femoral artery to hypertrophic bronchial, intercostal, and thoracic arteries	3/3 (100)	Maestro	1/2 Range: 29 – 57 years	10 days – 26 months
Weiss et al. (2018)[25] LOE: C Prospective study	Bariatric embolization	Femoral or radial artery	20/20 (100)	Maestro	4/16 44 ± 11 years (range: 27-68)	12 months
Wen et al. (2019)[26] LOE: B2 Prospective study	DEB-TACE	Femoral artery	52/120 (43)	Maestro	DEB-TACE (subject device): 44/8 59.90 ± 11.25 years cTACE (no subject device): 55/13 58.97 ± 12.11 years	Median: 18.5 months (quantile: 13.0 – 24.0 months)

Author (Year) LOE Study Type	Primary Clinical Indication	Microcatheter Application, Access	Patients, n/N (%)[a]	Devices Used (N)	Gender (M/F) Age (years)	Follow-up
Yang et al. (2018)[27] LOE: B2 Prospective study	DEB- TACE	Femoral artery	91/91 (100) [a]	Maestro	Elderly: 23/7 73.60 ± 6.33 years Middle-aged: 49/12 54.91 ± 7.00 years	Median:178 days (quantile: 117-242 days)
Ying et al (2018)[28] LOE: B2 Prospective study	DEB-TACE	NR	65/65 (100)	Maestro	53/12 57.46 ± 12.05 years	Median: 201.0 days (range: 137.5-259.0 days).
Yu et al. (2017)[29] LOE: B2 Prospective study	PAE	Right femoral arterial access	31/31 (100)	Maestro	31/10 60 - 72 years (mean 66) Study group: Median age: 66 years (IQR: 60.3-70.3) Control group: Median age: 66 years (IQR: 60-72)	1 month
Yu et al. (2017)[30] LOE: B2 Prospective study	PAE	Right femoral artery	31/31 (100)	Maestro	31/0 Median: 66 years (range: 60-71 years)	6 months
Yu et al. (2019)[31] LOE: B2 Prospective	PAE	Right femoral artery	82/82 (100)	Maestro	82/0 53 - 79 years (mean 66)	12 months

Author (Year) LOE Study Type	Primary Clinical Indication	Microcatheter Application, Access	Patients, n/N (%)[a]	Devices Used (N)	Gender (M/F) Age (years)	Follow-up
Yu et al. (2019)[32] LOE: C Prospective study	UAE	Right femoral artery	27/60 (45)	Maestro	0/60 NR	24 months
Yu et al. (2022)[33] LOE: C Prospective study	TACE with elective occlusion of feeding arteries in patients with HCC	Application: chemoembolization Access: femoral artery	8/8 (100)	Maestro (8)	6/2 64.5 years (IQR: 60–68.8 years)	Median 25 months (range 22-28 months)
Zhang et al. (2019)[34] LOE: B2 Prospective study	DEB-TACE	Femoral artery	66/66 (100)	Maestro	48/18 59.4 ± 9.9 years	Median: 9.2 months (range: 2.1 – 24.5 months)
Zhang et al. (2021)[35] LOE: C Case report	Endovascular management of hemorrhage	Application: Coil embolization to manage left superior thyroid artery hemorrhage Access: Right femoral artery	1/2 (50)	Maestro (1)	1/0 76 years	5 days
Zhang et al. (2022)[36] LOE: B1 Randomized trial	TACE in patients with HCC	Application: chemoembolization with gelatin sponge particles Access: femoral artery (TFA group) or radial artery (TRA group)	Transfemoral access group: 65/65 (100) Transradial access group: 65/65 (100)	Maestro (130)	TFA group: 54/11; 57.5 ± 10.9 years TRA group: 59/6; 58 ± 9.5 years	1 month

Author (Year) LOE Study Type	Primary Clinical Indication	Microcatheter Application, Access	Patients, n/N (%)[a]	Devices Used (N)	Gender (M/F) Age (years)	Follow-up
Zhao et al. (2019)[37] LOE: B2 Retrospective study	DEB-TACE and cTACE	Femoral artery	89/89 (100)	Maestro	DEB-TACE: 37/5 52.9 ± 11.9 years cTACE: 44/3 51.9 ± 13.1 years	Median: 9.9 months (range: 1.8 – 24.5 months)

[a] Multiple procedures

[b] Reflects entire study population (N = 21) including excluded patients

[c] Reflects demographics for 520 procedures; 425 procedures in male patients, 95 procedures in female patients; ≥ 65 years: 169 procedures, < 65 years: 351 procedures

[d] Reflects demographics for entire study population (N = 215)

Abbreviations: 2D = two-dimensional; ^{99}mTc-HSA = Technetium^{99}-macroaggregates of human serum albumin; BAE = bronchial artery embolization; bPAE = balloon occlusion prostatic artery embolization; BPH = benign prostatic hyperplasia; CBCT = cone beam computed tomography; cPAE = conventional prostatic artery embolization; CSM = CalliSpheres® microsphere; cTACE = conventional transarterial chemoembolization; DEB = drug-eluting bead; DEB-TACE = drug-eluting bead transarterial chemoembolization; F = female;; IQR = interquartile range; LOE = level-of-evidence; M = male; NR = not reported; PA = prostatic artery; PAE = prostatic artery embolization; SIRT = selective internal radiation therapy; TACE = transarterial chemoembolization; TAE = transarterial embolization; TFA = transfemoral access; TRA = transradial access; UAE = uterine artery embolization

Table 15. Maestro microcatheter: Safety and Performance Summary

Author (Year) LOE	Procedural Success n/N (%)	Device-Related Complications	Other AEs
Acharya et al. (2022)[1] LOE: B2	48/50 (98)	0/50 (0)	• No major AEs • At least 4 cases of dysuria, frequency, hematuria, nocturia, pain (access site, urethral, rectal, pelvic), or urgency • At least 3 cases of fever • ≤2 cases of epididymitis, scrotal swelling, UTI, facial flushing, nausea, penile discoloration, urinary leakage, urinary spasms
Becker et al. (2021)[2] LOE: B2	32/32 (100)	NR	-

Author (Year) LOE	Procedural Success n/N (%)	Device-Related Complications	Other AEs
Becker et al (2021)[3] LOE: B2	52/52 (100)	NR	-
Becker & Hinrichs (2022)[4] LOE: C	1/1 (100)	NR	• No inadvertent distal embolization in other organs occurred.
Bilhim et al. (2019)[5] LOE: A2	42/43 (98)	0/43 (0)	• Intraprostatic arterial rupture due to over-pressured embolization was reported in 2 cPAE cases • There were 46 minor AEs reported in 23 patients including irritative voiding (19; 44.2), dysuria (16; 34.2), penile skin lesions (3; 6.98), hematuria (2; 4.65), rectal bleeding (2; 4.65), acute urinary retention (1; 2.33), hematospermia (1; 2.33), groin hematoma (1; 2.33), and urinary tract infection (1; 2.33). • There were no major AEs including impotence or urinary incontinence.
Boeken (2021)[6] LOE: B1	173/215 (80.5)	NR	-
Chen et al. (2019)[7] LOE: B1	102/102 (100)	0/102 (0)	• [a] AEs reported 1 week following DEB-TACE session include fever (112; 85.5), pain (84; 64.1), nausea (53; 40.5), vomiting (40; 30.5), and other (16; 12.2).
Chen et al. (2021)[8] LOE: B1	335/335 (100)	NR	-
Cheng et al. (2020)[9] LOE: C	13/13 (100)	0/13 (0)	• [a] AEs reported include hematuria requiring readmission, which resolved spontaneously (1; 6.3).
Cheung et al. (2023)[10] LOE: C	1/1 (100)	NR	-
Córdova et al. (2022)[11] LOE: C	0/1 (0)	NR	• The patient, who presented with multiple AVM due to hereditary hemorrhagic telangiectasia, died 2 years after the procedure due to gigantic AVM with massive active bleeding.
Hakimé et al. (2021)[12] LOE: B1	165/165 (100)	0/165 (0)	• There were 83 patients that had self-limiting post-PAE syndrome with a median duration of 3 days (range: 1-21 days). • There was a total of 18 patients with self-resolving minor complications (10.9). Self-resolved complications (Clavien-Dindo Class I) included severe post-PAE syndrome requiring prolonged hospitalization (2; 1.2), hematuria (5; 3.0), hematospermia (n = 5;

