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 True Form Reshapable Guide Wire, hereafter referred to as True Form 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 True Form 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 0126) has been validated by the notified body (NB). The following information is intended for users/healthcare professionals. A supplemental SSCP with information for patients was not established since the True Form Guide Wire is not an implantable device for which patients are provided an implant card, nor is the device intended to be used directly by patients.

1 Device identification and general information

1.1 Device Trade Name

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

Table 1. Devices Included in this SSCP

Device Name	Product Numbers
True Form Guide Wire	TF14145S/EU, TF14165S/EU, TF14180S/EU, TF14180A/EU

1.2 Manufacturer Information

The name and address of the manufacturer of the True Form Guide Wire are provided in Table 2.

Table 2. Manufacturer Information

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

Abbreviations: USA = United States of America

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 is listed in Table 3.

1.6 Risk Class of Device

The EU device risk classification for the True Form 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
True Form Guide Wire	Class III	TF14145S/EU, TF14165S/EU, TF14180S/EU, TF14180A/EU	088445048821DV	US-MF-000001366	C04020101, C04020201	Peripheral Vascular Diagnostic Guidewires, Hydrophilic Peripheral Vascular Therapeutic Guidewires, Hydrophilic

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

1.7 Year of EU Market Introduction

The year that the True Form 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 True Form 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
True Form Guide Wire	2018	Merit Medical Ireland Ltd.	IE-AR000001011	BSI	2797

Abbreviations: BSI = British Standards Institution; EU = European Union; SRN = single registration number

2 Intended Use of the Device

2.1 Intended Purpose/Indications

The labeled intended purpose and indications for use for the True Form Guide Wire device configurations are summarized in Table 5.

Table 5. True Form Guide Wire: Intended Purpose/Indications for Use

Product Configuration	Intended Purpose/Indications for Use
True Form Guide Wire	The True Form Reshapable Guide Wire is intended to facilitate the placement of catheters within the peripheral vasculature for various diagnostic and interventional procedures. The True Form Reshapable Guide Wire is indicated for use in patients with peripheral vascular disease who require diagnostic or interventional procedures

2.1.1 Intended User(s)

For use by healthcare professional who are trained physicians.

2.1.2 Intended Patient Population

The True Form Reshapable Guide Wires are designed for use on adult patients during diagnostic and interventional procedures by trained physicians. Using their education and experience, the physician determines based on the individual patient, the appropriate guide wire to support the associated devices to be used during the procedure. The guide wire navigates the anatomy and facilitates placement of the associated devices.

2.2 Contraindications:

The labeled contraindications for the True Form Guide Wire device configurations are summarized in Table 6.

Table 6. True Form Guide Wire: Contraindications

Product Configuration	Contraindications
True Form Guide Wire	The True Form Reshapable Guide Wire should not be used in the coronary or neurovasculature.

3 Device Description

The Merit True Form Guide Wire is a polymer jacketed stainless-steel guide wire with hydrophilic coating and a 2-cm shapeable distal tip (see Figure 1 and Figure 2). The True Form Guide Wire consists of a 0.014” outer diameter wire supplied in lengths of 145 cm, 165 cm, and 180 cm. The micro guidewires are manufactured with a stainless-steel core wire, flattened at the distal end, with a 5-cm gold plated tungsten coil attached to the distal tip and is fully jacketed with

a radiopaque filled polymer jacket. The guidewire is fully coated with a hydrophilic coating. The tip of the wire is shapeable and comes in both straight and angled configurations. The wires are placed within a spiraled hoop dispenser with a flush luer attached and clips to secure the wire within the hoop.

