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 Impress Angiographic Catheter Family.

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

The English version of this SSCP document (SSCP 0037) has been validated by the notified body. The following information is intended for users/healthcare professionals. A more general information summary is provided with content specifically intended for patients and lay persons.

1.0 Device identification and general information

1.1 Device trade name(s):

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

Table 1 Devices Included in this SSCP

Device Name	Product Numbers
Diagnostic Peripheral & Radial Catheter Configurations	43035BER, 43035KA2, 43035MODCB1, 43035RIM, 43035STR, 44035RIM, 44035STS, 44038KA2, 44038MW2, 44038STS, 7440-P8, 465352CB1, 465352CB2, 465352HK0-8, 465352HK1-0, 465352RC, 465352SH0-8, 465352SH1-0, 465354RBI, 46535B1, 46535BER, 46535CB2, 46535MOT, 46535MOTC, 46535RC, 46535RIM, 46535RIMBNS, 46535SIM1, 465382CB1, 465382CB2, 46538BER, 46538CB1, 46538CB2, 46538KA2, 46538MPA1, 46538SIM1, 46538SIM2, 46538STS, 46538VER, 7440-G8, 7440-P7, 7440-P9, 7440-Q1, 48035MHK1, 48035MHK2, 48035MHK3, 48035MODS, 48038MIK, 48038MODS, 48038RE, 48038REBNS, 410035B1, 410035B2, 410035BER, 410035HH1, 410035HH3, 410035MANI, 410035MC, 410035MOT, 410035MOTC, 410035OSB1, 410035SIM1, 410035SIM2, 410035VER, 410038B1, 410038BER, 410038CB1, 410038CB2, 410038HH1, 410038HH3, 410038HS, 410038MANI, 410038MC, 410038MPA1, 410038N1, 410038N2, 410038N3, 410038N4, 410038SIM1, 410038SIM2, 410038VER, 411035STS, 411038RADIM, 411038STS, 412535HH1, 412535VER, 412538BER, 412538MPA1, 7440-F6, 53035BER, 53035KA2, 53035MODCB1, 53035RIM, 53035STR, 54035RIM, 54035STS, 54038KA2, 54038STS, 1628-204, 1628-220, 1628-239, 1628-240, 1628-241, 1628-236, 1628-Z7, 565352CB1, 565352CB2, 565352HK0-8, 565352HK0-8-SOR, 565352HK1-0, 565352RC, 565352SH0-8, 565352SH1-0, 565354RBI, 565354RBI-SOR, 56535B1, 56535BER, 56535BER-SOR, 56535MOT, 56535MRIMST, 56535RBI, 56535RIM, 56535RIM-SOR, 56535SIM1, 565382CB1, 565382CB2, 56538BER, 56538CB1, 56538CB2, 56538IRG1, 56538IRG2, 56538KA2, 56538MPA1, 56538MW2, 56538MW2-SOR, 56538SIM1, 56538SIM2, 56538STS, 56538VER, 56538VER-SOR, 7120-S, DEL56538CB2-NS, 1628-231, 1628-017M, 1628-019M, 1628-043, 57538CARN10, 57538CARN10S, 57538CARN15, 57538CARN15S, 57538CARN5, 57538CARN5S, 57538CS, 57538CSHK-WOR, 57538CSV-WOR, 57538CS-WOR, PP1628-017, PP1628-Y8, 1628-206, 1628-223, 1628-224, 1628-225, 1628-232, 58035MHK1, 58035MHK2, 58035MHK3, 58035RE, 58038MIK, 58038RE, 1628-197, 59035IUAC, 59035UAC, 59038UAC, 5100354RBI, 510035B1, 510035B2, 510035BER, 510035HH1, 510035HH3, 510035MANI, 510035MC, 510035MOT, 510035OSB1, 510035RBI, 510035SIM1,

Device Name	Product Numbers
	510035SIM2, 510035VER, 510038B1, 510038BER, 510038CB1, 510038CB2, 510038HH1, 510038HH3, 510038HS, 510038IRDC, 510038MANI, 510038MC, 510038MPA1, 510038N1, 510038N2, 510038N3, 510038N4, 510038PRDC, 510038SIM1, 510038SIM2, 510038VER, 512538BERBNS, 5IMP100381ULT1, 5IMP10038ULT1, 1628-234, 5IMP110381ULT2, 5IMP110381ULT4-T40, 5IMP11038ULT2, 5IMP11038ULT4-T40, PVI511038FH3, 511035STS, 511038RADIM, 511038STS, 1628-094, 1628-095H, 1628-113, 1628-208, 1628-221, 1628-222, 1628-228, 512538STRBNS, PVI512538FH3, QPL512538SIM2-BNS, 512535HH1, 512535SIM1, 512535VER, 512538BER, 512538HH1, 512538MPA1, PB-5003A, 4303510PIG-NB, 1623-E1, 4653510PIG-NB, 4653510STF-NB, 4653510UBF-NB, 465356MHK-NB, 465356SHP-NB, 46535AVS20MHK, 4653810MUBF-NB, 4903510PIG-NB, 4903510STF-NB, 4903510UBF-NB, 490356MHK-NB, 490356SHP-NB, 41103510PIG-NB, 5303510PIG-NB, 5653510PIG-NB, 5653510STF-NB, 5653510UBF-NB, 565356MHK-NB, 565356SHP-NB, 5653810MUBF-NB, 5653810PIG-NB, 565386MHK-NB, 5903510PIG-NB, 5903510STF-NB, 5903510UBF-NB, 5903810PIG-NB, 590386MHK-NB, 1624-B7, 51103510PIG-NB, 51103810PIG-NB
Diagnostic Cardiology Catheter and Kit Configurations	7440-Q3, 7440-Q4, 7440-Q5, 7440-Q6, THER510038JL35, THER510038JL40, THER510038JL45, THER510038JL50
Diagnostic Peripheral Catheters with Legato Hydrophilic Coating	44038KA2-H, 46538BER-H, 46538CB1-H, 46538CB2-H, 46538KA2-H, 46538STS-H, 46538VER-H, 48038MHK1-H, 48038MHK2-H, 48038MHK3-H, 410038B1-H, 410038B2-H, 410038BER-H, 410038CB2-H, 410038HH1-H, 410038MPA1-H, 410038SIM1-H, 410038SIM2-H, 410038STS-H, 410038VER-H, 412538BER-H, 412538HH1-H, 412538STS-H, 54038KA2-H, 56538BER-H, 56538CB1-H, 56538CB2-H, 56538KA2-H 56538RBI-H, 56538STS-H, 56538VER-H, 58038MHK1-H, 58038MHK2-H, 58038MHK3-H, 59035IUACTMB-H, 510038B1-H, 510038B2-H, 510038BER-H, 510038CB2-H, 510038HH1-H, 510038MANI-H, 510038MPA1-H, 510038SIM1-H, 510038SIM2-H, 510038STS-H, 510038VER-H, 512538BER-H, 512538HH1-H, 512538STS-H

1.2 Manufacturer Information

The name and address of the manufacturer of the Impress Angiographic Catheter Family are provided in Table 2.

Table *2* Manufacturer Information

Subject Device	Legal Manufacturer
Impress Angiographic Catheter Family	Merit Medical Systems, Inc. 1600 West Merit Parkway South Jordan, Utah 84095 U.S.A.

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 device(s) are listed in Table 3.

1.6 Risk Class of Device

The EU device risk classification(s) for the Impress Angiographic Catheter Family are listed in Table 3.

Table 3 Device Identification Information

Device Name	EU Device Class	Product Number	Basic UDI-DI	Single Registration Number (SRN)	EMDN/CND Code	EMDN/CND Terms
Impress Angiography Catheters	Class III	43035BER, 43035KA2, 43035MODCB1, 43035RIM, 43035STR, 44035RIM, 44035STS, 44038KA2, 44038MW2, 44038STS, 7440-P8, 465352CB1, 465352CB2, 465352HK0-8, 465352HK1-0, 465352RC, 465352SH0-8, 465352SH1-0, 465354RBI, 46535B1, 46535BER, 46535CB2, 46535MOT, 46535MOTC, 46535RC, 46535RIM, 46535RIMBNS, 46535SIM1, 465382CB1, 465382CB2, 46538BER, 46538CB1, 46538CB2, 46538KA2, 46538MPA1, 46538SIM1, 46538SIM2, 46538STS, 46538VER, 7440-G8, 7440-P7, 7440-P9, 7440-Q1, 48035MHK1, 48035MHK2, 48035MHK3, 48035MODS, 48038MIK, 48038MODS, 48038RE, 48038REBNS, 410035B1, 410035B2, 410035BER, 410035HH1, 410035HH3, 410035MANI, 410035MC, 410035MOT, 410035MOTC, 410035OSB1, 410035SIM1, 410035SIM2, 410035VER, 410038B1, 410038BER, 410038CB1, 410038CB2, 410038HH1, 410038HH3, 410038HS, 410038MANI, 410038MC, 410038MPA1, 410038N1, 410038N2, 410038N3, 410038N4,	088445048756EB	US-MF-000001366	C0104020101	PANORAMIC AND SELECTIVE PERIPHERAL DIAGNOSTIC ANGIOGRAPHY CATHETERS AND MICROCATHETERS
					C0104010101	CARDIAC ANGIOGRAPHY DIAGNOSTIC CATHETERS

Device Name	EU Device Class	Product Number	Basic UDI-DI	Single Registration Number (SRN)	EMDN/CND Code	EMDN/CND Terms
		410038SIM1, 410038SIM2, 410038VER, 411035STS, 411038RADIM, 411038STS, 412535HH1, 412535VER, 412538BER, 412538MPA1, 7440-F6, 53035BER, 53035KA2, 53035MODCB1, 53035RIM, 53035STR, 54035RIM, 54035STS, 54038KA2, 54038STS, 1628-204, 1628-220, 1628-239, 1628-240, 1628-241, 1628-236, 1628-Z7, 565352CB1, 565352CB2, 565352HK0-8, 565352HK0-8-SOR, 565352HK1-0, 565352RC, 565352SH0-8, 565352SH1-0, 565354RBI, 565354RBI-SOR, 56535B1, 56535BER, 56535BER-SOR, 56535MOT, 56535MRIMST, 56535RBI, 56535RIM, 56535RIM-SOR, 56535SIM1, 565382CB1, 565382CB2, 56538BER, 56538CB1, 56538CB2, 56538IRG1, 56538IRG2, 56538KA2, 56538MPA1, 56538MW2, 56538MW2-SOR, 56538SIM1, 56538SIM2, 56538STS, 56538VER, 56538VER-SOR, 7120-S, DEL56538CB2-NS, 1628-231, 1628-017M, 1628-019M, 1628-043, 57538CARN10, 57538CARN10S, 57538CARN15, 57538CARN15S, 57538CARN5, 57538CARN5S, 57538CS, 57538CSHK-WOR, 57538CSV-WOR, 57538CS-WOR, PP1628-017, PP1628-Y8, 1628-206, 1628-223, 1628-224, 1628-225, 1628-232, 58035MHK1, 58035MHK2, 58035MHK3, 58035RE, 58038MIK, 58038RE, 1628-197, 59035IUAC, 59035UAC, 59038UAC, 5100354RBI, 510035B1, 510035B2, 510035BER, 510035HH1, 510035HH3, 510035MANI, 510035MC, 510035MOT, 510035OSB1, 510035RBI, 510035SIM1, 510035SIM2, 510035VER, 510038B1, 510038BER, 510038CB1, 510038CB2, 510038HH1, 510038HH3, 510038HS, 510038IRDC, 510038MANI, 510038MC, 510038MPA1, 510038N1, 510038N2, 510038N3, 510038N4, 510038PRDC, 510038SIM1, 510038SIM2, 510038VER, 512538BERBNS, 5IMP100381ULT1, 5IMP10038ULT1, 1628-234, 5IMP110381ULT2,				

