Summary of Safety and Clinical Performance (SSCP)

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an up-to-date summary of the main aspects of the safety and clinical performance of the Merit Medical InQwire® Diagnostic Guide Wire. This device family will be referred to hereafter under the descriptor IQ Diagnostic Guide Wire.

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

The following information is intended for users/healthcare professionals. A supplemental SSCP with information for patients was not established since the IQ Diagnostic Guide Wire is not an implantable device for which patients are provided an implant card, nor is the device intended to be used directly by patients.

The English version of this SSCP document (SSCP0072_004) has been validated by the notified body (#2797).

1.0 Device identification and general information

1.1 Device trade name(s):

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

Table 1. Devices Included in this SSCP

Item		Description
Product Name: IQ Diagnostic Guide Wire		
IQ35F80B/EU	IQ35F80J1O5RS/EU	• Diameter: 0.035” or 0.038” • Core Wire: Fixed • Length: 80-260cm • Core Wire Distal Tip Configuration ○ Straight Configurations: Straight (S), Bentson (B), Bentson C (BC), Bentson Short Taper (BST), Newton Long Taper (NLT),
IQ35F80J3/EU	MDR-IQ35F80J3S/EU	
IQ35F100J15/EU	MDR-IQ35F80J3SHD/EU	
IQ35F150BC/EU	IQ35F150B/EU	
IQ35F150J15/EU	IQ35F150BST/EU	
IQ35F150J1O5RS/EU	IQ35F150J1O5/EU	
IQ35F150J3/EU	IQ35F150J1O5S/EU	

Item		Description
IQ35F150J3S/EU	IQ35F150J3F/EU	Newton Long Long Taper (NLLT), Newton Long Long Long Taper (NLLLT) • Curved Configurations: ○ J-tip (J) ○ J-tip Rosen (RS) • Curved and Straight Double-Ended Configuration: ○ J-tip (J)/Straight (S) • Distal J-Tip Radius Size:1.5-15mm • Wire Body: ○ Standard ○ Firm(F) ○ Heavy Duty (HD)
IQ35F150J6/EU	IQ35F150J3SHD/EU	
IQ35F150NLT/EU	IQ35F150NLLT/EU	
IQ35F180B/EU	IQ35F150S/EU	
IQ35F180BST/EU	IQ35F180BC/EU	
IQ35F180J1O5/EU	IQ35F180J15/EU	
IQ35F180J3/EU	IQ35F180J1O5RS/EU	
IQ35F180J3S/EU	IQ35F180J3F/EU	
IQ35F210J1O5/EU	IQ35F180J6F/EU	
IQ35F210J3/EU	IQ35F210J1O5F/EU	
IQ35F260B/EU	IQ35F220J3/EU	
IQ35F260J1O5/EU	IQ35F260BST/EU	
IQ35F260J1O5RS/EU	IQ35F260J1O5F/EU	
IQ35F260J3S/EU	IQ35F260J3/EU	
IQ38F80J3/EU	IQ35F260S/EU	
MDR-IQ38F150BC/EU	IQ38F150B/EU	
IQ38F150J3/EU	IQ38F150J15/EU	
IQ38F150J6/EU	IQ38F150J3F/EU	
IQ38F180J3F/EU	IQ38F150S/EU	
IQ38F260J3/EU	IQ38F180J6F/EU	
IQ35F150J3K/EU	IQ38F260S/EU	
IQ35F150J1O5K/EU	IQ35F150J3SK/EU	
IQ35F180J3K/EU	IQ35F150J1O5RSK/EU	
IQ35F210J3K/EU	IQ35F180BK/EU	
IQ38F150J6K/EU	IQ35F260J3K/EU	

1.2 Manufacturer Information

The name and address of the manufacturer of the IQ Diagnostic Guide Wire are provided in Table 2.

Table 2. Manufacturer Information

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

1.3 Manufacturer Single Registration Number (SRN)

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

1.4 Basic UDI-DI

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

1.5 Medical Device Nomenclature Description / Text

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

1.6 Risk Class of Device

The EU device risk classification(s) for the IQ Diagnostic Guide Wire 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
IQ Diagnostic Guide Wire	III	Per Table 1	088445048407DF	US-MF-000001366	C04020102	PERIPHERAL VASCULAR GUIDEWIRES, DIAGNOSTIC, NOT HYDROPHILIC

1.7 Year of EU Market Introduction

The year that the IQ Diagnostic Guide Wire 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 IQ Diagnostic Guide Wire 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
IQ Diagnostic Guide Wire	2000	Merit Medical Ireland Ltd.	IE-AR-000001011	BSI	2797

2.0 Intended Use of the Device

2.1 Intended Purpose

The Merit InQwire Diagnostic Guide Wire is used to facilitate the placement of devices during diagnostic and interventional procedures.

2.2 Indication(s) and Intended Patient Groups

INDICATIONS

The Merit InQwire Diagnostic Guide Wire is indicated for use in patients with disease and/or lesions of the peripheral vasculature or central circulatory system, excluding coronary arteries and cerebral vasculature.

INTENDED PATIENT GROUP/PATIENT POPULATION

The InQwire Diagnostic Guide Wires are designed for use during diagnostic and interventional procedures by physicians trained in diagnostic and interventional radiology, cardiology, nephrology, and vascular surgery procedures. Using their education and experience, the physician determines based on the individual patient, the appropriate guide wire to support the associated device(s) to be used during the procedure. The guide wire navigates the anatomy and facilitates placement of the associated device(s).

2.3 Contraindications:

The Merit InQwire Diagnostic Guide Wire is contraindicated for use in the coronary arteries and cerebral vasculature.

3.0 Device Description

3.1 Materials/Substances in Contact with Patient Tissues

The IQ Diagnostic Guide Wire is used to facilitate the placement of devices during diagnostic and interventional procedures. The IQ Diagnostic Guide Wire has a continuous polytetrafluoroethylene (PTFE)-coated coil, with an internal core wire and a safety wire. The core wire is fixed at the proximal end only and extends to a specified distance from the distal end. The distal segment of the core wire has a profiled taper. The core wire enhances the stiffness of the guidewire. The safety wire extends the full length of the guidewire and is welded at both the distal and proximal end. The safety wire is designed to provide strength and integrity and ensures that the guidewire components remain together. The materials of construction are identified in Table 5.

Table 5. Materials of Construction - IQ Diagnostic Guide Wire

Component	Material Specification
Core Wire	304V or 304V SLT Stainless Steel
Wire Coil	304 Stainless Steel with Polytetrafluoroethylene (PTFE – PFOA Free) Coating
Safety Wire	304V Stainless Steel

Abbreviations: PFOA = perfluorooctanoic acid, PTFE = polytetrafluoroethylene

IQ Diagnostic Guide Wires are offered in 0.035-in or 0.038-in outer diameter with different tip configurations (straight or J-tip), single ended or double ended (either end of the wire can be placed into the patient), standard, firm or heavy-duty shaft, and are available in lengths from 80 cm to 260 cm. The IQ Diagnostic Guide Wire is sold in stand-alone configurations or kitted with other devices. Please refer to the following Figure 1 and Figure 2.

Figure 1. IQ Diagnostic Guide Wire Structural Features

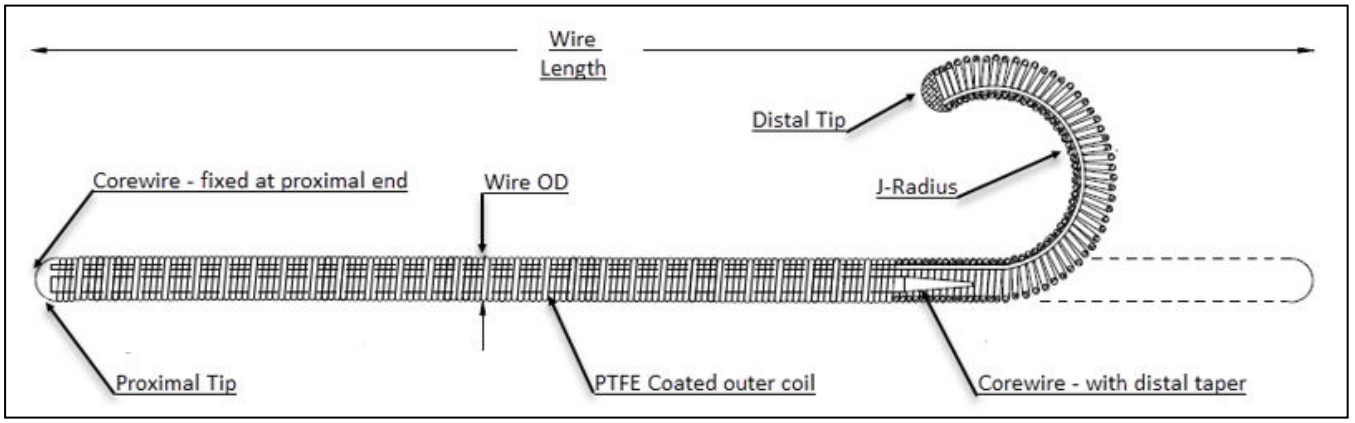

Figure 2. IQ Diagnostic Guide Wire – Representative Image

The IQ Diagnostic Guide Wire is packaged as sterile, single-use devices. The guide wire is placed inside a dispenser hoop with its distal end exiting the flush port on the inner side of the dispenser hoop (Figure 3). A J-tip straightener (Figure 4) is placed on the distal end of the guide wire to hold it in the dispenser hoop. The hooped guide wire assembly is sealed in a pouch. The pouch is packaged with an IFU in a carton. Merit utilizes ethylene oxide (EtO) sterilization for the IQ Diagnostic Guide Wire.

Figure 3. IQ Diagnostic Guide Wires in the Dispenser Hoop Packaging

Figure 4. J-tip Straightener

3.2 Operating Principles

The IQ Diagnostic Guide Wire is placed through a percutaneous sheath and advanced to the desired location according to the planned procedure by clinicians. It is used to facilitate the placement of devices during diagnostic and interventional procedures. Verification of guidewire placement is typically accomplished with fluoroscopy. The guide wire's ability to be guided through the vasculature to the desired location is provided by its

material properties and the procedural experience and skill of the clinician using the device. The guide wire acts as a thin, maneuverable, element over which a device may be advanced and positioned.

The IQ Diagnostic Guide Wire is commonly used in clinical practice over a wide range of specialties including interventional radiology. Guide wires are employed during procedures that require use of the Seldinger or modified Seldinger technique to place catheters and other devices in the vasculature.[1, 2]. The technique is performed in either of two ways the single or classical method or double puncture method. A needle is inserted though one wall of the vessel (single method) until 'flashback' is obtained; the needle is thus used to insert a guidewire which is advanced a short way up the vessel lumen. The needle can then be removed, and a dilator passed over the guidewire to allow a catheter to be advanced. At this stage the guidewire can either be left in situ or more often removed.[3] With the double puncture method, the needle is passed through both walls of the structure to obtain flashback. In recent years, many specialties have adopted this technique and applied it for their own purposes.