Author (Year) LOE	Procedural Success n/N (%)	Device-Related Complications	Other AEs
			3.0), erectile disfunction (1; 0.6), subjectively observed reduced semen volume (2; 1.2), and spontaneous passage of detached necrotic prostate tissue (2; 1.2). • Nontarget embolization: 3/165 (1.8) • Nontarget embolization leading to glans ulceration (n=2) • Nontarget embolization suspected to lead to hydronephrosis secondary to ischemic structure at the left vesicoureteric junction (Clavien-Dindo Class IIIa) resolved with placement of a double J ureteric stent for 3 months (n=1)There was one reported urinary tract infection (Clavien-Dindo Class II) resolved with oral antibiotics (1; 0.6).). • There was 1 reported case of common femoral artery pseudoaneurysm (Clavien-Dindo Class IIIa) resolved with off-label use of a 6 Fr AngioSeal vascular closure device (1; 0.6). • There were 4 reported cases of partial detachment of necrotic prostatic tissue causing bladder outflow obstruction (Clavien-Dindo Class IIIb) that was resolved with cystoscopic resection under general anesthesia (4; 2.4).
Lam et al. (2021)[13] LOE: C	26/26 (100)	0/26 (0)	• There were no periprocedural complications. • Patients experienced pain (73), fever (4), nausea (23), vomiting (46), and high blood pressure (19). • There was one reported case of postprocedural bradycardia and hypertension in a patient that had a 5-night hospital stay.
Liu et al. (2020)[14] LOE: B1	180/180 (100)	NR	-
Lyu et al (2023)[15] LOE: B2	54/54 (100)	0/54 (0)	• PES: 23/54 (n = 14 cTACE, n = 9 CSM TACE) • Pain: 14 (n = 10 cTACE, n = 4 CSM TACE) • Fever: 15 (n = 8 cTACE, n = 7 CSM TACE)
Ma et al. (2019)[16] LOE: B1	192/192 (100)	0/192 (0)	• During treatment AEs reported included pain, nausea/vomiting, and rise in blood pressure with similar rates between DEB-TACE and cTACE: 27.7% (26/94) versus 15.3% (15/98), 11.7% (11/94) versus 8.2% (8/98), and 4.3% (4/94) versus 1.0% (1/98), respectively. • DEB-TACE NRS pain grade was mild, moderate, and severe for 18 (69.2), 7 (26.9), and 1 (3.8) patient(s), respectively. cTACE NRS pain grade was mild and moderate for 14 (93.3) and 1 (6.7) patient(s),

Author (Year) LOE	Procedural Success n/N (%)	Device-Related Complications	Other AEs
			respectively. • During hospitalization AEs reported included pain, nausea/vomiting, and rise in blood pressure with similar rates between DEB-TACE and cTACE: 36.2% (34/94) versus 22.4% (22/98), 27.7% (26/94) versus 14.3% (14/98), and 10.6% (10/94) versus 11.2% (11/98), respectively. • DEB-TACE NRS pain grade was mild and moderate for 27 (79.4) and 7 (20.6) patients, respectively. cTACE NRS pain grade was mild, moderate, and severe for 19 (86.4), 2 (9.1), and 1 (4.5) patient(s), respectively.
Meine et al (2021)[17] LOE: C	Pre therapeutic SIRT: 22/22 (100) SIRT: 22/22 (100)	NR	NR
Nakhaei (2020)[18] LOE: B1	90/91 (98.9)	0/91 (0)	• Vasospasm: 1/91 (1) • Access site complications: 5/91 (5) • Symptomatic focal radial artery occlusion: 4/91 (4) • Access site pain without neurological deficits: 1/91 (1) • Lower extremity DVT: 1/91 (1)
Peng et al. (2020)[19] LOE: B1	367/367 (100)	0/367 (0)	• During the DEB-TACE procedure, there were 259 cases (58.9) of pain, 161 cases (36.6) of fever, 75 cases (17.0) of vomiting, 60 cases (13.6) of nausea, and 33 cases (7.5) of other safety events. • One- month following the procedure, there were 132 cases (30.0) of pain, 93 cases (21.1) of fever, 46 cases (10.5) of vomiting, 42 cases (9.5) of nausea, 6 cases (1.4) of bone marrow toxicity, 4 cases (0.9) of epichrosis, and 33 cases (7.5) of other safety events.
Pisco et al. (2018)[20] LOE: C	16/20 (80)	0/20 (0)	• Of 16 patients with successful procedures, there were 5 (31.3) AEs reported. Six months following chemoembolization, one patient reported ischemia of a small area in the bladder wall and required surgery for resolution. In this patient, the base of the bladder wall had 2 cm^2 of intraluminal necrotic tissue attached, without involvement of the urethra or ureters. There were 2 reported cases sexual dysfunction that resolved in 10 and 12 months. There was 1 reported case of acute urinary retention that required a bladder catheter for 1 week. There was 1 reported case of transient urinary urgency lasting 1 week.

Author (Year) LOE	Procedural Success n/N (%)	Device-Related Complications	Other AEs
Spink et al. (2017)[21] LOE: B2	70/70 (100)	NR	--
Sun et al. (2018)[22] LOE: B1	408/408 (100)	0/408 (0)	• [a] Of the 284 FD records, pain was reported following 275 procedures, in which pain was mild following 163 procedure, moderate following 105, and severe following 7. • Of the 284 FD, fever was reported following 207 procedures, in which fever was low following 99 procedure, moderate following 91, and severe following 17. • Of the 284 FD, vomiting was reported following 56 procedures and increased blood pressure following 75. • Of the 236 SHD records, pain was reported following 230 procedures, in which pain was mild following 161 procedure, moderate following 67, and severe following 2. • Of the 236 SHD group, fever was reported following 145 procedures, in which fever was low following 91 procedure, moderate following 42, and severe following 12. • Of the 236 SHD group, vomiting was reported following 52 procedures and increased blood pressure following 52.
Torres et al. (2017)[23] LOE: B1	137/137 (100)	0/137 (0)	• There were no major complications, urinary incontinence, or erectile dysfunction after PAE. • There were a total of 84 (61.3) minor AEs including 28 dysuria events (100- 300 µm: 12, 300-500 µm: 7, 100-500 µm: 9), 26 frequency events (100- 300 µm: 11, 300-500 µm: 6, 100-500 µm: 9), 9 hematuria events (100- 300 µm: 4, 300-500 µm: 2, 100-500 µm: 3), 8 hematospermia events (100- 300 µm: 4, 300-500 µm: 1, 100-500 µm: 3), 6 rectal bleeding events (100- 300 µm: 3, 300-500 µm: 1, 100-500 µm: 2), 6 inguinal hematoma events (100- 300 µm: 2, 300-500 µm: 2, 100-500 µm: 2) and 1 Glans penis skin lesion in the 100- 300 µm group. All AEs were mild and self-limited: 100- 300 µm: 86% (37/43), 300-500 µm: 41% (19/46), 100-500 µm: 58% (28/48) ($P < 0.001$). • There was 1 unrelated death reported at 3 months following PAE procedure due to myocardial infarction. This patient was not included in the analysis.
Vanstapel et al. (2021)[24] LOE: C	3/3 (100)	0/3 (0)	• In one patient, mild hemoptysis due to the presence of a hypertrophic thyrocervical vascular network re-occurred 7 months after the embolization procedure, which was effectively treated with re-

Author (Year) LOE	Procedural Success n/N (%)	Device-Related Complications	Other AEs
			embolization. The patient was asymptomatic at 18 months post-embolization. • In a second patient, mortality occurred 10 days after the embolization procedure. The patient had a history of pulmonary infections following bilateral lung transplantation (cytomegalovirus, influenza A, *P. aeruginosa*, and *Aspergillus fumigatus*) and died due to hemodynamic collapse secondary to status epilepticus caused by suspected septic fungal emboli. • In a third patient, hemoptysis was effectively terminated post-embolization, and the patient experienced no relapse during the follow-up of 26 months.
Weiss et al. (2018)[25] LOE: C	20/20 (100)	0/20 (0)	• There were zero major AEs. • A total of 11 minor AEs in 8 patients. One patient reported subclinical pancreatitis indicated by transient elevation of lipase levels, which was resolved with supportive care within 48 hours. At the 2 week endoscopy, 8 patients had superficial, asymptomatic ulcers in locations consistent with fundal embolization but were healed by 3 months. At the 1- month follow-up, 1 patient had delayed gastric emptying. The 3-month endoscopy indicated 1 patient had mild gastritis in the gastric body or antrum.
Wen et al. (2019)[26] LOE: B2	52/52 (100)	NR	-
Yang et al. (2018)[27] LOE: B2	91/91 (100)	0/91 (0)	• [a] Of the 36 procedures within the elderly group, during DEB-TACE procedure there were 39 reported events including pain (17; 47.2) fever (11; 30.6), vomiting (5; 13.9), nausea (5; 13.9), and other AEs (1; 2.8). • Of the 74 procedures within the middle-aged group, during DEB-TACE procedure there were 87 reported events including pain (47; 63.5) fever (30; 40.5), vomiting (2; 2.7), nausea (6; 8.1), and other AEs (2; 2.7). • Of the 36 procedures within the elderly group, 1 month following DEB-TACE procedure there were 15 reported events including pain (6; 16.7) fever (5; 13.9), vomiting (2; 5.6), and nausea (2; 5.6). • Of the 74 procedures within the middle-aged group, 1 month following DEB-TACE procedure there were 60 reported events including pain (36; 35.1) fever (18; 24.3), vomiting (9; 12.2), nausea (6; 8.1), and