Device Name	EU Device Class	Product Number	Basic UDI-DI	Single Registration Number (SRN)	EMDN/CND Code	EMDN/CND Terms
		5IMP110381ULT4-T40, 5IMP11038ULT2, 5IMP11038ULT4-T40, PVI511038FH3, 511035STS, 511038RADIM, 511038STS, 1628-094, 1628-095H, 1628-113, 1628-208, 1628-221, 1628-222, 1628-228, 512538STRBNS, PVI512538FH3, QPL512538SIM2-BNS, 512535HH1, 512535SIM1, 512535VER, 512538BER, 512538HH1, 512538MPA1, PB-5003A, 4303510PIG-NB, 1623-E1, 4653510PIG-NB, 4653510STF-NB, 4653510UBF-NB, 465356MHK-NB, 465356SHP-NB, 46535AVS20MHK, 4653810MUBF-NB, 4903510PIG-NB, 4903510STF-NB, 4903510UBF-NB, 490356MHK-NB, 490356SHP-NB, 41103510PIG-NB, 5303510PIG-NB, 5653510PIG-NB, 5653510STF-NB, 5653510UBF-NB, 565356MHK-NB, 565356SHP-NB, 5653810MUBF-NB, 5653810PIG-NB, 565386MHK-NB, 5903510PIG-NB, 5903510STF-NB, 5903510UBF-NB, 5903810PIG-NB, 590386MHK-NB, 1624-B7, 51103510PIG-NB, 51103810PIG-NB, 7440-Q3, 7440-Q4, 7440-Q5, 7440-Q6, THER510038JL35, THER510038JL40, THER510038JL45, THER510038JL50, 44038KA2-H, 46538BER-H, 46538CB1-H, 46538CB2-H, 46538KA2-H, 46538STS-H, 46538VER-H, 48038MHK1-H, 48038MHK2-H, 48038MHK3-H, 410038B1-H, 410038B2-H, 410038BER-H, 410038CB2-H, 410038HH1-H, 410038MPA1-H, 410038SIM1-H, 410038SIM2-H, 410038STS-H, 410038VER-H, 412538BER-H, 412538HH1-H, 412538STS-H, 54038KA2-H, 56538BER-H, 56538CB1-H, 56538CB2-H, 56538KA2-H 56538RBI-H, 56538STS-H, 56538VER-H, 58038MHK1-H, 58038MHK2-H, 58038MHK3-H, 59035IUACTMB-H, 510038B1-H, 510038B2-H, 510038BER-H, 510038CB2-H, 510038HH1-H, 510038MANI-H, 510038MPA1-H, 510038SIM1-H, 510038SIM2-H, 510038STS-H, 510038VER-H, 512538BER-H, 512538HH1-H, 512538STS-H				

1.7 Year of EU Market Introduction

The year that the Impress Angiographic Catheter Family was first placed on the EU market is presented in Table 4.

1.8 Authorised Representative (if applicable)

The name of the authorized representative(s) 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 Impress Angiographic Catheter Family 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
Impress Diagnostic Catheters	2007	Merit Medical Ireland Ltd.	IE-AR-000001011	BSI	2797
Impress Diagnostic Catheters with Legato Hydrophilic Coating	2010				

2.0 Intended Use of the Device

2.1 Intended Purpose

The Impress 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.

2.2 Indication(s) and Intended Patient Groups

The Impress Angiographic Catheters are indicated for use in patients undergoing diagnostic cardiology and peripheral angiography procedures in the peripheral circulatory system and coronary vasculature. Vascular access insertion sites are pre-determined by the physician performing the procedure based on the patient vascular disease process and anatomical vessel size.

The Impress Legato Hydrophilic Angiographic Catheters are indicated for use in patients undergoing peripheral angiography procedures in the peripheral circulatory system. Vascular access insertion sites are pre-determined by the physician performing the procedure based on the patient vascular disease process and anatomical vessel size.

Impress Angiographic Catheters are intended for use in patients undergoing intravascular diagnostic procedures by trained physicians.

2.3 Contraindications:

The Impress Angiographic Catheters have no known contraindications.

The Impress Legato Hydrophilic Angiographic Catheters are contraindicated for use in the coronary arteries.

3.0 Device Description

The Impress Angiographic Catheter Family is comprised of three configurations: Diagnostic Peripheral & Radial Catheter Configurations, Diagnostic Cardiology Catheter and Kit Configurations, and Diagnostic Peripheral Catheters with Legato Hydrophilic Coating.

They are sterile, non-pyrogenic devices and are intended for single use. The catheters consist of a winged hub, strain relief and radiopaque catheter shaft (see Figure 1). The catheter tip is available in a variety of shapes to accommodate differing vascular anatomies.

The catheter is designed to be introduced into a patient's vascular system for the delivery of radiopaque contrast media. It is fabricated from extruded sized lumen with semi-rigid, winged hubs at the proximal end (closest to the physician) of the catheter to assist the physician in manipulating the device within a patient’s vasculature. The Impress Angiographic Catheter is offered in a variety of catheter configurations (4 and 5 Fr, 30-125 cm lengths, hydrophilic-coated or non-hydrophilic-coated shaft, various tip shapes) to fit the requirements of the physician, the nature of the procedure and the patient's vasculature.

The catheter is inserted over a guide wire and through a vascular access sheath which has been placed into a peripheral blood vessel. The clinician guides the catheter to the area of interest using fluoroscopy and the pre-placed guide wire. Once the distal tip of the catheter is located where the

clinician desires, the guide wire is carefully withdrawn, leaving the catheter in place. The catheter is connected to a contrast injection device and the contrast media is injected at a predetermined rate to the area of interest.

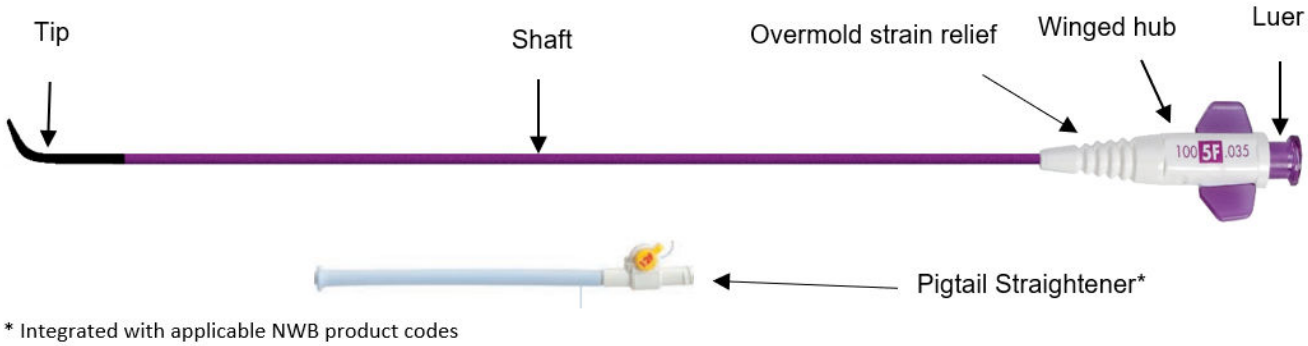


Figure 1. Impress Angiographic Catheter Structural Components

3.1 Materials/Substances in Contact with Patient Tissues

The materials of construction for the Impress Angiographic Catheter Family are summarized in Table 5. Material changes applicable for the Gen 2 Impress devices ae indicated in the table. The devices in the Impress Angiographic Catheter Family do not contain any medicinal substances.

Table 5 Materials of Construction: Impress Catheter Configurations

Component	Material Specification		Impress (with wire braid)	Impress Legato	Impress (non-braided)
	Current Design – applicable for Gen 2 if no change indicated	Gen 2 Impress – changes only in this column			
Wire Braid	304V or 316L Stainless Steel		X	X	
Body (Shaft)	Nylon				X
	Purple colorant – (PPS 090038001)				X
	Pebax 7233 SP01	Pebax 7233 SA01 MED	X	X	
	Barium sulfate				X
	Purple colorant – (PPS 090037001)				
		Tinuvin 783			
		Tinuvin 234			
		Irganox B1171			

Component	Material Specification		Impress (with wire braid)	Impress Legato	Impress (non-braided)
	Current Design – applicable for Gen 2 if no change indicated	Gen 2 Impress – changes only in this column			
		Irganox 1010			
	304V or 316L Stainless Steel				
Tip	Pebax 5533 SP01	Pebax 5533 SA01 MED	X	X	X
	Pebax 3533 SP01	Pebax 3533 SA01 MED			
	Tungsten carbide powder				
		Tinuvin 783			
		Tinuvin 234			
		Irganox B1171			
		Irganox 1010			
Hub	Xylex PC/PET	Polycarbonate	X	X	X
	Purple colorant				
Strain Relief	Pellethane, White colorant		X	X	X
Adhesive	PX-50 cyanoacrylate	Loctite 4306	X	X	X
Hydrophilic Coating	Photo-polyvinylpyrrolidone copolymer			X	
	Photo-polyacrylamide copolymer				
	Photocrosslinker				
	BASF Kollidon 90F				
	Sterile, non-pyrogenic water				
	Isopropanol				
Ink	TRP 4760 Purple		X	X	X
Thinner	TPV Thinner		X	X	X
Adhesive	Adhesive Paste, Anti-Static		X	X	
Pigtail Straightener (for applicable NWB product codes)	Nylon II Besno Resin				X
	Barium sulfate				

3.2 Operating Principals

1. A coated guide wire is recommended for use with Merit angiographic catheters.
2. Utilize aseptic technique, carefully remove the catheter from the package by grasping the hub and slowly withdrawing it from the package.
3. Introduce the catheter into the blood vessel using vascular entry technique of choice.
4. Flush all devices entering a blood vessel with sterile heparinized saline or similar isotonic solution before each use.
5. Wipe outer surface with sterile gauze moistened with heparinized saline prior to each use.
6. Activate hydrophilic coating by wiping outer surface with sterile gauze moistened with heparinized saline.
7. Do not use excessive force to advance or manipulate a catheter through the vessel. Advancement with excessive force may cause vascular damage with the associated device (guide wire).
8. If resistance is felt during advancement, stop immediately to identify the source of resistance, and confirm the tip position under fluoroscopy.
9. Refer to package label for flow rates and maximum pressure ratings.
10. Remove the catheter and guide wire as a single unit to avoid vessel wall damage.
11. Pigtail Catheters: Pigtail catheters are fitted with a curve straightener. It is split for easy removal after the catheter tip is on the guide wire.
    a. Slide straightener forward until pigtail is straight.
    b. Place catheter tip on guide wire and remove straightener by pulling on the straightener tab.