The IQ Diagnostic Guide Wire is placed through a percutaneous device which may be filled with heparinized saline solution to facilitate advancement of the wire through the vasculature. The guidewire is removed from the dispenser and inserted into the device and advanced to the desired location according to the planned procedure by clinicians.

The general operational steps associated with procedural use of the devices in the IQ Diagnostic Guide Wire are summarized in Table 6.

Table 6. Principles of Operation: IQ Diagnostic Guide Wire

Procedure	Operational Steps
Preparation	• Flush the hoop with saline prior to use. • In order to reduce the potential of clot formation, it is recommended that the guidewire be flushed with saline or heparinized saline prior to use.
Percutaneous delivery utilizing the Seldinger technique	• Advance the J-Tip Straightener into the hub of the intended catheter/device and remove the J-Tip Straightener. • Direct the wire into the hub and through needle. Remove J-Tip Straightener. • Remove needle cannula leaving the guidewire within the lumen of the vessel.

Dimensional and structural details of each IQ Diagnostic Guide Wire product code are provided in Table 7.

Table 7. . IQ Diagnostic Guide Wire Device Configurations

Catalog Code	Outer Diameter	Length	Distal Tip Configuration	Wire Body	Core	Configuration
Carton Shippers						
IQ35F80B/EU	0.035" (0.89 mm)	80 cm (31.5")	Straight Tip.Bentson (23 cm)	Standard	Fixed	10 per Carton
IQ35F80J1O5RS/EU	0.035" (0.89 mm)	80 cm (31.5")	1.5 mm J-Tip.Rosen	Standard	Fixed	10 per Carton
IQ35F80J3/EU	0.035" (0.89 mm)	80 cm (31.5")	3 mm J-Tip	Standard	Fixed	10 per Carton
MDR-IQ35F80J3S/EU	0.035" (0.89 mm)	80 cm (31.5")	3 mm J-Tip/Straight, Double-Ended	Standard	Fixed	10 per Carton
MDR-IQ35F80J3SHD/EU	0.035" (0.89 mm)	80 cm (31.5")	3 mm J-Tip/Straight, Double-Ended	Heavy Duty	Fixed	10 per Carton
IQ35F100J15/EU	0.035" (0.89 mm)	100 cm (39.4")	15 mm J-Tip	Standard	Fixed	10 per Carton
IQ35F150B/EU	0.035" (0.89 mm)	150 cm (59")	Straight Tip Bentson (23 cm)	Standard	Fixed	10 per Carton
IQ35F150BC/EU	0.035" (0.89 mm)	150 cm (59")	Straight Tip Bentson C (15 cm)	Standard	Fixed	10 per Carton
IQ35F150BST/EU	0.035" (0.89 mm)	150 cm (59")	Straight Tip Bentson ST (10 cm)	Standard	Fixed	10 per Carton
IQ35F150J15/EU	0.035" (0.89 mm)	150 cm (59")	15 mm J-Tip	Standard	Fixed	10 per Carton
IQ35F150J1O5/EU	0.035" (0.89 mm)	150 cm (59")	1.5 mm J-Tip	Standard	Fixed	10 per Carton
IQ35F150J1O5RS/EU	0.035" (0.89 mm)	150 cm (59")	1.5 mm J-Tip Rosen	Standard	Fixed	10 per Carton
IQ35F150J1O5S/EU	0.035" (0.89 mm)	150 cm (59")	1.5 mm J-Tip/Straight, Double-Ended	Standard	Fixed	10 per Carton
IQ35F150J3/EU	0.035" (0.89 mm)	150 cm (59")	3 mm J-Tip	Standard	Fixed	10 per Carton
IQ35F150J3F/EU	0.035" (0.89 mm)	150 cm (59")	3 mm J-Tip	Firm	Fixed	10 per Carton
IQ35F150J3S/EU	0.035" (0.89 mm)	150 cm (59")	3 mm J-Tip/Straight, Double-Ended	Standard	Fixed	10 per Carton
IQ35F150J3SHD/EU	0.035" (0.89 mm)	150 cm (59")	3 mm J-Tip/ Straight, Double-Ended	Heavy Duty	Fixed	10 per Carton
IQ35F150J6/EU	0.035" (0.89 mm)	150 cm (59")	6 mm J-Tip	Standard	Fixed	10 per Carton
IQ35F150NLLT/EU	0.035" (0.89 mm)	150 cm (59")	Straight Tip Newton LLT (18.5 cm)	Standard	Fixed	10 per Carton
IQ35F150NLT/EU	0.035" (0.89 mm)	150 cm (59")	Straight Tip Newton LT (13.5 cm)	Standard	Fixed	10 per Carton
IQ35F150S/EU	0.035" (0.89 mm)	150 cm (59")	Straight Tip	Standard	Fixed	10 per Carton
IQ35F180B/EU	0.035" (0.89 mm)	180 cm (71")	Straight Tip Bentson (23 cm)	Standard	Fixed	10 per Carton
IQ35F180BC/EU	0.035" (0.89 mm)	180 cm (71")	Straight Tip Bentson C (15 cm)	Standard	Fixed	10 per Carton
IQ35F180BST/EU	0.035" (0.89 mm)	180 cm (71")	Straight Tip Bentson ST (10 cm)	Standard	Fixed	10 per Carton
IQ35F180J15/EU	0.035" (0.89 mm)	180 cm (71")	15 mm J-Tip	Standard	Fixed	10 per Carton

Catalog Code	Outer Diameter	Length	Distal Tip Configuration	Wire Body	Core	Configuration
Carton Shippers						
IQ35F180J1O5/EU	0.035" (0.89 mm)	180 cm (71")	1.5 mm J-Tip	Standard	Fixed	10 per Carton
IQ35F180J1O5RS/EU	0.035" (0.89 mm)	180 cm (71")	1.5 mm J-Tip Rosen	Standard	Fixed	10 per Carton
IQ35F180J3/EU	0.035" (0.89 mm)	180 cm (71")	3 mm J-Tip	Standard	Fixed	10 per Carton
IQ35F180J3F/EU	0.035" (0.89 mm)	180 cm (71")	3 mm J-Tip	Firm	Fixed	10 per Carton
IQ35F180J3S/EU	0.035" (0.89 mm)	180 cm (71")	3 mm J-Tip/Straight, Double-Ended	Standard	Fixed	10 per Carton
IQ35F180J6F/EU	0.035" (0.89 mm)	180 cm (71")	6 mm J-Tip	Firm	Fixed	10 per Carton
IQ35F210J1O5/EU	0.035" (0.89 mm)	210 cm (83")	1.5 mm J-Tip	Standard	Fixed	10 per Carton
IQ35F210J1O5F/EU	0.035" (0.89 mm)	210 cm (83")	1.5 mm J-Tip	Firm	Fixed	10 per Carton
IQ35F210J3/EU	0.035" (0.89 mm)	210 cm (83")	3 mm J-Tip	Standard	Fixed	10 per Carton
IQ35F220J3/EU	0.035" (0.89 mm)	220 cm (87")	3 mm J-Tip	Standard	Fixed	10 per Carton
IQ35F260B/EU	0.035" (0.89 mm)	260 cm (102")	Straight Tip Bentson (23 cm)	Standard	Fixed	10 per Carton
IQ35F260BST/EU	0.035" (0.89 mm)	260 cm (102")	Straight Tip Bentson ST (10 cm)	Standard	Fixed	10 per Carton
IQ35F260J1O5/EU	0.035" (0.89 mm)	260 cm (102")	1.5 mm J-Tip	Standard	Fixed	10 per Carton
IQ35F260J1O5F/EU	0.035" (0.89 mm)	260 cm (102")	1.5 mm J-Tip	Firm	Fixed	10 per Carton
IQ35F260J1O5RS/EU	0.035" (0.89 mm)	260 cm (102")	1.5 mm J-Tip Rosen	Standard	Fixed	10 per Carton
IQ35F260J3/EU	0.035" (0.89 mm)	260 cm (102")	3 mm J-Tip	Standard	Fixed	10 per Carton
IQ35F260J3S/EU	0.035" (0.89 mm)	260 cm (102")	3 mm J-Tip/Straight, Double-Ended	Standard	Fixed	10 per Carton
IQ35F260S/EU	0.035" (0.89 mm)	260 cm (102")	Straight Tip	Standard	Fixed	10 per Carton
IQ38F80J3/EU	0.038" (0.97 mm)	80 cm (31.5")	3 mm J-Tip	Standard	Fixed	10 per Carton
IQ38F150B/EU	0.038" (0.97 mm)	150 cm (59")	Straight Tip Bentson (23 cm)	Standard	Fixed	10 per Carton
MDR-IQ38F150BC/EU	0.038" (0.97 mm)	150 cm (59")	Straight Tip Bentson C (15 cm)	Standard	Fixed	10 per Carton
IQ38F150J15/EU	0.038" (0.97 mm)	150 cm (59")	15 mm J-Tip	Standard	Fixed	10 per Carton
IQ38F150J3/EU	0.038" (0.97 mm)	150 cm (59")	3 mm J-Tip	Standard	Fixed	10 per Carton
IQ38F150J3F/EU	0.038" (0.97 mm)	150 cm (59")	3 mm J-Tip	Firm	Fixed	10 per Carton
IQ38F150J6/EU	0.038" (0.97 mm)	150 cm (59")	6 mm J-Tip	Standard	Fixed	10 per Carton
IQ38F150S/EU	0.038" (0.97 mm)	150 cm (59")	Straight Tip	Standard	Fixed	10 per Carton

Catalog Code	Outer Diameter	Length	Distal Tip Configuration	Wire Body	Core	Configuration
Carton Shippers						
IQ38F180J3F/EU	0.038" (0.97 mm)	180 cm (71")	3 mm J-Tip	Firm	Fixed	10 per Carton
IQ38F180J6F/EU	0.038" (0.97 mm)	180 cm (71")	6 mm J-Tip	Firm	Fixed	10 per Carton
IQ38F260J3/EU	0.038" (0.97 mm)	260 cm (102")	3 mm J-Tip	Standard	Fixed	10 per Carton
IQ38F260S/EU	0.038" (0.97 mm)	260 cm (102")	Straight Tip	Standard	Fixed	10 per Carton
Multipack Units						
IQ35F150J3K/EU	0.035" (0.89 mm)	150 cm (59")	3 mm J-Tip	Standard	Fixed	Multipack Unit
IQ35F150J3SK/EU	0.035" (0.89 mm)	150 cm (59")	3 mm J-Tip/Straight, Double-Ended	Standard	Fixed	Multipack Unit
IQ35F150J1O5K/EU	0.035" (0.89 mm)	150 cm (59")	1.5 mm J-Tip	Standard	Fixed	Multipack Unit
IQ35F150J1O5RSK/EU	0.035" (0.89 mm)	150 cm (59")	1.5 mm J-Tip Rosen	Standard	Fixed	Multipack Unit
IQ35F180J3K/EU	0.035" (0.89 mm)	180 cm (71")	3 mm J-Tip	Standard	Fixed	Multipack Unit
IQ35F180BK/EU	0.035" (0.89 mm)	180 cm (71")	Straight Tip Bentson (23 cm)	Standard	Fixed	Multipack Unit
IQ35F210J3K/EU	0.035" (0.89 mm)	210 cm (83")	3 mm J-Tip	Standard	Fixed	Multipack Unit
IQ35F260J3K/EU	0.035" (0.89 mm)	260 cm (102")	3 mm J-Tip	Standard	Fixed	Multipack Unit
IQ38F150J6K/EU	0.038" (0.97 mm)	150 cm (59")	6 mm J-Tip	Standard	Fixed	Multipack Unit

A biocompatibility assessment has been completed for the IQ Diagnostic Guide Wire, and biocompatibility testing was performed according to recommendations set forth in the ISO 10993 *Biological Evaluation of Medical Devices* series standards. The tissue contact categorizations for the IQ Diagnostic Guide Wire are summarized in Table 8.

