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 InQwire Amplatz Super Stiff Guide Wire, hereafter referred to as the InQwire Amplatz 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 InQwire Amplatz Guide Wire, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

The English version of this SSCP document (SSCP 0125) has been validated by the notified body. The following information is intended for users/healthcare professionals. Since the InQwire Amplatz Guide Wire is not a long-term implant device, a patient-directed SSCP is not required.

1.0 Device Identification and General Information

1.1 Device Trade Name

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

Table 1. Devices Included in this SSCP

Product Code	Diameter (inch)	Length (cm)	Flexible Tip Length (cm)	Tip Description
Amplatz Straight Tip, Short Taper				
IQA509	0.035"	260	1	Straight, Short Tip
IQA510	0.038"	260	1	Straight, Short Tip
IQA511	0.035"	180	1	Straight, Short Tip
IQA512	0.038"	180	1	Straight, Short Tip
IQA513	0.035"	75	1	Straight, Short Tip
IQA528	0.038"	145	3.5	Straight, Short Tip
IQA518	0.038"	145	4	Straight, Short Tip
IQA521	0.035"	75	4	Straight, Short Tip

Product Code	Diameter (inch)	Length (cm)	Flexible Tip Length (cm)	Tip Description
IQA522	0.035"	180	4	Straight, Short Tip
IQA527	0.035"	145	3.5	Straight, Short Tip
IQA524	0.035"	145	4	Straight, Short Tip
Amplatz Straight Tip				
IQA 517	0.038"	145	6	Straight
IQA 519	0.038"	180	6	Straight
IQA 520	0.038"	260	6	Straight
IQA 523	0.035"	145	7	Straight
IQA 525	0.035"	180	7	Straight
IQA 526	0.035"	260	7	Straight
IQA 563	0.035"	75	7	Straight
IQA 564	0.038"	75	6	Straight
Amplatz J 3mm				
IQA 500	0.035"	145	7	3mm J
IQA 501	0.035"	180	7	3mm J
IQA 502	0.035"	260	7	3mm J
IQA 503	0.038"	145	7	3mm J
IQA 504	0.038"	180	7	3mm J
IQA505[a]	0.035"	145	3.5 Short Taper	3mm J
IQA506[a]	0.035"	180	3.5 Short Taper	3mm J
IQA507[a]	0.035"	260	3.5 Short Taper	3mm J

Abbreviations: cm = centimeter

[a] Does not hold CE Marking under MDD and is pending CE approval under MDR

1.2 Manufacturer Information

The name and address of the manufacturer of the InQwire Amplatz 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 United States of America 84095-2416

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 are listed in Table 3.

1.6 Risk Class of Device

The EU device risk classification for the InQwire Amplatz Guide Wire is listed in Table 3.

Table 3. Device Identification Information

Device Name	EU Device Class	Product Number	Basic UDI-DI	Single Registration Number (SRN)	EMDN/CND Code	EMDN/CND Terms
InQwire Amplatz Guide Wire	III	IQA509, IQA510, IQA511, IQA512, IQA513, IQA528, IQA518, IQA521, IQA522,	088445048761E4	SRN-US-MF-000001366	C04020102	Peripheral Vascular Guidewires, Diagnostic, Not

Device Name	EU Device Class	Product Number	Basic UDI-DI	Single Registration Number (SRN)	EMDN/CND Code	EMDN/CND Terms
		IQA527, IQA524, IQA 517, IQA 519, IQA 520, IQA 523, IQA 525, IQA 526, IQA 563, IQA 564, IQA 500, IQA 501, IQA 502, IQA 503, IQA 504, IQA505[a], IQA506[a], IQA507[a]				Hydrophilic

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

[a] Does not hold CE Marking under MDD

1.7 Year of EU Market Introduction

The year that the InQwire Amplatz Guide Wire was first placed on the EU market is presented in Table 4.

1.8 Authorised Representative

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

1.9 Notified Body

The Notified Body (NB) involved in the conformity assessment of the InQwire Amplatz 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
InQwire Amplatz Guide Wire	2017	Merit Medical Ireland Ltd.	IE-AR-000001011	BSI	2797

Device Name	Year Placed on EU Market	Authorized Representative		Notified Body (NB)	
		Name	SRN	Name	ID Number

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

2.0 Intended Use of the Device

2.1 Intended Purpose

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

2.2 Indications and Intended Patient Groups

Indications

Indicated for use in patients with disease and/or lesions of the peripheral vasculature or central circulatory system, excluding coronary arteries and cerebral vasculature.

