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 Performa Angiographic Catheters (i.e., Performa Catheters).

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

The English version of this SSCP document has been validated by the notified body. The following information is intended for users/healthcare professionals.

1.0 Device identification and general information

1.1 Device trade name(s)

The Performa Catheter families covered by this SSCP are presented in Table 1.

Table 1 Devices Included in this SSCP

Device Name	Product Numbers
Performa Catheters	
Performa Diagnostic Cardiology Catheters (PDCC) *Includes the Performa Diagnostic Cardiology Catheter (PDCC) and Performa Pediatric Angiography Catheter (PPAC) groups*	4100381ULT1/B, 410038ULT1/B, 412538ULT1-RAD, 4RPL125, 4RPS110/B, 4RPS110-NB, 4RPS125, 5100381ULT1/B, 5100381ULT2/B, 5100381ULT4-T40/B, 5100381ULT4-T45/B, 510038ULT1/B, 510038ULT2/B, 510038ULT3/B, 510038ULT4-T40/B, 510038ULT4-T45/B, 5110381ULT1/B, 5110381ULT2/B, 5110381ULT4-T40/B, 5110382ULT3/B, 5125381ULT2, 512538ULT1, 512538ULT1-RAD, 512538ULT2, 512538ULT3, 5RPL110/A, 5RPL125/A, 5RPS110/A, 5RPS110-NB/A, 5RPS125/A, 6100381ULT1/B, 6100381ULT2/B, 610038ULT1/B, 610038ULT2/B, 610038ULT3/B, 610038ULT4-T40/A, 6110381ULT4-T40, 6RPL110/A, 6RPL110-NB, 6RPS110/A, 6RPS110-NB, 6RPS125, 7501-13/B, 7501-21/B, 7501-33/B, 7501-43/B, 7501-53/B, 7501-63/B, 7501-A3/B, 7501-B1/B, 7501-H1/B, 7502-23/B, 7503-13/B, 7503-21/B, 7503-33/B, 7503-53/B, 7503-63/B, 7503-A3/B, 7503-B1/B, 7506-11/B, 7507-13/B, 7507-23/B, 7507-33/B, 7507-43/B, 7508-13/B, 7508-23/B, 7509-11/B, 7509-23/B, 7509-43/B, 7509-53/B, 7509-63/B, 7510-13/B, 7510-23/B, 7511-13/B, 7512-13/B, 7513-13/B, 7513-23/B, 7513-43/B, 7513-53/B, 7513-A3/B, 7513-B3/B, 7513-C3/B, 7513-D3/B, 7513-F3/B, 7521-13/B, 7521-21/B, 7521-33/B, 7521-43/B, 7521-53/B, 7521-63/B, 7521-73/B, 7521-F1/B, 7521-M3/B, 7521-N3/B, 7521-P3/B, 7523-13/B, 7523-21/B, 7523-33/B, 7523-53/B, 7523-63/B, 7523-73/B, 7523-E3/B, 7523-F1/B, 7523-M3/B, 7523-N3/B, 7523-P3/B, 7526-11/B, 7527-13/B, 7527-23/B, 7527-33/B, 7528-13/B, 7528-23/B, 7528-33/B, 7529-11/B, 7529-23/B, 7529-33/B, 7529-43/B, 7529-53/B, 7529-63/B, 7531-13/B, 7531-33/B, 7532-13/B, 7533-

Device Name	Product Numbers
	13/B, 7533-23/B, 7533-33/B, 7533-43/B, 7533-53/B, 7534-13/B, 7534-23/B, 7569-11/B, 7569-23/B, 7569-33/B, 7569-43/B, 7572-11/B, 7574-21/B, 7600-11/B, 7601-13/B, 7601-21/B, 7602-11/B, 7602-23/B, 7700-10/B, 7700-20/B, 7700-30/B, 7700-A0/B, 7700-B0/B, 7700-C0/B, 7700-D0/B, 7701-10/B, 7701-20/B, 7701-30/B, 7701-A0/B, 7701-B0/B, 7701-C0/B, 7701-D0/B, 7702-10/B, 7702-20/B, 7703-10/B, 7703-20/B, 7704-10/B, 7704-20/B, 7704-70/B, 7706-10/B, 7707-10/B, 7708-10/B, 7708-20/B, 7708-30/B, 7708-40/B, 7756-10/B, 7756-20/B, 7757-10/B, 7757-20/B, 7776-11/B, 7776-21/B, 7776-33/B, 7776-43/B, 7776-B1/B, 7776-C3/B, 7777-21/B, 7777-33/B, 7777-B1/B
Performa Diagnostic Peripheral Catheter (PDPC)	4653510PIG-PNB, 5575-13/B, 5575-33/B, 5575-A3, 5575-B3, 5575-C3/B, 5576-13/B, 5576-23/B, 5576-33/B, 5576-A3/B, 5576-B3/B, 5576-C3/B, 5576-F3/B, 5576-G3/B, 5577-B3/B, 5577-C3/B, 5578-13/B, 5578-23/B, 5578-A3/B, 5578-B3/B, 5578-C3/B, 5582-13/B, 5582-23, 5582-33, 5582-43/B, 5583-13/B, 5583-23/B, 5583-A3/B, 5583-B3/B, 5584-13/B, 5584-23/B, 5584-33/B, 5584-43/B, 5584-53/B, 5584-63/B, 5584-A3/B, 5584-B3/B, 5584-D3/B, 5584-E3/B, 5585-13/B, 5585-23/B, 5585-A3/B, 5585-B3/B, 5585-C3, 5585-D3, 5585-E3, 5586-23/B, 5586-43/B, 5586-A3/B, 5586-B3/B, 5587-13/B, 5587-23/B, 5587-A3/B, 5588-13/B, 5589-13/B, 5589-23/B, 5589-A3/B, 5590-13/B, 5590-33/B, 5591-A3/B, 5591-B3/B, 5591-C3/B, 5591-E3/B, 5591-F3/B, 5592-13/B, 5592-23/B, 5592-33/B, 5592-A3/B, 5592-B3/B, 5592-C3/B, 5594-13/B, 7514-13/B, 7514-23/B, 7543-13/B, 7602-41/B, 7602-51/B, 7602-61/B, 7602-71/B, 7602-81/B, 7602-91/B, 7602-A1/B, 7602-B1/B, 7602-C1/B, 7602-D1/B, 7603-A1, 7603-B1, 7603-C1, 7673-11/B, 7673-21/B, 7673-31/B, 7673-41/B, 7673-51/B, 7673-61/B, 7674-11/B, 7674-31/B, 7710-20/B, 7710-40/B, 7710-50/B, 7710-B0/B, 7710-E0/B, 7711-10/B, 7711-A0/B, 7713-B0/B, 7715-10/B, 7715-A0/B, 7717-10/B, 7717-20/B, 7717-30/B, 7717-A0/B, 7717-B0/B, 7717-C0/B, 7718-10/B, 7718-20/B, 7718-30/B, 7718-40, 7718-A0/B, 7718-B0/B, 7718-C0/B, 7719-10/B, 7719-A0/B, 7720-10/B, 7720-20/B, 7720-80, 7720-A0/B, 7720-B0/B, 7745-A0/B, 7746-10/B, 7748-10/B, 7748-A0/B, 7749-A0/B
Performa Diagnostic Radial Catheters (PDRC) *Includes the Performa Angiographic Catheter (PAC) and Performa Peripheral Catheter (PPC) groups*	PV411038PIG, PV412538BERN/A, PV412538MP1/A, PV412538MP2SH, PV412538U1/A, PV412538U2/A, PV413538BERN, PV415038BERN, PV512538BERN, PV512538COB2/A, PV512538MP1/A, PV512538MP2SH, PV512538PIG/A, PV512538REN, PV512538U1, PV512538U1SH/A, PV512538U2, PV512538U2SH/A, PV512538U45SH, PV513538BERN, PV515038BERN, PV515038U1, PV612538MP2SH, PV612538PIG
Performa Vessel Sizing Catheters (PVSC)	46535AVS20MHK, 510035AVS20MHK, 510035AVS20PIG, 510035AVS2PIG, 510035AVS2STR, 56535AVS20MHK, 56535AVS20PIG, 56535AVS2MHK, 56535AVS2PIG, 7602-11M, 7602-11M65, 7602-20M, 7602-20M100SH, 7602-20M65, 7602-20M65SH, 7602-2M, 7602-2M65, 7603-11M100, 7603-11M65, 7603-20M100SH, 7603-20M65SH, 7603-2M100, 7603-2M65, 7673-11M100SH, 7673-11M65SH, 7673-20M100SH, 7673-20M65SH, 7673-2M, 7673-2M65, 7674-2M65, 7742-20M100SH, 7742-20M65SH, 7742-2M100SH, 7742-2M65SH, 7743-2M65SH, 7744-2M100SH, 7744-2M65SH, 7755-2M65, 7757-2MP65, 7757-2MP65SH, 7757-2MP65SHA, 7757-2MP65SHTC, 7757-2MP65SHTCB, 7757-2MP80, 7757-2MP80SH, 7757-2MP80SHTC
Custom Performa Catheters	
Performa Diagnostic Custom Cardiology Catheter	1625-37, 1628-049, 7445-88
Performa Diagnostic Custom Peripheral Catheter	7445-88, 1623-B62M, 1623-C720M, 1623-E320M, 1623-F820M, 1624-A32M, 1624-B220M, 1624-C620M, 1624-D110M, 1624-D719M, 1628-

