Summary of Safety and Clinical Performance (SSCP)

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the Merit Go2Wire™ Steerable Guide Wire System (Go2Wire)

The SSCP is not intended to replace the Instructions for Use (IFU) as the main document to ensure the safe use of the Go2Wire Steerable Guide Wire System (Go2Wire), nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

The English version of this SSCP document (SSCP 0144) has been validated by the notified body (NB#2797). The following information is intended for users/healthcare professionals. A supplemental SSCP with information for patients was not established since the devices in the Go2Wire family are not implantable devices for which patients are provided an implant card, nor are the devices intended to be used directly by patients.

1.0 Device identification and general information

1.1 Device trade name(s)

The Go2Wire device configurations and model numbers covered by this SSCP are presented in Table 1.

Table 1. Go2Wire Configurations Included in this SSCP

Catalog Code	Device Name	Tip Style	Outer Diameter	Length
G2WFS35145/EU	Go2Wire Steerable Guide Wire, Floppy tip, Extendable	Straight/Shapeable	0.035” (0.089 cm)	145 cm
G2WFS35145NE/EU	Go2Wire Steerable Guide Wire, Floppy tip, Non- Extendable	Straight/Shapeable	0.035” (0.089 cm)	145 cm
G2WFS35175/EU	Go2Wire Steerable Guide Wire, Floppy tip, Extendable	Straight/Shapeable	0.035” (0.089 cm)	175 cm
G2WFS35175NE/EU	Go2Wire Steerable Guide Wire, Floppy tip, Non- Extendable	Straight/Shapeable	0.035” (0.089 cm)	175 cm
G2WFS35210NE/EU	Go2Wire Steerable Guide Wire, Floppy tip, Non- Extendable	Straight/Shapeable	0.035” (0.089 cm)	210 cm
G2WFS35260/EU	Go2Wire Steerable Guide Wire, Floppy tip, Exchange	Straight/Shapeable	0.035” (0.089 cm)	260 cm
G2WFS35300/EU	Go2Wire Steerable Guide Wire, Floppy tip, Exchange	Straight/Shapeable	0.035” (0.089 cm)	300 cm
G2WIJ35145/EU	Go2Wire Steerable Guide Wire, Modified J tip, Extendable	Mod J Shapeable	0.035” (0.089 cm)	145 cm
G2WIJ35145NE/EU	Go2Wire Steerable Guide Wire, Modified J tip, Non- Extendable	Mod J Shapeable	0.035” (0.089 cm)	145 cm
G2WIJ35175/EU	Go2Wire Steerable Guide Wire, Modified J tip, Extendable	Mod J Shapeable	0.035” (0.089 cm)	175 cm

Catalog Code	Device Name	Tip Style	Outer Diameter	Length
G2WIJ35175NE/EU	Go2Wire Steerable Guide Wire, Modified J tip, Non-Extendable	Mod J Shapeable	0.035” (0.089 cm)	175 cm
G2WIJ35210NE/EU	Go2Wire Steerable Guide Wire, Modified J tip, Non-Extendable	Mod J Shapeable	0.035” (0.089 cm)	210 cm
G2WIJ35260/EU	Go2Wire Steerable Guide Wire, Modified J tip, Exchange	Mod J Shapeable	0.035” (0.089 cm)	260 cm
G2WIJ35300/EU	Go2Wire Steerable Guide Wire, Modified J tip, Exchange	Mod J Shapeable	0.035” (0.089 cm)	300 cm
G2WSS35145/EU	Go2Wire Steerable Guide Wire, Standard tip, extendable	Straight/Shapeable	0.035” (0.089 cm)	145 cm
G2WSS35145NE/EU	Go2Wire Steerable Guide Wire, Standard tip	Straight/Shapeable	0.035” (0.089 cm)	145 cm
G2WSS35175/EU	Go2Wire Steerable Guide Wire, Standard tip, extendable	Straight/Shapeable	0.035” (0.089 cm)	175 cm
G2WSS35175NE/EU	Go2Wire Steerable Guide Wire, Standard tip	Straight/Shapeable	0.035” (0.089 cm)	175 cm
G2WSS35210/EU	Go2Wire Steerable Guide Wire, Standard tip	Straight/Shapeable	0.035” (0.089 cm)	210 cm
G2WSS35260/EU	Go2Wire Steerable Guide Wire, Standard tip, exchange	Straight/Shapeable	0.035” (0.089 cm)	260 cm
G2WSS35300/EU	Go2Wire Steerable Guide Wire, Standard tip, exchange	Straight/Shapeable	0.035” (0.089 cm)	300 cm
G2WES35001/EU	Go2Wire Steerable Guide Wire, Extension System	Straight/Shapeable	0.035” (0.089 cm)	155 cm

1.2 Manufacturer Information

The name and address of the manufacturer of the Go2Wire Guide Wire and Go2Wire Guide Wire Extension Device are provided in Table 2.

Table 2. Manufacturer Information

Subject Device	Legal Manufacturer	Manufacturing Site
Go2wire™ Steerable Guide Wire	Merit Medical Systems, Inc. 1600 West Merit Parkway South Jordan, Utah 84095 USA	Merit Medical Systems, Inc. Parkmore Business Park West Ballybrit, Galway IRELAND
Go2wire™ Steerable Guide Wire Extension Device	Merit Medical Systems, Inc. 1600 West Merit Parkway South Jordan, Utah 84095 USA	Merit Medical Systems, Inc. Parkmore Business Park West Ballybrit, Galway IRELAND

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 Classificazione Nazionale dei Dispositivi medici (CND) code 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 Go2Wire are listed in Table 3.

Table 3. Device Identification Information

Device Name	EU Classification (Rule)	Product Number	Basic UDI-DI	Single Registration Number (SRN)	EMDN/CND Code	EMDN/CND Terms
Go2Wire	III (Rule 7)	All	0884450BUDI318PR	US-MF-000001366	C04020102	PERIPHERAL VASCULAR GUIDEWIRES, DIAGNOSTIC, NOT HYDROPHILIC

Abbreviations: EMDN = European Medical Device Nomenclature, EU = European Union

1.7 Year of EU Market Introduction

The year that the Go2Wire 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 Go2Wire 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
Go2Wire	2019	Merit Medical Ireland Ltd. Address: Parkmore Business Park West Galway, Ireland	IE-AR-000001011	BSI	2797

2.0 Intended Use of the Device

2.1 Intended Purpose

The labeled intended purpose for the Go2Wire Guide Wire and Go2Wire Guide Wire Extension Device configurations are summarized in Table 5.

Table 5. Go2Wire and Extension Device: Intended Purpose

Product Configuration	Intended Purpose
Go2Wire Guide Wire	The Merit GO2WIRE™ Guide Wire is used to facilitate the placement and exchange of devices during diagnostic and interventional procedures.
Go2Wire Guide Wire Extension Device	The GO2WIRE™ Guide Wire Extension Device is intended, when attached to the Merit GO2WIRE™ Guide Wire, to facilitate the exchange of devices during diagnostic and interventional procedures.

2.2 Indications and Intended Patient Population

2.2.1 Indications

The labeled indications for use for the Go2Wire Guide Wire and Go2Wire Guide Wire Extension Device configurations are summarized in Table 6.

Table 6. Go2Wire and Extension Device: Indications

Product Configuration	Indications
Go2Wire Guide Wire	The Merit GO2WIRE™ Guide Wire is indicated for use in patients with disease and/or lesions of the

Product Configuration	Indications
	peripheral vasculature or central circulatory system, excluding coronary arteries and cerebral vasculature.
Go2Wire Guide Wire Extension Device	The GO2WIRE™ Guide Wire Extension Device, when attached to the Merit GO2WIRE™ 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.