3.3 Accessories

All Impress catheters are compatible with devices associated with conventional percutaneous vascular access. No accessories are included with the subject devices. Table 6 shows additional accessories that are mentioned in the IFU, but are not included with the subject devices.

Table 6 Accessory Devices

Component	Accessory Description
Access Needle	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.
Guidewire	A guidewire is then threaded through the needle into the vessel, and the needle is removed.
Dilator	Dilator(s) are used to enlarge the skin and vessel entrance for the catheter sheath introducer.
Catheter Sheath Introducer	A Catheter Sheath Introducer is then placed over the guidewire into the vessel, and the guidewire is removed.

3.4 Previous Generations or Variant

The Gen 2 Impress design and the Gen 1 Impress design have similar use, similar designs, and similar material composition. A history of generations and variants is listed in Table 7.

Table 7 History of Generations/Variants - Impress Angiographic Catheter Family

Generations	Change/Difference	Reason for Change/Difference	Date of Implementation	Basic UDI-DI
Directive 93/42/EEC (MDD)				
DHF0223	Marker Banded Impress	Merit has identified the need to update the current Uterine Artery catheter based on clinical preference and patient's anatomy. An offering of an Impress Catheter with a flexible radiopaque marker-band with a hydrophilic coating. An offering of an Impress Catheter with a flexible radiopaque marker-band with a hydrophilic coating, will improve Merit's ability to compete in the world-wide radiology catheter market.	April 2019	<<UDI-DI if applicable>>
DHF0128	Hydrophilic Coated Impress Catheters	The purpose of this project is to launch a line of hydrophilic peripheral catheters. The catheters will be based on the currently marketed Impress catheter line. The majority of the product codes will use existing configurations of the Impress catheter with hydrophilic coating placed on the distal tip. Other codes will use existing Impress catheters with variations in distal tip curve configuration, distal tip inner diameter, removal of side holes, and lengths.	April 2010	<<UDI-DI if applicable>>

3.5 Gen 2 Device Description

The Impress Angiographic Catheter line was originally acquired from Mallinckrodt Medical and UMI in 1999. The product line now includes 4F and 5F designs in wire braided, non-wire braided, and hydrophilic coated formats with Gen 1 structures and materials as identified in Table 8 and Table 9. The Gen 2 Impress design changes incorporate structural and material upgrades which are also identified in these tables.

Table 8 Impress Angiographic Catheter Family Specifications

Attribute	Description
Length	30 to 125 cm
French Size (F)	4 Fr to 5 Fr
Color	Black tip, Purple shaft, White hub
Catheter Shape	Bentson 1, Bentson 2, Berenstein, Cobra 1, Cobra 2, Headhunter 1, KA2, Mani, Modified Hook 1, Modified Hook 2, Modified Hook 3, Multipurpose A1, RBI, Simmons 1, Simmons 2, Simmons 3, Straight Selective, Uterine Artery Catheter, Vertebral
Internal Diameter	0.038, 0.040, 0.046 inches
Pressure	1050 psi for both wire-braided and non-wire-braided catheters 1200 psi for 5F WB and NWB catheters
Recommended Guide Wire	0.035, 0.038 inches

Abbreviations: cm = centimeter; Fr = French; NWB = non-wire braided; psi = pounds per square inch; WB = wire braided

Table 9 Materials of Construction: Impress Catheter Configurations

Component	Material Specification		Impress (with wire braid)	Impress Legato	Impress (non-braided)
	Current Design – applicable for Gen 2 if no change indicated	Gen 2 Impress – changes only in this column			
Wire Braid	304V or 316L Stainless Steel		X	X	
Body (Shaft)	Nylon				X
	Purple colorant – (PPS 090038001)				X
	Pebax 7233 SP01	Pebax 7233 SA01 MED	X	X	
	Barium sulfate				X
	Purple colorant – (PPS 090037001)				
		Tinuvin 783			
		Tinuvin 234			

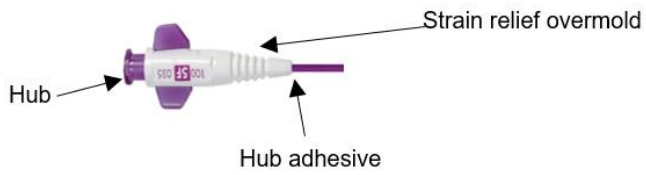
Component	Material Specification		Impress (with wire braid)	Impress Legato	Impress (non-braided)
	Current Design – applicable for Gen 2 if no change indicated	Gen 2 Impress – changes only in this column			
		Irganox B1171			
		Irganox 1010			
	304V or 316L Stainless Steel				
Tip	Pebax 5533 SP01	Pebax 5533 SA01 MED	X	X	X
	Pebax 3533 SP01	Pebax 3533 SA01 MED			
	Tungsten carbide powder				
		Tinuvin 783			
		Tinuvin 234			
		Irganox B1171			
		Irganox 1010			
Hub	Xylex PC/PET	Polycarbonate	X	X	X
	Purple colorant				
Strain Relief	Pellethane, White colorant		X	X	X
Adhesive	PX-50 cyanoacrylate	Loctite 4306	X	X	X
Hydrophilic Coating	Photo-polyvinylpyrrolidone copolymer			X	
	Photo-polyacrylamide copolymer				
	Photocrosslinker				
	BASF Kollidon 90F				
	Sterile, non-pyrogenic water				
	Isopropanol				
Ink	TRP 4760 Purple		X	X	X
Thinner	TPV Thinner		X	X	X
Adhesive	Adhesive Paste, Anti-Static		X	X	
	Nylon II Besno Resin				X

Component	Material Specification		Impress (with wire braid)	Impress Legato	Impress (non-braided)
	Current Design – applicable for Gen 2 if no change indicated	Gen 2 Impress – changes only in this column			
Pigtail Straightener (for applicable NWB product codes)	Barium sulfate				

Comparisons of the Gen 2 Impress and Gen 1 Impress are provided in Table 10 (wire braided) and Table 11 (non-wire braided). Particular aspects are identified where differences exist between the Gen 1 Impress catheters and the Gen 2 design. The pigtail straightener included with applicable non-wire braided product codes is not included in the table as there have been no changes to this component.

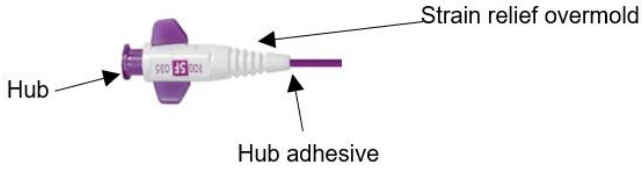
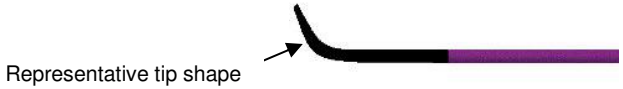
Table 10 Device Overview - Gen 2 Impress Wire Braided Catheters (Coated and Uncoated) and Gen 1 Impress Wire Braided Catheters (Coated and Uncoated)

Attribute	Gen 2 Impress	Gen 1 Impress
Name and Manufacturer	Impress Angiographic Catheter Family (Gen 2) Wire Braided Catheters – *Uncoated* Wire Braided Catheters - *Legato Hydrophilic Coating* Merit Medical Systems, Inc.	Impress Angiographic Catheter Family (Gen 1) Wire Braided Catheters – *Uncoated* Wire Braided Catheters - *Legato Hydrophilic Coating* Merit Medical Systems, Inc.
Regulatory Status	Class III (Rule 7) EC Cert: 541900 DE Cert: TBD	Class III (Rule 7) EC Cert: 541900 DE Cert: 538238
Technical Documentation	TDF0037	TEC0037
Variant Descriptions & Device Images	COMPLETE DEVICE - REPRESENTATIVE IMAGE 	
	HUB + STRAIN RELIEF ASSEMBLY	

Attribute	Gen 2 Impress	Gen 1 Impress
		
	Difference(s): New material Primary structural material: Polycarbonate	Key aspect: Hub primary structural material Primary structural material: Xylex PC/PET
	Difference(s): None	Key aspect: Strain relief overmold
	Difference(s): New adhesive Adhesive: Loctite 4306	Key aspect: Hub adhesive Adhesive: PX-50 cyanoacrylate
	Difference(s): Modified luer connector dimensions Applicable standard: ISO 80369-1:2018, ISO 80369-7:2016, ISO 80369-20:2016	Key aspect: Hub luer connector dimensional compliance with applicable standard Applicable standard: ISO 594-1:1986, ISO 594-2:1998
	SHAFT ASSEMBLY 	
	Difference(s): New materials Materials of construction: Pebax 7233 SA01 MED Tinuvin 783 Tinuvin 234 Irganox B1171 Irganox 1010 Barium sulfate* Purple colorant* 304V or 316L stainless steel (braid)* *both the Subject Device and the Equivalent Device contain this material	Key Aspect: Shaft composition Materials of construction: Pebax 7233 SP01 Barium sulfate* Purple colorant* 304V or 316L stainless steel (braid)* *both the Subject Device and the Equivalent Device contain this material

Attribute	Gen 2 Impress	Gen 1 Impress
	Materials of construction: Pebax 7233 SA01 MED Tinuvin 783 Tinuvin 234 Irganox B1171 Irganox 1010 Bismuth subcarbonate Purple colorant	Key aspect: Shaft structural components interfacing with tip Interfacing component: Shaft interfaces directly with tip with no intervening spacer
	Difference(s): None	Key aspect: Shaft length offerings
	TIP ASSEMBLY Representative tip shape 	
	Difference(s): New materials Materials of construction: Pebax 5533 SA01 MED Pebax 3533 SA01 MED Tinuvin 783 Tinuvin 234 Irganox B1171 Irganox 1010 Tungsten carbide powder * *both the Subject Device and the Equivalent Device contain this material	Key aspect: Tip composition Materials of construction: Pebax 5533 SP01 Pebax 3533 SP01 Tungsten carbide powder* *both the Subject Device and the Equivalent Device contain this material
	Difference(s): None	Key aspect: Scope offering of tip shapes
	TIP ASSEMBLY –Impress Legato Wire Braided catheter product codes only  Hydrophilic coated area	
	Difference(s): None	Key aspect: Hydrophilic coating composition and distribution

Table 11 Device Overview - Gen 2 Impress Non-Wire Braided Catheters and Gen 1 Impress Non-Wire Braided Catheters

Attribute	Gen 2 Impress	Gen 1 Impress
Name and Manufacturer	Impress Angiographic Catheter Family (Gen 2) Non-Wire Braided Catheters Merit Medical Systems, Inc.	Impress Angiographic Catheter Family (Gen 1) Non-Wire Braided Catheters Merit Medical Systems, Inc.
Regulatory Status	Class III (Rule 7) EC Cert: 541900 DE Cert: TBD	Class III (Rule 7) EC Cert: 541900 DE Cert: 538238
Technical Documentation	TEC0037	TEC0037
Variant Descriptions & Device Images	REPRESENTATIVE IMAGE – ENTIRE DEVICE 	
	HUB + STRAIN RELIEF ASSEMBLY 	
	Difference(s): New material Primary structural material: Polycarbonate	Key aspect: Hub primary structural material Primary structural material: Xylex PC/PET
	Difference(s): None	Key aspect: Strain relief overmold
	Difference(s): New adhesive Adhesive: Loctite 4306	Key aspect: Hub adhesive Adhesive: PX-50 cyanoacrylate
	Difference(s): Modified luer connector dimensions Applicable standard: ISO 80369-1:2018, ISO 80369-7:2016, ISO 80369-20:2016	Key aspect: Hub luer connector dimensional compliance with applicable standard Applicable standard: ISO 594-1:1986, ISO 594-2:1998
	TIP ASSEMBLY 	

Attribute	Gen 2 Impress	Gen 1 Impress
	Difference(s): New materials Materials of construction: Pebax 5533 SA01 MED Pebax 3533 SA01 MED Tinuvin 783 Tinuvin 234 Irganox B1171 Irganox 1010 Tungsten carbide powder * *both the Subject Device and the Equivalent Device contain this material	Key aspect: Tip composition Materials of construction: Pebax 5533 SP01 Pebax 3533 SP01 Tungsten carbide powder* *both the Subject Device and the Equivalent Device contain this material
	Difference(s): None	Key aspect: Scope offering of tip shapes

4.0 Risks and Warnings

4.1 Residual Risks and Undesirable Effects

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

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

All possible risk control measures have been implemented and verified and the Impress Angiographic Catheter Family has met all applicable regulations and standards. Through the clinical evaluation process, information relative to the clinical state-of-the-art and potential adverse events (AEs) are identified based on a review of the pertinent clinical evidence.