Patient Population

The InQwire Amplatz Guide Wires are designed for use on adult patients 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 Clinical Benefits

The InQwire Amplatz 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.

2.4 Contraindications

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

3.0 Device Description

The InQwire Amplatz Guide Wire is comprised of two tip configurations: Amplatz Straight Tip and Amplatz J 3 mm. The Stiff, Super Stiff, or "Amplatz" type guide wires are a combination of the strength of a stiff body shaft with the safety of a soft, a-traumatic tip. The guide wires have a polytetrafluoroethylene (PTFE)-coated flat wire coil, an inside core wire that is welded to the outside flat coil at three points (Proximal Tip, Distal Tip, and a Spot weld approx. 22 cm from the Distal Tip) (Figure 1).

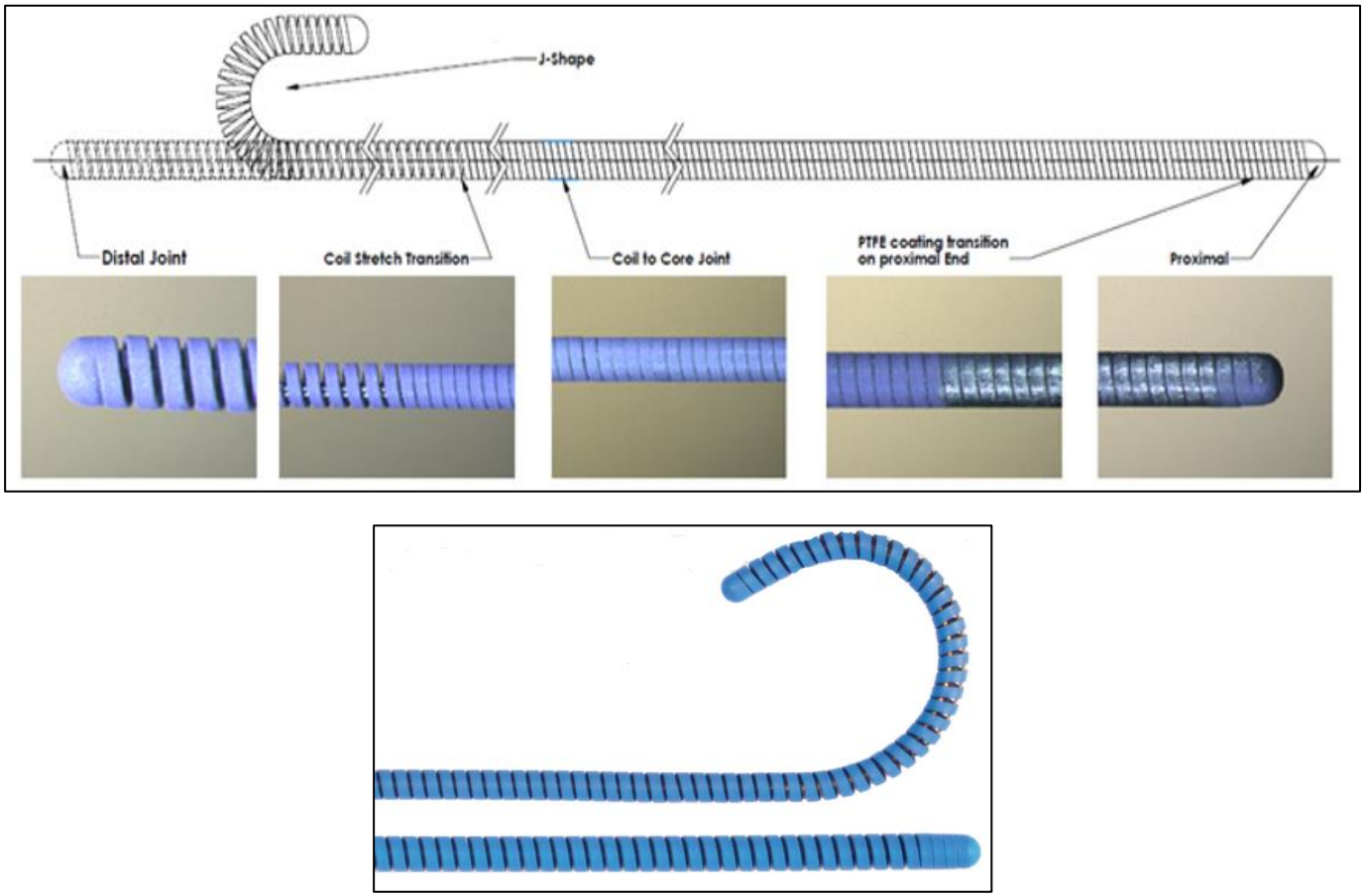

Figure 1. InQwire Amplatz Guide Wire Product Image

The InQwire Amplatz Guide Wires are offered in 0.035-in or 0.038-in outer diameters with different tip shapes (straight or J-Tip), tip lengths (1 cm to 7 cm), and are available in lengths from 75 cm to 260 cm. The InQwire Amplatz Guide Wires are packaged in a plastic hoop fitted with a luer hub. This packaging facilitates guide wire flushing with saline or heparinized saline prior to use.

3.1 Materials/Substances in Contact with Patient Tissues

The materials or substances in the InQwire Amplatz Guide Wire that may be in patient contact are summarized in Table 5. The InQwire Amplatz Guide Wire does not contain components requiring specific consideration, such as medicinal substances or non-viable animal or human tissues, and such components are not utilized during manufacturing.

Table 5. InQwire Amplatz Guide Wire Materials in Contact with Patient Tissues

Component	Material Specification
Coil Wire–Flat	304V Stainless Steel
Coil Coating	PTFE

Abbreviations: PTFE = polytetrafluoroethylene

The InQwire Amplatz Guide Wire configurations are intended for single-use only and are provided sterile to the end user. The device is not intended to be re-sterilized by the user. Merit utilizes ethylene oxide (EtO) sterilization for the InQwire Amplatz Guide Wire.

3.2 Operating Principals

Merit guide wires are placed through a transcutaneous device 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 guide wire 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 guide wire, 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.

Merit guide wires are 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 guide wire which is advanced a short

way up the vessel lumen. The needle can then be removed, and a dilator passed over the guide wire to allow a catheter to be advanced. At this stage the guide wire can either be left in situ or 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 taken on this technique and applied it for their own purposes.