2.2.2 Intended Patient Population

The intended patient populations for the Go2Wire Guide Wire and Go2Wire Guide Wire Extension Device are summarized in Table 7.

Table 7. Go2Wire and Extension Device: Patient Population

Product Configuration	Contraindications
Go2Wire Guide Wire	The Merit GO2WIRE™ Guide Wires are designed for use during diagnostic and interventional procedures by trained 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).
Go2Wire Guide Wire Extension Device	The GO2WIRE™ Guide Wire Extension Device is designed for use in conjunction with GO2WIRE™ Guide Wire. The GO2WIRE™ Guide Wire is used during diagnostic and interventional procedures by trained 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).

2.2.3 Intended Clinical Benefits

The Merit Go2Wire 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 placement of compatible diagnostic or therapeutic medical devices that may have a direct therapeutic or diagnostic function.

The Go2Wire Guide Wire Extension Device, when attached to the Merit GO2Wire 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

facilitate the exchange of devices during diagnostic and interventional procedures that may have a direct therapeutic or diagnostic function.

2.3 Contraindications

The labeled contraindications for the Go2Wire Guide Wire and Go2Wire Guide Wire Extension Device configurations are summarized in Table 8.

Table 8. Go2Wire and Extension Device: Contraindications

Product Configuration	Contraindications
Go2Wire Guide Wire	The Merit GO2WIRE™ Guide Wire is contraindicated for use in the coronary arteries and cerebral vasculature.
Go2Wire Guide Wire Extension Device	The GO2WIRE™ Guide Wire Extension Device, when attached to the Merit GO2WIRE™ Guide Wire, is contraindicated for use in the coronary arteries and cerebral vasculature.

3.0 Device Description

The Merit Go2Wire is a PTFE-coated steerable guide wire with a distal tip that is shapeable and radiopaque. The distal 100cm coil is precoated PTFE stainless steel coil wire. The remaining wire length is a stainless-steel guide wire coated with a white PTFE shrink tube (Figure 1). The Merit Go2Wire guide wire consists of 0.035 inch (0.89 cm) guide wire configurations available in various lengths of 145, 175, 210, 260, and 300 cm. The distal tip flex configurations are Floppy (Figure 2), Standard (Figure 3) and Intermediate Modified J (Figure 4). The distal tip shapes are either straight or modified J.-Guide wires are supplied sterile and non- pyrogenic. A torque device is included to facilitate wire steering within the vascular anatomy.

Figure 1. Go2Wire Guide Wire

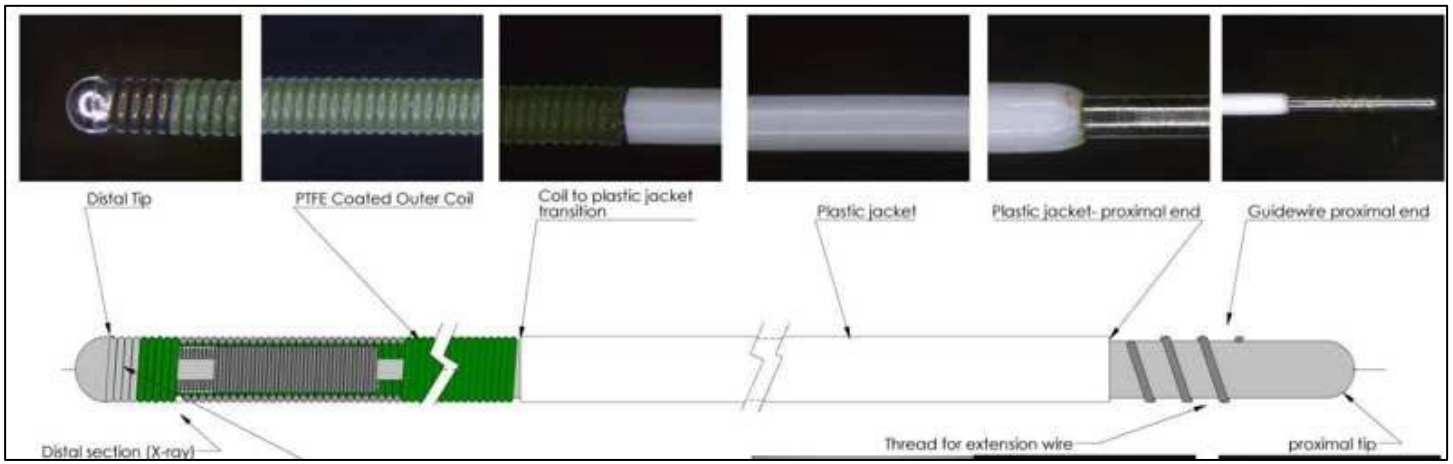


Figure 2. Go2Wire Guide Wire Floppy

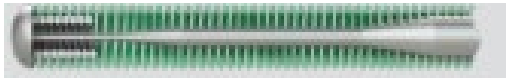


Figure 3. Go2Wire Guide Wire Standard

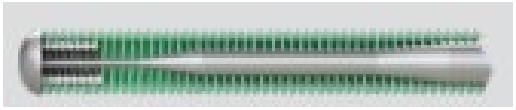
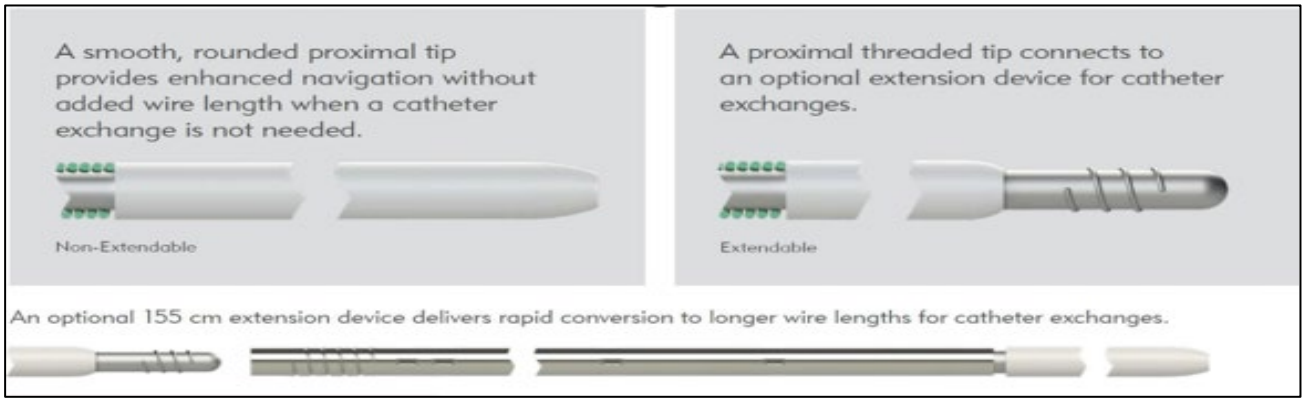


Figure 4. Go2Wire Intermediate Modified J

The Go2Wire Guide Wire Extension Device (Figure 5) is a PTFE coated stainless steel guide wire attachment that is 0.035 inch (0.089 cm) in diameter and 155 cm length. The Extension Device has a 152.5 cm long coating of white PTFE shrink tube. The non-coated stainless-steel attachment section is 2.5 cm in length. It is compatible with the shorter length (145cm & 175cm) Go2Wire guide wires that have been modified for attachment to the Extension Device.