Device Name	Product Numbers
	031, 1628-111, 1628-134, 1628-149, 1628-157, 1628-191, 1628-235, 1628-242/A, 1628-243/A, 1628-244/A, 1628-245/A, 1628-246/A, 1628-247/A, 1628-249/A, 1628-250/A, 1628-252/A, 1628-254/A, 1628-255/A, 1628-256/A, 1628-257/A, 1628-258/A, 1628-264, 1628-265, 1628-271, 1628-C1, 1628-D1, 1628-G5, 1628-G9, 1628-H2, 1628-J1, 1628-J2, 1628-R1, 1628-Y1, 7445-A2, 7445-A3, 7445-F4, 7445-J4
Vessel Sizing	INF00001, INF00004, INF00005
Performa Multipack Kits	
Performa Multipack Kits	7560-13, 7560-23, 7560-53, 7560-G3, 7660-13, 7660-23, 7660-53, 7660-63, 7660-A3, 7751-20
Performa Multipack Plus Kits	
Performa Cardiac MPLUS	5MPSW-145, 6MPPROW-145, 6MPSW-145, 6MPSW-S, 6MPSW-S-18G
Radial MPLUS	RADMPP-10, RADMPP-2, RADMPP-7, RADMPP-8

1.2 Manufacturer Information

The name and address of the manufacturer of the Performa Catheters are provided in Table 2.

Table 2 Manufacturer Information

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

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) codes and descriptors for the subject devices are listed in Table 3.

1.6 Risk Class of Device

The EU device risk classifications for the Performa Catheters are listed in Table 3.

Table 3 Device Identification Information

Device Name	EU Device Class	Product Number	Basic UDI-DI	Single Registration Number (SRN)	EMDN/CND Code	EMDN/CND Terms
Performa Catheters						
PDCC *Includes the PDCC and PPAC groups*	Class III	See Table 1	088445048757ED	US-MF-000001366	C0104020101	PANORAMIC AND SELECTIVE PERIPHERAL DIAGNOSTIC ANGIOGRAPHY CATHETERS AND MICROCATHETERS
					C0104010101	CORONARY ANGIOGRAPHY DIAGNOSTIC CATHETERS
PDPC	Class III	See Table 1	088445048757ED	US-MF-000001366	C0104020101	PANORAMIC AND SELECTIVE PERIPHERAL DIAGNOSTIC ANGIOGRAPHY CATHETERS AND MICROCATHETERS
					C0104010101	CORONARY ANGIOGRAPHY DIAGNOSTIC CATHETERS
PDRC *Includes the PAC and PPC groups*	Class III	See Table 1	088445048757ED	US-MF-000001366	C0104020101	PANORAMIC AND SELECTIVE PERIPHERAL DIAGNOSTIC ANGIOGRAPHY CATHETERS AND MICROCATHETERS
					C0104010101	CORONARY ANGIOGRAPHY DIAGNOSTIC CATHETERS
PVSC	Class III	See Table 1	088445048757ED	US-MF-000001366	C0104020101	PANORAMIC AND SELECTIVE PERIPHERAL DIAGNOSTIC ANGIOGRAPHY CATHETERS AND MICROCATHETERS
					C0104010101	CORONARY ANGIOGRAPHY DIAGNOSTIC CATHETERS
Custom Performa Catheters						
Performa	Class	See Table 1	088445048757ED	US-MF-	C0104020101	PANORAMIC AND

Device Name	EU Device Class	Product Number	Basic UDI-DI	Single Registration Number (SRN)	EMDN/CND Code	EMDN/CND Terms
Diagnostic Custom Cardiology Catheter	III			000001366		SELECTIVE PERIPHERAL DIAGNOSTIC ANGIOGRAPHY CATHETERS AND MICROCATHETERS
					C0104010101	CORONARY ANGIOGRAPHY DIAGNOSTIC CATHETERS
Performa Diagnostic Custom Peripheral Catheter	Class III	See Table 1	088445048757ED	US-MF-000001366	C0104020101	PANORAMIC AND SELECTIVE PERIPHERAL DIAGNOSTIC ANGIOGRAPHY CATHETERS AND MICROCATHETERS
					C0104010101	CORONARY ANGIOGRAPHY DIAGNOSTIC CATHETERS
Performa Multipack Kits						
Performa Cardiac Multipack Kits	Class III	See Table 1	088445048757ED	US-MF-000001366	C0104020101	PANORAMIC AND SELECTIVE PERIPHERAL DIAGNOSTIC ANGIOGRAPHY CATHETERS AND MICROCATHETERS
					C0104010101	CORONARY ANGIOGRAPHY DIAGNOSTIC CATHETERS
Performa Multipack Plus Kits						
Performa Cardiac Multipack Plus Kits	Class III	See Table 1	088445048757ED	US-MF-000001366	C0104020101	PANORAMIC AND SELECTIVE PERIPHERAL DIAGNOSTIC ANGIOGRAPHY CATHETERS AND MICROCATHETERS
					C0104010101	CORONARY ANGIOGRAPHY DIAGNOSTIC CATHETERS
Performa Radial Multipack Plus	Class III	See Table 1	088445048757ED	US-MF-000001366	C0104020101	PANORAMIC AND SELECTIVE PERIPHERAL DIAGNOSTIC

Device Name	EU Device Class	Product Number	Basic UDI-DI	Single Registration Number (SRN)	EMDN/CND Code	EMDN/CND Terms
(MPlus) Kits						ANGIOGRAPHY CATHETERS AND MICROCATHETERS
					C0104010101	CORONARY ANGIOGRAPHY DIAGNOSTIC CATHETERS

1.7 Year of EU Market Introduction

The year that the Performa Catheters were first placed on the EU market is presented in Table 4.

1.8 Authorised Representative (if applicable)

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

1.9 Notified Body

The Notified Body (NB) involved in the conformity assessment of the Performa Catheters 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
PDCC					
PDCC	2007	Merit Medical Ireland Ltd.	IE-AR-000001011	BSI	2797
PPAC	2008	Merit Medical Ireland Ltd.	IE-AR-000001011	BSI	2797
PDPC					
PDPC	2007	Merit Medical Ireland Ltd.	IE-AR-000001011	BSI	2797
PDRC					
PAC	2014	Merit Medical Ireland Ltd.	IE-AR-000001011	BSI	2797
PPC	Pending	Merit Medical Ireland Ltd.	IE-AR-000001011	BSI	2797
PVSC					
PVSC	2004	Merit Medical Ireland Ltd.	IE-AR-000001011	BSI	2797

2.0 Intended Use of the Device

2.1 Intended Purpose

The Performa Angiographic Catheter Family of devices are intended to be used to deliver radiopaque media to selected sites in the vascular system in conjunction with routine diagnostic procedures.