Merit guide wires are placed through a transcutaneous device which may be filled with heparinized saline solution to facilitate advancement of the wire through the vasculature. The guide wire is removed from the dispenser and inserted into the device and advanced to the desired location according to the planned procedure by clinicians.

3.3 Previous Generations or Variant

There have been no previous generations or variants of the InQwire Amplatz Guide Wire.

3.4 Accessories

The accessories listed in Table 6 are not supplied with the product but are required supplies for its use. Other devices and products which are intended to be used in combination with the device are listed below and in the device IFU.

Table 6. Additional Accessories and Products Not Included with the Device But Referenced in IFU

Component	Comment
Syringe	To be used with heparinized saline solution to wet the microcatheter surface to activate the hydrophilic coating and to flush the lumen of the microcatheter to purge air from inside the microcatheter.
Access Needle	An Access Needle is first used to enter the vasculature using the Seldinger technique. The needle is placed through the skin into the desired vessel.
Dilator	Dilator(s) are used to enlarge the skin and vessel entrance for the catheter sheath introducer.
Catheter Sheath Introducer	A Catheter Sheath Introducer is then placed over the guidewire and dilators into the vessel, and the guidewire and dilators are removed.

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 InQwire Amplatz 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 (AEs) are identified based on a review of the pertinent clinical evidence.

Intended clinical benefits: The InQwire Amplatz 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.

Articles published from June 1, 2019 to April 15, 2022 were reviewed. Based on the literature, guide wires have been successfully used in various diagnostic and interventional procedures. Guide wires are beneficial in that they facilitate diagnostic and therapeutic interventional procedures. For the clinical evaluation, the performance outcome was defined as follows:

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

Performance data for the InQwire Amplatz Guide Wire is derived from PMCF data due to the off-label use of the InQwire Amplatz Guide Wire in identified clinical literature. Performance data for benchmark competitor devices is derived from the clinical literature. Based on the PMCF data, the technical success rate for the InQwire Amplatz Guide Wire is high at a rate of 99.1%. The cumulative technical success rate for the benchmark competitor devices is 98.6%.