Intended clinical benefits: Impress Angiographic Catheters are used to gain access to an intended vascular site for the purpose of delivery of radiopaque media. As part of a minimally invasive system, the catheter aids with angiographic imaging for diagnosis and therapeutic treatment planning.

Articles published from May 7, 2007 to June 30, 2022 were reviewed. Given the capability for Impress Angiographic Catheter Family to deliver radioplaque media in a minimally invasive procedure, both clinicians and patients are deemed to assign high value to successful angiographic catheter performance. For the clinical evaluation, the performance outcome was defined as follows:

- Technical Success Rate: The successful access and delivery of contrast medium at the anatomical site of interest during a diagnostic or interventional procedure, without evidence of a delay or other complication attributable to the use of the device.

In cases where technical success of the Impress Angiographic Catheter Family is not specifically identified, technical success was inferred from procedural success.

Performance data for the Impress Angiographic Catheter Family and benchmark competitor devices is derived from clinical literature. Based on the literature, the technical success rate for the Impress Angiographic Catheter Family is high at a rate of 97%. The cumulative technical success rate for the benchmark competitor devices is 98.0%.

The potential complications/AEs related to the subject device as identified in the IFU are summarized in Table 12. In addition, the device/procedure-related adverse events identified in the literature and the corresponding risk assessment harms are presented in Table 13.

Table 12 Potential Hazards/Risks

Product Configuration	Potential Adverse Events
Impress Angiographic Catheter Family	• Thrombus formation/emboli • Plaque dislodgement • Vascular occlusion • Stroke • Death • Air embolism • Arterial wall damage • Infection • Vascular spasm • Foreign body/Tip Fracture

Table 13 Impress Angiographic Catheter Family Complications, Applicable Labeling and Identified Harms

Complications from the Literature	Incident Rate n/N (%)	Device Related	Procedure Related	IFU Complications	Harms	Time of Occurrence
Impress Angiographic Catheter Family						
Endoleak, type Ia[1]	3/100 (3%)		X	• N/A	• N/A	Periprocedural
Endoleak, type II[1]	2/100 (2%)		X	• N/A	• N/A	Periprocedural
Epididymo-orchitis[2]	3/100 (3%)		X	• N/A	• N/A	NR
Hemorrhage, intracranial[3]	15/100 (15%)		X	• N/A	• N/A	< 24 hours
Hemorrhage, subarachnoid[3]	1/100 (1%)		X	• N/A	• N/A	NR
Pain[2]	10/100 (10%)		X	• N/A	• N/A	NR
Pain/Fever/Vomiting[4]	17/100 (17%)		X	• N/A	• N/A	NR
Venous Injury[2]	1/100 (1%)		X	• N/A	• N/A	Periprocedural
Benchmark Devices						
Arterial dissection[5]	5/858 (0.6%)	X	X	• Arterial wall damage	• Soft Tissue Injury (3)	NR
Asymptomatic bradycardia[6]	1/858 (0.1%)		X	• N/A	• N/A	Post-operative
Atelectasis[6]	1/858 (0.1%)		X	• N/A	• N/A	Post-operative
Bradycardia[7]	1/858 (0.1%)		X	• N/A	• N/A	Periprocedural
Biliary puncture[7]	2/858 (0.2%)		X	• N/A	• N/A	Periprocedural
Cellulitis[6]	1/858 (0.1%)		X	• N/A	• N/A	Post-operative
Cholecystitis[8]	1/858 (0.1%)		X	• N/A	• N/A	NR
Endoleak (type III)[9]	3/858 (0.3%)		X	• N/A	• N/A	<7 days
Edematous ascitic decompensation[8]	1/858 (0.1%)		X	• N/A	• N/A	NR
Embolization coil – vascular foreign body[10]	1/858 (0.1%)		X	• N/A	• N/A	Periprocedural
Epistaxis[10]	1/858 (0.1%)		X	• N/A	• N/A	Periprocedural
Extravasation[5]	5/858 (0.6%)		X	• N/A	• N/A	NR
Femoral nerve neuropathy[11]	1/858 (0.1%)		X	• N/A	• N/A	NR

Complications from the Literature	Incident Rate n/N (%)	Device Related	Procedure Related	IFU Complications	Harms	Time of Occurrence
Fever[8]	5/858 (0.6%)		X	• N/A	• N/A	NR
Hematoma[9,12-14]	4/858 (0.5%)		X	• N/A	• N/A	<7 days,[9,12] NR[13,14]
Hematoma[5]	3/858 (0.3%)	X	X	• Vessel wall damage	• Soft Tissue Injury (2)	NR
Hemorrhagic shock[13]	1/858 (0.1%)		X	• N/A	• N/A	NR
Infection[15]	10/858 (1.2%)		X	• N/A	• N/A	NR
Intraperitoneal bleeding[7]	3/858 (0.3%)		X	• N/A	• N/A	Periprocedural
Ischemic hepatitis[16]	1/858 (0.1%)		X	• N/A	• N/A	<3 days
Ovarian dysfunction[15]	2/858 (0.2%)		X	• N/A	• N/A	NR
Pain[8,17]	26/858 (3.0%)		X	• N/A	• N/A	Periprocedural,[17] NR [8]
Pericardial effusion[10]	1/858 (0.1%)		X	• N/A	• N/A	Periprocedural
Phlebitis[18]	9/858 (1.0%)		X	• N/A	• N/A	NR
Postembolization syndrome[8]	10/858 (1.2%)		X	• N/A	• N/A	NR
Prostatitis[12]	1/858 (0.1%)		X	• N/A	• N/A	NR
Pseudoaneurysm[8,14]	2/858 (0.2%)		X	• N/A	• N/A	NR
Pulmonary hemorrhage[19]	1/858 (0.1%)		X	• N/A	• N/A	<5 days
Respiratory distress[7]	1/858 (0.1%)		X	• N/A	• N/A	Periprocedural
Septic arthritis[14]	1/858 (0.1%)		X	• N/A	• N/A	<30 days
Seroma[18]	1/858 (0.1%)		X	• N/A	• N/A	NR
Skin mottling[14]	14/858 (1.6%)		X	• N/A	• N/A	NR
Splenic infarction[20]	2/858 (0.2%)		X	• N/A	• N/A	>30 days
Tenesmus[17]	31/858 (3.6%)		X	• N/A	• N/A	Periprocedural
Thrombosis (acute)[7]	5/858 (0.6%)		X	• N/A	• N/A	Periprocedural,[7] >7 days[7]

Complications from the Literature	Incident Rate n/N (%)	Device Related	Procedure Related	IFU Complications	Harms	Time of Occurrence
Thrombosis (major)[9]	1/858 (0.1%)		X	• N/A	• N/A	<7 days
Thrombosis[6,11]	5/858 (0.6%)		X	• N/A	• N/A	5 days,[11] Post-operative[37]

Abbreviations: N/A = not applicable; NR = not reported

Safety data for the Impress Angiographic Catheter Family and for comparable benchmark guide wires are summarized in Table 14. Safety data for the Impress Angiographic Catheter Family and for benchmark competitor devices is derived from the clinical literature. Based on the clinical literature data, there were no device-related AEs for the Impress Angiographic Catheter Family with an incidence rate of 0%. Incidence of device-related AEs for benchmark competitor devices is 0.9%. Based on the comparative analysis, the UBL of the 1-sided 95% CI for p1-p2 is less than 0.10 (10%). Therefore, H_0 is rejected and the device-related AE rate for the Impress Angiographic Catheter Family is established as non-inferior to the comparable benchmark guidewires at a 95% confidence level. Therefore, the subject device/equivalent comparator satisfies the established acceptance criteria for safety measures.

Table 14 Comparative Safety for the Impress Angiographic Catheter Family

Device Type/Application	Impress Angiographic Catheter Family, n/N (%)	Benchmark Competitors, n/N (%)	Estimated Difference [95% UBL]	UBL < d
Impress Angiographic Catheter Family	0/100 (0)	8/858 (0.9)	-0.9 (-0.4)	PASS

Abbreviations: CI = confidence interval, UBL = upper bound limit

The results of the clinical risk/safety analysis demonstrate that the Impress Angiographic Catheter Family meets the established acceptance criteria with respect to safety measures and exhibit an acceptable overall safety profile. No new safety concerns specific to the subject device were identified in this evaluation, and the rates reported are consistent with available data for state-of-the-art alternative treatments.

4.2 Warnings and Precautions

The labeled warnings and precautions for the Impress Angiographic Catheter Family device configurations are summarized in Table 15.

Table 15 Impress Angiographic Catheter Family: Warnings & Precautions

Category	Labeling Statements
Warnings	• The Impress® angiographic catheter with Legato™ hydrophilic coating should not be used in the coronary arteries. • 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	• Inspect all catheters prior to use. Do not use if package is opened or damaged. • Do not use after expiration date. • Do not autoclave. • For catheters containing hydrophilic polymer coating on the distal surface of the catheter, the surface of the distal portion of the catheter must be completely wet with solution to remain lubricated. Proper caution must be taken to wet the catheter prior to and during use. • 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.
Reuse Precaution	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.

The labeled general caution for the devices in the Impress Angiographic Catheter Family is summarized below:

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

4.3 Other Relevant Safety Aspects

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

Merit has created 6 Corrective Action Reports (CARs) during the reporting period for this report (Table 16).

