SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP)
Guidewires
TF-0001
TD-27

For Publication in Eudamed

ROLE	DEPT	NAME / TITLE
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Signature Approval Matrix

This document must be reviewed and approved by all individuals listed below, or their authorized representatives.

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Approval	Clinical Affairs	Danyel Carr Sr. Director, Clinical Affairs
Approval	Quality	Dan Woda Sr. Quality Engineer
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Revision History

Revision	Date	Sections	Revision Description	Change Request #
A	05/17/2021	All	Initial Release	00103608
B	07/27/2023	All	Removing Worker Guidewires Class III per BSI response. SSCP-0003 will contain only Argon GW Class III devices	CR02813
C	19 Feb 2024	All	Harmonize the device name and Intended Purpose per the Declaration of Conformity	04434
D	11/01/2024	4.2	Updating BSI approved IFU numbers and revision numbers, there is no content update.	05591

Note: Approvals will be captured via the associated Change Request.

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Summary of safety and clinical performance

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 Guidewires including Stainless Steel, PTFE Coated Stainless Steel, and Nitinol Guidewires from 01/01/2017 to 07/31/2022 (Reporting Interval).

The SSCP is not intended to replace the Instructions for Use as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

The following information is intended for users/healthcare professionals. A supplemental SSCP with information for patients was not established since the Guidewires 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. Scope of this Summary of Safety and Clinical Performance (SSCP):

1.1. Device Trade Name:

- Guidewires
- EMDN Code C0402: Peripheral Vascular Guidewires; C0401 Coronary Artery Guidewires

1.2. Manufacturer Name and Address

The name and address of the manufacturer of the Guidewires is provided in Table 1.2.1

Table 1.2.1 Manufacturer Information

Manufacturer Name	Address of Manufacturer
Argon Medical Devices, Inc.	1445 Flat Creek Road Athens, Texas 75751, USA

1.3. Manufacturer Single Registration Number (SRN)

The Manufacturer Single Registration Number (SRN) is SRN: US-MF-000002324

1.4. Basic UDI-DI

The basic Unique Device Identifier (UDI) key is provided in Table 1.6.1.

1.5. European Medical Device Nomenclature

The EMDN Codes associated with these devices are EMDN Code C0402: Peripheral Vascular Guidewires; C0401 Coronary Artery Guidewires.

1.6. Class of Device

The EU device risk classification for the Guidewires is listed in Table 1.6.1.

Table 1.6.1 Device Identification Information

Product Number	Device Name and Description	Product Number	EU Device Class	Basic UDI-DI
388273	35/150/FC/SS/3J/CLASSIC	388273	III	08863332700062N
388275	38/150/FC/SS/3J/CLASSIC	388275	III	08863332700062N
388282	35/150/FC/PTFE/3J/CLASSIC	388282	III	08863332700042J
388284	38/150/FC/PTFE/3J/CLASSIC	388284	III	08863332700042J
388300	35/150/MC/PTFE/3J/CLASSIC	388300	III	08863332700142M
388301	35/150/MC/PTFE/ST/CLASSIC	388301	III	08863332700282Y
388768	35/175/FC/PTFE/3J/CLASSIC	388768	III	08863332700042J
388794	35/260/FC/PTFE/3J/CLASSIC	388794	III	08863332700042J
390182	35/150/FC/PTFE/3J/XTB	390182	III	08863332700202G
390186	35/175/FC/PTFE/3J/XTB	390186	III	08863332700202G
390282	35/150/FC/PTFE/3J/XTB	390282	III	08863332700302K
390284	38/150/FC/PTFE/3J/XTB	390284	III	08863332700202G
393182	35/150/FC/PTFE/3J/EXT	393182	III	08863332700182V
393184	38/150/FC/PTFE/3J/EXT	393184	III	08863332700182V
393186	35/175/FC/PTFE/3J/EXT	393186	III	08863332700182V
393187	38/175/FC/PTFE/3J/HD/Z	393187	III	08863332700182V
393282	35/150/FC/PTFE/3J/EXT	393282	III	08863332700212J
393999	35/180/FC/PTFE/DE-3J&ST	393999	III	08863332700242Q
395073	35/260/FC/PTFE/ST/MULLINS/HD	395073	III	088633327002932
395112	35/150/FC/PTFE/DE/3J/ST	395112	III	08863332700242Q
395170	35/180/FC/PTFE/BEN	395170	III	08863332700122H
395183	35/150/FC/PTFE/3J/CLASSIC	395183	III	08863332700042J
395205	21/125/FC/SS/ST	395205	III	08863332700072Q
395208	25/125/FC/SS/ST	395208	III	08863332700072Q
395212	32/150/FC/SS/ST	395212	III	08863332700072Q
395224	25/125/FC/PTFE/ST	395224	III	08863332700052L
395225	25/150/FC/PTFE/ST	395225	III	08863332700052L
395228	32/150/FC/PTFE/ST	395228	III	08863332700052L
395231	35/150/FC/PTFE/ST	395231	III	08863332700052L
395234	38/150/FC/PTFE/ST	395234	III	08863332700052L
395258	35/150/MC/PTFE	395258	III	08863332700282Y
395261	38/150/MC/PTFE	395261	III	08863332700282Y
395266	38/150/MC/PTFE/3J/HD	395266	III	08863332700272W
395270	25/125/FC/SS/3J	395270	III	08863332700062N
395273	35/150/FC/SS/3J	395273	III	08863332700062N
395275	38/150/FC/SS/3J	395275	III	08863332700062N
395279	25/125/FC/PTFE/3J	395279	III	08863332700042J
395280	35/150/FC/PTFE/1.5J/HD	395280	III	08863332700132K
395281	35/125/FC/PTFE/3J	395281	III	08863332700042J
395282	35/150/FC/PTFE/3J	395282	III	08863332700042J