Angiographic catheters with marker bands may also be used for anatomical measurements.

2.2 Indication(s) and Intended Patient Groups

Performa Angiographic Catheters are indicated for use in patients undergoing diagnostic cardiology and peripheral angiography procedures.

2.3 Contraindications

There are no labeled contraindications for use of the Performa Catheter devices.

3.0 Device Description

3.1 Materials/Substances in Contact with Patient Tissues

Performa Catheters include the Diagnostic Cardiology (PDCC), Diagnostic Peripheral (PDPC), Diagnostic Radial

(PDRC), and Vessel Sizing (PVSC) families. The Diagnostic Cardiology family includes the Performa Diagnostic Cardiology Catheter (PDCC) and Performa Pediatric Angiography Catheter (PPAC) groups. The Diagnostic Radial family includes the Performa Angiographic Catheter (PAC) and Performa Peripheral Catheter (PPC) groups. The Performa Catheters are plastic single-lumen catheters used for intravascular introduction of contrast media for diagnostic analysis of the patient's vasculature. The PVSC also has radiopaque marker bands that are attached to the shaft. It can be used like a ruler for anatomical measurements to determine accurate sizing of a vessel lumen prior to angioplasty, embolization, aortic stent graft placement or other interventional procedures. The Performa Catheters are available in 4, 5, and 6 French wire-braided and non-wire braided configurations in lengths from 40 to 150 cm with a variety of tip configurations suitable for facilitating their advancement into selected locations in the vasculature. They are available with or without side holes (up to 10) and with up to 20 marker bands (PVSC only). Custom catheters and catheter kits are also available.

The Performa Catheters include the following features:

- **Winged Polycarbonate Hub**: The proximal end of the catheter has a molded, winged hub incorporating a connector with a female Luer taper.
- **Strain Relief**: The strain relief is a separate sleeve that is adhered to the hub with adhesive to provide support for the hub – shaft transition.
- **Catheter Tip**: The tip of the catheter comes in a variety of shapes to accommodate differing vascular anatomies. The tip material has a soft construction and is rounded to limit vessel wall trauma during all phases of the procedure. The catheter tip is radiopaque for visualization under fluoroscopy.
- **Catheter Shaft**: The shaft of the catheter is constructed of a kink-resistant, radiopaque material that can remain in the body during the entire length of the procedure without significant changes in the stiffness and torque.

Performa Catheter details are summarized by family in Table 5.

Table 5. Device Configuration Summary

Family	Size (Fr)	Inner diameter (in [mm])	Length (cm)	Tip Types	Recommended Guidewire (in [mm])	Other Features
Performa Catheter						
PDCC *Includes the PDCC and PPAC groups*	4 - 6	0.041 (1.04) - 0.059 (1.50)	65 - 125	Varied	0.035 (0.89) - 0.038 (0.97)	Braided and Non-Braided Side Ports
PDPC	4 - 6	0.041 (1.04) - 0.054 (1.37)	40 - 125	Varied	0.035 (0.89) - 0.038 (0.97)	Braided and Non-Braided Side Ports

Family	Size (Fr)	Inner diameter (in [mm])	Length (cm)	Tip Types	Recommended Guidewire (in [mm])	Other Features
PDRC *Includes the PAC and PPC groups*	4 - 6	0.042 (1.07) - 0.059 (1.50)	110 - 150	Varied	0.038 (0.97)	Braided and Non-Braided Side Ports
PVSC	4 - 5	0.041 (1.04) - 0.052 (1.32)	65 - 100	Varied	0.035 (0.89)	Non-Braided Side Ports Marker Bands
Custom Performa Catheters						
Performa Diagnostic Custom Cardiology Catheter	5 - 6	1.7-2.0mm	100	Varied	0.038 (0.97)	Braided and Non-Braided Side Ports
Performa Diagnostic Custom Peripheral Catheter	4 - 6	0.041 (1.04) - 0.054 (1.37)	60 - 125	Varied	0.035 (0.89) - 0.038 (0.97)	Braided and Non-Braided Side Ports

Images of the Performa Catheters are provided below. Not all configurations are shown.

Figure 1. PDCC

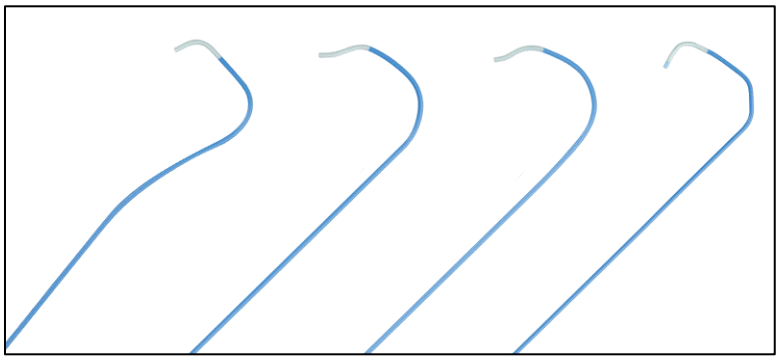


Figure 2. PPAC

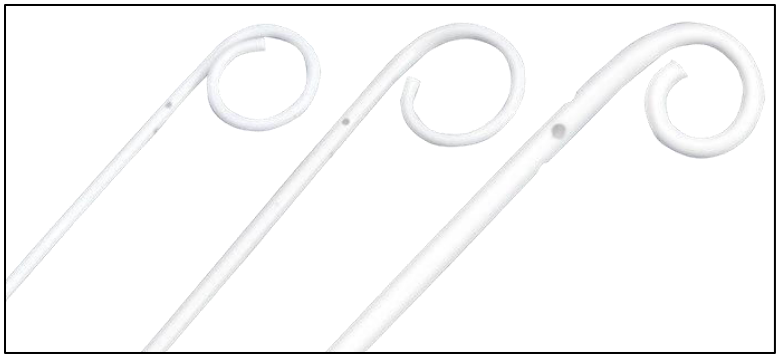


Figure 3. PDPC

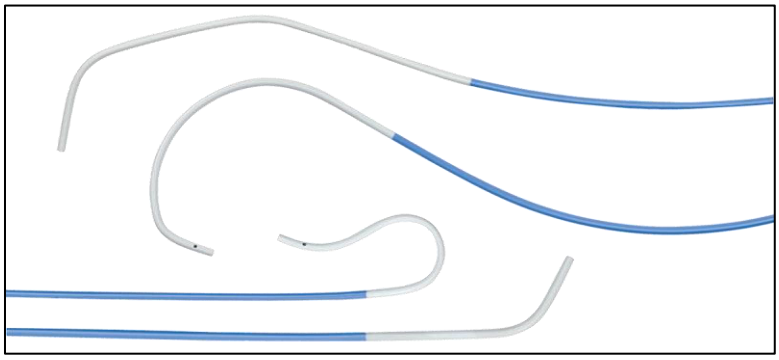


Figure 4. PDRC

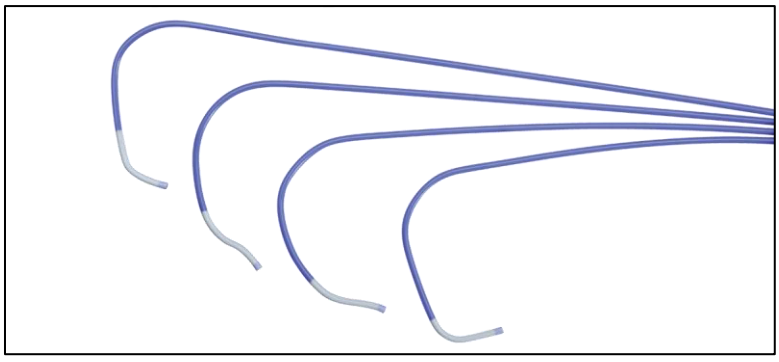
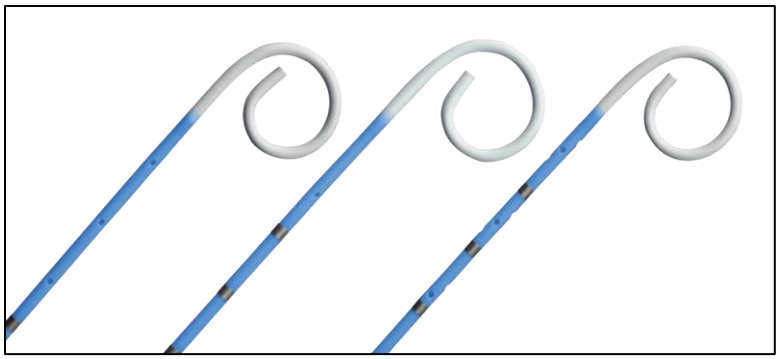


Figure 5. PVSC



The Performa Catheters are intended for single-use only and are provided sterile to the end user. Ethylene oxide (EtO) sterilization is utilized for the Performa Catheters. The EtO sterilization cycle is validated according to International Standard ISO 11135. The Performa Catheters are not intended to be re-sterilized by the user.