Figure 1. True Form Guide Wire configuration

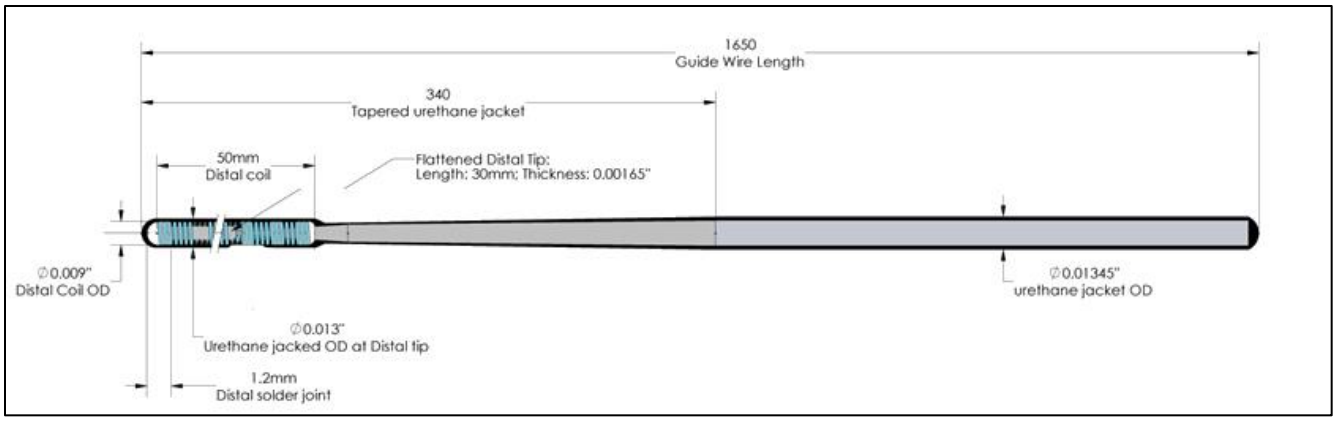
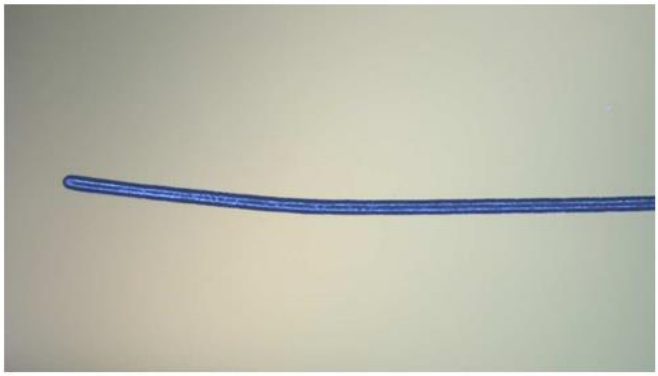


Figure 2. True Form Guide Wire – distal end



The guidewires are available in the configurations shown in Table 7.

Table 7. True Form Guide Wire Configurations

Part Number	Outer Diameter	Length	Shapeable Tip	Tip Shape
TF14145S/EU	0.014 in	145 cm	2 cm	0° ± 20°
TF14165S/EU	0.014 in	165 cm	2 cm	0° ± 20°
TF14180SEU	0.014 in	180 cm	2 cm	0° ± 20°
TF14180A/EU	0.014 in	180 cm	2 cm	45° ± 20°

Abbreviation: cm = centimeter, in = inch

3.1 Materials/Substances in Contact with Patient Tissues

A biocompatibility assessment has been completed for the True Form Guide Wire, and biocompatibility testing was performed according to recommendations set forth in the ISO 10993 Biological Evaluation of Medical Devices series of standards. Table 8 lists the materials or substances in the True Form Guide Wire that may be in patient contact, together

with their tissue contact categorization.

Table 8. True Form Reshapable Guidewires Device Materials

Product Component	Material in Contact with Patient Tissues	Categorization
Core Wire	Stainless steel: 304S/S	Externally communicating Circulating blood contact Limited duration (≤ 24 hours)
Coil Wire	Radiopaque Coil: Gold plated Tungsten	
	Solder: 95% Tin, 5% Silver	
Polymer Jacket	Polyurethane	
	Tungsten particles	
	Barium Sulfate	
Hydrophilic Coating	Coating: Polyvinyl Pyrrolidone	
	Primer: Methylene diphenyl diisocyanate	

Abbreviations: S/S = stainless steel

The devices in the True Form Guide Wire are intended for single-use only and are provided sterile to the end user. The subject devices are not intended to be re-sterilized by the user. Merit utilizes ethylene oxide (EtO) sterilization for the True Form Guide Wire.