The potential complications/AEs related to the subject device as identified in the IFU are summarized in Table 7. In addition, the device/procedure-related adverse events identified in the PMCF data and the corresponding risk assessment harms are presented in Table 8.

Table 7. InQwire Amplatz Guide Wire: Potential Adverse Events

Product Configuration	Potential Adverse Events
InQwire Amplatz Guide Wire	Potential complications which may result from the use of the device include but are not limited to: • Air Embolism/Thromboembolism • Allergic Reaction • Cardiac Arrhythmia • Amputation • Arteriovenous (AV) Fistula • Breathing Difficulty • Death • Embolism • Hematoma • Hemorrhage • Hemoglobinuria • 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.

Abbreviations: AV = arteriovenous; CVA = cerebrovascular accident; TIA = transient ischemic attack

Table 8. InQwire Amplatz Guide Wire Complications, Applicable Labeling and Identified Harms

Complications from PMCF data	Device-Related	Procedure-Related	IFU Complications	Global Harms (QRMT0030)
PMCF Data: Peripheral and Circulatory Use for Catheter, Stent, Balloon, or Other Device Placement				
Cardiac Arrhythmia		X	• NA	• NA
Hematoma	X		• Hematoma	• Hemorrhage Moderate
Vessel Dissection	X		• Vessel Dissection	• Soft Tissue Injury Major
Vessel Spasm	X		• Vessel Spasm	• Vasoconstriction

Abbreviations: IFU = instructions for use; NA = not applicable; PMCF = post-market clinical follow-up; QRMT = quality risk management table

The InQwire Amplatz Guide Wire has been used with a high level of safety during diagnostic and interventional procedures in patients. Device-related adverse events reported in the PMCF data for the InQwire Amplatz Guide Wire are shown in Table 9. Of the 222 cases, 7 complications occurred in 5 cases. Device-related adverse events reported in the clinical literature for comparable benchmark guide wires are shown in Table 10.

Table 9. Device-Related Adverse Events from InQwire Amplatz Guide Wire PMCF Data

Device-Related Adverse Event	Incidence Rate, n/N (%)	Timing of Adverse Event		
		Acute (≤ 30 days)	> 30 days	Not Reported
PMCF Data: Peripheral and Circulatory Use for Catheter, Stent, Balloon, or Other Device Placement				
Hematoma	1/222 (0.90%)	2	0	0
Vessel Dissection	2/222 (0.90%)	1	0	0
Vessel Spasm	2/222 (0.45%)	1	0	0

Abbreviations: PMCF = post-market clinical follow-up

Table 10. Device-Related Adverse Events from Benchmark Competitor Studies

Device-Related Adverse Event	Incidence Rate, n/N (%)	Timing of Adverse Event		
		Acute (≤ 30 days)	> 30 days	Not Reported
Cardiac tamponade due to right ventricle guidewire puncture[4]	1/1813 (0.06%)	1	0	0
Intraabdominal hemorrhage[5]	2/1813 (0.11%)	2	0	0
Major vascular complications[6]	3/1813 (0.17%)	3	0	0
Non-flow-limiting femoral artery dissection[7]	1/1813 (0.06%)	1	0	0
Self-contain aortic dissections[8]	2/1813 (0.11%)	2	0	0
Small retro-aortic pseudoaneurysm[8]	1/1813 (0.06%)	1	0	0

Safety data for the InQwire Amplatz Guide Wire and for comparable benchmark guide wires are summarized in Table 11. Safety data for the InQwire Amplatz Guide Wire is derived from PMCF data due to the off-label use of the InQwire Amplatz Guide Wire in clinical literature. Safety data for benchmark competitor devices is derived from the clinical literature. Based on the PMCF data, the incidence of device-related AEs for the InQwire Amplatz Guide Wire is low at a rate of 1.80%. Incidence of AEs for benchmark competitor devices is 0.552%. Based on the comparative analysis, the UBL of the 1-sided 95% CI for p1-p2 is less than 0.10 (10%). Therefore, H_0 is rejected and the device-related AE rate for the InQwire Amplatz Guide Wire is established as non-inferior to the comparable benchmark guidewires at a 95% confidence level. Therefore, the subject device/equivalent comparator satisfies the established acceptance criteria for safety measures.