The Performa Catheters do not contain any of the following:

- a medicinal substance (including a human blood or plasma derivative), or
- tissues or cells of human or animal origin, or their derivatives, or
- substances or combinations of substances that are intended to be absorbed by or locally dispersed in the human body.

Biocompatibility assessments have been completed for the Performa Catheters, 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 Performa Catheters are summarized in Table 6.

Table 6. Tissue Contact Categorization: Performa Catheters

Device	Categorization
Body	Externally communicating
Braid	No contact
Tip	Externally communicating
Marker Band	Externally communicating
Bumper Tip	Externally communicating
Hub	Externally communicating
Cap	No contact
Strain Relief	No contact

Device	Categorization
Adhesive	Externally communicating
Sleeve	No contact
Ink	No contact
Thinner	No contact
Processing Aids	No contact
Packaging (Product Contacting)	Solid to solid product contacting packaging

3.2 Operating Principles

The Performa Catheters are designed for percutaneous use in the mechanical delivery of radiopaque media to selected sites in the vascular system, acting as a conduit for such media in conjunction with routine diagnostic procedures.

3.3 Previous Generation(s) or Variant(s)

Changes to the Performa Catheters since initial introduction to market are summarized in Table 7; no such change was instigated by a safety concern or is expected to impact the safety or performance of the subject devices.

Table 7: Performa Catheters: History of Changes

Component	Description of Changes	Rationale
Luer	Luer was redesigned to conform to ISO 80369-7 requirements.	No effect to the pre-existing user interface.
Tip, Shaft, & Sleeve	Material change from SP01 Pebax to SA01 Med Pebax	Low risk per QRMT 0099 – no effect to existing user interface. Change is from non-medical to medical grade version of the same material.

3.4 Accessories and Devices Used in Combination

The accessories and devices utilized in combination with the Performa Catheters are those associated with conventional percutaneous vascular access. These include, but are not limited to access needle, introducer, dilator, guidewire, and contrast solution.

4.0 Risks and Warnings

4.1 Residual Risks and Undesirable Effects

The Merit Risk Management process is conducted in accordance with EN ISO 14971:2019. Risk assessment processes are utilized to 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 Performa Catheters have met all applicable regulations and standards. Through the clinical evaluation process, information relative to the clinical state-of-the-art and potential adverse events are identified based on a review of the pertinent clinical evidence.

Intended clinical benefits:

CLINICAL BENEFITS

Performa Angiographic Catheters provide an indirect clinical benefit to patients by facilitating intravascular site selection and the delivery of contrast media during routine diagnostic procedures.

The Performa Catheters are used to deliver radiopaque media to selected sites in the vascular system in conjunction with routine diagnostic procedures. Angiographic catheters with marker bands may also be used for anatomical measurements.

Articles published between 01-Jan-1999 and 15-Jul-2022 were reviewed. Based on the literature, Performa Catheters have been successfully used to deliver radiopaque media to selected sites in the vascular system in conjunction with routine diagnostic procedures. Professional recommendations and guidelines acknowledge the clinical benefits of devices used for diagnostic approaches to cardiac and peripheral vascular angiography in patients requiring delivery of radiopaque media to selected sites for vascular imaging. Comparable benchmark devices are shown to be safe and effective in the delivery of radiopaque media to selected sites in the vascular system in conjunction with routine diagnostic procedures. For the clinical evaluation, the performance outcomes were defined as follows:

- Technical Success: Rate of successful delivery of radiopaque media to selected sites in the vascular system in conjunction with routine diagnostic procedures.

In cases where technical success of the Performa Catheter was not specifically identified, technical success was inferred from procedural success.

Technical Success rates from the clinical literature were very high. Overall, the Technical Success rate was 98.8% for the Performa Catheters and 99.4% for the benchmark devices.

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

Table 8 Performa Catheters: Potential Complications

Potential Complications
• Thrombus formation/emboli • Plaque dislodgement • Vascular occlusion

Potential Complications
• Stroke • Death • Air embolism • Arterial wall damage • Infection • Vascular spasm • Foreign Body/ Tip Fracture

Table 9 Adverse Events: Clinical Literature Data

Complications from the Clinical Literature Data	Device Related	Procedure Related	IFU Complications	Harms	Typical Timing
Performa Catheters					
Pulsatile painful mass, right wrist	-	x	NA – procedure related	NA – procedure related	Postprocedural (>30 days and ≤3 months)
Small self-limiting groin hematoma	-	x	NA – procedure related	NA – procedure related	Timing not reported
Mild self-limiting skin discoloration over the embolized territory	-	x	NA – procedure related	NA – procedure related	Timing not reported
Ischemia (small area of bladder wall),	-	x	NA – procedure related	NA – procedure related	Postprocedural (>3 months)
Sexual dysfunction	-	x	NA – procedure related	NA – procedure related	Timing not reported
Urinary retention (acute)	-	x	NA – procedure related	NA – procedure related	Timing not reported
Urinary urgency (transient)	-	x	NA – procedure related	NA – procedure related	Timing not reported
Benchmark Devices					
Anemia	-	x	NA – procedure related	NA – procedure related	Timing not reported
Biliary sepsis	-	x	NA – procedure related	NA – procedure related	Timing not reported
Bleeding (hepatic arterial)	-	x	NA – procedure related	NA – procedure related	Timing not reported
Brain injury (traumatic)	-	x	NA – procedure related	NA – procedure related	Timing not reported
Cholangitis	-	x	NA – procedure related	NA – procedure related	Timing not reported

Complications from the Clinical Literature Data	Device Related	Procedure Related	IFU Complications	Harms	Typical Timing
Death	-	x	NA – procedure related	NA – procedure related	Postprocedural (≤7 days and >30 days)
Dislodgement of drainage catheter	-	x	NA – procedure related	NA – procedure related	Periprocedural
Dissection	-	x	NA – procedure related	NA – procedure related	Periprocedural
Ectopics (few)	-	x	NA – procedure related	NA – procedure related	Periprocedural
Elevated alanine transaminase	-	x	NA – procedure related	NA – procedure related	Postprocedural (≤7 days)
Elevated aspartate transaminase	-	x	NA – procedure related	NA – procedure related	Postprocedural (≤7 days)
Elevated bilirubin (total or serum)	-	x	NA – procedure related	NA – procedure related	Postprocedural (≤7 days)
Fatigue	-	x	NA – procedure related	NA – procedure related	Timing not reported
Fever	-	x	NA – procedure related	NA – procedure related	Postprocedural (≤7 days)
Fluid collections with findings of pancreatojejunostomy dehiscence	-	x	NA – procedure related	NA – procedure related	Timing not reported
Hematoma	-	x	NA – procedure related	NA – procedure related	Postprocedural (≤7 days)
Haemobilia	-	x	NA – procedure related	NA – procedure related	Periprocedural
Hemorrhage (gastrointestinal, pancreatic, or pulmonary)	-	x	NA – procedure related	NA – procedure related	Peri and Postprocedural (≤7 days)
Hemorrhagic cerebral infarct	-	x	NA – procedure related	NA – procedure related	Postprocedural (>30 days)
Hemorrhagic shock	-	x	NA – procedure related	NA – procedure related	Timing not reported
Hepatic failure	-	x	NA – procedure related	NA – procedure related	Periprocedural
Infection (pulmonary)	-	x	NA – procedure related	NA – procedure related	Timing not reported
Malignancy (recurrent)	-	x	NA – procedure related	NA – procedure related	Timing not reported
Multiorgan failure	-	x	NA – procedure related	NA – procedure related	Postprocedural (≤7 days)
Myocardial infarct	-	x	NA – procedure related	NA – procedure related	Postprocedural (>30 days and <3 months)