Author (Year) LOE	Procedural Success n/N (%)	Device-Related Complications	Other AEs
			other adverse events (1; 1.4).
Ying et al (2018)[28] LOE: B2	65/65 (100)	NR	-
Yu et al. (2017)[29] LOE: B2	31/31 (100)	0/31 (0)	• There were no peri-procedural complications, no postembolization pain of severity 2 out of 10, or any other AEs.
Yu et al. (2017)[30] LOE: B2	31/31 (100)	0/31 (0)	• Of 14 patients who underwent verapamil treatment after PAE, there were 3 reported AEs including 2 small groin hematomas and 1 acute retention of urine 2 weeks following PAE due to ball-valve effect of necrotic intravesical prostate. • Of the 16 patients who underwent PAE alone, 4 AEs were reported including 1 dysuria and mild hematuria due to UTI, 2 transient (< 3 days) dysuria and cystitis symptoms (score 3/10), and 1 transient (3 days) anal and perineal pain (score 3/10).
Yu et al. (2019)[31] LOE: B2	82/82 (100)	0/82 (0)	• Periprocedural complications were reported in 13 of 57 (22.8) IPP patients and included events such as major acute retention of urine (4; 7) requiring bladder catheterization, minor deterioration in symptoms of bladder outlet obstruction (4; 7), minor failed trial without catheter in patients who had indwelling bladder catheter prior to PAE procedure (2; 3.5), and minor passage of tissue fragments from the urethra causing occasional urinary flow obstruction (3; 5.3). Four patients TURP, including 2 patients with major acute retention of urine and 2 patients with minor deterioration in symptoms of bladder outlet obstruction. • Postprocedural AEs were reported in 38 of 57 (66.7) IPP patients and 12 of 25 (48) without IPP patients and included events such as dysuria (13 [22.8%] versus 5 [20%]), urethral pain (9 [15.8%] versus 3 [12%]), prostate and/or anal pain (4 [7%] versus 1 [4%]), fever (3 [5.3%] versus [0%]), transient urinary incontinence (6 [10.5%] versus 1 [4%]), and sexual dysfunction (3 [5.3%] versus 2 [8%]). Median dysuria grade was 5.5 (range: 1-9) and lasted for a median of 7 days (1-28 days). Median urethral pain grade was 5.5 (range: 1-10) and lasted for a median of 3 days (1-21 days). Median prostate and/or anal pain grade was 5 (range: 2-8) and lasted for a median of 6 days (3-10 days). Mean fever temperature was 38.4 ºC (range: 37.5 5 ºC - 39.3 ºC) and lasted for an average of 2.3 days (range: 1-4 days).

Author (Year) LOE	Procedural Success n/N (%)	Device-Related Complications	Other AEs
			Transient urinary incontinence lasted for a median of 8.5 days (range: 3-30 days). The 5 reported cases of sexual dysfunction included erectile dysfunction (2), reduced volume of ejaculated fluid (2), and a combination of the 2 (1).
Yu et al. (2019)[32] LOE: C	27/27 (100)[j]	0/27 (0)	• There were zero major events reported in all study groups.
Yu et al. (2022)[33] LOE: C	8/8 (100)	0/8 (0)	• There were no immediate or delayed complications. • Fever with no infection: 4/8 (50) • 1 grade deterioration of serum albumin levels: 2/8 (25) • 1-2 grade deterioration of serum bilirubin levels: 6/8 (75) • 1-3 grade deterioration of serum alanine aminotransferase levels: 7/8 (87.5)
Zhang et al. (2019)[34] LOE: B2	66/66 (100)	0/66 (0)	• The frequency of liver function damage, pain, nausea, vomiting, and fever were 29 (43.9), 27 (40.9), 22 (33.3), 13 (19.7), and 37 (56.1), respectively. • Within the 27 patients that reported pain, there were 15 (22.7) patients with mild pain, 7 (10.6) patients with moderate pain, and 5 (7.6) patients with severe pain. • Within the 37 patients that reported a fever, 21 (31.8) had low-grade fever, 6 (9.1) had moderate-grade fever, and 10 (15.2) had high-grade fever.
Zhang et al. (2021)[35] LOE: C	1/1 (100)	NR	• The patient, a 76-year-old male with COVID-19 and respiratory distress, died 5 days after the procedure due to multivisceral organ failure and septic collapse.

Zhang et al. (2022)[36] LOE: B1	130/130 (100)
	TFA group: 65/65 (100)
	TRA group 65/65 (100)
		0/130 (0)	• Access site pain
			  • TFA group: 9/65 (13.8)
			  • TRA group: 6/65 (9.2)
			• Access site bruising
			  • TFAI group: 7/65 (10.8)
			  • TRA group: 5/65 (7.7)
			• Access site hematoma
			  • TFA group: 1/65 (1.5)
			  • TRA group: 2/65 (3.1)

Author (Year) LOE	Procedural Success n/N (%)	Device-Related Complications	Other AEs

			Access artery occlusion
			• TFA group: 0/65 (0)
			• TRA group: 2/65 (3.1)
			PES
			• Fever
			  • TFA group: 8/65 (12.3)
			  • TRA group: 5/65 (7.7)
			• Abdominal pain
			  • TFA group: 24/65 (36.9)
			  • TRA group: 23/65 (35.4)
			• Nausea
			  • TFA group: 13/65 (20)
			  • TRA group: 14/65 (21.5)
			• Vomiting
			  • TFA group: 10/65 (15.4)
			  • TRA group: 12/65 (18.5)
			• Elevated bilirubin
			  • TFA group: 28/65 (43.1)
			  • TRA group: 26/65 (40)
			• Elevated alanine aminotransferase
			  • TFA group: 30/65 (46.2)
			  • TRA group: 21/65 (32.3)
			• Elevated aspartate aminotransferase
			  • TFA group: 37/65 (56.9)
			  • TRA group:33/65 (50.8)

Zhao et al. (2019)[37] LOE: B2	89/89 (100) \	0/89 (0)	• Pain during treatment was reported in 22 DEB-TACE patients compared to 8 cTACE patients ($P < 0.001$) in which, of the DEB-TACE patients, 20 had mild pain and 2 had severe pain, and all of the cTACE patients had mild pain. There were 6 DEB-TACE patients and 9 cTACE patients with nausea during treatment. During treatment there were also 2 DEB-TACE patients with rise in blood pressure. • Pain during hospitalization was reported in 24 DEB-TACE patients

Author (Year) LOE	Procedural Success n/N (%)	Device-Related Complications	Other AEs
			compared to 15 cTACE patients (*P* = 0.017) in which all the DEB-TACE patients had mild pain, and of the cTACE patients, 14 had mild pain and 1 had moderate pain. There were 5 DEB-TACE patients and 2 cTACE patients with nausea during hospitalization. During hospitalization there were 16 DEB-TACE patients and 7 cTACE patients with fever (*P* = 0.013).

[a] Based on number of procedures not patients

[b] Repeated attempts to cannulate the distal right hepatic artery ended in failure, likely due to the mass effect of multiple liver masses.

Abbreviations: AE = adverse event; ALB = albumin; ALT = alanine transaminase; AVM = arteriovenous malformation; cm^2 = squared centimeters; cPAE = conventional prostatic artery embolization; CSM = CalliSpheres® microsphere; cTACE = conventional transarterial chemoembolization; CTCAE = Common Terminology Criteria for Adverse Events; DEB-TACE = drug-eluting bead transarterial embolization; DVT = deep vein thrombosis; FD = first drug; Fr = French; IPP = intravesical prostatic protrusion; LOE = level-of-evidence; MRI = magnetic resonance imaging; NR = not reported; NRS = Numerical Rating Scale; PAE = Prostatic artery embolization; SIR = Society of Interventional Radiology; SIRT = selective internal radiation therapy; SHD = second or higher drug; TFA = transfemoral access; TRA = transradial access; TURP = transurethral resection of the prostate; µm = micron; UTI = urinary tract infection

5.4 Overall Summary of Clinical Performance and Safety

The performance of the Maestro microcatheter has been analyzed through a review of literature data. Articles published between 2009 and 30-September-2023 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 for the subject device and benchmark devices are very high. Overall, procedural success rate was 98.4% for the Maestro microcatheter and 98.1% for the benchmark devices (Table 16).

Table 16. Comparative Technical Success Rates

Attribute	Maestro	Benchmark Devices
Procedural Success Rate	3222/3273 (98.4%)	4652/4741 (98.1%)

The Maestro microcatheter has been used with a high level of safety during peripheral vascular infusion of diagnostic, embolic and/or therapeutic materials in patients. Safety data for the Maestro microcatheter from the literature data and for comparable benchmark microcatheters from the clinical literature are summarized in Table 17. The device-related AE rate for the Maestro microcatheter is 0%, and the overall device-related AE rate for the comparable benchmark devices is 0.11%

Table 17. Comparative Adverse Event Rates

Attribute	Maestro	Benchmark Devices
Device-Related adverse Event Rate	0/2246 (0%)	4/3558 (0.11%)

This assessment accounts for the various risk factors 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 endovascular diagnostic or interventional procedures based on the probable benefits.

The clinical data and information within the clinical evaluation report demonstrate that the risks associated with the devices in the Maestro microcatheter are acceptable when weighed against the clinical benefits to the patient. All peripheral vascular infusion modalities have a risk of complications and/or failure, and the risks for an individual are an unpredictable combination of patient, the primary surgical/interventional procedure, and device-related interactions. The subject devices are intended to facilitate treatment in patients who require or elect the controlled and selective infusion of diagnostic, embolic, or therapeutic materials in peripheral vasculature as their treatment modality.