Table 16 Corrective Action Report Summary

CAR Number	CAR Title	CAR Originate Date	CAR Description	CAR Status
CAR 18-01433	Repeated Impress fusing NCs	2/26/2018	Multiple NCs (NC08619, NC09021, NC09047, NC09074, NC09114 and NC09201) have been written for fuse failures that have been identified during production of Impress fused subassemblies and WIP.	Closed
CAR 18-01454	Repeated Impress tip detachment customer complaints	3/26/2018	This issue was previously documented under CAR 17-01261 but has been reassigned to new QE responsible for the product line; therefore that CAR has been voided and replaced with this one. Tip separation complaints have been received which were previously addressed under another CAR. The changes made in that CAR have not resulted in a significant mitigation of the occurrence rate. This CAR will be used to document a new plan for addressing the issue.	Closed
CAR 18-01643	Repeated Impress fusing NCs	8/14/2018	CAPA 18-01433 was generated to address multiple events relating and potentially relating to fusing issues on the impress product line. CAPA 18-01433 was closed 12-JUL-2018. Since this closure there have been additional instances of tip separations. This CAPA was previously extended because the root cause analysis was ongoing. Tip separation is a complex issue and Engineering is working on narrowing down the potential root causes by following a process map for Split Die machines used for fusing wire braided Impress. Refer to meeting minutes. Although the request for an extension was not submitted prior to the actual due date, as per QSP 993.004, work was being done on the CAPA and documented in meeting minutes and root cause analysis, which justifies the need for an extension. 07-Nov-18: Based on feedback from Engineering, CAPA Plan Due Date extended to 16-Nov-18. Engineering determined this date to be a realistic timeframe for the CAPA Plan Date.	Closed
CAR 19-02058	Repeated Impress tip elongated /	5/2/2019	CAPA 18-01643 was open to address investigations into complaints relating to tip separation of the Impress catheter. Upon investigation it was determined that there are different failure modes and that these failure modes should be managed under unique	Open

CAR Number	CAR Title	CAR Originate Date	CAR Description	CAR Status
	broke customer complaints		CAPAs. This CAPA will address the failure mode associated with excessive force applied to the catheter tip resulting in elongation and breakage. Data from the original CAPA may be used for root cause and investigation documentation for this CAR.	
CAR 19-02057	Repeated Impress tip degradation / fracturing complaints	5/2/2019	CAPA 18-01643 was open to address investigations into complaints relating to tip separation of the Impress catheter. Upon investigation it was determined that there are different failure modes and that these failure modes should be managed under unique CAPAs. This CAPA will address the failure mode associated with exposure to Vaporized Hydrogen Peroxide. Data from the original CAPA may be used for root cause and investigation documentation for this CAR.	Closed
CAR 21-03108	Fusing machine parameter verification due to repeated Impress fusing NCs	7/22/2021	Impress Equipment Parameter verifications.	Open

There have been no field escalations or product recalls during the period of this report.

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.

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

5.1 Summary of Clinical Data for the Equivalent Device

An equivalence assessment was performed for the Gen 2 Impress Angiographic Catheter Family (subject devices) and the Gen 1 Impress Angiographic Catheter Family (equivalent comparators). The structural and material differences are presented in Table 8 and Table 9. All clinical data for the Impress Angiographic Catheter Family is associated with the Gen 1 Impress design, and therefore equivalence will be demonstrated for the Gen 2 Impress design.

Any identified differences with regard to clinical, technical, and biological characteristics were analyzed and none 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 (Gen 1 Impress Angiographic Catheter Family) may

be used to support the safety and performance of the subject devices (Gen 2 Impress Angiographic Catheter Family). 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

Conformity of the Impress Angiographic Catheter Family is pending assessment and endorsement by the applicable NB. No pre-market or post-market clinical investigations of the device were conducted in the EU prior to the initial CE marking. A summary of all available clinical data for the Impress Angiographic Catheter Family is provided in Section 5.4.

5.3 Summary of Clinical Data from Other Sources

Scientific Literature Review

A review of relevant clinical literature for the Impress Angiographic Catheter Family was conducted for the time period of May 7, 2007 to June 30, 2022. Four articles were identified as pivotal data. Table 17 summarizes the safety and performance of the Impress Angiographic Catheter Family and were reviewed for safety and performance.

Table 17 Impress Angiographic Catheter Family: Summary Study Characteristics

Author (Year) LOE Study Type	Primary Clinical Indication	Device Application, Access	Patients, n/N (%)[a]	Devices Used (N)	Gender (M/F) Age (years)	Follow-up
Peripheral						
Aly et al (2022)[2] LOE: B2 Single-arm interventional	Renal venography in men with benign prostatic hyperplasia	Right internal jugular to catheterize the left renal vein and perform renal venography	36/36 (100)	Impress, 5F vertebral (36)	40-80 years	3 months
El-Gharib et al (2016)[4] LOE: C Prospective study	Transradial catheterization in patients with hepatocellular carcinoma	Left radial artery to catheterize the hepatic artery	20/20 (100)	Bern Impress (16) Cobra head Impress (4)	NR	1 month
Piasecki et al (2021)[3] LOE: B2 Retrospective, single-center study	Percutaneous mechanical thrombectomy using Tigertriever in stroke patients with large vessel occlusion	Femoral vein for angiographic confirmation of large vessel occlusion	30/30 (100)	Impress – size/shape not reported (30)	M/F: 14/16 Mean age, 66 years	3 months

Author (Year) LOE Study Type	Primary Clinical Indication	Device Application, Access	Patients, n/N (%)[a]	Devices Used (N)	Gender (M/F) Age (years)	Follow-up
Zhang et al (2020)[1] LOE: C Retrospective, single-center study	Endovascular looping chimney technique to reconstruct the left common carotid artery in patients with aortic arch pathologies	Left external carotid artery via brachial artery access for guidewire exchange and sheath placement	14/14 (100)	Impress 5 Fr VERT (14)	M/F: 10/4 Mean age, 52.86 ± 14.46 years Age range: 27–79 years	Up to 24 months

Table 18 Impress Angiographic Catheter Family: Safety and Performance Summary

Author (Year) LOE Study Type	Device (N)	Technical Success n/N (%)	Device-Related Adverse Events n/N (%)	Complications n/N (%)
Peripheral				
Aly et al (2022)[2] LOE: B2 Single-arm interventional	Impress, 5F vertebral (36)	33/36 (91.7)	0/36 (0)	Epididymo-orchitis: 3/36 (8.3) Venous injury: 1/36 (2.8) Pain: 10/36 (27.8)
El-Gharib et al (2016)[4] LOE: C Prospective study	Bern Impress (16) Cobra head Impress (4)	20/20 (100)	0/20 (0)	Pain, fever and vomiting: 17/20 (85)
Piasecki et al (2021)[3] LOE: B2 Retrospective, single-center study	Impress – size/shape not reported (30)	30/30 (100)	0/30 (0)	Subarachnoid hemorrhage resulting in pneumonia/death: 1/30 (3.3) Intracranial hemorrhage: 15/30 (50) All-cause mortality, 3 months (none related to endovascular procedure): 9/30 (30)
Zhang et al (2020)[1] LOE: C Retrospective, single-center study	Impress 5 Fr VERT (14)	14/14 (100)	0/14 (0)	Endoleak, type Ia: 3/14 (21.4) Endoleak, type II: 2/14 (14.3) Death from cerebral hemorrhage/abnormal coagulation: 1/14 (7.1)

5.4 Overall Summary of Clinical Performance and Safety

Data to support the safety and performance of the Impress Angiographic Catheter Family have been analyzed and provide evidence to support all the safety and performance outcomes. The clinical data demonstrate that the risks associated with the Impress Angiographic Catheter Family are acceptable when weighed against the clinical benefits to the patient. All angiography 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 angiography in patients who require or elect angiography as their treatment modality. The subject devices were deemed consistent with the SOA benchmark devices for safety and performance in this patient population. The Impress Angiographic Catheter Family devices are well established, having demonstrated acceptable safety and performance profile since the catheters were first commercialized in 2007. Based on design verification/validation testing results, safety and performance outcomes in the literature, and PMS data, there are no known uncertainties regarding safety and performance of the subject device or the intended use. The known risks are well-documented, and the risk of occurrence is low and not associated with any safety or performance signals.

The clinical indications identified in the IFUs for the Impress Angiographic Catheter Family product configurations are supported by the clinical evidence presented in the CER. 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 Impress Angiographic Catheter Family 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 positive impact to patient health and well-being through the use of the Impress Angiographic Catheter Family to facilitate angiography is fully described.
- Specific measurable clinical outcomes (e.g., technical success rate, AE rate) are associated with the use of the Impress Angiographic Catheter Family.
- The technical success rate for the Impress Angiographic Catheter Family is high and comparable to benchmark angiographic catheters.
- The AE rate for the Impress Angiographic Catheter Family 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 Impress Angiographic Catheter Family field actions/recalls is considered clinically acceptable.

Based on 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 Impress Angiographic Catheter Family is summarized in Table 19.

Table 19 Summary of Benefit/Risk Assessment[21,22]

Summary of the Benefit(s)	Summary of the Risk(s)	Summary of Other Factors
Impress Angiographic Catheter Family		
Impress Angiographic Catheters are used to gain access to an intended vascular site for the purpose of delivery of radiopaque media. As part of a minimally invasive system, the catheter aids with angiographic imaging for diagnosis and therapeutic treatment planning. Impress Angiographic Catheter Family Technical success rate: 97% (97/100) Benchmark Angiographic Catheter (SOA) Technical success rate: 98% (798/814) Subject device technical success rate is non-inferior to the comparable benchmark catheters at a 95% confidence level.	No device-related AEs occurred in the subject device literature. Device-related AEs that occurred in the benchmark literature occur at a low rate and are generally transient in nature. The reported device-related AEs are documented in product labeling. Impress Angiographic Catheter Family AE rate: 0% (0/100) Benchmark Angiographic Catheter (SOA) AE rate: 0.9% (8/858) Subject device technical success rate is non-inferior to the comparable benchmark catheters at a 95% confidence level.	The Impress Angiographic Catheter Family of devices provide a safe and effective way to administer diagnostic cardiology and peripheral angiography procedures.

5.5 Postmarket Clinical Follow-up (PMCF)

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

Post-Market Clinical Follow-Up will be performed to support the clinical safety and performance of the Impress Angiographic Catheter Family. The PMCF strategy for Impress Angiographic Catheter Family is to conduct a quantitative patient specific (high quality) survey to collect PMCF data. A total of 120 product evaluation surveys will be collected over a 12-month period. Surveys will include questions to identify safety and technical success of the Impress Angiographic Catheter Family. The PMCF data analysis will include consideration of the following:

- Safety or performance issues identified in the product feedback evaluation forms and what impact, if any, was contributed by the Impress Angiographic Catheter Family.

- Safety and performance data collected from the PMCF activity and the clinical evaluation literature for the subject device as compared to the safety and performance clinical literature data for the benchmark devices in accordance with the methods employed in the clinical evaluation.
- Safety or performance issues identified in the product feedback evaluation forms and whether the issues constitute a previously unidentified residual risk.
- Instances of off-label device use

6.0 Diagnostic or Therapeutic Alternatives

6.1 Review of Medical Condition

Conditions and vessel abnormalities indicated for angiography and alternative imaging techniques include (but are not limited to):

- vascular aneurysms
- atherosclerosis
- coronary artery disease (CAD)
- peripheral artery disease (PAD)
- arteriovenous malformations (AVMs)
- diseased blood vessels in order to evaluate stent placement
- injuries in patients after trauma
- dissections
- pulmonary embolism
- congenital abnormalities in children

A few of these conditions and abnormalities are discussed below as they relate to the state-of-the-art for angiographic catheters.