Table 8. Tissue Contact Categorization: IQ Diagnostic Guide Wire

Device	Categorization
IQ Diagnostic Guide Wires	Externally communicating, Circulating Blood Limited contact duration (< 24 hours)

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

The IQ Diagnostic Guide Wire is marketed globally. The original 510(k) premarket notification was submitted by Universal Medical Instrument (UMI) Corporation (K822586), and Merit Medical Systems Inc. acquired the rights to the technology, manufacturing, and marketing of Teflon-

coated guidewires from UMI in 1997. Merit first obtained CE-Marking for the IQ Diagnostic Guide Wire in 2000. On 30 March 2010, the Merit IQ Diagnostic Guide Wire was reclassified from Class IIa to Class III per 2007/47/EC, under CE 560101. IQ Diagnostic Guidewires were originally cleared under Premarket Notification 510(k) K002289, in October 2000, for distribution in the US. A subsequent submission to FDA for a modification to a PFOA-free PTFE coating was cleared by the FDA under Premarket Notification 510(k) K133230 on December 12, 2013. A history of the generations of the IQ Diagnostic Guide Wire is summarized in Table 9. Please note that the terms 'configuration' and 'established configuration' are used throughout this document. These terms are intended to have the same meaning as the term 'variant'.

Table 9. History of Generations - IQ Diagnostic Guide Wire

Generations	Change/Difference	Reason for Change/Difference	Date of Implementation	Basic UDI-DI
Directive 93/42/EEC (MDD)				
Base Catalog Code (e.g., IQ35F80B)	N/A	Original CE Mark under MDD	2000	N/A
Revision A Catalog Code (e.g., IQ35F80B/A)	1. LDPE J-Straightener replaced with HDPE J-Straightener 2. Ribbon Wire component reduction in dimensions	Product Improvement	2010	N/A
Revision B Catalog Code (e.g., IQ35F80B/B)	PTFE coating with reduced PFOA per US EPA 2010/2015 PFOA Stewardship Program	Change made in response to the US EPA PFOA Stewardship Program	2012	N/A
Regulation (EU) 2017/745 (MDR)				
Revision EU Catalog Code (e.g., IQ35F80B/EU)	MDR compliant labelling	To provide traceability to MDR product	Pending	088445048407DF

Abbreviations: HDPE = High Density Polyethylene, LDPE = Low Density Polyethylene, PFOA = Perfluorooctanoic acid, TFE = Polytetrafluoroethylene, US EPA = United States Environmental Protection Agency

All product codes in Table 7 are established configurations within the IQ Diagnostic Guide Wire product family.

3.4 Accessories (if applicable):

The IQ Diagnostic Guide Wire does not include or require an 'accessory for a medical device' as defined by the MDR.

3.5 Devices Used in Combination (if applicable)

There are no other devices and products intended to be used in combination with the IQ Diagnostic Guide Wire, other than generic surgical equipment and/or other generic devices such as catheters and sheaths.

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 IQ Diagnostic Guide Wire 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 are identified based on a review of the pertinent clinical evidence.

Intended clinical benefits:

CLINICAL BENEFITS

The InQwire Diagnostic Guide Wire has indirect clinical benefits for the patient since it assists other medical devices in achieving their intended purpose, without having a direct therapeutic or diagnostic function itself. It is used to gain vascular access and for placement of compatible medical devices that have a direct therapeutic or diagnostic function.

The IQ Diagnostic Guide Wire is used to gain vascular access and for the delivery of medical devices. As part of a minimally invasive system, the guide wire helps deliver devices that aid in diagnosis and treatment planning.

Articles published between January 1, 2013 and December 31, 2021 were reviewed. Based on the literature, guidewires have been successfully used to facilitate placement of devices during diagnostic and interventional procedures. Guidewires are beneficial in that they facilitate interventional

catheter and device placement by preserving venous access once it is established, directing the catheter into its desired target location, and preventing vascular or cardiac perforation of the catheter tip.[4, 5] For the clinical evaluation, the performance outcomes were defined as follows:

- Technical success: Rate of successful placement of devices during diagnostic and interventional procedures

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

Technical success rates from the clinical literature and Post Market Clinical Follow-Up (PMCF) are very high. Overall, technical success rate was 100% for the IQ Diagnostic Guide Wire and 91.8% for the benchmark devices.

The potential complications/adverse events related to the subject device as identified in the Instructions For Use (IFU) are summarized in Table 10. In addition, the device/procedure-related events identified in the Literature, and the corresponding risk assessment harms are presented in Table 11.

Table 10. IQ Diagnostic Guide Wire: Potential Complications

Potential Complications
Potential complications which may result from the use of the device include but are not limited to: • Air Embolism/Thromboembolism • Allergic Reaction • Amputation • Arteriovenous (AV) Fistula • Breathing difficulty • Cardiac arrythmia • Embolism • Hematoma • Haemorrhage • Infection or Sepsis/Infection • Myocardial ischemia or infarction • Pseudoaneurysm • Stroke (CVA)/Transient Ischemic Attacks (TIA) • Thrombus • Vessel Occlusion • Vessel Perforation • Vessel Dissection • Vessel Trauma or Damage • Vessel Spasm

Potential Complications
• Wire Entrapment/Entanglement • Foreign body/Wire Fracture Some of the stated potential adverse events may require additional surgical intervention.

Table 11. Adverse Events: Clinical Literature Data

Complications from the Clinical Literature Data	Device Related	Procedure Related	IFU Complications	Harms	Typical Timing
Sheared guidewire with/without embolization	X		Embolism Stroke (CVA)/Transient Ischemic Attack (TIA) Myocardial Infarction Cardiac Arrhythmia	• Foreign body, vascular • Procedure additional • Cardiac event	≤90 minutes
Fragmented guidewire/broken tip with/without embolization	X		Embolism Stroke (CVA)/Transient Ischemic Attack (TIA) Myocardial Infarction Cardiac Arrhythmia	• Soft tissue injury • Procedure delay • User dissatisfaction • Cardiac event	≤90 minutes
Intact guidewire embolization		X	Embolism Stroke (CVA)/Transient Ischemic Attack (TIA) Myocardial Infarction Cardiac Arrhythmia	• Foreign body, vascular • Cardiac event	≤90 minutes to 30 days
Coating embolization	X		Embolism Stroke (CVA)/Transient Ischemic Attack (TIA) Myocardial Infarction Cardiac Arrhythmia	• Foreign body, vascular • Procedure additional • Cardiac event	≤90 minutes to 30 days
Kink, buckle	X		Vessel Trauma or Damage	• Procedure delay	≤90 minutes

Complications from the Clinical Literature Data	Device Related	Procedure Related	IFU Complications	Harms	Typical Timing
				• Soft tissue injury	
Stretched coil (frayed guidewire)	X		Vessel Trauma or Damage	• Procedure delay • Soft tissue injury	≤90 minutes
Coiled, looped, or knotted guidewire	X		Thrombus	• Procedure delay • Thrombus	≤90 minutes
Entrapment in Inferior vena cava filters		X	Wire entrapment/ entanglement	• Procedure additional • Foreign body, vascular • Pulmonary event	≤90 minutes
Removal/insertion difficulties		X	Vessel Trauma or Damage Thromboembolism Embolism Stroke (CVA)/Transient Ischemic Attack (TIA) Myocardial Infarction Cardiac Arrhythmia	• Soft tissue injury • Foreign body vascular • Cardiac event	≤90 minutes
Vessel perforation & arterial puncture		X	Vessel Trauma or Damage Vessel Perforation Vessel Dissection	• Procedure delay • Soft tissue injury	≤90 minutes
Nerve trauma		X	N/A - not present in IFU This is a generic harm, similar to 'Pain'	• Soft tissue injury	≤90 minutes
Hemothorax		X	Breathing difficulty Hemorrhage Vessel perforation Additional surgical intervention	• Procedure delay • Foreign body vascular • Thrombus • Cardiac event	≤90 minutes

Complications from the Clinical Literature Data	Device Related	Procedure Related	IFU Complications	Harms	Typical Timing
				• Procedure additional	
Pneumothorax		X	Difficulty Breathing Additional surgical intervention	• Procedure additional	≤90 minutes
Thrombotic complications		X	Embolism Thrombus Vessel Occlusion	• Foreign body vascular • Procedure additional • User dissatisfaction	≤90 minutes
Septic complications		X	Infection or Sepsis/Infection	• Infection • Inflammation • Biologic exposure	≤30 days
Subcutaneous hematoma		X	Hematoma Vessel Trauma or Damage	• Procedure delay • Soft tissue injury	≤90 minutes
Dislodgement		X	Embolism Thrombus	• Procedure additional • Foreign body vascular • Pulmonary event	≤90 minutes
Aortic Regurgitation		X	Cardiac arrhythmia Myocardial ischemia Wire entrapment/ entanglement Additional surgical intervention	• Cardiac event	≤90 minutes
Asystole		X	Myocardial Infarction Cardiac Arrhythmia	• Cardiac event	≤90 minutes

The IQ Diagnostic Guide Wire has been used with a high level of safety during endovascular procedures in patients. Based on the PMCF data, the

reported cumulative Adverse Event (AE) rate for the IQ Diagnostic Guide Wire is 1.5% (5/326). Safety data for the IQ Diagnostic Guide Wire from the PMCF, and for comparable benchmark guidewires from the clinical literature are summarized in Table 12. No clinical literature data were identified for the IQ Diagnostic Guide Wire. The overall cumulative AE rate for the comparable benchmark guidewires is 4.2% (7/165).