The True Form Guide Wire is a single-use device, and the useful device lifetime of the device is contingent upon the duration of the medical procedure. Typically, intervention may last 10-30 minutes per device intended use for gaining vascular access and placement of catheters within the peripheral vasculature. From a conservative standpoint, the total procedural time has been assumed to be an hour (60 minutes) in order to account for particularly difficult or challenging cases.

3.2 Operating Principles

The True Form Guide Wire is used by clinicians for general intravascular use within the peripheral vasculature to facilitate placement of diagnostic or therapeutic catheters. The True Form Guide Wire is used under fluoroscopy to visualize tip movement with torque application. Prior to Guide Wire removal from the hoop dispenser, the hoop dispenser is flushed with heparinized saline. Once the Guide Wire is removed, the tip straightener can shape the distal tip to the desired shape according to standard practices. For insertion, starting with the flexible end, the Guide Wire is inserted into the catheter lumen using the insertion tool. The torque device is then secured in place over the proximal end of the Guide Wire to aid in steering the Guide Wire. Accepted angiographic techniques are used to steer and position the Guide Wire to the intended location. Once in the desired location, the Guide Wire is secured in place during advancement of the catheter over the wire and into the treatment location. Finally, the Guide Wire is removed prior to any intervention when the catheter is in position.

3.3 Previous Generations or Variants

The True Form Guide Wire is an established device which holds current CE-marking and is commercially marketed in the EU. There are no previous generations or variants of this device.

3.4 Accessories

The True Form Guide Wires may be packaged with components to aid in the insertion and use of the device. Table 9 lists

the components that may be included with the True Form Guide Wire, including a description.

Table 9. True Form Guide Wire Accessories

Part Number	Description	Device	Description
510061	Torque Device		The torque device is included to facilitate directional manipulation of the guide wire.
503248	Insertion Tool		A guide wire insertion tool is included to help direct and maneuver the delicate guide wire tip through other devices such as hemostasis valves and/or catheter hubs.
703070	Tip Straightener		The tip straightener is used by the physician to shape the tip.

4 Risks and Warnings

4.1 Residual Risks and Undesirable Effects

Potential hazards and/or risks associated with the use of the True Form Guide Wire identified in the device IFUs include the following:

- Hemorrhage
- Systemic or Disseminated Infection
- Ischemia
- Thrombus formation
- Vessel spasm
- Vessel damage
- Inflammatory reaction – Systemic
- Vasoconstriction
- Vascular Perforation
- Vascular Dissection
- Death
- Foreign Body Reaction
- Embolism
- Pulmonary Embolism
- Thrombosis
- Cerebral Infarction
- Chemical Toxic Effects
- Myocardial Infarction

The device/procedure-related adverse events identified from the clinical literature and post-market clinical follow-up data as well as the corresponding risk assessment harms are presented in Table 10. Of the 398 cases identified for the True Form Guide Wire (clinical literature: 181; PMCF data: 217), there was 1 report of a procedure-related pseudoaneurysm (0.6%). There were 10 adverse events identified in the 594 cases (1.7%) identified for the benchmark state-of-the-art guidewires with only 1 event characterized as device-related (0.2%).

Table 10. True Form Guide Wire and Benchmark Device Complications: Incidence and Timing

Adverse Events	Incidence Rate, n/N (%)	Device Related	Procedure Related	Time of Occurrence		IFU Complications	Harm Category (Severity)
				Procedural	Acute (≤ 30 days)		
Common femoral artery pseudoaneurysm	1/398 (0.2)		X	X		Vessel damage	Soft tissue injury (3)†
Vessel dissection (device related)	1/594 (0.2)	X	X	X		Vascular Dissection	Soft tissue injury (3)†
Vessel dissection	3/594 (0.5)		X	X		Vascular Dissection	Soft tissue injury (3)†
Vessel rupture	5/594 (0.8)		X	X		Vascular Perforation	Soft tissue injury (4)†
Death from post-procedural septic shock and respiratory failure	1/594 (0.2)		X		X	Death	Death (5)†