Figure 5. Go2Wire Extension Device



3.1 Materials/Substances in Contact with Patient Tissues

A biocompatibility assessment has been completed for the Go2Wire, 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 Go2Wire are summarized in Table 9 and Table 10.

Table 9. Tissue Contact Categorization: Go2Wire

Device	Categorization
Go2Wire	EC, CB, L
Go2Wire Extension Device	EC, CB, L

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

Table 10. Go2Wire Composition and Body Contact Categorization

Component		Material Specification	Categorization by Nature of body Contact and Duration
Go2Wire guide wire			
Core Wire		Stainless Steel 304V SLT	NC
Inner Coil		Platinum 92%/Tungsten 8%	EC, CB, L
Outer	Core	Stainless Steel 304	

Component		Material Specification	Categorization by Nature of body Contact and Duration
Coil	Coating	Lubriskin PFOA free PTFE, Green	
Tubing PTFE Heat Shrink		PTFE Shrink Tubing, White	
D Wire		Stainless Steel 304V	
J-Straightener		Natural Polypropylene	NC
Torque Device		Cap (Polycarbonate)	NC
		Body (Polypropylene)	
		Collet (Brass)	
Loctite 4304 (Processing aid)		Loctite 4304	NC
Isopropyl alcohol (Processing aid)		Isopropyl alcohol	NC
Denatured Alcohol 70-100% (Processing aid)		Ethanol	NC
Acetone (Processing aid)		Acetone	NC
Extension System			
Core Wire		Stainless Steel 304V	NC
Plastic Jacket		PTFE Shrink, White	EC, CB, L
Hypotube		Stainless Steel 304	
J introducer Retention		Low Density Polyethylene, Natural colour	NC
Isopropyl alcohol (Processing aid)		Isopropyl alcohol	NC
Packaging			
Retention Clip		85% Kraton 15% HDPE	NC
Dispenser	Tubing	High Density Polyethylene	NC
	Tri-Lock Female Luer	Polypropylene, White	
	4 Cavity Gridlock® Striated Clip	High Density Polyethylene	
	3 Cavity Clip	60%HDPE / 40%LDPE	
	2 Cavity Clip W/Extended Hub	MDPE 50/50	
	2 Cavity Clip	60%HDPE / 40%LDPE	
Pouch		1073B uncoated Tyvek LF100BN Biax Nylon.	NC
Carton		Cardboard - Printkote SBS 20pt material	NC

Component	Material Specification	Categorization by Nature of body Contact and Duration
Shipper box	Cardboard - natural kraft C-flute corrugated single wall	NC

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

3.2 Principles of Operation

Guidewires are introduced through a percutaneous access device (i.e., needle or introducer) that has been placed prior and advanced to the desired location according to the planned procedure by clinicians. They are used to facilitate the placement of devices during diagnostic and interventional procedures. Verification of guidewire placement is typically accomplished with fluoroscopy. Their ability to be guided through the vasculature by a clinician to their desired location is provided by the material properties of the guidewire, which acts as a thin, maneuverable, element over which a device may be advanced and positioned, and the level of procedural experience and skill of clinician using the device.

Guidewires are commonly used in clinical practice across a wide range of specialties including but not limited to interventional radiology. Guidewires are indispensable tools for obtaining access and navigation through different luminal structures, and are used by various specialties, ranging from intravascular applications to critical care and urological applications. Access to blood vessels, hollow organs and cavities is typically obtained using the Seldinger (wire) technique, named after a Swedish radiologist who introduced the procedure in 1953. The desired vessel or cavity is punctured with a sharp hollow needle, with ultrasound guidance if necessary. A round-tipped guidewire is then advanced through the lumen of the needle, and the needle is withdrawn. A sheath or blunt cannula is subsequently passed over the guidewire to the site to be treated. Alternatively, drainage tubes are passed over the guidewire (e.g., abscess drains or nephrostomies). After passing a sheath or tube, the guidewire is withdrawn.[1] A guidewire has two principal purposes during interventional procedures. Firstly, it must allow safe delivery of the therapeutic device to the deployment site and prevent trauma to the surrounding structures or vasculature. Secondly, the guidewire should also prevent significant distortion of the device during delivery allowing for proper functioning. The more complex the disease to be treated is, the more important the guidewire becomes in order to (safely) navigate through the anatomy. Guidewires are therefore the mainstay of interventional and endovascular procedures, as they provide safe access to the body and allow the safe passage of catheters, stents and other devices into the body.

The Go2Wire has a floppy wire distal tip transitioning into a stiffer core wire body. The Go2Wire wires are not typically used to gain vascular access. Most commonly they are used as a secondary wire after vascular access has been achieved. The Go2Wire wires are used almost exclusively through an introducer sheath as additional support is needed to navigate the vascular anatomy leading catheters to the desired location for the procedure.

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

There is no previous generation associated with the Go2Wire device.

3.4 Accessories

The Go2Wire guidewire is shipped with the following parts included in the Packaging.

- J Straightener
- Torque Device

The Go2Wire Extension Device is shipped with the following included in the Packaging

- J Introducer

4.0 Risks and Warnings

4.1 Residual Risks and Undesirable Effects

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

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

All possible risk control measures have been implemented and verified and the Go2Wire has met all applicable regulations and standards. Through the clinical evaluation process, information relative to the clinical state-of-the-art and potential adverse events (AEs) are identified based on a review of the pertinent clinical evidence.

The potential complications/AEs related to the subject device as identified in the IFUs are summarized in Table 11. In addition, there were zero (0) device/procedure-related events identified in the subject device literature and the CPM/PMCF survey data. Historical IFUs for Go2Wire have

included adverse event information derived from ad-hoc literature searches for SOA outcomes for guidewires. All device/procedure-related events identified in the Literature, and the corresponding risk assessment harms are presented in Table 12.

Table 11. Go2Wire: Potential Complications

Product Configuration	Potential Adverse Events
Go2Wire guidewire	• Air Embolism/Thromboembolism, • Allergic Reaction, • Arteriovenous (AV) Fistula, • Cardiac Arrythmia • Embolism, • Hematoma, • Hemorrhage, • Infection or Sepsis/Infection, • Myocardial Ischemia and/or Infarction, • Pseudoaneurysm, • Stroke (CVA)/Transient Ischemic Attacks (TIA), • Thrombus, • Vessel Occlusion, • Vessel Perforation, • Vessel Dissection, • Vessel Trauma or Damage, • Vessel Spasm, • Wire Entrapment/Entanglement, • Foreign body/Wire Fracture. • Some of the stated potential adverse events may require additional surgical intervention. • Other potential access site complications leading to bleeding, dissection, or perforation that may require intervention.
Go2Wire Guide Wire Extension Device	• Refer to original guide wire instructions for use for potential complications of wire usage. • Separation of the extension device from the guide wire body • Potential loss of wire tip position in the vasculature • Other potential access site complications leading to bleeding, dissection, or perforation that may require intervention.