Table 12. Comparative Adverse Event Rates: IQ Diagnostic Guide Wire

Attribute	Subject Device	Benchmark Devices
Cumulative AE Rate	5/326 (1.5%)	7/165 (4.2%)

This assessment accounts for the various risk factors associated with the IQ Diagnostic Guide Wire. Given that the complication rates are low and generally transient in nature, patients are assumed to accept the risks associated with endovascular diagnostic or interventional procedures based on the probable benefits.

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

4.2 Warnings and Precautions

The labeled warnings and precautions for the IQ Diagnostic Guide Wire are summarized in Table 13.

Table 13. Warnings and Precautions

Category	Labeling Statements
Warnings	• The safety and effectiveness of the InQwire Diagnostic Guide Wire has not been established in the coronary arteries or in the cerebral vasculature • 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	• Angiography should be undertaken only by an experienced angiographer. • The guide wire will collect blood and other foreign material in its lumen; neither autoclaving nor ultrasonic cleaning will completely remove foreign material, therefore the guide wire is recommended for single-patient use.

Category	Labeling Statements
	• Inspect the guide wire prior to use. Do not use any unit if sterile packaging is unintentionally opened before use or damaged. • Employ an aseptic technique during removal from the package and during use. • The guide wire is secured in the hoop dispenser by the locking J-tip straightener. To avoid damaging the guide wire during removal from the flush hoop, grasp the J-tip straightener near the base and slide it forward approximately 5mm or until the J-tip straightener is no longer attached to the flush hoop adaptor. Holding both the guide wire and J-tip straightener, continue to dispense guide wire from the hoop. • Do not use excessive force to advance the guide wire while the guide wire is in a vessel. Advancement with excessive force may cause coil penetration and vessel damage. Never push, auger, or withdraw a guide wire which meets resistance as this could potentially affect other indwelling devices. • Avoid withdrawing the PTFE coated guide wire back through a metal needle. The sharp edge of the needle may scrape the coating. It is suggested that a catheter or PTFE vessel dilator replace the needle as soon as the guide wire has reached the appropriate position. • During advancement of the catheter and guide wire within the aorta, it is recommended that the guide wire be removed at the appropriate level of the aorta. • Care should be taken when manipulating a catheter during placement and withdrawal to prevent possible intravascular tissue damage. If resistance is felt during advancement, manipulation, or removal from the catheter, stop immediately and confirm the guide wire tip position under fluoroscopy. • Note proximity of other potential indwelling devices within the patient's anatomy. Never push, auger, or withdraw a guide wire which meets resistance as this could potentially affect other indwelling devices. Resistance may be felt tactilely or noted by tip buckling during fluoroscopy. • A guide wire is a delicate instrument and remains the most fallible instrument used in a percutaneous procedure. Any time that a guide wire is used there is a possibility of thrombus formation/ emboli, vessel wall damage, and plaque dislodgement, which could result in myocardial infarction, cardiac arrhythmia or stroke. The physician should be familiar with the use of angiography products and the literature concerning the complications of angiography. • This device includes stainless-steel alloy components that contain Cobalt (EC No.: 231-158-0; CAS No.: 7440-48-4) defined as CMR 1B in a concentration above 0.1% weight by weight. • 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 Statement: 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.
Cautions	• Caution - Federal Law (USA) restricts this device to sale by or on the order of a physician.

4.3 Other Relevant Safety Aspects

There have been no field safety corrective actions or field notifications for the IQ Diagnostic Guide Wire.

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

5.1 Summary of Clinical Data for the Equivalent Device

The IQ Diagnostic Guide Wire has been commercialized for several years and has an established history of use. As an EU MDD and EU MDR Class III device, demonstration of equivalence to competitor devices is not permitted without access to the manufacturer technical file per MDR, Chapter VI, Article 61, Paragraph 5. Therefore, this evaluation is based on PMCF data currently available for the IQ Diagnostic Guide Wire.

5.2 Summary of Clinical Investigations of the Subject Device

Not applicable. There have been no pre-market or post-market clinical investigations performed for the IQ Diagnostic Guide Wire.

5.3 Summary of Clinical Data from Other Sources

The IQ Diagnostic Guide Wire has been used effectively for many years. Clinical data supporting the safety and performance of the IQ Diagnostic Guide Wire have been derived from the following sources:

- A post-market clinical follow-up (PMCF) study implemented in 2022 to collect patient-level survey data (high quality survey).
- An earlier post-market clinical data collection activity implemented in 2020 to collect clinician survey data (low quality survey).

Results from the high-quality patient-level PMCF surveys conducted in 2022 are summarized in Table 14.

Table 14. IQ Diagnostic Guide Wire – Patient Level (High Quality) PMCF Data Summary

Attribute	Count (n)	PMCF Reponses (N)	n/N (%)
Technical Success	318	326	318/326 (97.5)
Adverse Events	5	326	5/326 (1.5)

The IQ Diagnostic Guide Wire has been used with a high level of technical success during endovascular procedures in patients. Performance data for the IQ Diagnostic Guide Wire from the patient level (high quality) PMCF and for comparable benchmark guidewires are summarized in Table 15. Based on the patient level PMCF data, the reported technical success rate for the IQ Diagnostic Guide Wire is 97.5% (318/326). No clinical literature data were identified for the IQ Diagnostic Guide Wire. The overall technical success rate for the comparable benchmark guidewires is 91.8% (201/219). Comparing the technical success rates, the IQ Diagnostic Guide Wire met the established criteria for non-inferiority to SOA/Benchmark Devices. Therefore, the subject device meets the established acceptance criteria for Technical Success.

Table 15. Comparative Performance: IQ Diagnostic Guide Wire

Technical Success Rate			Estimated Difference (p1-p2) [Lower Bound Limit (LBL) of the 1- Sided 95% CI for (p1-p2)]	Non-Inferiority (NI) Margin for the Estimated Difference (p1-p2)	Non-Inferiority Established? (LBL>NI Margin?)
Subject Device		SOA/Benchmark Devices n/N (%)			
Data Source	n/N (%)				
PMCF	318/326 (97.5%)	**201/219 (91.8%)**	**5.8% [2.4%]**	**-10%**	**YES**

Abbreviations: CI = confidence interval, LBL = lower bound limit, NI = non-inferiority

The IQ Diagnostic Guide Wire has been used with a high level of safety during endovascular procedures in patients. Adverse event data for the IQ Diagnostic Guide Wire from the patient level (high quality) PMCF and for comparable benchmark guidewires are summarized in Table 16. Based on the patient level PMCF data, the reported adverse event rate for the IQ Diagnostic Guide Wire is 1.5% (5/326). No clinical literature data were identified for the IQ Diagnostic Guide Wire. The overall cumulative AE rate for the comparable benchmark guidewires is 4.2% (7/165). Comparing the AE rates, the IQ Diagnostic Guide Wire met the established criteria for non-inferiority to SOA/Benchmark Devices. Therefore, the subject device meets the established acceptance criteria for Adverse Event Rates.

Table 16. Comparative Adverse Event Rates: IQ Diagnostic Guide Wire

Device-Related AE Rate			Estimated Difference (p1-p2) [Upper Bound Limit (UBL) of the 1- Sided 95% CI for (p1-p2)]	Non-Inferiority (NI) Margin for the Estimated Difference (p1-p2)	Non-Inferiority Established? (UBL<NI Margin?)
Subject Device		Benchmark Devices n/N (%)			
Data Source	n/N (%)				
PMCF	**5/326 (1.5%)**	**7/165 (4.2%)**	**-2.7% [0.1%]**	**10%**	**YES**

Abbreviations: CI = confidence interval, UBL = upper bound limit, NI = non-inferiority

Results from the clinician PMCF surveys conducted in 2020 are summarized in Table 17. Data from the physician surveys support safety and performance of the IQ Diagnostic Guide Wire, However, as this survey collected user-level data as opposed to patient-level data, the information is considered low quality. These data are included for completeness, but they are not utilized in the comparison of clinical outcomes between the IQ Diagnostic Guide Wire and comparable benchmark devices.

Table 17. IQ Diagnostic Guide Wire - Case Use PMCF Data Summary

Attribute	Count (n)	PMCF Reponses (N)	n/N (%)
Technical Success	840	840	840/840 (100)
Adverse Events	0	840	0/840 (0)

5.4 Overall Summary of Clinical Performance and Safety

The clinical data demonstrate that the risks associated with the IQ Diagnostic Guide Wire are acceptable when weighed against the clinical benefits to the patient. All guidewires 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 placement of devices during diagnostic and interventional procedures. The subject devices were deemed consistent with the state-of-the-art benchmark devices for safety and performance in this patient population. The IQ Diagnostic Guide Wire is well established, having demonstrated acceptable safety and performance profile since the devices were first commercialized in 2000. Based on design verification/validation testing results, safety and performance outcomes in the literature, and PMS data, there are no known uncertainties regarding safety and performance of the subject device or the intended use. The known risks are well-documented, and the risk of occurrence is low and not associated with any safety or performance signals.

The clinical indications identified in the IFU for the IQ Diagnostic Guide Wire product configurations are supported by the clinical evidence presented in the CER. Furthermore, the IFU contains correct and sufficient information to reduce the risk of user error as well as information on residual risks

and their management as supported by clinical evidence (e.g., handling and use instructions, description of risks, warnings, precautions, cautions, indications and contraindications, and instructions for managing foreseeable unwanted situations). The overall clinical benefits to the patient of the IQ Diagnostic Guide Wire substantially outweigh any residual risks associated with their clinical use. The risk/benefit assessment for the IQ Diagnostic Guide Wire is summarized in Table 18

Table 18 Summary of Benefit/Risk Assessment[6, 7]

Factor	Notes	Assessment
Uncertainty Quality of the study design	• How robust were the data?	IQ Diagnostic Guide Wire: PMCF data of 840 data points
Quality of the study conduct	• How was/were the study/studies designed, conducted and analyzed?	PMCF data collected as case series
	• Are there missing data?	No
Robustness of the study results analysis	• Are the results from the study/studies repeatable?	N/A – case series
	• Is/Are this/these study/studies first-of-a-kind?	No
	• Are there other studies that achieved similar results?	Yes
Generalizability of the results	• Can the results of the study/studies be applied to the population generally, or are they more intended for discrete, specific groups?	Yes
Characterization of the disease/condition	• How does the disease/condition affect the patients that have it?	Atherosclerosis is a potentially serious condition where the body's medium and large arteries become clogged up by fatty substances, such as cholesterol. Hardening and narrowing of the arteries is potentially dangerous for two reasons: • Restricted blood flow to an organ can damage it and stop it functioning properly. • If a plaque ruptures (bursts) it will cause a blood clot to develop at the site of the rupture. The blood clot can block the blood supply to an important organ, such as the heart, triggering a heart attack, or the brain, triggering a stroke. The above carries the increased risk of death/serious complications
	• Is the condition treatable?	Yes
	• How does the condition progress?	Atherosclerosis is a major risk factor for many different conditions