Complications from the Clinical Literature Data	Device Related	Procedure Related	IFU Complications	Harms	Typical Timing
Nausea/vomiting	-	x	NA – procedure related	NA – procedure related	Postprocedural (≤7 days)
Neuropathy (peripheral)	-	x	NA – procedure related	NA – procedure related	Timing not reported
Neutropenia	-	x	NA – procedure related	NA – procedure related	Timing not reported
Pain (abdominal and other)	-	x	NA – procedure related	NA – procedure related	Postprocedural (≤7 days)
Perforation, Periprocedural	-	x	NA – procedure related	NA – procedure related	Periprocedural
Radial artery occlusion (distal, asymptomatic)	-	x	NA – procedure related	NA – procedure related	Timing not reported
Rapid deterioration of hemodynamic status after rebleeding	-	x	NA – procedure related	NA – procedure related	Postprocedural (≤7 days)
Recurrent bleeding	-	x	NA – procedure related	NA – procedure related	Timing not reported
Sepsis	-	x	NA – procedure related	NA – procedure related	Postprocedural (prior to discharge and >30 days)
Stent migration (partial)	-	x	NA – procedure related	NA – procedure related	Postprocedural (>30 days)
Subendocardial staining (minor)	-	x	NA – procedure related	NA – procedure related	Timing not reported
Swelling	-	x	NA – procedure related	NA – procedure related	Postprocedural (≤7 days)
Thrombocytopenia	-	x	NA – procedure related	NA – procedure related	Timing not reported
Thromboembolism (pulmonary)	-	x	NA – procedure related	NA – procedure related	Postprocedural (>30 days and <3 months)
Vasospasm (refractory)	-	x	NA – procedure related	NA – procedure related	Periprocedural

The Performa Catheters have been used with a high level of safety during endovascular procedures in patients. Safety data for the Performa Catheters and comparable benchmark devices from the clinical literature are summarized in Table 10. The cumulative AE rate for the Performa Catheters is 0.00% (0/157). The overall cumulative AE rate for the comparable benchmark devices is also 0.00% (0/638).

Table 10 Comparative Adverse Event Rates: Performa Catheters

Attribute	Subject Device	Benchmark Devices
Cumulative AE Rate	0/157 (0.00%)	0/638 (0.00%)

This assessment accounts for the various risk factors associated with the Performa Catheters. Given that the complication rates are low and generally transient in nature, patients are assumed to accept the risks associated with intravascular diagnostic procedures based on the probable benefits.

In summary, the safety of the subject device has been substantiated via objective evidence from clinical literature data. The results of the clinical risk/safety analysis demonstrate that the subject 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, 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 Performa Catheters are summarized in Table 11.

Table 11. Performa Catheters: Warnings & Precautions

Product Configuration	Labeling
Performa Catheters	**Warnings**
	• Angiographic catheters are single use. • Recommended guide wire size: See the individual catheter label. • Guide wire use has been associated with greater incidence of thrombus formation • Never withdraw the catheter against resistance until the cause of the resistance is determined by fluoroscopy. Movement of the catheter against resistance may result in catheter damage leading to potential catheter tip separation. • **Pigtail Catheters**: Ensure the pigtail straightener is removed from the catheter shaft by gently pulling on the tear-away tab handle prior to advancing the pigtail into the introducer sheath. • Anticoagulation therapy, per facility protocol, should be considered to reduce potential for thrombus formation on the device. • In the event of a malfunction of the device and/or changes in the performance of the device, exercise caution as this may indicate a change that may affect the safety of the device. • After use, dispose of device in a manner consistent with standard protocols for biohazard waste disposal.
	Precautions

Product Configuration	Labeling
	• Inspect all catheters prior to use. Do not use if package is opened or damaged. • Do not use after expiration date. • Do not autoclave. • Confirm compatibility of the catheter and other associated devices to be used prior to use. • Angiography should be undertaken only by an experienced angiographer. Physicians should be familiar with the use of Angiographic products and the literature concerning the complications of angiography. • For trans catheter high pressure contrast delivery, pressure injection tubing should be connected between the catheter hub and the Lindon nut connector on the power injector syringe. Ensure catheter and tubing compatibility for maximum PSI ratings. • Fluids intended for injection per the indications for use are radiographic contrast, heparinized saline, and saline. Do not inject other fluids without confirmation of compatibility from the fluid manufacturer. • If resistance is felt when removing the guidewire from the catheter, remove the guide wire and catheter as a unit to prevent potential damage to the vessel wall. • Exposure to VHP vaporized Hydrogen Peroxide may cause catheter failure. • 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.

4.3 Other Relevant Safety Aspects

There have been no field escalations or product recalls for the Performa Catheters.

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

5.1 Summary of Clinical Data for the Equivalent Device

Conformity of the device was assessed and endorsed by the NB on the basis of equivalence to the FEP Catheter manufactured by Merit Medical Systems, Inc (Basic UDI-DI: DEC0016).

The SSCP for the equivalent device is not available in Eudamed. There was no clinical data pertaining to the equivalent device evaluation. Long-term safety and performance of the equivalent device was confirmed by data relevant to the Performa Catheters.

5.2 Summary of Clinical Investigations of the Subject Device

Conformity of the Performa Catheters was initially assessed and endorsed by the applicable Notified Body in 2004. No manufacturer-sponsored pre-market clinical investigations have been performed as part of the development of the Performa Catheters.

5.3 Summary of Clinical Data from Other Sources

A review of relevant clinical literature published between 01-JAN-1999 and 15-JUL-2022 for device safety and performance was conducted. Table 12 and Table 13 summarize the literature included for the evaluation of the safety and performance of the Performa Catheters. For evaluation of performance, Technical Success was defined as the rate of successful delivery of radiopaque media to selected sites in the vascular system in conjunction with routine diagnostic procedures. For evaluation of safety, AEs were also summarized from the clinical literature data.

Table 12. Subject Devices: Summary Study Characteristics

Author (Year) LOE Study Type	Primary Clinical Indication	Device Application, Access	Patients, n/N (%)	Device	Gender (M/F)	Age (years)	Follow-up
Central Circulatory System							
Asai 2015[1], LOE: C, Retrospective single center study	X-ray angiography perfusion analysis during balloon occlusion test	Cerebral angiogram, ascending aorta, femoral artery approach	21/21 (100%)	"5F bolus flush catheter (Performa; Merit Medical, South Jordan, UT)"	M/F: 4/17	Mean age: 59.9 ±11.9	NR
Ghanavati 2017[2], LOE: C, Case Report	Anterior ST-elevation myocardial infarction	Coronary angiography, right radial artery approach	1/1 (100%)	"5-F Merit Performa catheter"	M	32	2 Months
Hadjivassilic 2017[3], LOE: C, Case Report	Ascending thoracic aortic pseudoaneurysms	Aortic angiogram, left femoral artery approach	1/1 (100%)	"5 Fr pigtail catheter (Performa Flush, Merit Medical, South Jordan, UT, USA)"	F	77	Hospital discharge
Hanna 2017[4], LOE: C, Case Report	Superficial femoral artery occlusions	Aortic angiograph, left radial artery approach	1/1 (100%)	"125-cm pigtail catheter (Performa; Merit Medical, South Jordan, UT)"	M	65	3 Months