Table 12: Go2Wire AE Results from Current Subject and Benchmark Device Literature Searches

Complications from the Literature	Device Related	Procedure Related	IFU Complications	Applicable IFU Cautions/Instructions	Identified Harms from Risk Review (Severity)	Timing of Event
Go2Wire						
No complications or adverse events reported	-	-	N/A	N/A	N/A	
Covidien Wholey Wire/Abbott Versacore						
Aortic insufficiency (moderate to trace)	-	X	NA	NA	NA	NR (up to 30 days)
Bleeding (anterior nasal septum)	-	X	NA	NA	NA	Up to 1 month
Blood product transfusion (any)	-	X	NA	NA	NA	Up to 30 days
Cardiac arrest	-	X	NA	NA	NA	Up to 5 months
Dissection (involving carotid)	-	X	NA	NA	NA	Periprocedural
Effusion (pericardial, tamponade physiology)	-	X	NA	NA	NA	Periprocedural
Effusion (worsening pericardial, increased in size during procedure)	-	X	NA	NA	NA	Periprocedural
Embolization (transcatheter heart valve)	-	X	NA	NA	NA	NR (up to 30 days)
Hematoma (residual hyperdense intramural)	X	X	Potential complications: hematoma	1. The physician should be trained with the use of angiography and angioplasty products and the potential procedural complications.	Hemorrhage (2)	Prior to discharge
Hemoptysis	-	X	NA	NA	NA	Up to 1 month
Hemorrhage (pulmonary)	-	X	NA	NA	NA	Periprocedural
Hypertrophy (moderate to severe, right ventricle)	-	X	NA	NA	NA	Up to 5 months
Hypoperfusion (cerebral)	-	X	NA	NA	NA	Preceded use of the

Complications from the Literature	Device Related	Procedure Related	IFU Complications	Applicable IFU Cautions/Instructions	Identified Harms from Risk Review (Severity)	Timing of Event
						device
Hypotension	-	X	NA	NA	NA	Periprocedural
Laceration (catheter induced)	-	X	NA	NA	NA	Periprocedural
Laceration (inferior vena cava, during sheath exchange)	-	X	NA	NA	NA	Periprocedural
Mortality	-	X	NA	NA	NA	Periprocedural up to 5 months
Mortality (in hospital or 30 days)	-	X	NA	NA	NA	Prior to discharge
Mortality (secondary to laceration)	-	X	NA	NA	NA	NR (presumed to be periprocedural)
Multiorgan failure	-	X	NA	NA	NA	Prior to discharge
Multisystem organ failure	-	X	NA	NA	NA	Prior to discharge
Pain (chest)	-	X	NA	NA	NA	Periprocedural
Perforation (left ventricular wire)	X	X	Potential complications: vessel perforation, vessel dissection, vessel trauma or damage. Other potential access site complications leading to bleeding, dissection, or perforation that may require intervention.	1. The physician should be trained with the use of angiography and angioplasty products and the potential procedural complications.	Soft Tissue Injury (3)	Periprocedural
Pseudoaneurysm (involving femoral, requring surgical repair)	-	X	NA	NA	NA	NR (up to 30 days)
Pulseless electrical activity arrest	-	X	NA	NA	NA	Prior to discharge
Reflux (gastroesophageal)	-	X	NA	NA	NA	Postprocedural (presumed prior to

Complications from the Literature	Device Related	Procedure Related	IFU Complications	Applicable IFU Cautions/Instructions	Identified Harms from Risk Review (Severity)	Timing of Event
						discharge)
Renal failure	-	X	NA	NA	NA	Prior to discharge
Respiratory failure	-	X	NA	NA	NA	Prior to discharge
Sepsis	-	X	NA	NA	NA	Prior to discharge
Stenosis (LPA, severe, immediately after implantation)	-	X	NA	NA	NA	Periprocedural
Stroke (30 days)	-	X	NA	NA	NA	Up to 30 days
Tamponade (required window)	-	X	NA	NA	NA	NR (up to 30 days)
Thrombosis (varix)	-	X	NA	NA	NA	Up to 6 months

Harms Severity: 1 = Negligible, 2 = Minor, 3 = Serious/Major, 4 = Critical, 5 = Catastrophic/Fatal

This assessment accounts for various factors related to the risks associated with the Go2Wire Guide Wire. Given that there were zero (0) adverse events associated with the use of the Go2Wire Guide Wire, patients are assumed to accept the risks associated with guide catheters based on the probable benefits.

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

4.2 Warnings and Precautions

The labeled warnings and precautions for the Go2Wire Guide Wire configurations are summarized in Table 13.

Table 13. Go2Wire: Warnings and Precautions

Product Configuration	Labeling
Go2Wire	**Warnings**
	The safety and effectiveness of the Go2Wire™ Guide Wires has not been established in the coronary arteries or in the cerebral vasculature. Preclinical testing with this device showed the potential for clot formation in the absence of anticoagulation. Appropriate anticoagulation therapy should be considered to reduce the potential for thrombus formation on the device. 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. Use extreme caution when withdrawing PTFE coated guide wires back through a metal needle, the sharp edge of the needle may scrape the coating. **WARNING RESISTANCE:** a. Wire advancement with excessive force may cause coil penetration and /or vessel damage. Never force a wire that meets resistance, immediately assess the tip under fluoroscopy to determine cause of resistance and/or the need for additional action to free the guide wire tip. b. Manipulating a guide wire when resistance is felt may cause guide wire damage, tip separation, and / or vascular injury. c. Extreme care should be taken when manipulating a catheter and wire combination to prevent possible intravascular tissue damage. If resistance is felt during advancement, manipulation, or removal, stop immediately and confirm wire position under fluoroscopy. d. The guide wire and catheter should be moved and removed as a unit when possible. e. When reintroducing a guide wire into a catheter or device within a vessel, confirm that the catheter tip is free within the lumen (i.e., not against the vessel wall). f. Always advance or withdraw a wire slowly. Free movement of the guidewire within a vessel or catheter provides valuable tactile information. g. Never push, twist, or withdraw a guidewire which meets resistance. Resistance may be felt tactilely or noted by tip buckling during fluoroscopy. h. Test all systems for resistance prior to use. After use, dispose of device in a manner consistent with standard protocols for biohazard waste disposal.
	Precautions

Product Configuration	Labeling
	PRIOR TO USE: 1. The physician should be trained with the use of angiography and angioplasty products and the potential procedural complications. 2. Confirm the compatibility of the guide wire with other interventional devices being used by testing the systems for any resistance prior to actual use. Free movement of the guide wire within the interventional device must be confirmed and maintained. 3. The guide wire should be completely hydrated with saline or heparinized saline prior to removal from the dispenser hoop. 4. To avoid guide wire tip damage during removal from the dispenser hoop, first remove the proximal guide wire body from the retention clip, then slide guide wire forward towards the flush hoop dispenser allowing the distal wire tip to exit. NOTE: Distal tip of wire may be positioned inside the flush hoop to protect the fragile tip. 5. Gently grasp guide wire tip and J straightener together as a unit and gently pull forward to withdraw the fragile distal wire tip from the dispenser. 6. The tip of the guide wire may be shaped using standard tip shaping practices. Do not shape the wire surface against a sharp edge, this may result in damage to the wire surface. 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.
Go2Wire Guide Wire Extension Device	**Warnings**
	The safety and effectiveness of the Go2Wire™ Guide Wires has not been established in the coronary arteries or in the cerebral vasculaturecerebral vasculature. Preclinical testing with this device showed the potential for clot formation in the absence of anticoagulation. Appropriate anticoagulation therapy should be considered to reduce the potential for thrombus formation on the device. 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.

Product Configuration	Labeling
	After use, dispose of device in a manner consistent with standard protocols for biohazard waste disposal.
	Cautions
	PRIOR TO USE: 1. The physician should be trained with the use of angiography and angioplasty products and the potential procedural complications. 2. Confirm the compatibility of the extension wire with other interventional devices being used by testing the systems for any resistance prior to actual use. Free movement of the extension wire within the interventional device must be confirmed and maintained. 3. The extension wire should be completely hydrated with saline or heparinized saline prior to removal from the flush dispenser hoop NOTE: Distal tip of extension wire may be positioned inside the dispenser hoop to protect the extension wire sleeve. Do not torque or manipulate the guide wire extension device, the extension device does not contain torquing abilities like the guide wires. Attempted torquing only results in limited maneuverability of the attached guide wire. The extension device is used for catheter exchanges only. Torquing and other manipulations may be resumed after removal of the extension device from the guide wire. 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.