Factor	Notes	Assessment
		involving the flow of blood. Left untreated, the outlook for atherosclerosis is poor. Treatment for atherosclerosis aims to prevent the condition from worsening to the point at which it can trigger a serious Cardiovascular Disease (CVD), such as a heart attack. According to the American College of Cardiology/American Heart Association (ACC/AHA) practice guidelines, patients with PAD fit clinically into one of four categories depending on their symptoms: asymptomatic, intermittent claudication (IC), chronic limb ischemia (CLI), or acute limb ischemia (ALI).[8] All patients with PAD have an increased cardiovascular morbidity and mortality e.g. a fourfold risk of myocardial infarction or at least a two-fold increase of ischemic stroke.[9]
Patient tolerance for risk, and perspective on benefit:	• Is there data regarding how patients tolerate the risks posed by the device? • Are the risks identifiable and definable?	N/A Yes
Disease severity	• Is the disease so severe that patients will tolerate a higher amount of risk for a smaller benefit?	In stable asymptomatic patients, conservative therapy is viable
Disease chronicity	• Is the disease/condition chronic? • How long do patients with the disease/condition live? • If chronic, is the illness easily managed with less invasive or difficult therapies?	Only if untreated All patients with PAD have an increased cardiovascular morbidity and mortality e.g. a fourfold risk of myocardial infarction or at least a two-fold increase of ischemic stroke.[9] Mortality rates in asymptomatic patients within five years are 19% increase and in symptomatic patients to up to 24%.[10] Modern practice employs an ‘‘endovascular-first” strategy in patients requiring intervention. Open surgery is reserved for patients with debilitating and/or treatment-resistant Intermittent Claudication and those with Chronic Limb Ischemia. Surgical or endovascular aortoiliac reconstruction is the mainstay of invasive therapy for significant distal aortic and iliac disease. The decision between open or endovascular repair for any lesion is made based on patient co-morbidities, life-expectancy, urgency, and local operator expertise. Open repair is preferred for complex or multisegment disease as patency rates are considered higher and avoids the risk of endoleaks whereas endovascular modalities carry lower periprocedural mortality and morbidity.[11]

Factor	Notes	Assessment
Patient-centric assessment	• How much do patients value this treatment?	High – endovascular access avoids morbidity and mortality associated with the alternatives of more invasive open surgery in symptomatic patients.
	• Are patients willing to accept the risk of this treatment to achieve the benefit?	Yes
	• Does the treatment improve overall quality of life?	Yes
	• How well are patients able to understand the benefits and risks of the treatment?	N/A- the guide wire is used as an accessory tool during a procedure
Availability of alternative treatments or diagnostics	• What other therapies are available for this condition?	Lifestyle changes, medication, open surgery, radiofrequency Guide Wires, endovascular aortic repair (EVAR), thoracic vascular aortic repair (TVAR), percutaneous valve replacement and chronic total occlusion (CTO) directing wires through occlusions
	• How effective are the alternative treatments?	Conservative treatment viable in stable asymptomatic patients;
	• How does their effectiveness vary by subpopulation?	N/A
	• How well-tolerated are the alternative therapies?	The decision between open or endovascular repair for any lesion is made based on patient co-morbidities, life-expectancy, urgency, and local operator expertise. Open repair is preferred for complex or multisegment disease as patency rates are considered higher and avoids the risk of endoleaks whereas endovascular modalities carry lower periprocedural mortality and mobility.
	• How does their tolerance vary by subpopulation?	N/A
	• What risks are presented by any available alternative treatments?	Death/serious complications if left untreated
Risk mitigation	• Could you identify ways to mitigate the risks (such as using product labeling, establishing education programs, providing add-on therapy, etc.)?	Well established technology that is compatible with standard interventional techniques; no additional labeling or clinician training have been identified to further mitigate risks
	• What is the type of intervention proposed?	N/A
Postmarket data	• Are there other devices with similar indications on the market? Are the probabilities for effectiveness and rates of harmful events from those devices similar to what is expected for the device under review?	Yes

Factor	Notes	Assessment
	• Is postmarket data available that change the risk/benefit evaluation from what was available when the previous devices were evaluated?	No
	• Is there reason to consider evaluation of any of the following elements further in the postmarket setting, due to the risk/benefit evaluation as described above? ○ Longer-term device performance. ○ Effectiveness of training programs or provider preferences in use of device. ○ Subgroups (e.g., pediatrics, women). ○ Rare adverse events.	Guide Wires are utilized on a transient basis, therefore long-term device performance is not applicable. Additionally, Guide Wires are well-established devices, and additional training/use cases are not deemed necessary. No safety/performance issues related to patient subgroups or rare adverse events have been identified. The IQ Diagnostic Guide Wire family includes established configurations that differ in wire outer diameter, tip shape, length, and body stiffness. The available PMCF data can be mapped to the design elements of wire outer diameter and tip shape, but not to length or body stiffness. Complaint data is available for all design configurations. This data is in line with the PMCF data and does not contain signals that raise concerns of safety or performance for any configuration. Mapping of the clinical data to the approved design configurations has been performed to provide guidance for the design of further PMCF data collection activities across the IQ Diagnostic Guide Wire product family.
	• Is there reason to expect a significant difference between real-world performance of the device and the performance found in pre-market experience with the device?	No; data presented is derived from realworld case studies and case series.
	• Is there data that otherwise would be provided to support approval, which could be deferred to the postmarket setting?	N/A
	• Is there off-label use, or on-label use that is different than originally expected?	No
Novel technology addressing unmet medical need	• How well is the medical need this device addresses being met by currently available therapies?	Highly effective
	• How desirable is this device to patients?	Highly desirable as compared to surgical intervention

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.

The plan for ongoing PMCF for the IQ Diagnostic Guide Wire involves collection of additional quantitative high-quality survey data from individual clinical case use of the device. Analysis of these survey data will include consideration of the following:

- Assessment of any safety or performance issues identified in the patient level survey data to determine what impact if any was contributed by the IQ Diagnostic Guide Wire.
- As part of the annual update, safety and performance data collected from the PMCF activity and the clinical literature will be analyzed and compared to the safety and performance clinical literature data for the benchmark guide wires.
- Assessment if any safety or performance issues identified in the patient level survey data constitutes a previously unidentified residual risk.
- Assessment of the representation of product configurations within the current PMCF dataset to determine if the collection of data for configurations with higher representation may be de-emphasized in favor of configurations with lower representation.

6.0 Diagnostic or Therapeutic Alternatives

6.1 Review of Medical Condition

Atherosclerosis is a potentially serious condition where the body's medium and large arteries become clogged up by fatty substances, such as cholesterol. These substances are called plaques or atheroma. Hardening and narrowing of the arteries is potentially dangerous for two reasons:

- Restricted blood flow to an organ can damage it and stop it functioning properly.
- If a plaque ruptures (bursts), it will cause a blood clot to develop at the site of the rupture. The blood clot can block the blood supply to an important organ, such as the heart, triggering a heart attack, or the brain, triggering a stroke.

Atherosclerosis is a major risk factor for many different conditions involving the flow of blood. Collectively, these conditions are known as cardiovascular disease (CVD). Examples of CVD include:

- Peripheral arterial disease (PAD)/peripheral vascular disease (PVD): where the blood supply to the legs is blocked, causing muscle pain
- Coronary heart disease: where the main arteries that supply your heart (the coronary arteries) become clogged up with plaques
- Stroke: a very serious condition where the blood supply to your brain is interrupted
- Heart attack: a very serious condition where the blood supply to your heart is blocked

Risk factors that can dangerously accelerate the process of atherosclerosis include smoking, a high-fat diet, a lack of exercise, being overweight or

obese, diabetes and high blood pressure (hypertension). Left untreated, the outlook for atherosclerosis is poor. Treatment for atherosclerosis aims to prevent the condition from worsening to the point at which it can trigger a serious Cardiovascular Disease (CVD), such as a heart attack.

Cardiovascular disease (CVD) is responsible for 1 in every 4 deaths in the USA and the leading cause of death globally and results in enormous societal burden.[12] Approximately 44 million people are affected by Peripheral Vascular Disease (PVD) each year in the US, Europe (the UK, Germany, France, Italy and Spain) and Asia (India, China and Australia). The majority of all PVD devices are used in conjunction with a guidewire, (averaging 1.3 guidewires per procedure). Guide wires are used to traverse the vasculature to lead other devices such as catheters, balloons and stents to the appropriate location for the procedure. Peripheral arterial disease (PAD) or peripheral vascular disease (PVD) is defined as narrowing and obstruction of antegrade flow of major systemic arteries other than those of the cerebral and coronary circulations.[8] There are many causes of PAD including vasculitis, dysplastic syndromes, degenerative conditions, thrombosis, and thromboembolism, however, the most common by far is atherosclerosis. This occurs most commonly in the lower limbs and causes a range of clinical syndromes.

PAD is a frequent and underestimated vascular atherosclerotic disease, strongly related to age and associated with cardio- and cerebrovascular co-morbidities.[13] Within the population, 3-10% are affected by PAD, and 20% of all patients are 70 years of age and older.[10] The ratio of asymptomatic and symptomatic patients is 4:1.[14] Men are more often affected than women but only at younger ages.[15] A rising worldwide prevalence is expected due to prolonged life expectancy.[16] According to the Global Burden of Disease Study 2013, PAD was responsible for over 40,000 deaths in 2013, an increase of 155% from 1990.[17] As atherosclerosis is a systemic process, there exists a strong correlation with coronary artery disease (CAD) and cerebrovascular disease. Clinical severity of one of these syndromes predicts that in the others.[8] According to the American College of Cardiology/American Heart Association (ACC/AHA) practice guidelines, patients with PAD fit clinically into one of four categories depending on their symptoms: asymptomatic, intermittent claudication (IC), chronic limb ischemia (CLI), or acute limb ischemia (ALI).[8] All patients with PAD have an increased cardiovascular morbidity and mortality e.g. a fourfold risk of myocardial infarction or at least a two-fold increase of ischemic stroke.[9] A complication of PAD is Critical Limb Ischemia (CLI) - Critical limb ischemia (CLI) is a condition that occurs when blood flow to the limbs is severely restricted from atherosclerosis. Patients with critical limb ischemia (CLI) carry an increased risk of major amputation without revascularization.[18] Mortality rates in asymptomatic patients within five years are 19% increase and in symptomatic patients to up to 24%.[10] The prognosis of patients with intermittent claudication (IC) is determined by cardiac or cerebrovascular complications. Only 2% have a major amputation within 10 years.[19]

The market for diagnostic guidewires consists of many different types of guidewires that can be used in a number of different applications both within and outside the vasculature. During use, via percutaneous access, the guidewires will ultimately direct other devices (dilators, introducer sheaths, catheters, diagnostic and therapeutic devices) into the desired vasculature, organ, or body cavity for diagnostic imaging or therapeutic procedures.