6.2.1 Aneurysms

Aneurysms are abnormal dilatations on the walls of blood vessels, which often appear near a vessel bifurcation point.[23] Brain (intracranial) aneurysms occur mostly between the ages of 35 and 60.[23] Overall, females suffer more aneurysms than males (female to male ratio is 3:2); however, before age 40, males and females are equally affected. The rupture of an aneurysm can be fatal; about 500,000 people per year die worldwide due to ruptured aneurysms.[23] World regions of the highest incidence include Finland and Japan.[23]

Potential risk factors for aneurysm growth or rupture include alcohol abuse, cigarette smoking, female sex, certain genetic conditions, hormonal therapy, older age, family history, and uncontrolled hypertension.[23] Most aneurysms are asymptomatic; about 10% to 15% of unruptured brain aneurysms are symptomatic.[23] Abdominal aortic aneurysms (AAA) occur in the abdominal aorta and have significant clinical implications; rupture of AAAs have an 85% chance of mortality.[24] Risk factors for AAA include cigarette smoking, excess weight, White or Native American race, male sex, older age, family history, and cardiovascular disease (CVD).[24] Aneurysms (peripheral, aortic, brain) can be detected using a variety of imaging techniques, such as computerized tomography, magnetic resonance imaging (MRI), ultrasound, or angiography.[25] There are a variety of surgical and endovascular methods for management of aneurysms.

6.2.2 Atherosclerosis, Coronary Artery Disease, and Peripheral Artery Disease

Atherosclerosis (buildup of fatty deposits) can occur in any vessel of the body and can cause CAD, stroke, and peripheral arterial disease.[26] CAD is a type of CVD that involves the narrowing of the epicardial arteries due to fatty deposits formation.[27] CAD can have long, stable, and asymptomatic periods, which can become unstable due to an acute atherothrombotic event due to plaque rupture or erosion.[27] The clinical manifestations can present as an acute process (acute coronary syndrome) or a chronic process (chronic coronary syndromes [CCS]).[28] Symptoms include stable angina (such as chest pain or dyspnea), heart failure or asymptomatic left ventricular impairment, or cardiac arrhythmias. [28]

PAD occurs due to atherosclerosis involving the aorta, iliac, and lower extremities.[29] Symptoms of PAD include pain and numbness, particularly when walking.[29] In severe cases, PAD can result in infection and gangrene requiring amputation.[29] PAD affects 10% to 15% of the global population and about 20% of adults over the age of 60.[29] In 2010, the worldwide incidence of PAD was 202 million.[29] Risk factors for PAD include tobacco use, hypercholesterolemia, diabetes mellitus, and hypertension.[30] Four general populations of patients at increased risk of PAD include: (1) patients 65 years and older, (2) patients 50 to 64 years old with risk factors for atherosclerosis or family history of PAD, (3) patients less than 50 years old with diabetes mellitus and one additional risk factor for atherosclerosis, and (4) individuals with known atherosclerosis in another vascular bed (including coronary, carotid, subclavian, renal, mesenteric artery stenosis, or abdominal aortic aneurysm).[30]

6.2.3 Arteriovenous Malformations

AVMs and arteriovenous fistulae are abnormal passageways between arteries and veins that result in ballooning of the vessel. About 0.1% of the population have cerebral AVMs, and only 12% of those who have cerebral AVMs exhibit symptoms.[31] AVM affects males and females equally, and there is not an increased risk for specific ethnic and racial groups.[31] For most patients, symptoms peak in their 40's.[31]

The primary features of AVMs include the presence of one or multiple direct arteriovenous connections that allow high-flow shunting through smaller feeding arteries.[31] The high-flow shunting changes the structure of both the feeding arteries and the draining vessels. AVMs can occur sporadically and are less dependent on family history. Cerebral AVMs could present with intracranial hemorrhage, seizures, headaches, and long-term disabilities.[31] Management options include observation with medical attention, surgical resection, stereostatic radiotherapy, and endovascular embolization.[31] Management of unruptured AVMs are exceptionally difficult due to a poorly defined natural history and low annual hemorrhage rates.[31]

6.3 Treatment Options and Interventions

6.3.1 Conservative Management: Non-Invasive Functional/Physiologic

6.3.1.1 Ankle Brachial Index

The ratio of the blood pressure measured at a patient's ankle to that measured in the upper arm is referred to as the ankle-brachial index (ABI).[29] ABI can be obtained non-invasively using a sphygmomanometer and a handheld Doppler probe.[32] A reduced ABI confirms the existence of a significant stenosis or occlusion between a patient's heart and ankle.[33] ABI is based on quantitative and objective results, as well as a correlation between clinical symptoms and severity.[33] Thus, ABI can be an effective method for clinical evaluation and diagnosis in patients with occlusive conditions such as PAD.[29,32] ABI can also be used as a tool for measuring progression of the disease or the response to a treatment.[33] Although simple, ABI can be time consuming and requires training and experience.[29] In a study looking at sensitivity and specificity of ABI, it was found that sensitivity was between 61-96% and specificity was 56-90%.[29] ABI has been shown to provide false results in patients with diabetes, or with renal failure and is also unable to identify the location of the stenosis/occlusion.[29,33,34]

6.3.1.2 Segmental limb pressures

Segmental limb pressures are used in patients with PAD. They are useful, because unlike ABI measures, they can be used to help determine the site of occlusions or stenosis.[29] The difference in blood pressures at specific locations is used locate the occlusion or stenosis. In general, 4 blood pressure cuffs are placed on the leg in question. The blood pressure is measured at each of the 4 cuff sites. If a pressure gradient greater than 20

mmHg is measured it is representative of occlusion or stenosis.[29,34] Segmental pressures can be difficult to interpret and an average error of 8.5 mmHg is seen when inappropriate cuffs are used.[29,34]

6.3.1.3 Plethysmography

Plethysmography measures blood volume changes in the lungs, heart, aorta, or lower limbs.[35] There are several different plethysmographic methods (Strain gauge, photo, impedance, and air plethysmography [APG]).[29] Plethysmography can detail information such as the venous filling index, ejection fraction, residual volume fraction and arterial pulse wave shape.[29] Strain gauge plethysmography (SGP) can be used to quantitatively assess the peripheral arterial and venous systems.[29,36] A flexible strain gauge is filled with a conductive medium and fit snugly to the limb. Changes in blood volume is estimated from proportional changes in the electrical impedance of the strain gauge.[29] Limitations with SGP include temperature sensitivity and chemical hazard.[29] Photoplethysmography (PPG) uses infrared light source and a light detector to estimate the variation of blood volume.[29,37] PPG produces a pulsatile wave form that is examined for regularity and pulsatile quality to detect artifacts potentially causing a low displayed oxygen saturation.[29,37] Impedance plethysmography (IPG) uses electrical impedance to derive changes in blood volume and to determine the peripheral vascular response to the quantity and velocity of circulating blood.[29,35] It is used for the assessment of blood flow in the lungs, heart, aorta, and periphery.[35] Shabani Varaki et al reported that IPG was less successful in distinguishing between healthy and pathological groups.[29] APG is used to evaluate venous function in the lower extremities and to detect the presence of an occlusion. It consists of an air-filled chamber that encloses the lower limb and as blood volume changes, air is displaced and measured.[29] APG is an uncomfortable procedure which leads it to not be used routinely.[29] Plethysmography has many benefits, mainly the fact that it is non-invasive. Although, it is limited by the time, personnel requirements and qualitative in nature which leads to high variance.[29,38]

6.3.1.4 Doppler waveforms

A variety of ultrasonography tools and modalities are available for non-invasive diagnostic testing. Different doppler modalities include bright mode (B-mode), continuous wave (CW), and pulsed wave (PW). Vascular ultrasonography is used to assess the vascular system and for localizing disease.[29,34] B-mode ultrasonography creates a 2-D real-time picture of blood vessels and is used to gather information about diameter changes in vasculature. CW doppler ultrasound utilizes the sound of venous flow and its wave form with respiration. This allows the clinician to diagnose venous reflux with the audible signal. PW doppler ultrasound utilizes the sound of venous flow as well and is able to overcome the limitation of depth that is seen in CW. This allows PW to categorize peripheral arterial stenosis.[29] Vascular ultrasonography is one of the top 3 most commonly used non-invasive diagnostics and therapeutic management tools. However, the doppler wave forms have limitations that include difficulty in reproducibility based on the angle of insonation, errors in interpretation and when disease is present in a proximal segment and the waveform becomes abnormal, as in tandem stenoses or occlusions which leads to false results.[34]

6.3.2 Anatomic/ Non-Invasive Imaging Treatments

6.3.2.1 Magnetic Resonance Imaging

MRI is a non-invasive imaging technology that produces 3-D detailed images of anatomical areas of the body. The main principle of MRI is the excitement and detection of protons found in the water of living tissues.[39] The proton excitement is created using powerful magnets which force the protons to align with that specific magnetic field, then a current is applied causing the protons to spin out of their equilibrium. Once the current is deactivated a sensor detects the energy released as the protons realign with the magnetic field.[39] Magnetic resonance angiography (MRA) is a technique used for the visualization and diagnosis of stenosis, including its anatomic location.[25] MRA has had a lot of improvement in technology over the past years and is useful in the non-invasive visualization of the vasculature.[40,41] One of MRA's clear advantages is the lack of radiation exposure.[33] MRA also has automated post image processing that reconstructs images much faster than other imaging modalities. In order to complete a proper MRA a contrast media is needed to enhance the viewing of veins and soft tissues.[25,33] Post contrast complications can arise and is an important drawback of MRA. Artazcoz et al 2015 discussed several of MRAs limitations which include: increased time for imaging, operator-dependent, higher cost of equipment resulting in higher cost for the patient and listing the major limitation of MRA as the inability to evaluate metal.[33]

6.3.2.2 Duplex Ultrasound

Duplex ultrasound (DU) can be used for detecting flow velocities, anatomical features, deep vein thrombosis and the degree of stenosis.[25,29,33] DU combines all 3 modalities of doppler waveforms, which makes it the best technique for non-invasive assessment of the severity of a lesion.[29,33] DU has advantages over other anatomical treatments due to its portability with ability to perform the test at the bedside, rapid interpretation of results, cost-effectiveness, and lack of ionizing-radiation or contrast. It is also available in situations where patient is too critically ill for the CT scanner.[42] The disadvantages of DU is that it is highly operator dependent and requires the availability of a trained operator such as an registered vascular technologist (RVT) to perform the studies.[29,42] DU also has limitations when patients have ulcerations, pain, swelling, heavily calcified arteries and obesity. 5-20% patients have these symptoms and cannot undergo DU wave exposure.[29]