The subject devices were deemed consistent with the SOA 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 devices were first commercialized in 2008 and 2017, respectively. Based on design verification/validation testing results, safety and performance outcomes in the literature, and postmarket surveillance (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 IFUs for the Maestro microcatheter product configurations are supported by the clinical evidence presented in the clinical evaluation report. Furthermore, the IFUs contain 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 their clinical use.

In accordance with the Acceptable Benefit/Risk Requirement, an evaluation of clinical data and informational materials demonstrates the following:

- The IFU, labeling and promotional materials, collectively, provide the correct medical condition and target patient population for the clinical application of the Maestro microcatheter
- The positive impact to patient health and well-being through the use of the Maestro microcatheter to facilitate the peripheral vascular infusion of diagnostic, embolic, or therapeutic material is fully described.
- Specific measurable clinical outcomes (e.g., procedural success) are associated with the use of the Maestro microcatheter.
- The procedural success rate for the Maestro microcatheter is high and comparable to benchmark devices
- The device-related AE rate for the Maestro microcatheter is low, and these rates are consistent with the SOA benchmark devices in all

cases

- The incidence of AEs based on postmarket surveillance/vigilance reporting as well as the lack of Maestro microcatheter field actions/recalls is considered clinically acceptable.

Based on a review of the clinical data, the overall benefits to patients outweigh the overall risks when the devices are used for their intended purpose. The risk/benefit assessment for the Maestro microcatheter is summarized in Table 18.

Table 18. Summary of Benefit/Risk Assessment

Summary of the Benefits	Summary of the Risks	Summary of Other Factors
Maestro		
The Maestro microcatheter facilitates infusion of diagnostic, embolic, or therapeutic materials into vessels. The measurable parameter used for the benefits is procedural success– defined as 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 for Maestro are comparable to those for benchmark devices. Procedural success Maestro: 3222/3273 (98.4%) Benchmark devices: 4652/4741 (98.1%) The subject device performance is determined to be noninferior to the benchmark devices at the 95% confidence level,	No device-related adverse events (AEs) were identified in the clinical literature for the subject device. The data is comparable with the device-related AE rate for the benchmark devices (0.11%). Device-related AEs Maestro: 0/2246 (0%) Benchmark devices: 4/3558 (0.11%) The subject device safety is determined to be non-inferior to the benchmark devices at the 95% confidence level.	Not applicable

5.5 Ongoing 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.

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 Maestro microcatheter to collect cases or data point. A minimum of 149 data points representing 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 Diagnostic or Therapeutic Alternatives

Microcatheters are used in a variety of endovascular procedures. They can be used for the peripheral vascular infusion of diagnostic, embolic and/or therapeutic materials.[38] Diseases that require endovascular treatment involving microcatheters include, but are not limited to, the following medical conditions which are described in further detail:

- Benign and malignant tumors (most commonly hepatocellular carcinoma [HCC])
- Benign Prostatic Hyperplasia (BPH)
- Uterine fibroids
- Vascular hemorrhage
- Other vascular abnormalities (i.e., aneurysms, pseudoaneurysms, vascular malformations, endoleaks)

6.1 Review of the Medical Condition

6.1.1 Hepatocellular Carcinoma

Hepatic cancer (liver cancer) is the fifth most common cancer, and second most common cause of cancer-related death worldwide.[39] About 90% of primary liver cancers are classified as HCC.[39] The incidence of HCC increases with advancing age in all populations, with the most likely incidence occurring at around 70 years.[39] The mean peak age of incidence is lower in Chinese and black African populations, and higher in Japanese populations.[39] HCC is about 2 to 2.5 times more likely to occur in males than females.[39] HCC has the highest occurrence rate in East Asia and sub-Saharan Africa, which account for about 85% of all cases.[39] In Europe, there is a significantly high incidence rate within men in Southern Europe (10.5 per 100,000, age-standardized incidence).[39]

The most common etiological factors for the development of HCC include chronic viral hepatitis B and C (HBV and HCV, respectively), alcohol intake, non-alcoholic fatty liver disease (NAFLD), and aflatoxin exposure.[39] Cirrhosis is also a significant stage in the viral carcinogenesis for HCC; HCC occurs in 80% to 90% of patients with cirrhosis.[40] In Europe, HCV infection that occurred in 1940-1960 led to the currently seen incidence of HCC.[39] Similarly, the rate of HCC deaths has increased in the US due to an increase in chronic HCV and HBV incidence from 1990 to 2004, as well as an increase in NAFLD.[39] More recently, global widespread HBV vaccination has decreased the rate of HBV-related HCC in endemic countries.[39]

6.1.2 Benign Prostatic Hyperplasia

BPH is the primary cause of male lower urinary tract symptoms (LUTS) and affects over 50% of men over the age of 60 years.[41] It is the nonmalignant hyperplasia of prostate tissue characterized by stromal and epithelial cell proliferation in the prostate transition zone (surrounding the urethra).[42] Long-term, untreated disease can lead to the development of chronic high-pressure retention (a potentially life-threatening emergency). The hyperplasia results in compression of the urethra that leads to LUTS development.[42] Risk factors for BPH include metabolic syndrome (i.e., hypertension, glucose intolerance, insulin resistance, dyslipidemia), obesity, genetics, and age.[42] Direct hormonal effects of testosterone on prostate tissue have also been investigated. Global differences in the definition of BPH make interpretation of population-based statistics regarding BPH difficult; however, age is a common predictor and is correlated with the development of BPH in most populations.[42]

The severity of BPH on the quality of life can be assessed with the international prostate symptom score (IPSS).[42] The IPSS stratifies patients into 3 groups based on symptoms with numeric ranges: mild (0-7), moderate (8-19), and severe (20-35).[42] The IPSS is useful for treatment decisions, which range from close observation to medical or surgical intervention.[42]

6.1.3 Uterine Fibroids

Uterine fibroids are the most common gynecological tumors; these tumors result from inappropriate growth of uterine smooth muscle tissue or myometrium.[43] They are benign smooth muscle tumors that may occur in over 70% of premenopausal women. The prevalence increases with age until a peak in the 40's.[43] By the age of 50 years, the estimated cumulative incidence of tumors is greater than 80% in black African women and nearly 70% in white women.[43,44] Fibroids account for approximately 240,000 cases, or 40% of all hysterectomies performed annually in the United States (US) and nearly 20,000 inpatient admissions in the United Kingdom.[43]

Uterine fibroids are typically found in 3 locations: subserosal (outside the uterus), intramural (inside the myometrium), and submucosal (inside the uterine cavity).[45] Physical exams and ultrasound imaging are the gold standard diagnostic methods that can be done with high sensitivity.[45] The exact pathophysiology behind uterine fibroid development is unclear, but may depend on estrogen and progesterone levels.[45] Risk factors include endogenous estrogen levels, early menarche, nulliparity, obesity, family history, and late entry to menopause.[45] Treatment and management ranges from surveillance to medication or surgery.[45]

6.1.4 Vascular Hemorrhage

Hemorrhage is the acute loss of blood from a damaged blood vessel.[46] Hemorrhage can be either external or internal, and can appear in nearly all vascular areas of the body.[46] External bleeding is typically visible from a body orifice or traumatic wound.[46] Internal bleeding requires more comprehensive evaluation that includes physical examination, imaging, and laboratory testing.[46] The presentation and management of the hemorrhage will vary by the anatomic location and extent of injury.[46]

Hemorrhage can result in a variety of complications; in general, the decreased blood flow may result in tissue hypoxia, organ failure, seizures, coma, or death.[46] Other general complications may include re-bleeding, infection, deep vein thrombosis (DVT). In the case of the brain, decreased blood flow may result in ischemic attacks, stroke, and other associated neurological or cognitive disorders.[46]

Specific hemorrhage cases that commonly require the use of embolism or therapeutic treatment via microcatheters include gastrointestinal (GI) bleeding or postpartum hemorrhage (PPH). Upper GI bleeding occurs with an estimated annual incidence of 40 to 160 cases per 100,000 individuals.[47-49] Most upper GI bleeding is due to nonvariceal causes including peptic ulcers, duodenal ulcers, benign and malignant tumors, ischemia, gastritis, arteriovenous malformations (AVMs), Mallory-Weiss tears, trauma, or iatrogenic causes.[50,51] Nonvariceal upper GI bleeding can result in a mortality exceeding 10%.[52,53] Additional causes of upper GI bleeding include upper GI tract malignancies, gastric varices, and unidentified

causes.[47] PPH refers to excessive bleeding after childbirth. There are variety of potential causes of PPH, including mechanical vascular injury and systemic coagulopathy.[54] PPH accounts for 25% of maternal deaths worldwide and over 30% in some developing countries.[55,56]

In addition to vascular hemorrhage, additional vascular conditions that may require administration of diagnostic, embolic, or therapeutic materials using microcatheters include aneurysms, pseudoaneurysms, vascular malformations, endoleaks, and other related vascular abnormalities.[57] The Society of Interventional Radiology (SIR) notes that transarterial embolization (TAE) is also applicable for these conditions in the pediatric setting.[57]