† Severity of hazard graded on a scale of 1-5; 3=serious/major, 4=critical, 5=catastrophic/fatal

The risk management documents associated with the True Form Guide Wire have been reviewed, and the identified complications/adverse events are captured within the harms and hazards included in the risk assessment. No new safety concerns specific to the True Form Guide Wire were identified in this evaluation, and the rates reported are consistent with the available data for state-of-the-art guidewires. All known and foreseeable hazards and associated risks have been identified and reduced as far as possible, and the residual risks are deemed acceptable.

4.2 Warnings and Precautions

The labeled warnings and precautions for the True Form Guide Wire device configurations are summarized in Table 11.

Table 11. True Form Guide Wire: Warnings & Precautions

Product Configuration	Labeling
True Form Guide Wire	**Warnings**
	• If the guide wire is to remain unused at any time during the procedure, be sure to rehydrate with heparinized saline prior to reinsertion. • If resistance is felt during advancement, stop movement to assess and define cause of resistance. Remove wire and inspect tip for damage prior to proceeding. • Always maintain visualization of the guide wire under fluoroscopy, ensuring that the tip is moving freely when torque is applied. • Anticoagulation therapy, per facility protocol, should be considered to reduce potential for thrombus formation on the device. • In the event of a malfunction of the device and/or changes in the performance of the device, exercise caution as this may indicate a change that may affect the safety of the device. • After use, dispose of device in a manner consistent with standard protocols for biohazard waste disposal. • There are insufficient safety and performance data to support the use of the device in pediatric populations.
	Precautions
	• Do not use in case of any surface irregularities, bends, or kinks. Any damage of the guide wire may change its characteristics likely to affect its performance. • Use the device prior to the “Use Before” date noted on the package. • This device should be used only by physicians thoroughly trained in percutaneous intravascular techniques and procedures in relevant areas of the anatomy. • Do not attempt to move the guide wire without observing the guide wire tip. Always maintain visualization of the guide wire under appropriate imaging. • Do not push, pull, or rotate the wire against resistance. If resistance is met, discontinue movement of the guide wire, determine the reason for resistance and take appropriate action before continuing. Movement of the catheter or guide wire against resistance may result in separation of the catheter or guide wire tip, damage to the catheter, or vessel damage. • The hydrophilic coating has a lubricious surface only when properly hydrated. • Do not wipe the guide wire with dry gauze as it may damage the hydrophilic coating. • Do not move the torque device on the guide wire when the torque device is tightened as it may damage the guide wire • If using a Y-connector on the catheter, do not manipulate the guide wire with the Y-connector in the locked position as the guide wire may be damaged. • Do not expose guide wires to extreme temperatures. • Extreme care should be taken when shaping the guide wire distal tip. Over-manipulation of the guide wire distal tip may cause damage. Damaged guide wires should not be used. • Do not withdraw through a metal entry needle, a metal dilator, or use this wire with devices that contain metal parts such as atherectomy catheters or laser catheters. • Use of alcohol, antiseptic solutions, or other solvents must be avoided. • Consider the use of systemic anticoagulation to prevent or reduce clotting. • 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,

Product Configuration	Labeling
	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.
	Reuse Precaution
	• For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.

The general caution statement in the labeling for the True Form Guide Wire is as follows:

Rx Only Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician trained and/or experienced in the use of this device.

There is no MR compatibility information provided in the labeling for the True Form Guide Wire.

4.3 Storage

Store the True Form Guide wire in a cool, dark, dry area. Avoid hot or humid temperatures, direct sunlight, UV rays or anywhere where the product could become wet when storing.

4.4 Other Relevant Safety Aspects

There have been no Corrective Action Reports (CARs), field escalations, or product recalls during the period between January 1, 2017 and July 31, 2021.