6.3.2.3 Computed Tomography (CT)

CT is a non-invasive imaging technique that generates cross-sectional images of the body. A CT scanner works by creating a narrow x-ray beam that rotates around the patient.[43] Computed tomography angiography (CTA) is a technique allows for the visualization of smaller and distal vessels, as well as larger vasculature.[33] Similar to MRA, CTA requires contras media due to the limitations of x-rays. Unfortunately, these contrast agents are potentially nephrotoxic. In comparison to MRA, CTA examinations are significantly lower in cost and shorter time of evaluation. The disadvantages

of CTA is the evaluation of severely calcified lesions, which leads to a blooming artefact that results in an overestimation of stenosis.[33] In addition foreign bodies within the x-ray filed can induced beam scatter which may disrupt visualization of the injured vessel.[42]

6.3.3 Interventional Catheter Angiography

Catheter Angiograms (CA) are the gold standard due to its superior resolution and ability to isolate small caliber vascular anomalies as well as provide therapeutic options.[43,44] CA should be used in instances in which non-invasive imaging is inconclusive or not able to be performed.[38,44,45] CA are diagnostic tests that use x-rays to image vasculature. It consists of a long flexible catheter that is inserted percutaneously into the blood stream under imaging guidance to deliver contrast into the vasculature making them visible on x-ray.[44,46] Angiograms are established as a safe, and accurate method of evaluation of vascular disease. CA has the advantage of better spatial resolution, the ability to make adjustments during delivery to optimize imaging and to evaluate blood flow rate and directionality. Complications for CA are uncommon but include access-site related issues and contrast related reactions.[44] Disadvantages of CA revolve around its invasive nature. There is potential for procedure-related complications, increased radiation exposure, and lengthy procedure times.[44]

6.3.4 New Technologies

Emerging technologies for patient requiring cardiac or peripheral diagnostic angiography are being created to diagnose accurately, easily, cheaply, quickly, and without extensive training.[29] There are several emerging techniques such as: pulse wave velocity (PWV), vascular optical tomographic imaging (VOTI), and polymer-based sensors. PWV is not a new diagnostic tool, yet its use in diagnosing PAD and CVD risks is relatively new.[47] PWV can be used to assessment of blood pressure, vascular stiffness and to monitor therapeutic effects of clinical studies.[29,47] However, no studies have yet to validate PWV with similar diagnostic techniques. VOTI is a new non-invasive imaging technique to measure distal foot perfusion from hemoglobin concentration.[29] VOTI is similar to MRIs, where radiofrequency pulses result in an image.[48] According to Shabani Varaki et al[29] no information about the training requirements or cost of the equipment have been released. Polymer-based sensors are used in a wide variety of projects and are still in early stages of development to be used for non-invasive vascular diagnostics.[29] Polymer-based sensors that do not require constant human supervision that allow transmitting of valuable data are being tested.[29,49] A new solution that is capable of providing an early diagnosis is what these new emerging technologies are seeking. However, all 3 new technologies are early in the development phase and have yet to report safety and efficacy data.

6.4 Standard of Care Recommendations

The relevant standard of care and clinical practice guides for management of peripheral vascular and coronary disease as well as cardiac abnormalities are summarized in Table 20. These guidelines inform on appropriate and relevant safety and performance measures for the target therapy and alternative therapies.

Table 20 Standard of Care Guidelines and Recommendations for the Management of Medical Condition

Recommendation	Level of Evidence	Grade/Strength of Recommendation
2017 ESC Guidelines on the Diagnosis and Treatment of Peripheral Arterial Diseases[50]		
Recommendations for imaging of extracranial carotid arteries		
DUS (as first-line imaging), CTA and/or MRA are recommended for evaluating the extent and severity of extracranial carotid stenoses.	I	B
When CAS is being considered, it is recommended that any DUS study be followed by either MRA or CTA to evaluate the aortic arch as well as the extra- and intracranial circulation.	I	B
When CEA is considered, it is recommended that the DUS stenosis estimation be corroborated by either MRA or CTA (or by a repeat DUS study performed in an expert vascular laboratory.	I	B
Recommendations on the management of acute mesenteric ischemia		
Diagnosis: In patients with suspected acute mesenteric ischemia, urgent CTA is recommended.	I	C
Diagnosis: In patients with suspicion of acute mesenteric ischemia, the measurement of D-dimer should be considered to rule out the diagnosis.	IIa	B
Treatment: In patients with acute thrombotic occlusion of the superior mesenteric artery, endovascular therapy should be considered as first line therapy for revascularization.	IIa	B
Treatment: In patients with acute embolic occlusion of the superior mesenteric artery, both endovascular and open surgery therapy should be considered.	IIa	B
Recommendations on imaging in patients with lower extremity artery disease		
DUS is indicated as a first-line imaging method to confirm LEAD lesions.	I	C
DUS and/or CTA and/or MRA are indicated for anatomical characterization of LEAD lesions and guidance for optimal revascularization strategy.	I	C
Data from an anatomical imaging test should always be analyzed in conjunction with symptoms and hemodynamic tests prior to a treatment decision.	I	C
DUS screening for AAA should be considered	IIa	C

Recommendation	Level of Evidence	Grade/Strength of Recommendation
Recommendations on revascularization of aorto-iliac occlusive lesions		
An endovascular-first strategy is recommended for short (i.e. <5 cm) occlusive lesions.	I	C
An endovascular-first strategy should be considered in long and/or bilateral lesions in patients with severe comorbidities.	IIa	B
An endovascular-first strategy may be considered for aorto-iliac occlusive lesions if done by an experienced team and if it does not compromise subsequent surgical options	IIb	B
Recommendations on revascularization of femoro-popliteal occlusive lesions		
An endovascular-first strategy is recommended in short (i.e., <25 cm) lesions	I	C
In patients unfit for surgery, endovascular therapy may be considered in long (i.e., >25 cm) femoro-popliteal lesions.	IIb	C
Recommendations on revascularization of infra-popliteal occlusive lesions		
For revascularization of infra-popliteal arteries: endovascular therapy should be considered.	IIa	B
Recommendations on the management of chronic limb-threatening ischemia		
In CLTI patients with below-the-knee lesions, angiography including foot runoff should be considered prior to revascularization.	IIa	C
2016 AHA/ACC Guideline on the Management of Patients with Lower Extremity Peripheral Artery Disease[30]		
25		
Duplex ultrasound, CTA, or MRA of the lower extremities is useful to diagnose anatomic location and severity of stenosis for patients with symptomatic PAD in whom revascularization is considered	I	B-NR
Invasive angiography is useful for patients with CLI in whom revascularization is considered.	I	C-EO
Invasive angiography is reasonable for patients with lifestyle-limiting claudication with an inadequate response to GDMT for whom revascularization is considered.	IIa	C-EO
Invasive and noninvasive angiography (i.e., CTA, MRA) should not be performed for the anatomic assessment of patients with asymptomatic PAD.	III: Harm	B-R
Recommendations for Endovascular Revascularization for Claudication		
Endovascular procedures are effective as a revascularization option for patients with lifestyle-limiting claudication and hemodynamically significant aortoiliac occlusive disease	I	A
Endovascular procedures are reasonable as a revascularization option for patients with lifestyle-limiting claudication and hemodynamically significant femoropopliteal disease	IIa	B-R

Recommendation	Level of Evidence	Grade/Strength of Recommendation
The usefulness of endovascular procedures as a revascularization option for patients with claudication due to isolated infrapopliteal artery disease is unknown	IIb	C-LD
Endovascular procedures should not be performed in patients with PAD solely to prevent progression to CLI	III	B-NR
Recommendations for Endovascular Revascularization for Claudication		
Endovascular procedures are recommended to establish in-line blood flow to the foot in patients with nonhealing wounds or gangrene	I	B-R
A staged approach to endovascular procedures is reasonable in patients with ischemic rest pain	IIa	C-LD
Evaluation of lesion characteristics can be useful in selecting the endovascular approach for CLI	IIa	B-R
Use of angiosome-directed endovascular therapy may be reasonable for patients with CLI and nonhealing wounds or gangrene	IIb	B-NR
Management of Patients With Peripheral Artery Disease (Compilation of 2005 and 2011 ACCF/AHA Guideline Recommendations)[25]		
Contrast Angiography		
Contrast angiography provides detailed information about arterial anatomy and is recommended for evaluation of patients with lower extremity PAD when revascularization is contemplated	B	Class I
A history of contrast reaction should be documented before the performance of contrast angiography and appropriate pretreatment administered before contrast is given.	B	Class I
Decisions regarding the potential utility of invasive therapeutic interventions (percutaneous or surgical) in patients with lower extremity PAD should be made with a complete anatomic assessment of the affected arterial territory, including imaging of the occlusive lesion, as well as arterial inflow and outflow with angiography or a combination of angiography and noninvasive vascular techniques.	B	Class I
Digital subtraction angiography is recommended for contrast angiographic studies because this technique allows for enhanced imaging capabilities compared with conventional unsubtracted contrast angiography.	A	Class I
Before performance of contrast angiography, a full history and complete vascular examination should be performed to optimize decisions regarding the access site, as well as to minimize contrast dose and catheter manipulation.	C	Class I
Selective or super selective catheter placement during lower extremity angiography is indicated because this can enhance imaging, reduce contrast dose, and improve sensitivity and specificity of the procedure.	C	Class I
The diagnostic lower extremity arteriogram should image the iliac, femoral, and tibial bifurcations in profile without vessel overlap	B	Class I

Recommendation	Level of Evidence	Grade/Strength of Recommendation
When conducting a diagnostic lower extremity arteriogram in which the significance of an obstructive lesion is ambiguous, transstenotic pressure gradients and supplementary angulated views should be obtained	B	Class I
Patients with baseline renal insufficiency should receive hydration before undergoing contrast angiography.	B	Class I
Follow-up clinical evaluation, including a physical examination and measurement of renal function, is recommended within 2 weeks after contrast angiography to detect the presence of delayed adverse effects, such as atheroembolism, deterioration in renal function, or access site injury (e.g., pseudoaneurysm or arteriovenous fistula).	C	Class I
Noninvasive imaging modalities, including MRA, CTA, and color flow duplex imaging, may be used in advance of invasive imaging to develop an individualized diagnostic strategic plan, including assistance in selection of access sites, identification of significant lesions, and determination of the need for invasive evaluation.	B	Class IIa
Treatment with n-acetylcysteine in advance of contrast angiography is suggested for patients with baseline renal insufficiency (creatinine >2.0 mg per dL).	B	Class IIa
1999 ACC/AHA Guidelines for Coronary Angiography		
Recommendations for Coronary Angiography in Patients with Known or Suspected CAD Who Are Currently Asymptomatic or Have Stable Angia[51]		
CCS class III and IV angina on medical treatment.	B	Class I
High-risk criteria on noninvasive testing regardless of anginal severity	A	Class I
Patients who have been successfully resuscitated from sudden cardiac death or have sustained (>30 seconds) monomorphic ventricular tachycardia or non-sustained (<30 seconds) polymorphic ventricular tachycardia.	B	Class I
CCS class III or IV angina, which improves to class I or II with medical therapy.	C	Class IIa
Serial noninvasive testing with identical testing protocols, at the same level of medical therapy, showing progressively worsening abnormalities.	C	Class IIa
Patients with angina and suspected coronary disease who, due to disability, illness, or physical challenge, cannot be adequately risk stratified by other means.	C	Class IIa
CCS class I or II angina with intolerance to adequate medical therapy or with failure to respond, or patients who have recurrence of symptoms during adequate medical therapy as defined above.	C	Class IIa
Individuals whose occupation involves the safety of others (e.g., pilots, bus drivers, etc.) who have abnormal but not high-risk stress test results or multiple clinical features that suggest high risk.	C	Class IIa
CCS class I or II angina with demonstrable ischemia but no high-risk criteria on noninvasive testing.	C	Class IIb