6.2 Treatment Options and Interventions

6.2.1 Embolization Therapy

Microcatheters have been used in a variety of endovascular embolization procedures, which include TAE, transarterial chemoembolization (TACE), prostatic artery embolization (PAE), uterine artery embolization (UAE), and bariatric artery embolization. Generally, embolization procedures are performed under local anesthesia and sedation.[58] Patients typically go home during the same day or 1 day post-procedure.[58]

6.2.1.1 Transarterial Embolization

TAE is used to block blood flow to abnormal tissue or vascular lesions, resulting in shrinkage or destruction of the tissue or lesion.[58] Blockage is achieved with a variety of embolic agents delivered via a microcatheter, such as gelfoam (gelatin sponge), coils, particles such as polyvinyl alcohol (PVA), and liquid agents that solidify after injection.[58] TAE is used to treat hepatic cancers, GI bleeding, and renal bleeding.[59] TAE was first demonstrated in 1974 in patients with malignant hepatic tumors.[60] The first use of embolization to control acute GI hemorrhage was reported in 1972.[50] Embolization has since become standard-of-care as a minimally invasive treatment option, especially in patients with GI bleeding that cannot be controlled or accessed via endoscopic techniques.[61] SIR lists the following broad indications for TAE:[57]

- Occlusion of aneurysms (congenital and acquired), pseudoaneurysm, vascular malformations, or other vascular abnormalities with potential for harm
- Treatment of acute or recurrent hemorrhage
- Devascularization of benign tumors, harmful nonneoplastic tissue, malignancies for palliation, or to reduce operative blood loss
- Flow redistribution to protect normal tissue or facilitate subsequent treatments

- Management of endoleaks (i.e., direct sac puncture or collateral vessel embolization)

The potential benefits of TAE for HCC include curative treatment at earlier stages of disease, or a bridge to curative transplantation or palliation at later stage disease.[62] Common mild AEs include mild discomfort (i.e., pain or cramping), fatigue, or flu-like symptoms.[58] Common major complications of TAE in HCC patients include liver and renal failure, abscess in the liver and spleen, bile duct damage, cholecystitis, and mortality.[63]

6.2.1.2 Transarterial Chemoembolization

Conventional transarterial chemoembolization (cTACE) involves the additional step of injecting chemotherapeutic agents directly into the blood vessels to treat a tumor, followed by the injection of embolic particles to block blood flow.[58] The combination of chemotherapy and embolization tends to minimize damage to healthy tissue.[58] Traditionally used chemotherapeutic agents include doxorubicin, cisplatin, and mitomycin C (as deoxyribonucleic acid [DNA] crosslinker).[58] Additional embolic agents used in TACE include lipiodol and drug-eluting beads (DEBs).[58] The use of DEBs in TACE allows for controlled release of drug into the tumor and lower systemic drug concentrations compared to cTACE.[39] TACE provides significantly fewer side effects from doxorubicin leakage, and significant improvements in the long term survival in patients treated for advanced HCC in a 2010 randomized clinical trial involving 212 patients.[64] About half of all HCC patients treated with TAE or TACE are expected to achieve median survival of 20 months.[62] The overall survival (OS) decreases for patients with large tumors (median 13 to 16 months).[65,66] Currently, combination of TACE with other systemic drugs has not shown improved survival.[46,67] Major complications of TACE include liver failure, death from any cause, and abscess.[62] AEs related to TAE and TACE occur in about 10% of HCC patients.[62] Furthermore, TACE is not recommended to be used in patients with decompensated liver disease, advanced liver and/or kidney disfunction, macroscopic vascular invasion, or extrahepatic spread.[39]

6.2.1.3 Prostatic Artery Embolization

First introduced in clinical practice in 2020, PAE is a relatively new and minimally invasive therapy for LUTS that are caused by BPH.[68] It induces ischemia and shrinkage of the prostate, which results in the reduction of LUTS.[68] It can be completed in an outpatient setting. The benefit of PAE in patients with BPH is the reduction of IPSS (typically reduction of 10–12 points at 6 months).[41] A 2020 randomized controlled trial (RCT) consisting of 90 patients with BPH ≥ 50 mL and LUTS demonstrated that PAE provides better urinary and sexual symptoms improvements compared to combined medication therapy for up to 24 months.[41] Combining evidence from 2 studies, one systematic review suggested that patients who underwent PAE experienced a lower complications rate than those who underwent surgical prostate resection.[69]

Major complication rates for PAE are low; data from over 2000 patients demonstrated a <0.5% major complication rate.[70] Pelvic pain during and 1

to 3 days after PAE is common.[68] PAE may be more challenging or not feasible in patients with severe atherosclerosis or difficult pelvic anatomy.[70] An estimated 20% to 25% of patients either do not respond to PAE or have relapse of LUTS at midterm and long-term follow-up.[65]

6.2.1.4 Uterine Artery Embolization

UAE involves the direct injection of an embolic agent into one or both uterine arteries.[45] UAE was first described in 1995 and is conducted by interventional radiologists to treat uterine fibroids, as it decreases the total blood supply to the uterus and the fibroid.[45] It is a minimally invasive approach that minimizes bleeding symptoms compared to other surgical options.[45] It is associated with significant immediate post-procedure discomfort, but the effects reside quickly.[43] Common complications include vaginal discharge and fever (4.0% rates), bilateral UAE failure (4.0%), and postembolization syndrome (PES) (2.9%).[43] UAE may be beneficial to women with symptomatic uterine fibroids who wish to preserve their uterus.[43] However, other studies have noted associated of UAE with higher miscarriage rates and reduced ovarian reserve.[71] One meta-analysis in 2020 noted that UAE may result in higher complication rates for treating giant fibroids (≥ 10 cm and/or uterine volume ≥ 700 cc).[72]

6.2.1.5 Bariatric Artery Embolization

Bariatric artery embolization involves embolization of the left gastric artery (LGA) as a means of weight management.[73] By blocking the gastric artery, blood flow is restricted to the gastric fundus and the production of appetite inducing hormones is reduced.[73] A 2020 published review of clinical data from human trials (137 patients) suggested an average weight loss of 8 to 9 kg from bariatric artery embolization procedures.[73] Commonly reported complications of bariatric artery embolization include superficial gastric ulcers; major complications such as gastric perforation and splenic infarct were reported at a less common rate.[73] Patient metabolic profile improvements (including decreased hemoglobin A1c, total cholesterol, triglycerides, high-density lipoprotein, and low-density lipoprotein) were also reported.[73] As of now, bariatric artery embolization is still an investigational procedure that is not endorsed by the American Society of Metabolic and Bariatric Surgery, but it may still provide benefits to patients who are not eligible for bariatric surgery.[46]

6.2.2 Alternative Treatments

Alternative therapeutic options vary depending on the relevant medical condition. Common alternative treatments that do not involve embolization or therapeutic delivery with the use of microcatheters are summarized below.

6.2.2.1 Surgery

6.2.2.1.1 Liver Cancer

Liver resection and transplantation are surgical approaches to the treatment of liver cancer and HCC.[39] Resection is effective in complete removal of an identified tumor. It is typically performed via open surgery.[39] Surgical resection is a recommended treatment for HCC without cirrhosis.[39] For HCC with cirrhosis, resection is recommended in patients with single tumors if the liver remnant is of adequate volume and liver function can be preserved.[39] For patients with multiple tumors, resection may be performed if liver remnant volume, liver function, patient performance, and comorbidities are appropriate.[39] Transplantation involves the removal of the entire liver and replacement with a graft from a living donor/cadaver.[74] Liver transplantation is recommended for certain patients meeting the Milan criteria who do not meet the criteria for resection.[39] Extrahepatic metastasis and macrovascular invasion are either cautions or contraindications for surgery.[39,75]

Surgical resection is associated with mortality rates of less than 5% over 30 days; 5-year survival rates tend to exceed 50%.[76] For cirrhotic patients, the expected perioperative mortality rate after liver resection is less than 3%.[39] Tumor recurrence is observed at high rates after resection (recurrence rates above 70% have been reported at 5 years after resection).[75] Complications of resection include liver abscess, abdominal abscess, liver failure, bile leak, renal failure, wound infection, and bleeding.[74] Complications of liver transplantation include graft rejection or failure, hepatic artery thrombosis, biliary stricture, wound infection, and death.[74]

6.2.2.1.2 Benign Prostatic Hyperplasia

Treatment options for BPH range from close observation (for low IPSS) to medical or surgical intervention (for higher IPSS). For BPH patients who cannot tolerate or do not benefit from medical therapy, various surgical options exist. The historical standard surgical option is transurethral resection of the prostate (TURP) for prostate glands up to 80 cm^3 to 100 cm^3 and open prostatectomy for prostate glands larger than 80 cm^3 to 100 cm^3. Improvements in IPSS are achieved with both TURP (by 15 to 16 points) and open prostatectomy (by 13 to 18 points).[77] Potential complications of TURP and open prostatectomy collectively include infection, major bleeding, sepsis, incontinence, urinary retention, urethral stricture, urinary tract infection (UTI), transfusion requirement, and sexual dysfunction.[77] Open prostatectomy is associated with higher morbidity rates than TURP. Less invasive surgical techniques have been developed in response to the considerable morbidity associated with the standard techniques. However, these are not generally recommended in patients with very large prostate sizes and are not as effective as PAE for patients with certain prostate enlargement traits (e.g., prominent median lobes).[77]