Author (Year) LOE Study Type	Primary Clinical Indication	Device Application, Access	Patients, n/N (%)	Device	Gender (M/F)	Age (years)	Follow-up
Izutsu 2021[5], LOE: B2, Retrospective cohort	Internal carotid artery aneurysm (14) or dissection (1), neck tumor (17)	Manual injection of contrast medium in the ipsilateral common carotid artery, common femoral artery approach	32/32 (100%)	"4-Fr diagnostic catheter (Performa; Merit Medical, South Jordan, UT, USA)"	M/F: 9/23	Mean, range: 58.3, 22-79	NR
Khelimskii 2019[6], LOE: C, Case Report	Subannular pseudoaneurysms of the aortic root	Angiographic evaluation of the left ventricle in anteroposterior and oblique views, right radial artery access	1/1 (100%)	"6-F Performa Pigtail (Merit Medical System, Malvern, Pennsylvania)"	F	68	3 Months
Peripheral Vasculature							
Koury 2020[7], LOE: B2, Prospective observational study	Need for abdominopelvic transarterial interventional procedures, including chemoembolization of hepatocellular carcinoma, embolization of hepatic metastasis in neuroendocrine tumors, and other embolization procedures	NR (procedures performed by interventional radiologist), distal radial artery access	42/42 (100%)	"5 F 125 cm Long angiographic catheter (Performa, Merit Medical Systems)… straight pigtail, Berenstein, Ultimate 1, Cobra 2"	M/F: 26/16	Mean ±standard deviation, range: 62.0 ±11.4, 27.6-82.8	30 Days
Little 2021[8], LOE: B2, Prospective pilot study	Genicular artery embolization	Angiography of the genicular arterial anatomy, common femoral artery approach	38/38 (100%)	"Cobra Performa catheter (Merit Medical, USA)"	M/F: 18/20	Median, range: 60, 45-83	6 Weeks, 3 months, 1 year
Pisco 2018[9], LOE: C, Prospective Cohort Study	Biopsy-proven diagnosis of prostate cancer (stage T2NOMOPCa) without extracapsular extension	Catheterize the left hypogastric artery and its anterior division, TFA	20/20 (100%)	5-F catheter (PPC; Merit Medical Systems, Inc)	M/F: 20/0	Mean ±standard deviation, range: 67.5 ±6.4, 54-78	12 - 18 Months

Table 13. Subject Devices: Safety and Performance Summary

Author (Year) LOE Study Type	Device	Technical Success n/N (%)	Device-Related Adverse Event n/N (%)	Patient /Procedure-Related Adverse Event n/N (%)	Complications [a]
Central Circulatory System					
Asai 2015[1], LOE: C, Retrospective single center study	"5F bolus flush catheter (Performa; Merit Medical, South Jordan, UT)"	20/20 (100%)	0/20 (0.00%)	0/20 (0.00%)	NA
Ghanavati 2017[2], LOE: C, Case Report	"5-F Merit Performa catheter"	1/1 (100%)	0/1 (0.00%)	1/1 (100%)	Pulsatile painful mass in his right wrist (1)
Hadjivassilic 2017[3], LOE: C, Case Report	"5 Fr pigtail catheter (Performa Flush, Merit Medical, South Jordan, UT, USA)"	1/1 (100%)	0/1 (0.00%)	0/1 (0.00%)	NA
Hanna 2017[4], LOE: C, Case Report	"125-cm pigtail catheter (Performa; Merit Medical, South Jordan, UT)"	2/2 (100%)	0/2 (0.00%)	0/2 (0.00%)	NA
Izutsu 2021[5], LOE: B2, Retrospective cohort	"4-Fr diagnostic catheter (Performa; Merit Medical, South Jordan, UT, USA)"	39/41 (95.1%) There was undetected antegrade ophthalmic artery flow on angiography in 2 patients.	0/32 (0.00%)	0/32 (0.00%)	NA
Khelimskii 2019[6], LOE: C, Case Report	"6-F Performa Pigtail (Merit Medical System, Malvern, Pennsylvania)"	1/1 (100%)	0/1 (0.00%)	0/1 (0.00%)	NA
Central Circulatory System Totals		**64/66 (97.0%)**	**0/57(0.00%)**	**1/57(1.75%)**	
Peripheral Vasculature					
Koury 2020[7], LOE: B2, Prospective observational study	"5 F 125 cm Long angiographic catheter (Performa, Merit Medical Systems)… straight pigtail, Berenstein, Ultimate 1, Cobra 2"	42/42 (100%) In 1 case, the guidewire did not progress through the vessel due to vasospasm, but ipsilateral proximal radial artery access was successfully obtained, with no need for conversion to transfemoral artery approach.	0/42 (0.00%)	0/42 (0.00%)	NA

Author (Year) LOE Study Type	Device	Technical Success n/N (%)	Device-Related Adverse Event n/N (%)	Patient /Procedure-Related Adverse Event n/N (%)	Complications [a]
Little 2021[8], LOE: B2, Prospective pilot study	"Cobra Performa catheter (Merit Medical, USA)"	38/38 (100%)	0/38 (0.00%)	5/38 (13.2%)	Small self-limiting groin hematoma (1) Mild self-limiting skin discoloration over the embolized territory (4)
Pisco 2018 [9], LOE: C, Prospective cohort study	"5-F catheter (PPC; Merit Medical Systems, Inc)"	20/20 (100%)	0/20 (0.00%)	5/20 (25.0%)	Ischemia (small area of bladder wall): 1, Sexual dysfunction: 2, Urinary retention (acute): 1, Urinary urgency (transient): 1
Peripheral Vasculature Totals		**100/100 (100%)**	**0/100 (0.00%)**	**10/100 (10.0%)**	
Cumulative Totals		**164/166 (98.8%)**	**0/157 (0.00%)**	**11/157 (7.01%)**	

5.4 Overall Summary of Clinical Performance and Safety

Comparative performance and safety data for the Performa Catheters and benchmark devices are presented in Table 14. Performance data for the Performa Catheters and benchmark devices is derived from clinical literature. Based on the clinical data, the Technical Success rate for the Performa Catheters is 98.8%. The Technical Success rate for the benchmark devices is 99.4%. The difference in Technical Success rates between the Performa Catheters (p1) and benchmark devices (p2) is significantly greater than -0.10 (i.e., p1 – p2 > -0.10), confirming that the performance outcomes of the subject devices are non-inferior to benchmark competitor devices.

Table 14. Comparative Performance for Merit Angiographic Catheters

Device Type/Application	Subject Device, n/N (%)	Benchmark Competitors, n/N (%)	Estimated Difference [95% LBL]	LBL > -0.10
Technical Success				
Clinical literature	164/166 (98.8%)	614/618 (99.4%)	-0.56% (-2.05%)	PASS

Abbreviations: CI = confidence interval, LBL = lower bound limit

Based on the clinical data, the Device-Related AE rate for the Performa Catheters is 0.00%. The Device-Related AE rate for benchmark devices is also 0.00%. Accordingly, the difference in AE rates between the Performa Catheters (p1) and benchmark devices (p2) is less than 0.10 as well (i.e., p1 – p2 <0.10), confirming that the

safety outcomes of the subject devices are non-inferior to those of benchmark competitor devices; however, as no events were revealed in either the subject or benchmark competitor device literature, no confidence interval could be calculated.

Table 15. Comparative Safety for Merit Angiographic Catheters

Device Type/Application	Subject Device, n/N (%)	Benchmark Competitors, n/N (%)	Estimated Difference [95% UBL]	UBL < 0.10
Device-Related AEs				
Clinical literature	0/157 (0.00%)	0/638 (0.00%)	0.00%[a]	PASS [a]

Abbreviations: CI = confidence interval, UBL = upper bound limit. [a] No confidence interval or p-value could be calculated, given that no events were revealed in either the subject or benchmark competitor device literature.

Data to support the safety and performance of the Performa Catheters have been analyzed and provide evidence to support all of the safety and performance outcomes. Based upon a review of the clinical data, the overall benefits to patients of using the device for its intended purpose outweigh the overall risks. The risk/benefit assessment for the Performa Catheters is summarized in Table 16.