Recommendation	Level of Evidence	Grade/Strength of Recommendation
symptomatic man or postmenopausal woman without known coronary heart disease with ≥2 major clinical risk factors and abnormal but not high-risk criteria on noninvasive testing (performed for indications stated in the ACC/AHA noninvasive testing guidelines).	C	Class IIb
Asymptomatic patients with prior MI with normal resting left ventricular function and ischemia on noninvasive testing but without high-risk criteria.	C	Class IIb
Periodic evaluation after cardiac transplantation.	C	Class IIb
Candidate for liver, lung, or renal transplant ≥40 years old as part of evaluation for transplantation.	C	Class IIb
Angina in patients who prefer to avoid revascularization even though it might be appropriate.	C	Class III
Angina in patients who are not candidates for coronary revascularization or in whom revascularization is not likely to improve quality or duration of life.	C	Class III
As a screening test for CAD in asymptomatic patients.	C	Class III
After coronary artery bypass grafting (CABG) or angioplasty when there is no evidence of ischemia on noninvasive testing, unless there is informed consent for research purposes.	C	Class III
Coronary calcification on fluoroscopy, electron beam computed tomography, or other screening tests without criteria listed above.	C	Class III
Recommendations for Coronary Angiography in Unstable Coronary Syndromes		
High or intermediate risk for adverse outcome in patients with unstable angina refractory to initial adequate medical therapy, or recurrent symptoms after initial stabilization. Emergent catheterization is recommended.	B	Class I
High risk for adverse outcome in patients with unstable angina. Urgent catheterization is recommended.	B	Class I
High- or intermediate-risk unstable angina that stabilizes after initial treatment.	A	Class I
Initially low short-term–risk unstable angina that is subsequently high risk on noninvasive testing.	B	Class I
Suspected Prinzmetal variant angina.	B	Class I
Low short-term–risk unstable angina, without high-risk criteria on noninvasive testing.	C	Class IIb
Recurrent chest discomfort suggestive of unstable angina but without objective signs of ischemia and with a normal coronary angiogram during the past 5 years.	C	Class III
Unstable angina in patients who are not candidates for coronary revascularization or in patients for whom coronary revascularization will not improve the quality or duration of life.	C	Class III

Abbreviations: AAA = abdominal aorta aneurysm; CABG = coronary artery bypass grafting; CAD = coronary artery disease; CAS = carotid artery stenting; CCS = Canadian Cardiovascular Society; CEA = carotid endarterectomy; CLI = critical limb ischemia; CLTI = chronic limb-threatening ischemia; CTA = computed tomography angiography; DUS =

Recommendation	Level of Evidence	Grade/Strength of Recommendation

duplex ultrasound; GDMT = guideline-directed management and therapy; LEAD = lower extremity artery disease; MI = myocardial infarction; MRA = magnetic resonance angiography; PAD = peripheral artery disease

6.5 Professional Guidelines and Recommendations

Clinical practice guidelines and consensus statements issued by the following professional societies were reviewed to inform on management of peripheral vascular and coronary disease as well as cardiac abnormalities.

- 2017 European Society of Cardiology (ESC) Guidelines on the Diagnosis and Treatment of Peripheral Arterial Diseases, in collaboration with the European Society for Vascular Surgery (ESVS)[50]
- 2016 American College of Cardiology/American Heart Association (ACC/AHA) Guidelines on the Management of Patients with Lower Extremity Peripheral Artery Disease[30]
- Management of Patients With Peripheral Artery Disease (Compilation of 2005 and 2011 American College of Cardiology Foundation/American Heart Association [ACCF/AHA] Guideline Recommendations)[25]
- 1999 ACC/AHA Guidelines for Coronary Angiography: Executive Summary and Recommendations[51]

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 angiography procedures relevant to peripheral vascular and coronary disease as well as cardiac abnormalities.

The 1999 ACC/AHA Guidelines for Coronary Angiography and ACCF/AHA guidelines on the Management of Patients With Peripheral Artery Disease (Compilation of 2005 and 2011) use LOE A, B, and C and classifications of Class I, II, and III which are summarized below:

Level of Evidence A: The presence of multiple randomized clinical trials.

Level of Evidence B: The presence of a single randomized trial or nonrandomized studies.

Level of Evidence C: Expert consensus.

Class I: Conditions for which there is evidence and/or general agreement that this procedure is useful and effective.

Class II: Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of performing the 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: Conditions for which there is evidence and/or general agreement that the procedure is not useful/effective and in some cases may be harmful.

The 2016 ACC/AHA Guidelines on Management of Patients with Lower Extremity Peripheral Artery Disease utilize a LOE and/or class (strength) of recommendation grading system shown in Figure 2[30,51] and Figure 3.[30,51] The 2017 ESC Guidelines on the Diagnosis and Treatment of Peripheral Arterial Diseases utilize a LOE and/or class (strength) of recommendation grading system described in Figure 4 and Figure 5. These guidelines inform on appropriate and relevant safety and performance measures for the target therapy and alternative therapies.

Figure 2. ACC/AHA Levels of Evidence[30]

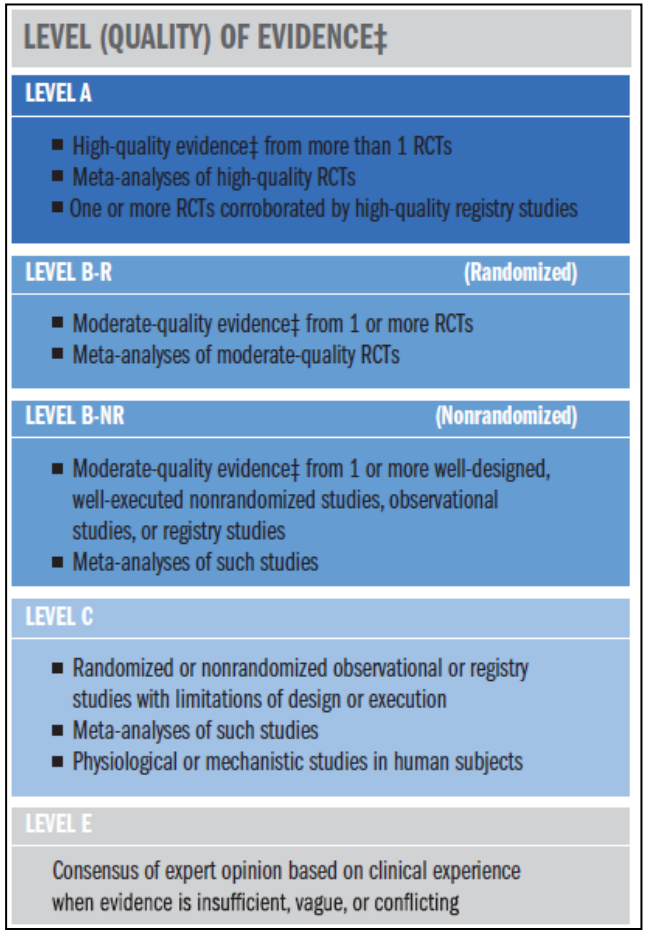


Figure 3. AHA/ACC Classes of Recommendation[30]

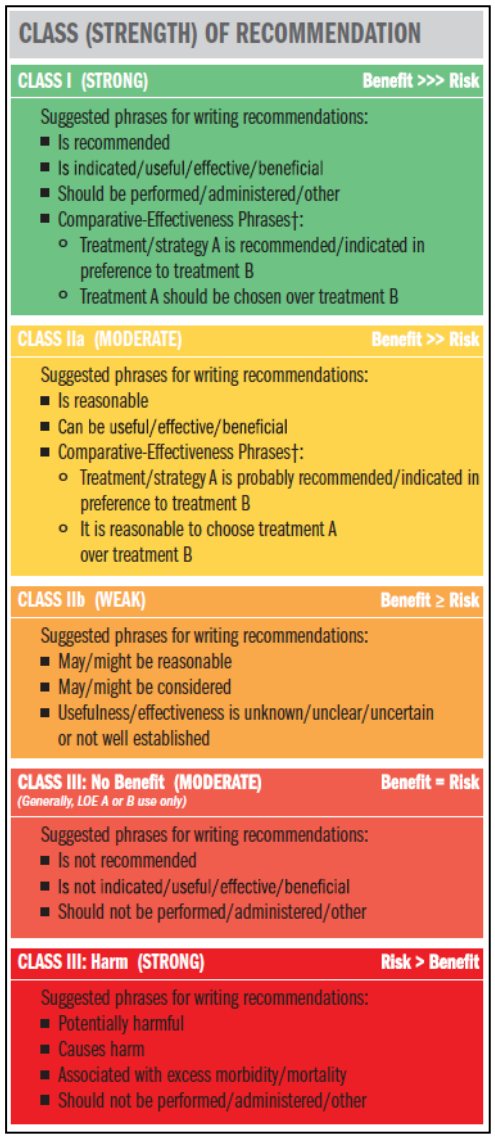


Figure 4. ESC Levels of Evidence[50]

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

Figure 5. ESC Classes of Recommendation[50]

Classes of recommendations	Definition	Suggested wording to use
Class I	**Evidence and/or general agreement that a given treatment or procedure is beneficial, useful, effective.**	**Is recommended/is indicated**
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 favour of usefulness/efficacy.***	**Should be considered**
Class IIb	***Usefulness/efficacy is less well established by evidence/opinion.***	**May be considered**
Class III	**Evidence or general agreement that the given treatment or procedure is not useful/effective, and in some cases may be harmful.**	**Is not recommended**

7.0 Suggested profile and training for users

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 Impress Angiographic Catheter Family:

Table 21 Applicable Standards

Standard #	Title	Impress Angiographic Catheter Family – all variants	Gen 2 Impress Catheter Family – all variants
General			
ISO 10993	Biological Evaluation of Medical Devices	x	
Product Specific Standards			
IEC 62366-1:2015	Medical Devices – Application of usability engineering to medical devices	x	
ISO 80369-7:2016	Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications		x
EN 10555-1:2013	Intravascular Catheters - Sterile and Single-Use Catheters Part 1: General requirements *Partial compliance is claimed. Applicable sections: 4.1, 4.2, 4.3, 4.4, 4.6, 4.7, 4.8, 4.9, 4.10, 4.11, 4.12*	x	

All of these standards and guidelines have been applied in full where applicable to the Impress Angiographic Catheter Family.

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10.0 Revision History

SSCP Revision	ECN Number	Date Issued DD/MM/YYYY	Change Description	SSCP Author	Revision Validated by the Notified Body
REV 001	ECN164629	11/05/2023	Initial SSCP for the Impress Angiographic Catheter Family	Aly Jimenez	☒ Yes Validation language: English ☐ No