The IQ Diagnostic Guide Wire is intended to facilitate the placement overall of devices during a wide range of diagnostic and interventional procedures. The wires come in a variety of diameter and lengths with straight and curved tips. The wires also have numerous tapered flexible distal sections that deliver support. These wires are suitable for catheter placement and exchanges in tortuous anatomy; for positioning large or stiff devices in complex procedures where additional support is needed to advance the associated device to the appropriate location.

There are no known significant differences in the physiology or anatomy of the vasculature in different patient populations, therefore the results reported in the literature are applicable to all guidewire devices encompassing all outer diameter devices including those distributed by Merit.

Additionally, the procedures (Seldinger and modified Seldinger technique) in which they are used for placing central venous catheters are not significantly different in Australia, USA, countries of the European Union, or in other geographic jurisdictions. Thus, results from clinical reports and studies performed on guidewires are equally applicable to the use of these devices in any territory.

6.2 Alternative Treatment Options and Interventions

The following details a summary of the current options available for diagnosing and treatment of Peripheral Artery Disease.

PAD Diagnostics

Key diagnostic methods used in patients with suspected PAD include the following:

- The Ankle Brachial Pressure Index (ABPI) – the systolic blood pressure in the upper arm is measured and then a similar measurement is taken at the ankle. Then the second result (ankle) is divided by the first result (arm). For patients with PAD, the blood pressure in the ankle will be lower due to a reduction in blood supply, so the results of the ABPI would be less than 1.
- Ultrasound scan - where sound waves are used to build up a picture of the arteries in the leg. This can identify exactly where in the arteries there are blockages or narrowing.
- Angiogram - a special dye known as a contrast agent is injected into the leg. The agent shows up clearly on a computerized tomography (CT) or magnetic resonance imaging (MRI) scan.

PAD Treatment

The management of PAD focusses on two main goals: improving quality of life by reducing symptoms and reducing vascular morbidity and mortality.[8] There are two main types of treatment used in the management of peripheral arterial disease (PAD):

- Lifestyle changes - making lifestyle changes to improve symptoms and reduce the risk of developing a more serious cardiovascular disease

(CVD), such as coronary heart disease. Lifestyle changes include stopping smoking and regular exercise

- Medication - different medications can be used to treat the underlying causes of peripheral arterial disease (PAD) while reducing the risk of developing another cardiovascular disease (CVD):
    - Statins - Statins work by helping to reduce the production of LDL cholesterol by the liver.
    - Antihypertensives - used to treat high blood pressure. A widely used type of antihypertensive is an angiotensin-converting enzyme (ACE) inhibitor. ACE inhibitors block the actions of some of the hormones that help to regulate blood pressure. They help to reduce the amount of water in the blood and widen your arteries, which will both decrease blood pressure.
    - Antiplatelets - One of the biggest potential dangers of atherosclerosis is a piece of fatty deposit (plaque) breaking off from your artery wall. This can cause a blood clot to develop at the site of the broken plaque. If a blood clot develops inside an artery that supplies the heart with blood (a coronary artery) it can trigger a heart attack. Similarly, if a blood clot develops inside any of the blood vessels going to the brain, it can trigger a stroke. Antiplatelet medication is prescribed to reduce the risk of blood clots. This medication reduces the ability of platelets (tiny blood cells) to stick together, so if a plaque does break apart, there is a lower chance of a blood clot developing.
    - Cilostazol – if leg pain is severe, cilostazol may be prescribed. Cilostazol reduces the ability of the blood to clot, while causing the arteries in the legs to expand, which should both help improve the blood supply to your legs. However, cilostazol can potentially cause a wide range of side effects, which is why it is only used to treat the most problematic cases of PAD.

If above treatments are ineffective, surgery may be utilized. There are two main types of surgery for PAD:

- Angioplasty - An angioplasty is carried out under a local anesthetic, which means the patient is awake during the operation, but the legs will be numbed by the anesthetic, so the patient does not feel any pain. The surgeon inserts a tiny hollow tube known as a catheter into one of the arteries in the groin. The catheter is then guided to the site of the blockage. On the tip of the catheter is a balloon. Once the catheter is in place, the balloon is inflated, which helps widen the vessel. Sometimes a hollow metal tube known as a stent may be left in place to help keep the artery open.
- Bypass graft - A bypass graft is performed under a general anesthetic, which means the patient will be asleep during surgery and will not experience any pain. During surgery the surgeon will remove a small section of a healthy vein in the leg. The vein is then grafted (joined) onto the blocked vein so the blood supply can be rerouted, or bypassed, through the healthy vein. Sometimes a section of artificial tubing can be used as an alternative to a grafted vein.

Shen et al. (2018) also describe the design, principles, performances, and applications of a novel image-guided master – slave robotic system for vascular intervention (VI), including the performance evaluation and in vivo trials.[20] This new robotic system can accomplish in real time a number

of VI operations, including guidewire translation and rotation, balloon catheter translation, and contrast agent injection. The master–slave design prevents surgeons from being exposed to X-ray radiation, which means that they are not required to wear a heavy lead suit.

Modern practice employs an ‘‘endovascular-first” strategy in patients requiring intervention. Open surgery is reserved for patients with debilitating and/or treatment-resistant Intermittent Claudication and those with Chronic Limb Ischemia. Surgical or endovascular aortoiliac reconstruction is the mainstay of invasive therapy for significant distal aortic and iliac disease. The decision between open or endovascular repair for any lesion is made based on patient co-morbidities, life-expectancy, urgency, and local operator expertise. Open repair is preferred for complex or multisegment disease as patency rates are considered higher and avoids the risk of endoleaks whereas endovascular modalities carry lower periprocedural morbidity and mortality.[11]

As discussed by Patel et al. (2015), several literature papers also demonstrate the feasibility of the transradial approach (TRA) to address different peripheral vascular lesions.[21] The TRA has long been used to address practically all coronary artery lesion subsets. It has shown significant benefits when compared with transfemoral approach (TFA), particularly a reduction in puncture-site related bleeding complications. TRA can be utilized effectively to address peripheral vascular lesions, including the renal, iliac, subclavian, carotid, vertebrobasilar, and superficial femoral systems. The TRA is an effective alternative for TFA to address most peripheral vascular lesion subsets. However, there is a need for the development of radial-specific hardware to track bulky devices. TRA is emerging as a useful tool for most peripheral vascular interventions, offering the advantages of very low local vascular and bleeding complications, higher patient and staff comfort, rapid turnover, and lower hospital costs. Industry needs to focus on the development of dedicated hardware to address specific peripheral vascular lesions, so that technique becomes more simple and easier to reproduce. Further miniaturization of hardware will increase procedural safety and operator comfort level. Leibundgut et al. (2018) also describe how transradial access for percutaneous coronary interventions (PCI) has become more frequent in recent years.[22] The latest ESC guidelines recommend the transradial access for the management of acute coronary syndromes (ACS) (class I, level A).[23] Radial access is also associated with reduced incidence of acute kidney injury after PCI.[24] Optimized guide support, the latest guidewire and balloon technologies, and additional accessories such as extension catheters provide enough backup to successfully cross severely calcified lesions via the radial route. However, more complex procedures inevitably result in more complications. Smaller-sized guide catheters with the radial approach may limit the ability to remove damaged gear through the access site. Undeployed or lost stents, broken guidewires, twisted guiding catheters, trapped balloon catheters, and other interventional tools have been successfully removed by the femoral access or cardiac surgery.[25]

Other advances include new technologies such as the PowerWire Radiofrequency Guidewire (Baylis Medical, Quebec, Canada) which can be used for recanalization of long-segment occlusions. Horikawa and Quencer (2017) discuss this specialized guidewire, its atraumatic radio-frequency energy delivery tip, and the successful use of this device with low frequency of complications.[26] Although rare, complications of central venous interventions can be catastrophic. When performing angioplasty, venous rupture can occur. A brachiocephalic vein rupture typically results in mediastinal

hematoma or hemothorax.

Saab et al. (2019) also describe the orbital atherectomy system, a novel form of atherectomy that uses orbital sanding and pulsatile forces, an effective method of treatment for peripheral atherosclerotic lesions with varying levels of occlusion.[27] Although the device only has a general indication from the FDA to treat atherosclerotic lesions, they are effective in treating all kinds of lesions, and can therefore mitigate effects of all severities of peripheral artery disease. This approach to endovascular therapy involves the use of differential sanding to preferentially ablate fibrous, fibrofatty and calcified lesions, while deflecting healthy intima away from the crown. The eccentrically mounted crown design allows the device to employ rhythmic pulsating forces that penetrate the medial layer, and cause cracking in the lesions in order to facilitate easier balloon inflation and intravascular drug elution. The combination of vessel modification and lumen enlargement through sanding can effectively restore blood flow to the extremities, and can eliminate risk of critical limb ischemia, as well as subsequent amputation. Extensive lab testing and clinical trials have confirmed the high success rates and low major adverse events associated with this form of treatment. The device is economically viable as well, since its cost is offset by the lower frequency of adjunctive therapy sessions when compared to other devices. Considering the results outlined in this manuscript, the Diamondback 360° is an effective form of atherectomy therapy for peripheral artery disease. In-depth understanding of the operation preparation, procedure, and best imaging techniques can help to optimize outcomes.[28] Outdated methods of intervention including balloon angioplasty are much less effective for treating calcified lesions. These challenging vessels require much higher inflation pressure thus increasing the incidence of plaque rupture, embolization and dissection.[29] The orbital atherectomy system (OAS) is a novel device treating calcified lesions in both above-the-knee (ATK) and below-the-knee (BTK) situations, using an eccentrically mounted crown to create an orbital sanding mechanism and ablate intimal calcium. The OAS (Cardiovascular Systems Inc., St. Paul, MN, USA) creates a pulsatile, pounding force through the rotation of an offset crown, which effectively cracks the medial calcification of the smooth muscles and enhances vessel compliance. The safety and efficacy of this intervention strategy has been explored in many past clinical studies.

6.3 Professional Guidelines and Recommendations

Clinical practice guidelines and consensus statements issued by the following professional societies were reviewed to inform on the management IFBs and tissue/thrombus retrieval:

- 2016 AHA/ACC Guideline on the Management of Patients With Lower Extremity Peripheral Arterial Disease
- 2017 ESC Guidelines on the Diagnosis and Treatment of Peripheral Arterial Diseases

The published guidelines reflect the judgment 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. These guidelines inform on appropriate and relevant safety and

performance measures for the target therapy and alternative therapies. Although the guidelines may describe the clinical use of various devices, the application of such devices may or may not be within the labeled indications for use provided by the manufacturer. Therefore, the guidelines represent current clinical practice and not necessarily intended device use.