Table 16. Summary of Benefit/Risk Assessment[10,11]

Factor	Notes	Assessment
Uncertainty		
Quality of the study design	How robust were the data?	The data were derived from 8 articles of various design.
Quality of the study conduct	How was/were the study/studies designed, conducted and analyzed?	Case report (4), retrospective cohort (1), retrospective single center study (1), prospective observational study (1), prospective pilot study (1)
	Are there missing data?	Yes, 2 articles did not report catheter size, 6 articles did not report catheter length, and no article reported catheter configuration (e.g., PDCC, PPAC, PAC, etc.).
Robustness of the study results analysis	Are the results from the study/studies repeatable?	Yes, the methods reported were of sufficient detail to enable replication of study result.
	Is/Are this/these study/studies first-of-a-kind?	No
	Are there other studies that achieved similar results?	Yes
Generalizability of the results	Can the results of the study/studies be applied to the population generally, or are they more intended for discrete, specific groups?	The results of described studies can be generalized to patients requiring cardiac or peripheral diagnostic angiography procedures in the course of their treatment.
Characterization of the disease/condition	How does the disease/condition affect the patients that have it?	In general, the effect is proportional to the severity of the suspect condition and its potential to impact patient quality and longevity of life.
	Is the condition treatable?	
	How does the condition progress?	

Factor	Notes	Assessment
Patient tolerance for risk, and perspective on benefit:	Is there data regarding how patients tolerate the risks posed by the device?	No Device-Related AEs were revealed by searches of the subject or benchmark competitor device clinical literature. Patient tolerance to risks of the angiographic procedure are expected to be proportional to the severity of the suspect condition.
	Are the risks identifiable and definable?	Yes
Disease severity	Is the disease so severe that patients will tolerate a higher amount of risk for a smaller benefit?	In general, risk tolerance is proportional to the severity of the suspect condition and its potential to impact patient quality and longevity of life.
Disease chronicity	Is the disease/condition chronic?	Varies
	How long do patients with the disease/condition live?	The longevity of patients that undergo diagnostic angiographic procedure can vary by severity of condition.
	If chronic, is the illness easily managed with less invasive or difficult therapies?	NA, while angiographic catheters have been used in the course of treatment for patients with chronic medical conditions, they are not used to manage the illness.
Patient-centric assessment	How much do patients value this treatment?	NA, angiographic catheters do not provide a treatment; they are used to aid with angiographic imaging for diagnosis and therapeutic treatment planning.
	Are patients willing to accept the risk of this treatment to achieve the benefit?	NA
	Does the treatment improve overall quality of life?	NA
	How well are patients able to understand the benefits and risks of the treatment?	The benefits of the angiographic catheter are indirect, and the risks are well understood based on consultation with the treating physician.
Availability of alternative treatments or diagnostics	What other therapies are available for this condition?	NA, angiographic catheters are not therapeutic; neither are alternative methods of imaging.
	How effective are the alternative treatments?	Imaging by catheterization is considered the gold standard for diagnostic angiographic procedures. Non-invasive methods have lower sensitivity and specificity.
	How does their effectiveness vary by subpopulation?	NA, subpopulations were not revealed by clinical literature review.
	How well-tolerated are the alternative therapies?	Varies by alternative method. Non-invasive methods are generally well-tolerated; some patients may be contraindicated for exercise ECG.
	How does their tolerance vary by subpopulation?	NA, subpopulations were not revealed by clinical literature review.
	What risks are presented by any available alternative treatments?	Risks vary by alternative method. Risks of CT imaging can relate to radiation exposure. Risks of exercise ECG can relate to increased heart rate.

Factor	Notes	Assessment
Risk mitigation	Could you identify ways to mitigate the risks (such as using product labeling, establishing education programs, providing add-on therapy, etc.)? What is the type of intervention proposed?	No additional risk mitigation methods have been identified. NA
Postmarket data	Are there other devices with similar indications on the market? Are the probabilities for effectiveness and rates of harmful events from those devices similar to what is expected for the device under review?	Yes
	Is postmarket data available that change the risk/benefit evaluation from what was available when the previous devices were evaluated?	No
	Is there reason to consider evaluation of any of the following elements further in the postmarket setting, due to the risk/benefit evaluation as described above? • Longer-term device performance. • Effectiveness of training programs or provider preferences in use of device. • Subgroups (e.g., pediatrics, women). • Rare adverse events.	No
	Is there reason to expect a significant difference between real-world performance of the device and the performance found in pre-market experience with the device?	No; data presented are derived from real-world case reports as well as retrospective and prospective studies.
	Is there data that otherwise would be provided to support approval, which could be deferred to the postmarket setting?	No
	Is there off-label use, or on-label use that is different than originally expected?	No
Novel technology addressing unmet medical need	How well is the medical need this device addresses being met by currently available therapies?	Comparable angiographic catheters are available.
	How desirable is this device to patients?	Use of the subject devices to facilitate diagnostic angiographic procedures is desirable.
Summary of the Benefit	**Summary of the Risk**	**Summary of Other Factors**
Merit Angiographic Catheters		
Performa Catheters Technical Success: 98.8% (164/166) Benchmark devices Technical Success: 99.4% (614/618)	Performa Catheters 0/157 (0.00%) Benchmark devices 0/638 (0.00%)	Angiographic catheters are safe and perform as intended in delivering radiopaque media to selected sites in the vascular system in conjunction with routine diagnostic procedures. Angiographic catheters with marker bands may also be used for anatomical measurements.

Factor	Notes	Assessment
Technical Success for subject devices was determined to be non-inferior to the benchmark devices.	Device-related AE rates for subject devices were determined to be non-inferior to the benchmark devices.	

5.5 Postmarket Clinical Follow-up (PMCF)

PMCF includes the circulation of an evaluation form to health care professionals that use the Performa Catheters to collect cases (or data points). The following process will be performed.

- Marketing and Sales leadership will determine which clinicians will be requested to complete an Evaluation Form.
- Health care professionals will be requested to provide feedback about patient cases in which the Performa Angiographic Catheter was used.
- A minimum of 59 data points representing separate patient cases will be collected from a minimum 0f 15 different users.
- The Product Feedback questions, which are relevant to the Performa Angiographic Catheter performance and safety criteria defined in CER0039, are included below.
- The questions will be formatted in an Evaluation Form in a paper or electronic medium.
- PMCF data collection activity will begin on the date of implementation of the PMCF plan. Twenty-four (24) months from the date of implementation are allotted for the data collection, data analysis and report documentation process.
- If an evaluation form contains information that meets the definition of a complaint, it will be assessed by the complaint handling team as required by GPS 999.016, Field Assurance Complaint System.

Twenty-four (24) months have been allocated to allow for dissemination of the evaluation form and performance of literature search and for the follow up activities, such as data analysis and documentation of a PMCF Evaluation Report. Acceptance Criteria for the PMCF evaluation include the following:

- An answer of “YES” for a safety question is not an indication of a safety issue without additional information clearly identifying a defect, failure mode, or performance issue
- An answer of “NO” for a performance question is not an indication of a performance issue without additional information clearly identifying a defect, failure mode, or performance issue
- If any survey question is not populated it will not indicate a negative response for that question. It will

indicate that the survey question was inadvertently missed, and the question will not be included in the final analysis.

6.0 Diagnostic or Therapeutic Alternatives

As established by standard of care guidelines and recommendations[12-18], invasive angiography is a gold standard method for diagnostic imaging in the course of treatment for patients with pulmonary and coronary conditions. Drawbacks of the procedure may include risk of contrast-induced nephropathy[19] and radiation exposure[19] as well as those risks that are relevant to all invasive procedures, which can vary by medical condition type and severity and be impacted by patient demographics and comorbidities. Therefore, non-invasive methods as well as sham testing, have been considered relative to invasive coronary angiographic methods in the diagnosis of patients with and without coronary artery disease (CAD), respectively. Their findings are relevant to the benefits of invasive coronary angiography from the patient and physician user perspectives.