Table 11. Comparative Safety for InQwire Amplatz Guide Wire

	Subject Device, n/N (%)	Benchmark Competitors, n/N (%)	Estimated Difference [95% LBL]	UBL < 10%
Device-related AE Rate	4/222 (1.80%)	10/1813 (0.552%)	1.25% (2.75%)	PASS

Abbreviations: AE = adverse event; CI = confidence interval; LBL = lower bound limit; PMCF = post-market clinical follow-up; UBL = upper bound limit

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

4.2 Warnings and Precautions

The warnings and precautions for the InQwire Amplatz Guide Wire are listed in Table 12.

Table 12. InQwire Amplatz Guide Wire: Warnings & Precautions

Product Configuration	Labeling
InQwire Amplatz Guide Wire	**Warnings/Precautions** • Use extreme caution when withdrawing PTFE coated guide wires 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 access needle as soon as the guide wire has reached the appropriate position. • Extreme care should be taken when manipulating a catheter and wire combination within the vessel 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 and catheter tip position under fluoroscopy. The guide wire and catheter should be removed as a unit when possible to prevent potential damage to the vessel wall. • 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). • Always advance or withdraw a wire slowly. Free movement of the guidewire within a catheter provides valuable tactile information. Never push, auger, or withdraw a guidewire which meets resistance as this could potentially affect other indwelling devices. Resistance may be felt tactilely or noted by tip buckling during fluoroscopy. Test all systems for resistance prior to use. • 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. • There are insufficient safety and performance data to support the use of the device in pediatric populations. **Cautions** • A guide wire is a delicate instrument. 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 adverse procedural complications and /or adverse patient outcomes. The physician should be familiar with the use of angiography products and the literature concerning the complications of angiography. Angiography should be undertaken only by an experienced angiographer. • To avoid damaging the guide wire tip during removal from the flush hoop, slide proximal portion of guide wire body forward in the flush hoop loop allowing the distal wire tip to exit the flush hoop. Gently grasp guide wire tip and J straightener together as a unit and gently pull forward to withdraw the distal wire portion from the flush hoop. • Advancement with excessive force may cause coil penetration and vessel damage. • This device includes stainless-steel alloy components that contain Cobalt (EC No.: 231-158-0; CAS No.: 7440-48-

Product Configuration	Labeling
	4) defined as CMR 1B in a concentration above 0.1% weight by weight.
	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.

Abbreviations: CAS = Chemical Abstracts Service; CMR = carcinogenic, mutagenic, reprotoxic; EC = Enzyme Commission; EU = European Union; PFTE = polytetrafluoroethylene

The labeled general caution for the InQwire Amplatz Guide Wire is summarized below:

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

4.3 Other Relevant Safety Aspects

The InQwire Amplatz Guide Wire has not been subject to any field safety corrective actions.

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

5.1 Summary of Clinical Data for the Equivalent Device

An equivalence assessment was performed for the new Merit InQwire Amplatz Guide Wire variants not previously Conformité Européenne (CE)-marked and the established equivalent variants previously CE-marked under MDD in 2017. In accordance with MDR, Annex XIV, Part A, Section 3, the manufacturer has established sufficient access to the data necessary to substantiate the claimed equivalence. The equivalence rationale for the new InQwire Amplatz Guide Wire variants: IQA505, IQA506 and IQA507; and the established equivalent InQwire Amplatz Guide Wire variants are duly justified with regard to clinical, technical, and biological characteristics with no identified impact on safety and performance (S&P) outcomes.

The three variants of the InQwire Amplatz Guide Wire and the previously established equivalent InQwire Amplatz Guide Wire variants have similar use, similar designs, and similar material composition. In accordance with MEDDEV 2.7/1 Rev 4 Appendix A1, MDCG 2020-5, and MDR, Annex XIV, Part A, Section 3, the clinical, technical, and biological equivalence of the new InQwire Amplatz Guide Wire variants and established InQwire Amplatz Guide Wire variants has been established through this analysis. Therefore, clinical data collected in this evaluation pertaining to the

established equivalent InQwire Amplatz Guide Wire variants may be used to support the S&P of the new InQwire Amplatz Guide Wire variants.