Table 19. Standard of Care Guidelines and Recommendations for the Management of Medical Condition

Recommendation
2017 ESC Guidelines on the Diagnosis and Treatment of Peripheral Arterial Diseases[30]
Recommendations on the management of acute mesenteric ischaemia
Treatment: In patients with acute thrombotic occlusion of the superior mesenteric artery, endovascular therapy should be considered as first line therapy for revascularization.
Treatment: In patients with acute embolic occlusion of the superior mesenteric artery, both endovascular and open surgery therapy should be considered.
Recommendations for treatment strategies for renal artery disease - Revascularization
In cases of hypertension and/or signs of renal impairment related to renal arterial fibromuscular dysplasia, balloon angioplasty with bailout stenting should be considered.
Balloon angioplasty, with or without stenting, may be considered in selected patients with RAS and unexplained recurrent congestive heart failure or sudden pulmonary oedema
Recommendations on imaging in patients with lower extremity artery disease
An endovascular-first strategy is recommended for short (i.e. <5 cm) occlusive lesions.
An endovascular-first strategy should be considered in long and/or bilateral lesions in patients with severe comorbidities.
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
Recommendations on revascularization of femoro-popliteal occlusive lesions
An endovascular-first strategy is recommended in short (i.e. <25 cm) lesions
In patients unfit for surgery, endovascular therapy may be considered in long (i.e. >_25 cm) femoro-popliteal lesions.
Recommendations on revascularization of infra-popliteal occlusive lesions
For revascularization of infra-popliteal arteries: endovascular therapy should be considered.
Recommendations on the management of chronic limb-threatening ischaemia
In CLTI patients with below-the-knee lesions, angiography including foot runoff should be considered prior to revascularization.
2016 AHA/ACC Guideline on the Management of Patients with Lower Extremity Peripheral Artery Disease[31, 32]
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
Endovascular procedures are reasonable as a revascularization option for patients with lifestyle-limiting claudication and hemodynamically significant femoropopliteal disease

Recommendation
The usefulness of endovascular procedures as a revascularization option for patients with claudication due to isolated infrapopliteal artery disease is unknown
Endovascular procedures should not be performed in patients with PAD solely to prevent progression to CLI
Recommendations for Endovascular Revascularization for CLI
Endovascular procedures are recommended to establish in-line blood flow to the foot in patients with nonhealing wounds or gangrene
A staged approach to endovascular procedures is reasonable in patients with ischemic rest pain
Evaluation of lesion characteristics can be useful in selecting the endovascular approach for CLI
Use of angiosome-directed endovascular therapy may be reasonable for patients with CLI and nonhealing wounds or gangrene
Management of Patients With Peripheral Artery Disease[33]
Endovascular Treatment for Claudication
Endovascular procedures are indicated for individuals with a vocational or lifestyle-limiting disability due to intermittent claudication when clinical features suggest a reasonable likelihood of symptomatic improvement with endovascular intervention and (a) there has been an inadequate response to exercise or pharmacological therapy and/or (b) there is a very favorable risk-benefit ratio (e.g., focal aortoiliac occlusive disease)
Endovascular intervention is recommended as the preferred revascularization technique for TASC type A iliac and femoropopliteal arterial lesions.
Translesional pressure gradients (with and without vasodilation) should be obtained to evaluate the significance of angiographic iliac arterial stenoses of 50% to 75% diameter before intervention.
Provisional stent placement is indicated for use in the iliac arteries as salvage therapy for a suboptimal or failed result from balloon dilation (e.g., persistent translesional gradient, residual diameter stenosis >50%, or flow-limiting dissection).
Stenting is effective as primary therapy for common iliac artery stenosis and occlusions.
Stenting is effective as primary therapy in external iliac artery stenoses and occlusions.
Stents (and other adjunctive techniques such as lasers, cutting balloons, atherectomy devices, and thermal devices) can be useful in the femoral, popliteal, and tibial arteries as salvage therapy for a suboptimal or failed result from balloon dilation (e.g., persistent translesional gradient, residual diameter steno-sis >50%, or flow-limiting dissection).
The effectiveness of stents, atherectomy, cutting balloons, thermal devices, and lasers for the treatment of femoral-popliteal arterial lesions (except to salvage a suboptimal result from balloon dilation) is not well-established.
The effectiveness of uncoated/uncovered stents, atherectomy, cutting balloons, thermal devices, and lasers for the treatment of infrapopliteal lesions (except to salvage a suboptimal result from balloon dilation) is not well established.
Endovascular intervention is not indicated if there is no significant pressure gradient across a stenosis despite flow augmentation with vasodilators.
Primary stent placement is not recommended in the femoral, popliteal, or tibial arteries.
Endovascular intervention is not indicated as prophylactic therapy in an asymptomatic patient with lower extremity PAD.
Endovascular treatments for Chronic Limb Ischemia (CLI)
For individuals with combined inflow and outflow disease with CLI, inflow lesions should be addressed first.
For individuals with combined inflow and outflow disease in whom symptoms of CLI or infection persist after inflow revascularization, an outflow revascularization procedure should be performed.
If it unclear whether hemodynamically significant inflow disease exists, intra-arterial pressure measurements across suprainguinal lesions should be measured before and after the administration of a vasodilator. (Level of Evidence: C)

Recommendation
For patients with limb-threatening lower extremity ischemia and an estimated life expectancy of 2 years or less in patients in whom an autogenous vein conduit is not available, balloon angioplasty is reasonable to perform when possible as the initial procedure to improve distal blood flow.
or patients with limb-threatening ischemia and an estimated life expectancy of more than 2 years, bypass surgery, when possible and when an autogenous vein conduit is available, is reasonable to perform as the initial treatment to improve distal blood flow.
Endovascular Treatment for Renovascular Disease: RAS
Renal stent placement is indicated for ostial atherosclerotic RAS lesions that meet the clinical criteria for intervention.
Balloon angioplasty with bailout stent placement if necessary is recommended for fibromuscular dysplasia lesions.
Endovascular Treatment for Mesenteric Arterial Disease
Percutaneous interventions (including transcatheter lytic therapy, balloon angioplasty, and stenting) are appropriate in selected patients with acute intestinal ischemia caused by arterial obstructions. Patients so treated may still require laparotomy
Endovascular Treatment for Chronic Intestinal Ischemia
Percutaneous endovascular treatment of intestinal arterial stenosis is indicated in patients with chronic intestinal ischemia.

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

All applied common specifications (CS), international standards harmonized under the medical device directives and/or the MDR, relevant adopted monographs of the European pharmacopoeia (MDR, Article 8 (2)), and other relevant standards, as applicable, are summarized in **Table *20***.

Table 20 Standard Conformance Summary

Document Number	Document Title	Compliance (Full/Partial)
MDR 2017/745	Medical Device Regulation (MDR) of the European Union (Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices	Full
Directive 2010/63/EU	Protection of animals used for scientific purposes	Full
Directive 2004/10/EC	Application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances	Full
Commission Regulation (EU) No 207/2012	Commission Regulation (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices	Full
MDCG 2019-9 Aug 2019	Summary of Safety & Clinical Performance	Full
MDCG 2019-1 Jan 2019	MDCG guiding principles for issuing entities rules on Basic UDI-DI	Full

Document Number	Document Title	Compliance (Full/Partial)
MDCG 2018-1 Apr 2021	Guidance on BASIC UDI-DI and changes to UDI-DI	Full
MDCG 2020-6 Apr 2020	Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC	Full
MDCG 2020-7 Apr 2020	Post-market clinical follow-up (PMCF) Plan Template	Full
MDCG 2020-8 Apr 2020	Post-market clinical follow-up (PMCF) Evaluation Report Template	Full
MDCG 2021-24 Oct 2021	Guidance on classification of medical devices	Full
MEDDEV 2.7.1 Rev 4 2016	Clinical Evaluation: A guide for manufacturers and notified bodies under directives 93/42/EEC and 90/385/EEC	Full
MEDDEV 2.12/2 Rev 2 2012	Post Market Clinical Follow-up studies	Full
MEDDEV 2.12/1 Rev 8 2013	Guidance on classification of medical devices	
ISO 11737-1:2018	Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products	Full
EN ISO 13485:2016 + EN ISO 13485:2016/AC:2018	Quality Systems – Medical Devices – Quality Management Systems. Requirements for Regulatory Purposes	Full
EN ISO 14971:2019	Medical Devices - Application of Risk Management to Medical Devices	Full
EN ISO 15223-1:2021	Medical Devices - Symbols to be used with medical device labels, labelling, and information to be supplied. Part 1: General Requirements	Full
EN ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer	Full
EN 556-1 :2001 2001	Sterilization of medical devices – Requirements for medical devices to be labelled “sterile”	Full
ISO 11135:2014 + ISO 11135:2014/Amd 1:2018	Sterilization of health care products -- Ethylene oxide -- Requirements for development, validation and routine control of a sterilization process for medical devices	Full
AAMI TIR 28:2016	Product Adoption and process equivalency for ethylene oxide sterilization	Full
ISO 14644-1:2015	Classification of Air Cleanliness, Clean rooms & Associated Controlled Environments. Part 1: Classification of air cleanliness	Full
ISO 14644-2:2015	Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration	Full
EN ISO 10993-1:2020	Biological Evaluation of Medical Devices – Part 1: Evaluation and testing	Full
ISO 10993-3:2014	Biological Evaluation of Medical Devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	Full
ISO 10993-4:2017	Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood	Partial
ISO 10993-5:2009	Biological Evaluation of Medical Devices – Part 5: Tests for cytotoxicity: In Vitro methods	Full
ISO 10993-7:2008	Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide sterilization residuals	Full

Document Number	Document Title	Compliance (Full/Partial)
+ ISO 10993-7:2008/Cor 1:2009 + ISO 10993-7:2008/Amd 1:2019		
ANSI/AAMI ST72:2019	Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing	Full
ISO 10993-10:2010	Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and sensitization	Full
ISO 10993-11:2017	Biological Evaluation of Medical Devices – Part 11: Tests for system toxicity	Full
ISO 10993-12:2021	Biological Evaluation of Medical Devices – Part 12: Sample preparation and reference materials	Full
ISO 10993-18:2020	Biological Evaluation of Medical Devices – Part 18: Chemical Characterization of Medical Device Materials within a Risk Management Process	Full
ISO 10993-19:2020	Biological evaluation of medical devices — Part 19: Physico-chemical, morphological and topographical characterization of materials	Full
EN ISO 10993-23:2021	Biological evaluation of medical devices — Part 23: Tests for irritation	Full
ASTM F2475-20	Standard Guide for Biocompatibility of Medical Device Packaging Materials	Full
IEC 62366-1:2015+AMD1:2020	Medical Devices – Application of usability engineering to medical devices	Partial Compliant to ISO62366-1 Annex C - Product released to manufacture pre 2015 and as such only IEC 62366-1:2015+AMD1:2020 Annex C applies
ISO 11607-1:2020	Packaging for Terminally Sterilized Medical Devices. Part 1: Requirements for materials, sterile barrier systems, and packaging systems.	Full
ISO 11607-2:2020	Packaging for Terminally Sterilized Medical Devices. Part 2: Validation requirements for forming, sealing and assembly processes	Full
ISO 2233:2001	Packaging – Complete, filled transport packages and unit loads – Conditioning for testing	Full
ASTM F 2096 -11	Standard Test Method for Detecting Gross Leaks in Medical Packaging by Internal Pressurization (Bubble Test)	Full
ASTM F 1929 -15	Standard Test Method for Detecting Seal Leaks in porous Medical Packaging by Dye Penetration	Full
ASTM F88/F88M -21	Standard Test Method for Seal Strength of Flexible Barrier Materials.	Full
ASTM D 4169 -16	Standard Practice for Performance Testing of Shipping Containers and Systems	Full
ASTM F1980 -16	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	Full