4.3 Other Relevant Safety Aspects

The Corrective and Preventive Action (CAPA) process for the subject devices is conducted at Merit in response to field complaints or product issues. In accordance with the procedure, a risk assessment is conducted to evaluate the significance of the risk of the issue and its associated impact. If the CAPA requires escalation, the appropriate management representatives are required to review and assess the escalation based on

their scope of responsibility.

There have been no Corrective Action Reports (CARs), field actions, or escalations during the reporting period for this report.

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

5.1 Summary of Clinical Data for the Equivalent Device

An equivalent device was not established as part of the conformity assessment for the subject device.

5.2 Summary of Clinical Investigations of the Subject Device

There were no pre-market clinical investigations performed to support safety and performance of the Go2Wire Guide Wire. Refer to Section 5.3.3 for details regarding post-market clinical follow-up activities for the subject device.

5.3 Summary of Clinical Data from Other Sources

5.3.1 Scientific Literature Review

The Go2Wire Guide Wire has been used effectively since their market introduction in 2020. Clinical data supporting the safety and performance of the Go2Wire Guide Wire have been derived from the following sources:

- **Subject device literature review:** A comprehensive literature review using the Embase®, MEDLINE, and PubMed databases for the period from December 2019 to November 2021. Literature search strategies were designed to identify articles relevant to the devices in the Go2Wire. There were 0 articles identified to support the safety and performance of the Go2Wire Guide Wire.
- **Benchmark state-of-the-art guidewire literature review:** A comprehensive systematic literature review using Embase, MEDLINE, PubMed, and Google Scholar was performed for the period from 2016 to 2021. A total of 13 articles were identified with information pertaining to the safety and performance of the benchmark guidewires.

Table 14. Safety and Performance: Benchmark Guidewires

Device Type/Application	Technical Success n/N (%)	Device-related Adverse Events n/N (%)
Clinical Literature	100/100 (100)	1/100 (1.00%)

5.3.2 Post-Market Surveillance

Post-market surveillance (PMS) occurs continuously, with reviews occurring at regular, defined intervals to track and identify trends in device complaints. Reportable complaints are complaints that, upon evaluation of the available information, meet the reporting criteria established by a national regulatory authority for all countries/regions applicable to device(s) of the complaint. With total sales of over 7,700 units, there have been no complaints and no reportable events for the reporting period of December 2019 to December 2022 for the Go2Wire Guide Wire or Go2Wire Extension Device.

The frequencies of complaints, reportable complaints, and their associated reported complications (complaint type) did not present any new risks or unanticipated frequency of risks associated with use of the Go2Wire. The on-market experience reinforces that potential risks have been reduced as far as possible, that the potential benefits of the device outweigh the overall and individual potential risks, and that the potential risks remain acceptable.

5.3.3 Postmarket Clinical Follow-up (PMCF)

Postmarket clinical follow-up (PMCF) plans for the Go2Wire have been established as identified in Table 15. The intent of the PMCF Plan is to document methods and procedures for collecting and evaluating clinical data with the aim of confirming the safety and performance throughout the expected lifetime of the device, ensuring the continued acceptability of identified risks, and detecting emerging risks based on factual evidence. PMCF data have been collected in accordance with per the activities identified in Table 15.

Table 15. Post Market Surveillance and Post Market Clinical Follow-Up Data

Product	PMCF Plan Reference Number	PMCF Report Reference Number
Go2Wire	PMCFP-QRMTI0037-001 REV 001	PMCFER-QRMTI0037-001 REV 001 (Interim)
Go2Wire Extension Device		PMCFER-QRMTI0037-001 REV 002 (Final)
Go2Wire	PMCFP-QRMTI0037-001 REV 003	PMCFER-QRMTI0037-001 REV 004 (Final)
Go2Wire Extension Device		

As part of the initial PMCF activities (PMCFP-QRMTI0037-001 REV 001), an evaluation form was circulated to health care professionals that used the medical device to collect feedback on device use. User feedback was obtained from 33 cases, and these results are summarized in Table 16.

Table 16. PMCF Data for Go2Wire

Clinician	Did guidewire successfully reach the target location? n/N (%)	Was the guidewire able to facilitate the placement of devices during diagnostic/interventional procedures? n/N (%)	Were there any complications experienced that were directly related to the use of the guidewire? n/N (%)
1	1/2 (50)	1/2 (50)	0/2 (0)
2	6/6 (100)	6/6 (100)	0/6 (0)
3	2/2 (100)	2/2 (100)	0/2 (0)
4	2/2 (100)	2/2 (100)	0/2 (0)
5	8/8 (100)	8/8 (100)	0/8 (0)
6	3/3 (100)	2/3 (67)	0/3 (0)
7	4/4 (100)	4/4 (100)	0/4 (0)
8	3/3 (100)	3/3 (100)	0/3 (0)
9	2/2 (100)	2/2 (100)	0/2 (0)
10	1/1 (100)	1/1 (100)	0/1 (0)
Total	**32/33 (97)**	**31/33 (94)**	**0/33 (0)**

The initial PMCF survey conducted under PMCFP-QRMTI0037-001 REV 001 was not designed to gather specific safety and performance details from each case, and therefore it was not considered high-quality data in accordance with MDCG 2020-6. Therefore, additional PMCF activity was initiated under PMCFP-QRMTI0037-001 REV 002 to collect high-quality patient-level surveys from a minimum of 203 clinical cases involving use of the Go2Wire and Go2Wire Extension System. This PMCF activity was performed between October 2022 and January 2023. Patient-level safety and performance data were collected from a total of 210 clinical cases (Table 17). Target location access was achieved in 100% (210/210) of cases. Of those cases involving device placement (173 cases) or exchange (49 cases), all procedures were reported as successful. There were no adverse events (AEs) reported. Of the 210 procedures performed, 144 involved target treatment sites in the peripheral vasculature, whereas 68 were identified as central circulatory (excluding coronary arteries and cerebral vasculature). The Extension Device was utilized in 33 of the cases reported (Table 18). All 33 procedures were technically successful and there were no AEs related to the use of the Extension Device. Reported device use times were < 60 minutes in 97.6% of the cases, and this is consistent with the specified device lifetime for the Go2Wire.