6.2.2.1.3 Uterine Fibroids

Various surgical procedures can be used to treat uterine fibroids. Hysterectomy remains the established treatment for fibroids.[45] Hysterectomy consists of the removal of the uterus via open or laparoscopic surgery.[45] It is a permanent solution for acquired symptomatic fibroids for women who do not wish to preserve fertility.[45] For asymptomatic fibroids, hysterectomy is primarily indicated for women not undergoing hormone replacement therapies.[43] Myomectomy is an alternative invasive surgical option for those who wish to preserve fertility.[45] The clinical outcome of myomectomy is dependent on the location and size of the fibroid.[45] Currently, there are no large RCTs showing that myomectomy improves fertility compared to other non-surgical treatments.[45] However, some studies indicate that myomectomy is associated with lower risk of miscarriage and greater pregnancy rates than UAE.[71] Furthermore, there is a possible chance of recurrence; about 10% of patients undergoing myomectomy for uterine fibroids may require hysterectomy within 5 to 10 years due to recurrence.[43]

6.2.2.2 Radiofrequency Ablation

6.2.2.2.1 Liver Cancer

Radiofrequency ablation (RFA) utilizes radiofrequency (RF) energy that is directed to target tissue, converted to heat energy, and causes tissue necrosis. Furthermore, the heat induces necrosis in surrounding peri-tumoral tissue with the potential to destroy satellite tumor cells.[39] RFA is a less invasive therapy option than surgical resection, and may be recommended as first-line treatment in very early stage disease.[64] RFA is the standard of care for patients with Barcelona Clinic Liver Cancer (BCLC) 0 and A tumors that are not suitable for surgery.[39] In early stage disease where tumors were <3 cm in diameter, RFA demonstrated similar outcomes to resection, but demonstrated lower morbidity.[64] In a study with 162 patients with cirrhosis, the OS and recurrence-free survival rates were 67.9% and 25.9%, respectively.[39] Ablation methods have limitations observed in tumors close to the gallbladder, liver hilum, or with neighboring intestine, so laparoscopic surgery may be preferred for those indications.[64]

6.2.2.2.2 Benign Prostatic Hyperplasia

RFA for BPH, also known as transurethral needle ablation (TUNA), is a minimally invasive procedure for treating symptomatic benign BPH while preserving the urethra and adjacent structures.[78] In a clinical study consisting of 121 patients who underwent TUNA for BPH, there was a 75% improvement of quality of life (QOL) scores (P<0.001).[78] Patient IPSS scores also improved from a median score of 19 pre-TUNA to a median score of 7 at 12 months post-TUNA, a 65% improvement (P<0.001). The average relapse-free survival for TUNA was 6.1 years.[78] Although this single-

center study demonstrated that TUNA (or RFA) was safe and effective, larger Level of Evidence (LOE) studies are still needed to determine its effectiveness compared to TURP or PAE.

6.2.2.2.3 Uterine Fibroids

RFA for uterine fibroids may also be performed via open or laparoscopic surgery.[79] In a systematic review of 32 studies (1283 patients), RFA was found to decrease fibroid volume (66%), increase quality of life scores, and reduce symptom severity.[79] Annual reintervention rates due to fibroid-related symptoms ranged from about 4.2% to 11.5% through 3 years.[79] Fertility effects of RFA are not well established, but early studies do not seem to present issues with fertility.[79]

One noted disadvantage of RFA is that directed energy may treat one fibroid at a time in the center, while fibroids are known to expand mostly from the periphery.[43] While the technology is promising, long-term data is needed to support these methods compared to more established methods such as UAE.[43] RFA may be suited well for single fibroids, while UAE may be well suited for larger or multiple fibroids.[79]

6.3 Professional/Clinical Guidelines and Standard-of-Care Recommendations

Clinical practice guidelines and consensus statements issued by the following professional societies were reviewed to inform on the management of the relevant medical conditions:

- Hepatocellular Carcinoma: European Society for Medical Oncology (ESMO) Clinical Practice Guidelines for Diagnosis, Treatment and Follow-up[64]
- European Association for the Study of the Liver (EASL) Clinical Practice Guidelines: Management of Hepatocellular Carcinoma[39]
- The Management of Uterine Leiomyomas (Society of Obstetricians and Gynaecologists of Canada)[43]
- Society of Interventional Radiology Quality Improvement Standards for Percutaneous Transcatheter Embolization[57]
- Society of Interventional Radiology Multisociety Consensus Position Statement on Prostatic Artery Embolization for Treatment of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia (From the Society of Interventional Radiology, the Cardiovascular and Interventional Radiological Society of Europe, Societe Francaise de Radiologie, and the British Society of Interventional Radiology: Endorsed by the Asia Pacific Society of Cardiovascular and Interventional Radiology, Canadian Association for Interventional Radiology, Chinese

College of Interventionalists, Interventional Radiology Society of Australasia, Japanese Society of Interventional Radiology, and Korean Society of Interventional Radiology) [77]

- 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[80]

The published guidelines reflect the judgement of acknowledged experts in the field who, based on their experience and on a detailed examination of the available literature, provide guidance to the general medical community on vascular associated procedures. The guidelines examine the clinical evidence for various therapeutic and interventional treatments for patients needing the controlled and selective infusion of diagnostic, embolic, or therapeutic materials into peripheral vasculature for specific medical conditions. Several of the identified guidelines utilize an LOE and/or class (strength) of recommendation grading system similar to that adopted from the European Society of Cardiology (ESC) guidelines,[81] the Infusion Nurses Society (INS),[82] or as established by Atkins et al. (2004).[83] They utilize a LOE and strength of recommendation grading system as in Table 19 and Table 20. The ESC LOE classification system is based on the characteristics of the studies supporting the consensus recommendations (Table 19).[81] The recommendation grade is indicative of the relative strength of the recommendation (Table 20).[81] Alternative systems for scoring LOE and strength of recommendation include those established by the INS group (Figure 1),[84] the GRADE (Grading of Recommendations, Assessment, Development, and Evaluations) system (Table 21) described by Atkins et al. (2004),[83] those established by the Canadian Task Force on Preventive Health Care (Figure 2),[43] and those established by the Infectious Diseases Society of America (Figure 3).[64] The SIR grading methodology for evidence grading is summarized in Figure 4.

Therefore, the guidelines represent current clinical practice and not necessarily intended device use.

Table 19. Clinical Level of Evidence[85]

LOE	Description
A	Data derived from multiple randomized clinical trials or meta-analyses
B	Data derived from a single randomized clinical trial or large non-randomized studies
C	Consensus of opinion of the experts and/or small studies, retrospective studies, registries

Abbreviations: LOE = level-of-evidence

Table 20. Strength of Recommendation Grades[85]

Class of Recommendation	Definition
Class I	Evidence and/or general agreement that a given treatment or procedure is beneficial, useful, effective
Class II	Conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of the given treatment or procedure
Class IIa	Weight of evidence/opinion is in favor of usefulness/efficacy
Class IIb	Usefulness/efficacy is less well established by evidence/opinion
Class III	Evidence or general agreement that the given treatment or procedure is not useful/effective, and in some cases may be harmful

Figure 1. Strength of the Body of Evidence[82]

Strength of the Body of Evidence	Evidence Description*
I	Meta-analysis, systematic literature review, guideline based on randomized controlled trials (RCTs), or at least 3 well-designed RCTs.
I A/P	Evidence from anatomy, physiology, and pathophysiology references as understood at the time of writing.
II	Two well-designed RCTs, 2 or more multicenter, well-designed clinical trials without randomization, or systematic literature review of varied prospective study designs.
III	One well-designed RCT, several well-designed clinical trials without randomization, or several studies with quasi-experimental designs focused on the same question. Includes 2 or more well-designed laboratory studies.
IV	Well-designed quasi-experimental study, case-control study, cohort study, correlational study, time series study, systematic literature review of descriptive and qualitative studies, or narrative literature review, psychometric study. Includes 1 well-designed laboratory study.
V	Clinical article, clinical/professional book, consensus report, case report, guideline based on consensus, descriptive study, well-designed quality improvement project, theoretical basis, recommendations by accrediting bodies and professional organizations, or manufacturer directions for use for products or services. Includes standard of practice that is generally accepted but does not have a research basis (eg, patient identification). May also be noted as Committee Consensus, although rarely used.
Regulatory	Regulatory regulations and other criteria set by agencies with the ability to impose consequences, such as the AABB, Centers for Medicare & Medicaid Services (CMS), Occupational Safety and Health Administration (OSHA), and state Boards of Nursing.