Document Number	Document Title	Compliance (Full/Partial)
Product-specific Standards		
ISO 11070:2014/A1:2018	Sterile Single-Use Intravascular Catheter Introducers Section 4 “General Requirements” and Section 8 “Additional requirements for guidewires” are only applicable.	Full
ASTM F640-20	Standard Test Methods for Determining Radiopacity for Medical Use	Full

9.0 References

1. Schummer W, Schummer C, Gaser E, Bartunek R. Loss of the guide wire: mishap or blunder? *Br J Anaesth*. Jan 2002;88(1):144-6. doi:10.1093/bja/88.1.144
2. Wald M, Happel CM, Kirchner L, Jeitler V, Sasse M, Wessel A. A new modified Seldinger technique for 2- and 3-French peripherally inserted central venous catheters. *Eur J Pediatri*. 2008;167(11):1327-1329.
3. Kipling M, Mohammed A, Medding RN. Guidewires in clinical practice: applications and troubleshooting. *Expert Rev Med Devices*. 2009;6(2):187-195. doi:10.1586/17434440.6.2.187
4. Andrews RT, Bova DA, Venbrux AC. How much guidewire is too much? Direct measurement of the distance from subclavian and internal jugular vein access sites to the superior vena cava-atrial junction during central venous catheter placement. *Crit Care Med*. 2000;28(1):138-142.
5. Rufener JB, Andrews RT, Pfister ME, et al. An evaluation of commonly employed central venous catheter kits and their potential risk for complications of excess guidewire introduction. *Journal of Clinical Anesthesia*. 2003;15(4):250-256. doi:10.1016/s0952-8180(03)00060-6
6. AAMI/FDA Ad Hoc Risk Working Group. Postmarket risk management: A framework for incorporating benefit-risk assessments into correction and removal decisions. . Association for the Advancement of Medical Instrumentation; 2016.
7. Factors to consider when making benefit-risk determinations in medical device premarket approval and de novo classifications: Guidance for industry and Food and Drug Administration staff. (US Food & Drug Administration) (2019).
8. Conte SM, Vale PR. Peripheral Arterial Disease. *Heart Lung Circ*. Apr 2018;27(4):427-432. doi:10.1016/j.hlc.2017.10.014
9. Zheng L, Yu J, Li J, et al. Prevalence of and risk factors for peripheral arterial disease among Chinese hypertensive patients with and without known cardiovascular disease. *Acta Cardiol*. 2008;63(6):693-639.
10. Diehm C, Schuster A, Allenberg JR, et al. High prevalence of peripheral arterial disease and co-morbidity in 6880 primary care patients: cross-sectional study. *Atherosclerosis*. 2004;172(1):95-105. doi:10.1016/s0021-9150(03)00204-1
11. Chen J, Stavropoulos SW. Management of Endoleaks. *Semin Intervent Radiol*. Sep 2015;32(3):259-64. doi:10.1055/s-0035-1556825
12. Benjamin EJ, Blaha MJ, Chiuve SE, et al. Heart Disease and Stroke Statistics-2017 Update: A Report From the American Heart Association. *Circulation*. Mar 7 2017;135(10):e146-e603. doi:10.1161/CIR.0000000000000485
13. Lawall H, Huppert P, Espinola-Klein C, Rumenapf G. The Diagnosis and Treatment of Peripheral Arterial Vascular Disease. *Dtsch Arztebl Int*. Oct 28 2016;113(43):729-736. doi:10.3238/arztebl.2016.729

10.3238/arztebl.2016.0729

14. Alahdab F, Wang AT, Elraiyah TA, et al. A systematic review for the screening for peripheral arterial disease in asymptomatic patients. *J Vasc Surg*. Mar 2015;61(3 Suppl):42S-53S. doi:10.1016/j.jvs.2014.12.008
15. Vouyouka AG, Egorova NN, Salloum A, et al. Lessons learned from the analysis of gender effect on risk factors and procedural outcomes of lower extremity arterial disease. *J Vasc Surg*. Nov 2010;52(5):1196-202. doi:10.1016/j.jvs.2010.05.106
16. Fowkes FGR, Rudan D, Rudan I, et al. Comparison of global estimates of prevalence and risk factors for peripheral artery disease in 2000 and 2010: a systematic review and analysis. *The Lancet*. 2013;382(9901):1329-1340. doi:10.1016/s0140-6736(13)61249-0

17. Vos T, Barber RM, Bell B, et al. Global, regional, and national incidence, prevalence, and years lived with disability for 301 acute and chronic diseases and injuries in 188 countries, 1990–2013: a systematic analysis for the Global Burden of Disease Study 2013. *The Lancet*. 2015;386(9995):743-800. doi:10.1016/s0140-6736(15)60692-4
18. Bradbury AW, Adam DJ, Bell J, et al. Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) trial: A description of the severity and extent of disease using the Bollinger angiogram scoring method and the TransAtlantic Inter-Society Consensus II classification. *J Vasc Surg*. May 2010;51(5 Suppl):32S-42S. doi:10.1016/j.jvs.2010.01.075
19. Norgren L, Hiatt WR, Dormandy JA, et al. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II). *J Vasc Surg*. Jan 2007;45 Suppl S:S5-67. doi:10.1016/j.jvs.2006.12.037
20. Shen H, Wang C, Xie L, Zhou S, Gu L, Xie H. A novel remote-controlled robotic system for cerebrovascular intervention. *Int J Med Robot*. Dec 2018;14(6):e1943. doi:10.1002/rcs.1943
21. Patel T, Shah S, Pancholy S, et al. Utility of transradial approach for peripheral vascular interventions. *Cath Lab Digest*. 2015;23(8)
22. Leibundgut G, Degen C, Riede F. Transcutaneous Puncture of an Undeflatable Coronary Angioplasty Balloon Catheter. *Case Rep Cardiol*. 2018;2018:6252809. doi:10.1155/2018/6252809
23. Roffi M, Patrono C, Collet J-P, et al. 2015 ESC Guidelines for the management of acute coronary syndromes in patients presenting without persistent ST-segment elevation. *European Heart Journal*. 2016;37(3):267-315. doi:10.1093/eurheartj/ehv320
24. Ando G, Cortese B, Russo F, et al. Acute Kidney Injury After Radial or Femoral Access for Invasive Acute Coronary Syndrome Management: AKI-MATRIX. *J Am Coll Cardiol*. May 11 2017;doi:10.1016/j.jacc.2017.02.070
25. Alexiou K, Kappert U, Knaut M, Matschke K, Tugtekin SM. Entrapped coronary catheter remnants and stents. *Tex Heart Inst J*. 2006;33:139-142.
26. Horikawa M, Quencer KB. Central Venous Interventions. *Tech Vasc Interv Radiol*. Mar 2017;20(1):48-57. doi:10.1053/j.tvir.2016.11.006
27. Saab F, Martinsen BJ, Wrede D, Behrens A, Adams GL, Mustapha J. Orbital atherectomy for calcified femoropopliteal lesions: a current review. *J Cardiovasc Surg*. 2019;60(2):212-220.
28. Ford ES, Li C, Pearson WS, Zhao G, Mokdad AH. Trends in hypercholesterolemia, treatment and control among United States adults. *Int J Cardiol*. Apr 15 2010;140(2):226-35. doi:10.1016/j.ijcard.2008.11.033
29. Mustapha JA, Diaz-Sandoval LJ, Karenko B, Saab F. Atherectomy and critical limb ischemia: a treatment approach for severely calcified vessels. *Vasc Dis Mgt*. 2013;10(10):E198-E207.
30. Aboyans V, Ricco JB, Bartelink MEL, et al. 2017 ESC Guidelines on the Diagnosis and Treatment of Peripheral Arterial Diseases, in collaboration with the European Society for Vascular Surgery (ESVS): Document covering atherosclerotic disease of extracranial carotid and vertebral, mesenteric, renal, upper and lower extremity arteriesEndorsed by: the European Stroke Organization (ESO)The Task Force for the Diagnosis and Treatment of Peripheral Arterial Diseases of the European Society of Cardiology (ESC) and of the European Society for Vascular Surgery (ESVS). *Eur Heart J*. Mar 1 2018;39(9):763-816. doi:10.1093/eurheartj/ehx095
31. Gerhard-Herman MD, Gornik HL, Barrett C, et al. 2016 AHA/ACC Guideline on the Management of Patients With Lower Extremity Peripheral Artery Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *J* Am Coll Cardiol. Mar 21 2017;69(11):e71-e126. doi:10.1016/j.jacc.2016.11.007

32. Gerhard-Herman MD, Gornik HL, Barrett C, et al. 2016 AHA/ACC Guideline on the Management of Patients With Lower Extremity Peripheral Artery Disease: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol. Mar 21 2017;69(11):1465-1508. doi:10.1016/j.jacc.2016.11.008
33. Rooke TW, Hirsch AT, Misra S, et al. Management of patients with peripheral artery disease (compilation of 2005 and 2011 ACCF/AHA Guideline Recommendations): a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. Apr 9 2013;61(14):1555-70. doi:10.1016/j.jacc.2013.01.004

10.0 Revision History

SSCP Revision	ECN Number	Date Issued	Change Description	SSCP Author	Revision Validated by the Notified Body
001	ECN163134	OCT-2022	Initial release of the SSCP for the InQwire Diagnostic Guide Wire. Includes updated EU part numbers.	Kurt Sly	☐ Yes Validation language: English ☒ No
002	ECN164449	NOV-2022	Update Catalog Codes to remove 'EU' suffix and update Generation information to reflect MDR 'EU' revision.	Kurt Sly	☐ Yes Validation language: English ☒ No
003	ECN165383	DEC-2022	Update Catalog Codes in Table 1 and Table 7 with '/EU' to reflect MDR 'EU' revision (e.g., IQ35F150S/EU), per Notified Body's request for Item consistency in Technical Documentation.	Kurt Sly	☐ Yes Validation language: English ☒ No
004	ECN165726	JAN-2023	Correction to Catalog Codes in Table 1 and Table 7 to include MDR-IQ35F80J3SHD/EU.	Kurt Sly	☒ Yes Validation language: English ☐ No
005	ECN188568	26/11/2024	Adding translations	Kurt Sly	☐ Yes Validation language: English ☒ No