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

5.1 Summary of Clinical Data for the Equivalent Device

The devices in the True Form Guide Wire have been commercialized for several years and have an established history of use. In addition, the subject devices utilize well-established technology and exhibit a low complaint/incident rate. Therefore, this evaluation is based on scientific literature currently available for the True Form Guide Wire. No equivalent device was used to establish conformity of the True Form Guide Wire.

5.2 Summary of Clinical Investigations of the Subject Device

Conformity of the True Form Guide Wire was initially assessed and endorsed by the applicable Notified Body in 2018. No manufacturer-sponsored pre-market clinical investigations have been performed as part of the development of the devices in the True Form Guide Wire.

5.3 Summary of Clinical Data from Other Sources

To evaluate device safety and performance, a review was conducted of relevant clinical literature published between

January 01, 2017 and August 31, 2021. Table 12 and Table 13 summarize the literature included for the evaluation of the safety and performance of the True Form Guide Wire. For evaluation of performance, technical success was defined as the ability of the guidewire to facilitate placement of devices during diagnostic and interventional procedures. For evaluation of safety, device/procedure-related adverse events were defined as any complications occurring during the procedure or the pre-discharge period attributed to the use of the subject device or could be foreseeably related to the subject device.

Table 12. True Form Guide Wire: Summary Study Characteristics

Author (Year) LOE Study Type	Primary Clinical Indication	Device Application, Access	Patients, n/N (%)*	Devices Used (N)	Gender (M/F) Age (years)	Follow-up
Cao (2021)[1] LOE: C Retrospective, single-center study	Renal artery embolization	Delivery of embolization microcatheter, left radial artery	16/43 (37.2)	True Form Guide Wire (NR)	14M/2F Mean 56.06 ± 18.42	4 weeks
Hakimé (2021)[2] LOE: B1 Retrospective, single-center study	Prostate artery embolization	Catheterization of prostatic arteries, common femoral or left radial artery	165/165 (100)	0.016-in§ True Form Guide Wire (NR)	165M/0F† Mean age [range] 68 ± 8.4 [45–89] years	12 months

Abbreviations: in = inch; NR = not reported
* n = number of patients treated with device, N = total patients
§ Device available only in 0.014-inch configuration, likely erroneously reported
† All patients assumed to be male, not explicitly reported

Table 13. True Form Guide Wire: Safety and Performance Summary

Author (Year) LOE Study Type	Device	Fluoroscopy Time (min)	Procedure Time (min)	Performance Measures	Safety Measures	Other Notes
				Technical Success, n/N (%)	Adverse Events*, n/N (%)	
Cao (2021)[1] LOE: C Retrospective, single-center study	True Form Guide Wire	Mean 11.59 ± 6.74	Mean 31.31 ± 17.52	16/16 (100)	0/16 (0)	-
Hakimé (2021)[2] LOE: B1 Retrospective, single-center study	True Form Guide Wire	NR	Median [range] 120 [90–180]	165/165 (100)§	1/165 (0.6)	Study-defined technical success (adequate PCR on final CBCT angiography) was 98.8%; study-defined clinical success (improved symptoms in line with CIRSE standards) was 96.4%; the only complication that could be foreseeably attributed to guidewire use was 1 incidence of common femoral artery pseudoaneurysm
Total				**181/181 (100%)**	**1/181 (0.5%)**	

Abbreviations: CBCT = cone-beam computed tomography; CIRSE = Cardiovascular and Interventional Radiology Society of Europe; NR = not reported; PCR = prostate contrast retention
* Adverse events include complications that could be foreseeably attributed to the use of the subject device
§ Bilateral prostate artery embolization was achieved in all patients

Clinical data from post-market clinical follow-up (PMCF) activities were collected and evaluated as part of the most recent clinical evaluation. Clinicians were asked to provide specific and quantifiable safety and performance data related to patient cases in which the True Form Guide Wire was used. A total of 217 data points were collected from 12 respondents at the time of this evaluation. The product feedback questions relevant to the performance and safety of the True Form Guide Wire were formatted in an electronic evaluation form and the results are provided in Table 14.