From a patient perspective, use of invasive coronary angiography, relative to sham testing (i.e., physician blinding to angiographic findings), has been associated with improvements in patient rated condition severity, quality of life, pain scores, and satisfaction.[20] The British Heart Foundation Coronary Microvascular Angina (CorMicA) randomized controlled trial of patients with angina symptoms and/or signs of ischemia but without obstructive CAD (INOCA) found that, relative to sham testing, patients that underwent invasive coronary angiography had greater mean improvements in Seattle Angina Questionnaire (a self-administered disease-specific measure of angina severity), quality of life (0.02 vs -0.07, P=0.024), and visual analog scale (5.4 vs. -9.1, P<0.001) scores at 6 months.[20] Although no significant improvements in psychological distress were observed, ratings of treatment satisfaction among patients that underwent invasive coronary angiography, including ratings of effectiveness (10.7 vs -1.1, P=0.013), convenience (9.3 vs -5.5, P<0.001), and global satisfaction (13.1 vs. -4.0, P=0.001), were also improved.[20] A cost-effectiveness analysis of patients enrolled in the CorMicA trial further revealed that, relative to those that underwent sham testing, patients that underwent invasive coronary angiography had a greater mean quality of life gain (0.652 vs 0.548) at 12 months.[21] The authors concluded that introducing stratified medicine using an adjunctive interventional diagnostic procedure (i.e., invasive coronary angiogram) with mechanistically targeted medical therapy is likely to be cost-effective in patients with signs and symptoms of angina.[21]

However, caution should be exercised when determining the type and extent of angiographic imaging in potentially at-risk patient populations. A systematic review to determine the current radiation doses reported from pediatric cardiac catheterization revealed that the majority of studies observed greater dose area product during interventional (mean range: 312.9 - 10,900 cGycm2), rather than diagnostic (294 - 2,080 cGycm2), procedures.[22] Similarly, the review revealed that the majority of studies (15 vs 23 studies) observed greater fluoroscopy during interventional (highest reported: 77 minutes), rather than diagnostic (41 minutes), procedures; accordingly, effective dose estimates were also greater among interventional procedures, among studies that examined such dosing from both interventional and diagnostic procedures.[22] The authors concluded, however, that "caution should be given to categorizing anticipated radiation dose according to 'diagnostic' and 'interventional' procedures because diagnostic radiation doses can be greater on occasion."[22]

They further recommended that additional attention be paid to "optimizing the radiation dose and standardization of practice between imaging centers".[22]

Patient complications of invasive angiographic imaging have been reported. Among adult patients (average age 61.0 years) that underwent diagnostic procedures with use of invasive coronary angiography as part of the CorMicA trial, reported adverse events related to the interventional diagnostic procedure included persistent atrial fibrillation (1/151, 0.662%)) and paroxysmal atrial fibrillation (8/151, 1.30%); transient bradycardia and sinus pauses during acetylcholine were also reported but were not thought by the author group to constitute an adverse event.[20] Serious adverse events (4/151, 2.65%) following the interventional diagnostic procedure included cardiac death, nonfatal myocardial infarction, stroke, or heart failure hospitalization.[20] Among pediatric populations, reported complications observed with catheterization procedures have included transient loss of pulsation (8/300, 2.67%), hematoma at the puncture site (6/300, 2.00%), bleeding from the puncture site (4/300, 1.33%), rigors (12/300, 4.00%), urticaria (2/300, 0.667%), seizures (2/300, 0.667%), recurrent cyanotic spells (5/300, 1.67%), and fever (12/300, 4.00%).[23] Other cited procedural complications of diagnostic angiography have included arrhythmias[13], contrast allergic or anaphylactoid reactions[13], contrast-induced nephropathy[13], death[13,15], infection[13], myocardial infarction[13], need for emergency revascularization[13], skin injury[22], stroke[13], and vascular damage[13].

From a physician perspective, use of invasive coronary angiography has been associated with diagnostic utility, including fewer missed diagnoses as well as measures of greater sensitivity and specificity, relative to sham testing[20] and non-invasive methods[24], respectively; although, opportunities for improved patient management with use of adjunctive assessment remain.[21] Coronary anatomy at angiography may not fully indicate the presence and severity of myocardial ischemia, as a result of discrepancies in the assessment of lesion severity and lesion-level ischemia.[25] Fraction flow reserve (FFR), measured by pressure wire assessment, has been proposed to improve the management of patients that have undergone angiography for the diagnosis of chest pain.[25] Using invasive FFR (iFFR) measurement during coronary angiography as a reference standard, therefore, a meta-analysis of computed tomography (CT) imaging techniques examined the relative sensitivity and specificity of CT angiography (CTA), stress myocardial CT perfusion (stress CTP), computer simulation of fractional flow reserve by CT (FFR-CT), and transluminal attenuation gradients (TAG) for the detection of CAD.[21] At the patient level, the sensitivity of these methods ranged from 92% (stress CTP) to 88% (FFR-CT), and the specificity ranged from 48% (CTA) to 82% (stress CTP).[21] At the vessel level, sensitivity ranged from 86% (CTA) to 57% (TAG), and specificity ranged from 89% (stress CTP) to 62% (TAG).[21] The authors concluded that stress CTP and FFR-CT "have incremental value over CTA for non-invasive diagnosis of ischemia-causing CAD".[21]

Evidence from high-quality studies relevant to angiographic and alternative technologies additionally highlighted the lesser diagnostic value of non-invasive imaging methods, relative to invasive angiography without adjunctive FFR assessment. When used in the diagnosis of patients with INOCA, sham testing was found in the CorMicA trial to result in more missed diagnoses of microvascular and vasospastic angina (27 vs 2 missed diagnoses, relative risk: 0.08, P<0.001), relative to invasive coronary angiography.[20] When used for the diagnosis of stable CAD, cardiogoniometry was found in a well-powered single-centre case series study to be 74.6% accurate with sensitivity and specificity of 75.0% (56.6-88.5) and 74.4% (63.3-83.4), respectively; these findings align with the

cited literature, wherein sensitivity and specificity ranges of 65-80% and 70-85% were estimated.[24] Exercise-echocardiography (ECG) was found to be the least accurate at 45.1%, with sensitivity and specificity of 68.1% (42.7-83.6) and 36.6% (25.2-50.3), respectively.[24] Other non-invasive methods for the diagnosis of stable CAD, including stress-ECG, myocardial perfusion scintigraphy, single photon emission computed cosmography (SPECT) and cardiac magnetic resonance imaging (MRI), were cited has having greater efficiency than exercise-ECG testing but with low sensitivity and specificity of 75-90%, collectively.[24] The 24-hour Holter-ECG has also been cited as having relatively low sensitivity.[24]

Dual-axis rotational coronary angiography (DARCA) has been proposed as a new technique for acquiring images of the coronary tree using a single contrast injection.[19] When used in patients that underwent elective coronary angiography as part of a prospective, self-controlled study, the DARCA technique was found to significantly reduce the contrast volume used as well as radiation exposure, relative to conventional coronary angiography, without sacrificing sensitivity.[19] In fact, all lesions were detected using both methods; the authors reported that "a strong correlation could be seen in the number of lesions, vessel diameter and percentage of stenosis with both methods".[19]

7.0 Suggested profile and training for users

The Performa Angiographic Catheters are intended for use by physicians trained in diagnostic and interventional radiology, cardiology, nephrology, and vascular surgery procedures.

8.0 Applicable Harmonized Standards and Common Specifications

The following harmonized standards and guidance documents were applied or considered during the design and development of the Performa Catheters.

- ISO 10555-1:2013 & ISO 10555-1:2013/Amd 1:2017 Intravascular catheters — Sterile and single-use catheters — Part 1: General requirements — Amendment 1
- ISO 10993-1:2018 & EN ISO 10993-1:2009, OJ Pub: 02Dec2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009) & EN ISO 10993-1:2009/AC:2010, OJ Pub: 18Jan2011
- EN ISO 80369-7:2017 & ISO 80369-7:2016 (EQV), Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications
- IEC 62366-1:2015, Pub Date: 2015-02-24 & IEC 62366-1:2015/COR1:2016, Pub Date: 2016-07-14 and IEC 62366-1:2015/Amd 1:2020, Medical devices — Part 1: Application of usability engineering to medical devices

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10.0 Revision History

SSCP Revision	ECN Number	Date Issued	Change Description	SSCP Author	Revision Validated by the Notified Body
REV 001	ECN 165661	04/10/2023	Initial release.	Sara VanWyk	☐ Yes Validation language: English ☒ No