**Sufficient sample size is needed with preference for power analysis adding to the strength of evidence.*

Table 21. GRADE Scoring System[83]

GRADE	Definition
High/1/A	Further research is unlikely to change our confidence in the estimate of effect
Moderate/2/B	Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate

GRADE	Definition
Low/3/C	Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate
Very Low/4/D	Any estimate of effect is very uncertain

Abbreviations: GRADE = Grading of Recommendations, Assessment, Development, and Evaluations

Figure 2. Evidence Statements and Classification of Recommendations (Based on the Ranking of the Canadian Task Force on Preventive Health Care)[43]

Quality of evidence assessment		Classification of recommendations	
I:	Evidence obtained from at least one properly randomized controlled trial	A.	There is good evidence to recommend the clinical preventive action
II-1:	Evidence from well-designed controlled trials without randomization	B.	There is fair evidence to recommend the clinical preventive action
II-2:	Evidence from well-designed cohort (prospective or retrospective) or case–control studies, preferably from more than one centre or research group	C.	The existing evidence is conflicting and does not allow to make a recommendation for or against use of the clinical preventive action; however, other factors may influence decision-making
II-3:	Evidence obtained from comparisons between times or places with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of treatment with penicillin in the 1940s) could also be included in this category	D.	There is fair evidence to recommend against the clinical preventive action
		E.	There is good evidence to recommend against the clinical preventive action
III:	Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees	L.	There is insufficient evidence (in quantity or quality) to make a recommendation; however, other factors may influence decision-making

Figure 3. Levels of Evidence and Grades of Recommendation (Based on the Infectious Diseases Society of America-United States Public Health Service Grading System)[64]

Levels of evidence

I	Evidence from at least one large randomised, controlled trial of good methodological quality (low potential for bias) or meta-analyses of well-conducted randomised trials without heterogeneity
II	Small randomised trials or large randomised trials with a suspicion of bias (lower methodological quality) or meta-analyses of such trials or of trials with demonstrated heterogeneity
III	Prospective cohort studies
IV	Retrospective cohort studies or case–control studies
V	Studies without control group, case reports, expert opinions

Grades of recommendation

A	Strong evidence for efficacy with a substantial clinical benefit, strongly recommended
B	Strong or moderate evidence for efficacy but with a limited clinical benefit, generally recommended
C	Insufficient evidence for efficacy or benefit does not outweigh the risk or the disadvantages (AEs, costs, . . .), optional
D	Moderate evidence against efficacy or for adverse outcome, generally not recommended
E	Strong evidence against efficacy or for adverse outcome, never recommended

Figure 4. Levels of Evidence and Strength of Recommendation by the Society of Interventional Radiology[86]

LEVEL OF EVIDENCE

A HIGH QUALITY EVIDENCE

Types of Evidence	Characteristics of Evidence
Multiple RCTs	Homogeneity of RCT study population
Systematic reviews or meta-analyses of high-quality RCTs	Intention-to-treat principle maintained
RCT data supported by high-quality registry studies	Appropriate blinding
	Precision of data (narrow CIs)
	Appropriate follow-up (consider duration and patients lost to follow-up)
	Appropriate statistical design

B MODERATE QUALITY EVIDENCE—Randomized Study Design

Types of Evidence	Characteristics of Evidence
≥ 1 RCTs	RCTs with limitations (eg, < 80% follow-up, heterogeneity of patient population, bias, etc)
Systematic reviews or meta-analyses of moderate-quality RCTs	Imprecision of data (small sample size, wide CIs)

C MODERATE QUALITY EVIDENCE—Nonrandomized Study Design

Types of Evidence	Characteristics of Evidence
Nonrandomized trials	Nonrandomized controlled cohort study
Observational or registry studies	Observational study with dramatic effect
Systematic reviews or meta-analyses of moderate quality studies	Outcomes research
	Ecological study

D LIMITED QUALITY EVIDENCE

Types of Evidence	Characteristics of Evidence
Observational or registry studies with limited design and execution	Case series
	Case-control studies
Systematic reviews or meta-analyses of studies limited by design and execution	Historically controlled studies

E EXPERT OPINION

Types of Evidence	Characteristics of Evidence
Expert consensus based on clinical practice	Expert opinion without explicit critical appraisal or based on physiology, bench research, or "first principles"

STRENGTH OF RECOMMENDATION

Strong Recommendation	Moderate Recommendation	Weak Recommendation	No Recommendation
Supported by high quality evidence for or against recommendation	Supported by moderate quality evidence for or against recommendation; new research may be able to provide additional context	Supported by weak quality evidence for or against recommendation; new research likely to provide additional context	Insufficient evidence in the literature to support or refute recommendation

Recommendations from the abovementioned guidelines and consensus statements are summarized below in Table 22, Table 23, Table 24, and Table 25.

Table 22. Standard of Care Guidelines and Recommendations for the Management of HCC

Recommendation	Recommendation Grade[a]	LOE[a]
Hepatocellular Carcinoma: ESMO Clinical Practice Guidelines for Diagnosis, Treatment and Follow-up (2018)[64]		
In the case of a long-anticipated waiting time (>3 months), patients may be offered resection, local ablation or TACE in order to minimize the risk of tumor progression and to offer a 'bridge' to transplant.	B	III
Outside clinical trials, the use of therapeutic algorithms based on prognostic scores of unknown predictive values is currently not recommended for the selection of candidates to initial and repeated TACE.	A	III
Conventional lipiodol-based TACE is the standard of care for patients with intermediate HCC, although using DEB-TACE is an option to minimize systemic side effects of chemotherapy.	C	I
The combination of TACE with systemic agents such as sorafenib—either sequential or concomitant—is not recommended in clinical practice.	E	I
Patients with more advanced stages of HCC who are treated with TACE or systemic agents are evaluated clinically for signs of liver decompensation and for tumour progression by dynamic CT or MRI every 3 months to guide therapy decisions.	A	III
EASL Clinical Practice Guidelines: Management of Hepatocellular Carcinoma (2018)[39]		
TACE is recommended for patients with BCLC stage B and should be carried out in a selective manner.	Strong	High
The use of drug-eluting beads has shown similar benefit to conventional TACE (cTACE; gelfoam-Lipiodol particles) and either of the two can be utilized.	Strong	High
TACE should not be used in patients with decompensated liver disease, advanced liver and/or kidney dysfunction, macroscopic vascular invasion or extrahepatic spread.	Strong	High
There is insufficient evidence to recommend bland embolisation, selective intra-arterial chemotherapy and lipiodolisation.	Moderate	N/A
TARE/SIRT using yttrium-90 microspheres has been investigated in patients with BCLC-A for bridging to transplantation, in patients with BCLC-B to compare with TACE, and in patients with BCLC-C to compare with sorafenib. Current data show a good safety profile and local tumour control but fail to show overall survival benefit compared to sorafenib in BCLC-B and -C patients. The subgroup of patients benefitting from TARE needs to be defined.	Moderate	N/A

Recommendation	Recommendation Grade[a]	LOE[a]
There is insufficient evidence to recommend scores that better select BCLC-B candidates for first TACE or for subsequent sessions.	Moderate	N/A

[a]: Grading of recommendations and LOE are based on the Infectious Diseases Society of America-United States Public Health Service Grading System

Abbreviations: BCLC = Barcelona Clinic Liver Cancer; CT = computed tomography; cTACE = conventional transarterial chemoembolization; DEB-TACE = doxorubicin-eluting bead transarterial chemoembolization; EASL = European Association for the Study of the Liver; ESMO = European Society for Medical Oncology; HCC = hepatocellular carcinoma; LOE = level-of-evidence; MRI = magnetic resonance imaging; N/A = not applicable; TACE = transarterial chemoembolization; TARE = transarterial radioembolization; SIRT = selective internal radiation therapy

Table 23. Standard of Care Guidelines and Recommendations for the Management of Uterine Leiomyomas (Fibroids)

Recommendations	Quality of Evidence Assessment[a]	Classification of Recommendations[a]
Management of Uterine Leiomyomas (Society of Obstetricians and Gynaecologists of Canada, 2015)[43]		
Of the conservative interventional treatments currently available, uterine artery embolization has the longest track record and has been shown to be effective in properly selected patients.	II-3	N/A
Uterine artery occlusion by embolization or surgical methods may be offered to selected women with symptomatic uterine fibroids who wish to preserve their uterus. Women choosing uterine artery occlusion for the treatment of fibroids should be counselled regarding possible risks, including the likelihood that fecundity and pregnancy outcomes may be impacted.	II-3	A
In women who present with acute uterine bleeding associated with uterine fibroids, conservative management with estrogens, selective progesterone receptor modulators, antifibrinolytics, Foley catheter tamponade, and/or operative hysteroscopic intervention may be considered, but hysterectomy may become necessary in some cases. In centers where available, intervention by uterine artery embolization may be considered.	III	B

[a]: Evidence statements and grading of recommendations are based on the ranking of the Canadian Task Force on Preventive Health Care

Abbreviations: N/A = not applicable

Table 24. Standard of Care Guidelines and Recommendations for the Management of Benign Prostate Hyperplasia

Recommendations	SOR[a]	LOE[a]
Society of Interventional Radiology Multisociety Consensus Position Statement on Prostatic Artery Embolization for Treatment of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia (2019)[77]		

Recommendations	SOR[a]	LOE[a]
PAE is an acceptable minimally invasive treatment option for appropriately selected men with BPH and moderate to severe LUTS.	Strong	B
PAE can be considered as a treatment option in patients with BPH and moderate to severe LUTS who have very large prostate glands (>80 cm^3), without an upper limit of prostate size.	Moderate	C
PAE can be considered as a treatment option in patients with BPH and acute or chronic urinary retention in the setting of preserved bladder function as a method of achieving catheter independence.	Moderate	C
PAE can be considered as a treatment option in patients with BPH and moderate to severe LUTS who wish to preserve erectile and/or ejaculatory function.	Weak	C
PAE can be considered in patients with hematuria of prostatic origin as a method of achieving cessation of bleeding.	Strong	D
PAE can be considered as a treatment option in patients with BPH and moderate to severe LUTS who are deemed not to be surgical candidates for any of the following reasons: advanced age, multiple comorbidities, coagulopathy, or inability to stop anticoagulation or antiplatelet therapy.	Moderate	E
PAE should be included in the individualized patient-centered discussion regarding treatment options for BPH with LUTS.	Strong	E
Interventional radiologists, given their knowledge of arterial anatomy, advanced microcatheter techniques, and expertise in embolization procedures, are the specialists best suited for the performance of PAE.	Strong	E

[a]: Strength of recommendations and level-of-evidence grading is based on the Society of Interventional Radiology methodology.