5.2 Summary of Clinical Investigations of the Subject Device

Conformity of the InQwire Amplatz Guide Wire is pending assessment and endorsement by the applicable NB. No pre-market clinical investigations of the device were conducted in the EU prior to the initial CE marking. A summary of all available clinical data for the InQwire Amplatz Guide Wire is provided in Section 5.3.

5.3 Summary of Clinical Data from Other Sources

PMCF Data

The clinical evidence supporting the safety and performance of the InQwire Amplatz Guide Wire includes post-market clinical follow-up (PMCF) data from 222 high-quality surveys in which the InQwire Amplatz Guide Wire was used (see Table 13). The high-quality surveys confirmed:

- The InQwire Amplatz Guide Wire successfully reached the target location (primary success) in most cases.
- The InQwire Amplatz Guide Wire was able to facilitate placement of the device during a diagnostic or interventional procedure (secondary success) in most cases.
- The InQwire Amplatz Guide Wire exhibited a low complication rate.

Table 13. InQwire Amplatz Guide Wire PMCF Results

Attribute	Count (n)	PMCF Reponses (N)	n/N (%)
Primary Success	221	222	221/222 (99.5%)
Secondary Success	220	222	220/222 (99.1%)
Device-related AEs	4	222	4/222 (1.80%)

Abbreviations: AE = adverse event; PMCF = postmarket clinical follow-up

5.4 Overall Summary of Clinical Performance and Safety

Data to support the safety and performance of the InQwire Amplatz Guide Wire have been analyzed and provide evidence to support all the safety and performance outcomes. Based on a review of the clinical data, the overall benefits to patients of using the device for its intended purpose outweigh the overall risks.

5.5 Ongoing 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 InQwire Amplatz Guide Wire is detailed in PMCFP-QRMT0030-001.

As a result of the analysis of PMS data and the recommendation of the Risk Review Report, RR-QRMT0030-001 REV 002, Post-Market Clinical Follow-Up will be performed to support the clinical safety and performance of the InQwire Amplatz Guide Wire. The PMCF strategy for InQwire Amplatz Guide Wire is to conduct a quantitative patient specific (high quality) survey to collect PMCF data. The PMCF data analysis will include consideration of the following:

- Assess any safety or performance issues identified in the product feedback evaluation forms to determine what impact if any was contributed by the InQwire Amplatz Guide Wire.
- As part of the annual update to CER0125, safety and performance data collected from the PMCF activity and the clinical literature for the subject device will be analyzed and compared to the safety and performance clinical literature data for the benchmark devices in accordance with the methods employed in the clinical evaluation.
- Assess if any safety or performance issues identified in the product feedback evaluation forms constitutes a previously unidentified residual risk. Update the product risk assessment (QRMT0030) as necessary.
- Address any instances of off-label use within the Risk Review Report and PMCFER

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 CVD. Examples of CVD include:[10]

- 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
- Cerebrovascular disease: a condition in which vasculature supplying the brain become clogged with plaques
- Rheumatic heart disease: where rheumatic fever caused by streptococcal bacteria causes damage to the heart muscle and heart valves
- Congenital heart disease: a condition in which birth defects disrupt the normal development and function of the heart due to structural malformations at birth
- Deep vein thrombosis and pulmonary embolism: a condition in which there are blood clots located in veins of the leg that may dislodge and move to the heart and/or lungs

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 CVD, such as a heart attack. 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.[11]

The Merit Medical InQwire Amplatz Guide Wires are used to facilitate the placement of devices during diagnostic and interventional procedures. The InQwire Amplatz Guide Wires are indicated for use in patients with disease and/or lesions of the peripheral vasculature or central circulatory system, excluding coronary and cerebral vasculature. Therefore, InQwire Amplatz Guide Wire may be used for CVD conditions including PVD, congenital heart disease, or deep vein thrombosis/pulmonary embolism.