Table 14. Summary Performance and Safety Measures for PMCF Data

Evaluation Form	Procedures	Technical Success, n/N (%)	Adverse Events, n/N (%)
EF1	5	5/5 (100%)	0/5 (0%)
EF2	4	4/4 (100%)	0/4 (0%)
EF3	10	10/10 (100%)	0/10 (0%)
EF4	1	1/1 (100%)	0/1 (0%)
EF5	5	5/5 (100%)	0/5 (0%)
EF6	20	2/20 (10%)	0/20 (0%)
EF7	32	32/32 (100%)	0/32 (0%)
EF8	25	25/25 (100%)	0/25 (0%)
EF9	20	20/20 (100%)	0/20 (0%)
EF10	15	15/15 (100%)	0/15 (0%)
EF11	30	30/30 (100%)	0/30 (0%)
EF12	50	50/50 (100%)	0/50 (0%)
Total	217	199/217 (91.7%)	0/217 (0%)

5.4 Overall Summary of Clinical Performance and Safety

The overall safety and performance data from the clinical literature and PMCF activities for the True Form Guide Wire are summarized in **Error! Reference source not found.**. These data demonstrate a technical success rate of 95.5% and d evice/procedure-related adverse event rate of 0.3%.

Table 15. Summary Performance and Safety Measures for PMCF Data

Clinical Data Source	Total Procedures	Technical Success, n/N (%)	Adverse Events, n/N (%)
Clinical Literature	181	181/181 (100)	1/181 (0.6)
PMCF Activity	217	199/217 (91.7)	0/217 (0.0)
Cumulative Total	398	380/398 (95.5)	1/398 (0.3)

These clinical data have been analyzed and they provide evidence to support the safety and performance measures established for the True Form Guide Wire. Based upon a review of the clinical data, the overall benefits to patients of using the device for its intended purpose outweigh the overall risks.

5.5 Post-Market Surveillance (PMS)

Post-market surveillance (PMS) occurs continuously, with reviews occurring at regular, defined intervals to track and identify trends in device complaints. Other PMS activities include on-going monitoring and investigation of field events such as physician or patient concerns or comments, customer reported adverse clinical events, adverse events identified

through regular, periodic literature reviews, and the routine trending of events reported in all commercially released products. 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. There have been no reportable events for the reporting period of January 1, 2017 to July 31, 2021 for the True Form Guide Wire.

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 True Form Guide Wire. The commercial market experience with the True Form Guide Wire reinforces that the potential risks have been reduced as far as possible, the potential benefits of the device outweigh the overall and individual potential risks, and the potential risks remain acceptable.

5.6 Postmarket Clinical Follow-up (PMCF)

Ongoing PMCF activities include clinician surveys requesting specific and quantifiable safety and performance data from clinical cases in which the True Form Guide Wire is used. Under the current PMCF plan, a total of 185 high-quality patient-level surveys will be collected from multiple clinicians in Europe and the United States. Safety and performance endpoints include device-related adverse events and technical success defined as follows:

Device-related Adverse Event: Complications occurring during the procedure or the follow-up period that are attributed to the use of the subject device.

Technical Success: Ability of the guidewire to facilitate placement of devices during diagnostic and interventional procedures.

In addition, the following background information relating to the procedure and guidewire use will be collected:

- Procedure Date
- Patient age and gender
- Catalog/part number for the True Form Guide Wire
- Lot number for the True Form Guide Wire
- Indications for use
- Type of procedure (e.g., diagnostic, interventional)
- Type of device placed using the True Form Guide Wire
- Procedure time

New clinical data obtained from this PMCF activity will be incorporated into subsequent clinical evaluations for the True Form Guide Wire.