Abbreviations: BPH = benign prostate hyperplasia; cm^3 = cubic centimeters; LOE = level-of-evidence; LUTS = lower urinary tract symptoms; PAE = prostatic artery embolization; SOR = Strength of recommendation

Table 25. Standard of Care Guidelines and Recommendations for the Management of Aneurysms

Recommendations	Class of Recommendation	LOE
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[80]		
Aneurysms of the Abdominal Aorta, Its Branch Vessels, and the Lower Extremities:		
Abdominal Aortic and Iliac Aneurysms		
Endovascular repair of infrarenal aortic aneurysms in patients who are at high surgical or anesthetic risk as	IIb	B

Recommendations	Class of Recommendation	LOE
determined by the presence of coexisting severe cardiac, pulmonary, and/or renal disease is of uncertain effectiveness		
Visceral Artery Aneurysms		
Open repair or catheter-based intervention is indicated for visceral aneurysms measuring 2.0 cm in diameter or larger in women of childbearing age who are not pregnant and in patients of either gender undergoing liver transplantation.	I	B
Open repair or catheter-based intervention is probably indicated for visceral aneurysms 2.0 cm in diameter or larger in women beyond childbearing age and in men	IIa	B

Abbreviations: ACCF = American College of Cardiology Foundation; AHA = American Heart Association; cm = centimeter; LOE = level-of-evidence

Guidelines issued by SIR in 2021 were used to inform on the appropriate rates of technical success, clinical success, and AEs for percutaneous transcatheter embolization.[57] The published standards reflect the judgement of Standards Division members, who are acknowledged experts in the field of interventional radiology. The relevant rates for specific indications are summarized in Table 26 and Table 27.

Table 26. Technical and Clinical Success Rates and Thresholds for Percutaneous Transcatheter Embolization[57]

Location/Pathology	Reported Success Rates	Suggested Threshold
Indication: Treatment of acute or recurrent hemorrhage (e.g., hemoptysis, gastrointestinal bleeding, posttraumatic and iatrogenic hemorrhage, and hemorrhagic neoplasms)		
Gastrointestinal – Upper		
Technical success	99.2% (95% CI: 98.3% – 100%)	98.3%
Clinical success	82.1% (95% CI: 73% – 88.6%)	75%
Gastrointestinal – Lower		
Technical success	97.8% (95% CI: 96% – 99.6%)	96%
Clinical success	86.1% (95% CI: 79.9% – 90.6%)	80%
Bronchial arteries		
Technical success	92% (81% – 100%)	85%
Clinical success	88% (82% – 98.5%)	83%

Location/Pathology	Reported Success Rates	Suggested Threshold
Splenic		
Technical success	90.1% (72.7% – 100%)	89%
Clinical success	85.7% (84% – 87.8%)	82%
Renal arteries		
Technical success	83.5% (65% – 100%)	75%
Clinical success	87.3% (78% – 100%)	80%
Hypogastric/lumbar		
Technical success	92.6% (91% – 95%)	88.6%
Clinical success	-	-
Indication: Occlusion of congenital or acquired aneurysm, pseudoaneurysm, vascular malformation, or other vascular abnormalities		
Pulmonary arteriovenous malformation		
Technical success	92.4% (90.6% – 100%)	83%
Clinical success	-	-
Indication: Devascularization of benign tumors or malignancies for palliation (e.g., reduce pain, slow tumor growth, or prevent hemorrhage) or to reduce operative blood loss		
Preoperative spine embolization		
Technical success	68.3% (95% CI: 60.0% – 76.6%)	60%
Clinical success	-	-
Indication: Devascularization of nonneoplastic tissue that produces adverse health effects to the patient		
Splenic (hypersplenism)		
Technical success	99% (99% – 100%)	98%
Clinical success	72% (58% – 96.3%)	55%
Varicocele		
Technical success	92% (84% – 95.7%)	83%

Location/Pathology	Reported Success Rates	Suggested Threshold
Clinical success	-	-
Prostate		
Technical success	94.2% (76.7% – 100%)	80%
Clinical success	87% (76.3% – 100%)	80%
Pelvic congestion syndrome		
Technical success	99.8% (96.2% – 100%)	95%
Clinical success	84% (68.3% – 100%)	68%
Indication: Flow redistribution to protect normal tissue or facilitate other subsequent treatments (e.g., right portal vein embolization to induce left lobe hypertrophy prior to surgical resection)		
Portal vein		
Technical success	99.3% (99.3% – 100%)	98.5%
Clinical success	96.1%	90%
Indication: Endoleak management, including direct sac puncture or collateral vessel embolization, for type II endoleaks		
Endoleak type II		
Technical success	84% (77.2% – 89.8%)	80%
Clinical success	68.4% (61.2% – 75.1%)	61%

Abbreviations: CI = confidence interval

Table 27. Rates and Thresholds for AEs for Percutaneous Transcatheter Embolization[57]

AEs	Reported Rates	Suggested Threshold
Bronchial artery embolization		
Spinal infarction	0.25% (0.1% – 0.3%)	0.45%
Transient chest/back pain	16.6% (3% – 33.7%)	42.0%
Dysphagia	2.2% (0.9% – 3.5%)	4.8%

Postembolization syndrome	21% (1.7% – 31%)	43.8%
Pulmonary artery malformations		
Air embolus	6.58%	10%
Pleurisy	10.5%	12%
Pulmonary infarction	1.32%	3%
Nontarget embolization	0.7%	2%
Re-embolization required	9.3%	12%
Renal arteries		
Nontarget embolization	6%	10%
Hypogastric/lumbar		
Mortality (not procedure-related)	21.6% (12% – 22%)	27.6%
Femoral artery occlusion at access site	1.3%	2%
Increased serum creatinine	1.3%	2%
Endoleak type II		
Procedure-related mortality	1.7% (0.9% – 1.8%)	2.6%
Required secondary intervention	13.4% (0.9% – 14.7%)	27.2%
Secondary rupture	1.5% (0% – 1.8%)	3.3%
Aneurysm-related death	0.5% (0% – 0.6%)	1.1%
Conversion to open repair	4% (1.4% – 4.3%)	6.9%
GI – Upper		
Nontarget embolization	0.65%	-
Rebleeding	15.4% (29.6% – 42.6%)	28.3%
Re-embolization required	11.3% (10% – 16.2%)	17.5%
Bowel ischemia	0.4%	1%
GI – Lower		
Bowel ischemia	2.9%	5%

Splenic		
Abscess/sepsis (splenic injury)	1.4% (0.8% – 2%)	2.3%
Rebleeding	3.3% (1.6% – 4.5%)	5.0%
Infarction (major)	1.5% (0% – 3.8%)	5.3%
Portal vein embolization		
Portal vein occlusion (main/left)	0.8% (0.5% – 1.2%)	1.4%
Varicocele		
Nontarget embolization	0.1% (0.03% – 2%)	2.1%
Pelvic congestion syndrome		
Nontarget embolization	2.6% (2.4% – 4%)	4.2%
Vessel perforation	0.7%	2%
Prostatic artery embolization		
Bladder wall ischemia	0.1% (0.08% – 0.15%)	0.2%
Hematuria	5.1% (4.4% – 5.5%)	6.2%
Rectal bleeding	3.9% (3% – 4.5%)	5.4%
UTI	0.1% (0.08% – 0.15%)	0.2%
Acute urinary retention	5.8% (4.5% – 7.8%)	9.1%

Abbreviations: AE = adverse event; GI = gastrointestinal; UTI = urinary tract infection

7 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 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:

- ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- ISO 594-2, Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock fittings
- ISO 80369-7, Small-bore connectors for liquids and gases in healthcare applications – Part 7: Connectors for intravascular or hypodermic applications.
- EN 10555-1, Intravascular Catheters - Sterile And Single-Use Catheters Part 1: Angiographic Catheters
- ISO 11135, Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices

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10 Revision History

SSCP Revision	ECN Number	Date Issued DD/MM/YYYY	Change Description	Revision Validated by the Notified Body
001	ECN152278	Jul 2021	Initial release	☐ Yes Validation language: English ☒ No
002	ECN167935	27/10/2023	SSCP update for the Maestro Microcatheter	☒ Yes Validation language: English ☐ No
003	ECN182853	21/10//2024	SSCP update to add additional length configurations and reflect change to hub material	☒ Yes Validation language: English ☐ No
004	ECN194878	08/03/2025	Adding translations	☐ Yes Validation language: English ☒ No