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.[11] 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. 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.[12] 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.[14] The ratio of asymptomatic and symptomatic patients is 4:1.[15] Men are more often affected than women but only at younger ages.[16] A rising worldwide prevalence is expected due to prolonged life-expectancy.[17] 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.[18] As atherosclerosis is a systemic process, there exists a strong correlation with CAD and cerebrovascular disease. Clinical severity of one of these syndromes predicts that in the others.[12] According to the ACC/AHA practice guidelines, patients with PAD fit clinically into one of four categories depending on their symptoms: asymptomatic, IC, CLI, or ALI.[12] 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.[19] A complication of PAD is 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.[20] Mortality rates in asymptomatic patients within five years are 19% increase and in symptomatic patients to up to 24%.[14] The prognosis of patients with IC is determined by cardiac or cerebrovascular complications. Only 2% have a major amputation within 10 years.[21]

6.2 Treatment Options and Interventions

PAD Treatment

The management of PAD focusses on two main goals: improving quality-of-life by reducing symptoms and reducing vascular morbidity and mortality.[12] 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 helping to reduce the production of low-density lipoprotein (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.[22] 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 IC and those with CLI. 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.[23]

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.[24] 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. [24,25] 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.[26] The latest European Society of Cardiology (ESC) guidelines recommend the transradial access for the management of acute coronary syndromes (ACS) (class I, level A).[27] Radial access is also associated with reduced incidence of acute kidney injury after PCI.[28] 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.[29]

For below-the-knee (BTK) lesions although endovascular-first approach leads to better limb salvage outcomes and lower complications compared to venous bypass, the antegrade revascularization approach fails in 20% of cases.[30] In a small scale, retrospective study, Stahlberg et al. (2022) reported similar outcomes of in terms of feasibility, safety, and limb salvage from retrograde plantar-arch and transpedal-access approaches when antegrade revascularization of BTK lesions failed.[30] Alternative technological advances to improve percutaneous transluminal angioplasty (PTA) outcomes in BTK lesions include the Tack Endovascular System.[31] In femoropopliteal lesions, post-angioplasty dissection has been linked to adverse effects on arterial patency and is presumed to pose a similar or greater risk in smaller diameter BTK vessels.[31] The Tack Endovascular System aims to treat post-angioplasty dissection using a nitinol scaffold implant to reposition intiomomedial flaps to the outer arterial wall.[31] In a prospective, single arm study, Geraghty et al. (2021) showed promising safety and efficacy results for the Tack Endovascular System in terms of 6-month patency, limb salvage, clinical target revascularization.

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.[32] 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.[33] 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 PAD. 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 AEs 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 PAD. In-depth understanding of the operation preparation, procedure, and best imaging techniques can help to optimize outcomes.[34] 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.[35] The orbital atherectomy system (OAS) is a novel device treating calcified lesions in both above-the-knee (ATK) and 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.

7.0 Suggested Profile and Training for Users

For use by physicians trained in diagnostic and interventional radiology, cardiology, nephrology, and vascular surgery procedures.

8.0 Applicable Harmonized Standards and Common Specifications

The following harmonized standards and guidance documents were applied or considered during the design and development of the InQwire Amplatz Guide Wire:

- FDA Guidance on Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling (October 1995)

- ISO 11070:2014/Amd. 1:2018(en) Sterile single-use intravascular introducers, dilators and guidewires
- ISO 10993-1:2009 (E) Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- ISO 10993-3, Biological Evaluation of Medical Devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity;
- ISO 10993-4, Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood;
- ISO 10993-5, Biological Evaluation of Medical Devices – Part 5: Tests for cytotoxicity: In-Vitro methods;
- ISO 10993-10, Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and sensitization;
- ISO 10993-11, Biological Evaluation of Medical Devices – Part 11: Tests for system toxicity;
- ISO 11135-1:2014, Sterilization of health care products–Ethylene oxide–Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

All of these standards and guidelines have been applied in full where applicable to the InQwire Amplatz Guide Wire.

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10.0 Revision History

SSCP Revision	ECN Number	Date Issued DD/MM/YYYY	Change Description	Revision Validated by the Notified Body
REV 001	ECN161986	DEC-2022	Initial SSCP for the InQwire Amplatz Guide Wire	☐ Yes Validation language: English ☒ No
Rev 002	ECN165647	DEC-2022	Removal of 'The information in this document is proprietary to Merit Medical Systems, Inc.' from the footer of this document	☐ Yes Validation language: English ☒ No

SSCP Revision	ECN Number	Date Issued DD/MM/YYYY	Change Description	Revision Validated by the Notified Body
Rev 003	ECN179930	10/10/2023	Revised SSCP to address comments/questions from the notified body during review.	☒ Yes Validation language: English ☐ No
Rev 004	ECN188541	28/10/2024	Adding translations	☐ Yes Validation language: English ☒ No