6 Diagnostic or Therapeutic Alternatives

Peripheral artery disease (PAD) most commonly refers to atherosclerosis of the aortoiliac, femoropopliteal, and infrapopliteal arterial segments, leading to decreased perfusion of the lower extremities.[3] Accumulation of atherosclerotic plaque causing partial or complete occlusion of blood vessels supplying the lower extremities can lead to symptoms ranging from mild claudication to major tissue loss.[4] The estimated global prevalence of PAD in 2017 was 118.1 million, representing a 30% increase in prevalence over a 10-year period.[5] In the USA, PAD is estimated to affect approximately 6.5 million people age 40 years and older.[5]

Diagnosis of PAD is performed using the ankle-brachial index (ABI) which is the ratio between systolic blood pressure measured at the ankle and arms.[6] An ABI of ≤0.9 is interpreted as abnormal due to reduced blood supply to the ankle and is typically used to formally diagnose PAD.[4,6] After formal diagnosis of PAD, imaging techniques such as duplex ultrasound and angiography are used to determine the anatomical location and severity of occlusions in the peripheral vasculature.[4,6]

6.1 Endovascular Intervention for Peripheral Artery Disease

Endovascular therapy for PAD consists of minimally invasive interventional treatments where devices such as angioplasty balloons or stents are delivered using guidewires via the vasculature and deployed at lesions in the peripheral vasculature. Endovascular therapy for PAD has become significantly more popular than the historical gold standard of bypass surgery in recent years, with major society guidelines now recommending an endovascular-first approach to treat symptomatic PAD, especially for short lesions.[3,6] Guidewires are essential tools in endovascular therapy since they must pass through tortuous vessels, traverse the occlusion, and aid in delivering a variety of devices to treat the occlusion.[7]

Various types of endovascular interventional devices are available to physicians, including percutaneous transluminal angioplasty (PTA), drug-coated balloon (DCB) angioplasty, occlusion perfusion catheters, microneedle perfusion catheters, stents, and atherectomy.[8] While each endovascular interventional device has its own advantages and disadvantages, it is commonly agreed that endovascular therapy is a safer treatment option compared to bypass surgery, and is especially recommended for patients with severe comorbidities.[6] In a systematic review of 31 studies reporting 813 endovascular procedures and 3,835 bypass surgery procedures, endovascular procedures were found to carry a lower risk of wound infection, wound lymph leakage, but equal risk of wound hematoma, compared to bypass surgery.[9] In terms of performance outcomes, endovascular procedures were associated with a lower primary patency rate, higher target lesion revascularization (TLR), and a similar amputation rate compared to bypass surgery.[9] Another study reviewing 500 patients with lower extremity bypass and 2,066 patients with peripheral vascular intervention (PVI) for below-knee lesions found significantly better one-year primary patency associated with PVI. One-year major amputation and mortality rates were similar between the two groups.[10]

6.2 Embolization

Embolization is a technique frequently used to treat hemorrhage as well as conditions such as vascular malformations, aneurysms, and tumors.[11] In the case of oncological applications, embolization can be used to target vessels that supply blood to a tumor. Cutting off the blood supply to the tumor serves different purposes including reducing the chances of blood loss during subsequent surgical excision and causing tumor necrosis. Embolic particles can also be loaded with

chemotherapeutic agents to limit dilution of chemotherapeutics within the target region.[11]

Percutaneous transcatheter embolization is used to treat damaged vasculature via the occlusion of blood vessels.[11] Embolic agents are deployed intravascularly from catheters and act to decrease blood flow to the targeted area.[11] There are many embolic agents available, including mechanical occlusion devices (e.g., metallic coils, balloons, stents, flow diverters, plugs, and shape memory foams), particulates (e.g., non-calibrated particulates and calibrated microspheres), and liquids/gels (e.g., sclerosing agents, in-situ gelling solutions, and shear-thinning gels).[11]

Rates of procedural success for embolization in the treatment of gastrointestinal bleeding range between 93% to 100%, and between 51% to 88% for clinical success.[11] In the case of postpartum hemorrhage, transcatheter arterial embolization procedures have technical success rates between 90% to 100%, and clinical success rates between 86% to 98%.[12] Overall, complications associated with embolization include those related to the puncture site, embolization site, and after embolization.[13] Complications related to the puncture site are usually minor and include pain, bleeding, and hematoma.[13] Major complications such as infection or pseudoaneurysm can occur but are rare.[13] Complications related to the embolization site include damage to the neighboring organs and distal infarction of vessels.[13] Lastly, complications that occur post-embolization include post-embolization syndrome, which can present as fever, vomiting, pain, and nausea.[13]

6.3 Alternative Therapies

Alternatives to endovascular therapy for PAD include bypass surgery and medical therapy, and alternatives to embolization include surgical management.