Table 17. High Quality Patient-Level PMCF Data

Respondent Identifier	Number of Procedures /Cases N	Safety		Performance (Technical Success) (Procedure Success = Successful Target Access + Successful Placement/ Exchange)				
		Device Related AEs n/N (%)	Other AEs n/N (%)	Successful target location access n/N (%)	Procedures/involving placement of catheter/balloon/stent N_p	Successful Placement n/N_p (%)	Procedures Involving exchange N_e	Successful Exchange n/N_e (%)
US01	11	0/11 (0)	0/11 (0)	11/11 (100)	11	11/11 (100)	0	-
US02	20	0/20 (0)	0/20 (0)	20/20 (100)	20	20/20 (100)	0	-
US03	20	0/20 (0)	0/20 (0)	20/20 (100)	20	20/20 (100)	0	-
US04	20	0/20 (0)	0/20 (0)	20/20 (100)	15	15/15 (100)	5	5/5 (100)
US05	20	0/20 (0)	0/20 (0)	20/20 (100)	20	20/20 (100)	1	1/1 (100)
US06	20	0/20 (0)	0/20 (0)	20/20 (100)	16	16/16 (100)	7	7/7 (100)
US07	20	0/20 (0)	0/20 (0)	20/20 (100)	20	20/20 (100)	2	2/2 (100)
US08	15	0/15 (0)	0/15 (0)	15/15 (100)	10	10/10 (100)	8	8/8 (100)
US09	2	0/2 (0)	0/2 (0)	2/2 (100)	2	2/2 (100)	0	-
US10	2	0/2 (0)	0/2 (0)	2/2 (100)	2	2/2 (100)	0	-
US11	2	0/2 (0)	0/2 (0)	2/2 (100)	2	2/2 (100)	0	-
US12	5	0/5 (0)	0/5 (0)	5/5 (100)	5	5/5 (100)	2	2/2 (100)
US13	4	0/4 (0)	0/4 (0)	4/4 (100)	4	4/4 (100)	0	-
US14	20	0/20 (0)	0/20 (0)	20/20 (100)	10	10/10 (100)	11	11/11 (100)
US15	10	0/10 (0)	0/10 (0)	10/10 (100)	8	8/8 (100)	2	2/2 (100)
US16	10	0/10 (0)	0/10 (0)	10/10 (100)	1	1/1 (100)	9	9/9 (100)
US17	2	0/2 (0)	0/2 (0)	2/2 (100)	2	2/2 (100)	0	-
US18	3	0/3 (0)	0/3 (0)	3/3 (100)	3	3/3 (100)	0	-
US19	2	0/2 (0)	0/2 (0)	2/2 (100)	2	2/2 (100)	0	-
US20	2	0/2 (0)	0/2 (0)	2/2 (100)	0	-	2	2/2 (100)
Total	**210**	**0/210 (0)**	**0/210 (0)**	**210/210 (100)**	**173**	**173/173 (100)**	**49**	**49/49 (100)**

Table 18. Overall Safety and Performance Data Reported for the Go2Wire Extension Device

Respondent Identifier	Number of Procedures/Cases N	Safety		Performance
		Device Related AEs n/N (%)	Other AEs n/N (%)	Technical Success n/N (%)
US02	11	0/11 (0)	0/11 (0)	11/11 (100)
US03	5	0/5 (0)	0/5 (0)	5/5 (100)
US04	5	0/5 (0)	0/5 (0)	5/5 (100)
US07	4	0/4 (0)	0/4 (0)	4/4 (100)
US08	1	0/1 (0)	0/1 (0)	1/1 (100)
US09	2	0/2 (0)	0/2 (0)	2/2 (100)
US12	2	0/2 (0)	0/2 (0)	2/2 (100)
US15	2	0/2 (0)	0/2 (0)	2/2 (100)
US20	1	0/1 (0)	0/1 (0)	1/1 (100)
Total	**33**	**0/33 (0)**	**0/33 (0)**	**33/33 (100)**

5.4 Overall Summary of Clinical Performance and Safety

For purposes of the subject device clinical evaluation, the performance and safety outcomes were defined as follows:

PERFORMANCE:

Technical Success (Go2Wire Guide Wire): Demonstrated ability to access the target vascular location and support the placement of diagnostic or therapeutic interventional devices.

Technical Success (Go2Wire Extension Device): Demonstrated ability for the Go2Wire with Extension Device to support the exchange of diagnostic or therapeutic interventional devices.

SAFETY:

Device-related AE: Any event or complication that is, or could be, associated with the device or the procedural aspects of device use.

The Go2Wire has been used with a high level of Technical Success during diagnostic and interventional procedures in patients (Table 19). Performance data for the Go2Wire Guide Wire is derived from the PMCF data summarized in Table 16 and Table 17. Performance for the comparable benchmark guidewires is derived from the clinical literature data summarized in Table 14. As detailed in the clinical data, the reported Technical Success rate for the Go2Wire is high (99.0%) and similar to that reported for the benchmark devices (100%). Based on the lower bound limit (LBL) of the 1-sided 95% confidence interval, the Go2Wire exhibits a Technical Success rate that is non-inferior to the benchmark guidewires.

Table 19. Comparative Performance for Go2Wire

Device Type/Application	Subject Device n/N (%)	Benchmark Competitors, n/N (%)	Estimated Difference [95%LBL]	LBL > -10%
Technical Success				
Clinical Literature (Table 14)	-	100/100 (100)		
PMCF Data (Table 16)	31/33 (93.9)			
PMCF Data (Table 17)	173/173 (100)			
Total	204/206 (99.0)	100/100 (100)	-1.0% [-2.1%]	PASS

The Go2Wire has been used with a high level of safety during diagnostic and interventional procedures in patients (Table 20). Safety data for the Go2Wire Guide Wire is derived from the PMCF data summarized in Table 16 and Table 17. Safety for the benchmark devices is derived from the clinical literature data summarized in Table 14. The Device-related AE rate for the Go2Wire guidewire is 0.0% (0/243). The cumulative Device-related AE rate for the comparable benchmark guidewires is 1.0% (1/100).

Table 20. Comparative Safety for Go2Wire

Device Type/Application	Subject Device n/N (%)	Benchmark Competitors, n/N (%)	Estimated Difference [95%UBL]	UBL < 10%
Device-related AEs				
Clinical Literature (Table 14)	-	1/100 (1.0)		
PMCF Data (Table 16)	0/33 (0.0)			
PMCF Data (Table 17)	0/210 (0.0)			
Total	0/243 (0.0)	1/100 (1.0)	-1.0% [0.64%]	PASS

The clinical data demonstrate that the risks associated with the Go2Wire Guide Wire are acceptable when weighed against the clinical benefits to the patient. All microcatheter procedures have a risk of complications and/or failure, and the risks for an individual are an unpredictable combination of patient, the primary interventional procedure, and device-related interactions. The subject devices are intended to facilitate the placement and exchange of devices during diagnostic and interventional procedures in the peripheral circulatory system and the central circulatory system excluding the coronary arteries and the cerebral vasculature. The subject devices were deemed consistent with the state-of-the-art benchmark devices for safety and performance in this patient population. The Go2Wire guidewire is well established, having demonstrated acceptable safety and performance profile since the guidewires were first commercialized in 2019. 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 Go2Wire guide wire are supported by the clinical evidence presented in the Clinical Evaluation Report (CER). Furthermore, the IFU contains correct and sufficient information to reduce the risk of user error as well as information on residual risks and their management as supported by clinical evidence (e.g., handling and use instructions, description of risks, warnings, precautions, cautions, indications and contraindications, and instructions for managing foreseeable unwanted situations). The overall clinical benefits to the patient of the Go2Wire substantially outweigh any residual risks associated with its clinical use. The risk/benefit assessment for the Go2Wire is summarized in Table 21.