Surgical bypass approaches such as common femoral endarterectomy have long been considered the gold standard treatment for femoropopliteal occlusions.[14] While bypass surgery is associated with high primary patency rates, it is being supplanted by endovascular therapies in the treatment of PAD due to the high rate of post-surgical complications such as wound infections, hematomas and seromas leading to morbidity and mortality rates as high as 15%.[14] Bypass surgery is still considered the intervention of choice for long lesions and infrapopliteal lesions causing severe critical limb ischemia (CLI).[6]

For patients with mild symptoms from PAD including intermittent claudication (IC), revascularization using endovascular or open surgical means is not recommended if the symptoms do not compromise daily life activities.[6] For such patients, major society guidelines recommend medical therapy in the management of PAD.[3,6] Pharmacological measures include antihypertensive drugs such as diuretics, beta-blockers, calcium antagonists, angiotensin-converting enzyme (ACE) inhibitors, and angiotensin receptor blockers (ARB); lipid-lowering drugs such as statins; and antithrombotic drugs.[3,6] Non-pharmacological measures include cardiovascular risk factor management strategies like smoking cessation, healthy diet, weight loss, and regular physical exercise.[6]

An alternative therapy to embolization is surgery, which can be used to treat bleeding in the gastrointestinal system and postpartum hemorrhage.[15,16] Historically, surgery served as the first-line treatment for non-variceal upper gastrointestinal bleeding (NVUGIB), and the approach is still employed in current times.[16] A 2019 meta-analysis with 13 studies spanning 1,077 patients with refractory NVUGIB compared transcatheter arterial embolization to surgery and reported that there was a significant decrease in further intervention and rebleeding in the surgery group compared to the embolization group.[16] On the other hand, the authors reported that there was a nonsignificant decrease in

complications and mortality in the embolization group compared to the surgery group.[16] The authors concluded that embolization is an effective and safe treatment option for refractory NVUGIB, and that while there was a higher rebleeding rate for embolization, this did not impact clinical outcomes.[16]

7 Suggested profile and training for users

The True Form Guide Wire is intended for use by healthcare professionals who are trained physicians.

8 Applicable Standards and Common Specifications

The following international standards and guidance documents were applied or considered during the design and development of the True Form Guide Wire.

- ISO 11135, Sterilization of health care products -- Ethylene oxide -- Requirements for development, validation and routine control of a sterilization process for medical devices
- ISO 10993-1, Biological Evaluation of Medical Devices – Part 1: Evaluation and testing
- BS EN 62366, Medical devices – Application of usability engineering to medical devices
- ISO 11070, Sterile Single-Use Intravascular Catheter Introducers, Dilators and Guidewires
- FDA Guidance Document: Coronary and Cerebrovascular Guidewire Guidance (January 1995)
- FDA CTQ Indicators technical document - Critical to Quality Indicators: Hydrophilic Coated and Hydrophobic Coated Vascular and Neurological Devices - August 2015 – DRAFT
- EN ISO 80369-7:2016, Small bore connectors for liquids and gases in healthcare applications – Part 7: Connectors for intravascular or hypodermic applications

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10 Revision History

SSCP Revision	ECN Number	Date Issued DD/MM/YYYY	Change Description	SSCP Author	Revision Validated by the Notified Body
001	ECN 156272	December 2021	Initial SSCP for True Form Reshapable Guide Wire	Arun Mahadevan, PhD	☐ Yes Validation language: English ☒ No
002	ECN 167124	02/05/2023	Updated SSCP for True Form Reshapable Guide Wire in response to Notified Body questions.	Craig Nordhausen, PhD	☒ Yes Validation language: English ☐ No