Table 21. Summary of Benefit/Risk Assessment[2, 3]

Factor	Notes	Assessment
Uncertainty		
Quality of the study design	• How robust were the data?	0 articles PMCF data (n=210)
Quality of the study conduct	• How was/were the study/studies designed, conducted and analyzed?	N/A
	• Are there missing data?	No
Robustness of the study results analysis	• Are the results from the study/studies repeatable?	N/A – case reports and case series
	• Is/Are this/these study/studies first-of-a-kind?	No

Factor	Notes	Assessment
	• 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 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
Patient tolerance for risk, and perspective on benefit:	• Is there data regarding how patients tolerate the risks posed by the device?	Yes, risks posed by the device are no different than those associated with typical interventional catheter procedures.
	• Are the risks identifiable and definable?	Yes, potential complications identified in the IFU
Disease severity	• Is the disease so severe that patients will tolerate a higher amount of risk for a smaller benefit?	In stable asymptomatic patients, conservative therapy is viable
Disease chronicity	• Is the disease/condition chronic?	Only if untreated
	• How long do patients with the disease/condition live?	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.[4] Mortality

Factor	Notes	Assessment
		rates in asymptomatic patients within five years are 19% increase and in symptomatic patients to up to 24%.[5]
	• If chronic, is the illness easily managed with less invasive or difficult therapies?	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.[6]
Patient-centric assessment	• How much do patients value this treatment?	High—successful placement and exchange of devices during peripheral diagnostic and interventional procedures.
	• 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

Factor	Notes	Assessment
	• 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; Technical Success rates: • 99.0% (204/206) for Go2 Wire† • 100% (100/100) for benchmark devices Device-related AE rates: • 0.0% (0/243) for Go2Wire† • 1.0% (1/100) for benchmark devices † Criteria met for establishing non-inferiority of Go2Wires to the benchmark devices
	• Is postmarket data available that change the risk/benefit evaluation from what was available when the previous devices were evaluated?	No

Factor	Notes	Assessment
	• 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.	None of the additional postmarket elements are considered applicable to the subject device. 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.
	• Is there reason to expect a significant difference between real-world performance of the device and the performance found in pre-market experience with the device?	No; data presented are derived from real-world case 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
Summary of the Benefit(s)	**Summary of the Risk(s)**	**Summary of Other Factors**
Go2Wire		
Go2Wire Technical Success Rate: 99% Benchmark Guidewires Technical Success Rate: 100%	Go2Wire AE Rate: 0.00% Benchmark Devices: AE Rate: 1.00%	Guidewires are well established technology that are compatible with standard interventional techniques.

5.5 Ongoing Postmarket Clinical Follow-up (PMCF)

In order to confirm ongoing safety and performance of the Go2Wire Guide Wire and Go2Wire Extension Device, PMCF activities over the next 12-month period are intended to collect additional high quality patient-level data from a minimum of 100 clinical cases. Based on clinical use patterns with the Go2Wire and Extension Device seen in the previous PMCF activity, it is anticipated that approximately 16% of these 100 cases will include

usage of the Extension Device. The results of this PMCF activity will be reported in the planned updates to the clinical evaluation.

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 size 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 cause it to stop functioning properly.
- If a plaque ruptures, 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 of lower limbs with intermittent claudication and critical limb ischemia. 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 the heart (the coronary arteries) become clogged up with plaques which could cause a myocardial infarction: a condition where the blood supply to your heart is blocked.
    - Stroke: a condition where the blood supply to (part of) the brain is interrupted

Risk factors that can significantly 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 serious CVD, such as a heart attack.

The Merit Go2Wire Guide Wire is used to facilitate the placement and exchange of devices during diagnostic and interventional procedures in the peripheral circulatory system and the central circulatory system, excluding the coronary arteries and cerebral vasculature.

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. Approximately 44 million people are affected by 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 PVD is defined as narrowing and obstruction of antegrade flow of major systemic arteries other than those of

the cerebral and coronary circulations. 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. Within the population, 3-10% are affected by PAD, and 20% of all patients are 70 years of age and older. The ratio of asymptomatic and symptomatic patients is 4:1. Men are more often affected than women but only at younger ages. A rising worldwide prevalence is expected due to prolonged life expectancy. 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.[7] As PAD caused by 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. 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). 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. A complication of PAD is Critical Limb Ischemia (CLI) - CLI is a condition that occurs when blood flow to the limbs is severely restricted from atherosclerosis. Patients with CLI carry an increased risk of major amputation without revascularization. Mortality rates in asymptomatic patients within five years are 19% increase and in symptomatic patients to up to 24%.[5] The prognosis of patients with intermittent claudication (IC) is determined by cardiac or cerebrovascular complications. Only 2% have a major amputation within 10 years.

The market for 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.

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.

6.1.1 Treatment Options and Interventions

The following details a summary of the current options available for diagnosing and treatment of PAD.

6.1.1.1 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 directly into the leg. The agent also shows up clearly on a computerized tomography (CT) or magnetic resonance imaging (MRI) scan when injected intravenously.

The Go2Wire Guide Wires are used during angiography to assist in the placement of diagnostic catheters that deliver contrast media for the purpose of imaging the vasculature.

6.1.1.2 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 PAD:

- Lifestyle changes - making lifestyle changes to improve symptoms and reduce the risk of developing a more serious 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 PAD while reducing the risk of developing another CVD:
    - Statins - Statins work by reducing 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 rupture of plaque in the arterial 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.

- o 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 with the patient awake during the intervention. The puncture site will be numbed by the anesthetic, so the patient does not feel any pain. The interventionalist 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 scaffold 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 anesthesia, 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 artery so the blood supply can be rerouted, or bypassed, through the healthy vein. Sometimes a section of artificial tubing is used as an alternative to a grafted vein.

7.0 Suggested Profile and Training for Users

The Go2Wire Guide Wire and Extension Device are intended to be used by physicians trained in diagnostic and interventional radiology, cardiology, nephrology, and vascular surgery procedures.

8.0 Applicable Harmonized Standards and Common Specifications

The following harmonized standards and guidance documents were applied or considered during the design and development of the Go2Wire.

Table 22. Applicable Standards

Title	State of the Art Date/Version	Merit Compliance Date/Version	Merit Compliance†	Justification for Partial Compliance§
Medical devices - Information to be supplied by the manufacturer	EN ISO 20417:2021	EN ISO 20417:2021	Full	N/A
Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	EN ISO 15223-1:2021, *[EU-MDR Harmonized]* ISO15223-1:2021 *[ISO]*	EN ISO 15223-1:2021, *[EU-MDR Harmonized]* ISO15223-1:2021 *[ISO]*	Full	N/A
Sterilization of medical devices – Requirements for medical devices to be labelled “sterile” Requirements for terminally sterilized medical devices	EN 556-1:2001 + EN 556- 1:2001/AC:2006, *[EU-MDD Harmonized][CEN]*	EN 556-1:2001 + EN 556- 1:2001/AC:2006, *[EU-MDD Harmonized][CEN]*	Full	N/A
Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices	EN ISO 11135:2014 ISO 11135:2014 (EQV) + EN ISO 11135:2014/A1:2019 ISO 11135:2014/Amd1:2018 (EQV) *[CEN]*	EN ISO 11135:2014 ISO 11135:2014 (EQV) + EN ISO 11135:2014/A1:2019 ISO 11135:2014/Amd1:2018 (EQV) *[CEN]*	Ful	N/A
Sterilization of medical devices -- Microbiological methods -- Part 1: Determination of a population of microorganisms on products	EN ISO 11737-1:2018 ISO 11737-1:2018(EQV) *[CEN]*	EN ISO 11737-1:2018 ISO 11737-1:2018(EQV) *[CEN]*	Full	N/A
Product Adoption and process equivalency forethylene oxide sterilization	AAMI TIR28:2016 *[AAMI]*	AAMI TIR28:2016 *[AAMI]*	Full	N/A
Biological Evaluation of Medical	ISO 10993-7:2008 +	ISO 10993-7:2008 +	Full	N/A

Title	State of the Art Date/Version	Merit Compliance Date/Version	Merit Compliance†	Justification for Partial Compliance§
Devices – Part 7:Ethylene Oxide sterilization residuals	ISO 10993-7:2008/Cor1:2009 + ISO 10993-7:2008/Amd 1:2019 *[ISO]*	ISO 10993-7:2008/Cor1:2009 + ISO 10993-7:2008/Amd 1:2019 *[ISO]*		
Bacterial endotoxins -Test methods, routinemonitoring, and alternatives to batch testing	ANSI/AAMI ST72:2019 *[ANSI/AAMI]*	ANSI/AAMI ST72:2019 *[ANSI/AAMI]*	Full	N/A
Classification of Air Cleanliness, Clean rooms & Associated Controlled Environments. Part 1: Classification of air cleanliness	EN ISO 14644-1:2015 ISO 14644-1:2015(EQV) *[CEN]*	EN ISO 14644-1:2015 ISO 14644-1:2015(EQV) *[CEN]*	Full	N/A
Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration	EN ISO 14644-2:2015 ISO 14644-2:2015(EQV) *[CEN]*	EN ISO 14644-2:2015 ISO 14644-2:2015(EQV) *[CEN]*	Full	N/A
Quality Systems – Medical Devices – Quality Management Systems. Requirements for Regulatory Purposes	EN ISO 13485:2016	EN ISO 13485:2016	Full	N/A
Medical Devices - Application of Risk Management to Medical Devices	EN ISO 14971:2019	EN ISO 14971:2019	Full	N/A
Biological Evaluation of Medical Devices – Part 1: Evaluation and testing	EN ISO 10993-1:2020 ISO 10993-1:2018(EQV) *[CEN]*	EN ISO 10993-1:2020 ISO 10993-1:2018(EQV) *[CEN]*	Full	N/A
Biological evaluation of medical devices -- Part 4: Selection of tests for interactions with blood	EN ISO 10993-4:2017 ISO 10993-4:2017(EQV) *[CEN]*	ISO 10993-4:2017 *[ISO]*	Full	N/A

Title	State of the Art Date/Version	Merit Compliance Date/Version	Merit Compliance†	Justification for Partial Compliance§
Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity	EN ISO 10993-5:2009 ISO 10993-5:2009(EQV) *[EU-MDD Harmonized][CEN]*	ISO 10993-5:2009 *[ISO]*	Full	N/A
Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization	ISO 10993-10:2021	ISO 10993-10:2021	Full	N/A
Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	EN ISO 10993-11:2018 ISO 10993-11:2017(EQV) *[EU-MDD Harmonized][CEN]*	EN ISO 10993-11:2018 *[CEN]*	Full	N/A
Biological Evaluation of Medical Devices – Part 12: Sample preparation and reference materials	ISO 10993-12:2021 *[ISO]*	ISO 10993-12:2021 *[ISO]*	Full	N/A
Biological Evaluation of Medical Devices – Part 18: Chemical Characterization of Medical Device Materials within a Risk Management Process	EN ISO 10993-18: 2020 ISO 10993-18: 2020 *[ISO]* [EU-MDD Harmonized] [CEN]	ISO 10993-18: 2020 *[ISO]*	Full	N/A
Standard Guide for Biocompatibility of Medical Device Packaging Materials	ASTM F2475-20 *[ASTM]*	ASTM F2475-20 *[ASTM]*	Full	N/A
Sterile single-use intravascular introducers, dilators and guide wires	EN ISO 11070:2014 ISO 11070:2014 (EQV) + EN ISO11070:2014/A1:2018 ISO 11070:2014/Amd1:2018 (EQV) *[CEN]*	EN ISO 11070:2014 ISO 11070:2014 (EQV) + EN ISO 11070:2014/A1:2018 ISO 11070:2014/Amd1:2018 (EQV) *[CEN]*	Full*	*Go2Wire is compliant to all relevant sections applicable for guide wires, refer to Note at end of this table for full detail.
Standard Test Methods for	ASTM F640-20	ASTM F640-20	Full	N/A

Title	State of the Art Date/Version	Merit Compliance Date/Version	Merit Compliance†	Justification for Partial Compliance§
Determining Radiopacity for Medical Use				
Medical Devices – Application of usability engineering to medical devices	IEC 62366- 1:2015+AMD1:2020*[IEC]*	IEC 62366- 1:2015+AMD1:2020*[IEC]*	Full	N/A
Packaging for Terminally Sterilized Medical Devices. Part 1: Requirements for materials, sterile barrier systems, and packaging systems.	EN ISO 11607-1:2020 ISO 11607-1:2019(EQV) *[CEN]*	EN ISO 11607-1:2020 ISO 11607-1:2019(EQV) *[CEN]*	Full	N/A
Packaging for Terminally Sterilized Medical Devices. Part 2: Validation requirements for forming, sealing and assembly processes	EN ISO 11607-2:2020 ISO 11607-2:2019(EQV) *[CEN]*	EN ISO 11607-2:2020 ISO 11607-2:2019(EQV) *[CEN]*	Full	N/A
Packaging -- Complete, filled transport packages and unit loads -- Conditioning for testing	EN ISO 2233:2001*[CEN]* ISO 2233:2000 (EQV)	EN ISO 2233:2001 *[CEN]*	Full	N/A
Standard Practice for Performance Testing of Shipping Containers and Systems	ASTM D4169 – 22 *[ASTM]*	ASTM D4169 – 22 *[ASTM]*	Full	N/A
Standard Test Method for Detecting Gross Leaks in Medical Packaging by Internal Pressurization (Bubble Test)	ASTM F2096 - 11 (R2019) *[ASTM]*	ASTM F2096 - 11 (R2019) *[ASTM]*	Full	N/A
Standard Test Method for Detecting Seal Leaks in porous Medical Packaging by Dye Penetration	ASTM F1929 - 15 *[ASTM]*	ASTM F1929 - 15 *[ASTM]*	Full	N/A

Title	State of the Art Date/Version	Merit Compliance Date/Version	Merit Compliance†	Justification for Partial Compliance§
Standard Test Method for Seal Strength of Flexible Barrier Materials	ASTM F88 / F88M – 21 *[ASTM]*	ASTM F88 / F88M – 21 *[ASTM]*	Full	N/A
Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	ASTM F1980 - 16 *[ASTM]*	ASTM F1980 – 16 [ASTM]	Full	N/A

*****The GO2Wire™ Guide Wire product is complaint the relevant sections of the ISO 11070:2014/A1:2018 which apply to guidewires only, these are Section 4 "General Requirements" and Section 8 "Additional requirements for guidewires".
Sections 5,6,7 and 9 of ISO 11070:2014/A1:2018 and their accompanying Annex's are not in the scope as these apply to introducers and dilators only and therefore are not applicable to the GO2Wire™ Guide Wire Product.
†Note: Per (EU) 2017/745 Articles 8 & 9, 'Full' compliance is claimed for compliance to relevant parts of the standard.
§Note: 'Partial' compliance is claimed where the standard allows an alternative process, e.g., UOUP per Annex C under IEC 62366-1.

9.0 References

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10.0 Revision History

SSCP Revision	ECN Number	Date Issued DD/MM/YYYY	Change description	SSCP Author	Revision validated by the Notified Body
001	ECN159377	MAR-2022	Initial SSCP for GO2Wire Guide Wire	Robert Shifko, Medical Writer	☐ Yes Validation language: English ☒ No
002	ECN165570	08/10/2023	Update to Go2Wire SSCP to address notified body questions and incorporate current PCMF and benchmark literature data. Product codes revised to include /EU designation. Document updates to align with current SSCP template.	Craig Nordhausen, PhD Director, Clinical Research	☒ Yes Validation language: English ☐ No