Product Number	Device Name and Description	Product Number	EU Device Class	Basic UDI-DI
395284	38/150/FC/PTFE/3J	395284	III	08863332700042J
395289	35/150/FC/PTFE/6J	395289	III	08863332700042J
395309	32/150/MC/PTFE/3J	395309	III	08863332700142M
395312	35/150/MC/PTFE/3J	395312	III	08863332700272W
395315	38/150/MC/PTFE/3J	395315	III	08863332700142M
395320	35/150/MC/PTFE/3J/SLIP	395320	III	08863332700142M
395330	38/260/MC/PTFE/3J	395330	III	08863332700142M
395332	32/150/FC/PTFE/3J/HD	395332	III	08863332700132K
395333	38/260/MC/PTFE/Straight	395333	III	08863332700282Y
395337	35/125/MC/PTFE/6J	395337	III	08863332700142M
395345	35/150/FC/PTFE/DE/3J/LT	395345	III	08863332700232N
395350	35/180/FC/PTFE/1.5J/HD	395350	III	08863332700132K
395352	35/150/FC/PTFE/15J/LT	395352	III	08863332700172T
395367	25/260/FC/PTFE/ST	395367	III	08863332700052L
395368	32/260/FC/PTFE/ST	395368	III	08863332700052L
395369	35/260/FC/PTFE/ST	395369	III	08863332700052L
395370	38/260/FC/PTFE/ST	395370	III	08863332700052L
395382	35/150/FC/PTFE/LT	395382	III	08863332700152P
395384	35/150/FC/PTFE/LLT	395384	III	08863332700252S
395398	35/150/MC/PTFE/1.5J	395398	III	08863332700142M
395406	21/260/FC/PTFE/3J	395406	III	08863332700042J
395420	25/150/FC/PTFE/1.5J	395420	III	08863332700042J
395457	18/150/FC/PTFE/ST	395457	III	08863332700052L
395465	18/150/FC/PTFE/3J	395465	III	08863332700042J
395469	18/260/FC/PTFE/ST	395469	III	08863332700052L
395470	18/150/FC/PTFE/1.5J	395470	III	08863332700042J
395501	21/150/FC/PTFE/ST	395501	III	08863332700052L
395504	21/125/FC/PTFE/ST	395504	III	08863332700052L
395509	21/150/FC/SS/ST	395509	III	08863332700072Q
395522	21/260/FC/PTFE/ST	395522	III	08863332700052L
395523	21/150/PTFE/3J	395523	III	08863332700042J
395559	25/150/FC/PTFE/3J	395559	III	08863332700042J
395585	25/260/FC/PTFE/3J	395585	III	08863332700042J
395600	32/150/FC/PTFE/3J	395600	III	08863332700042J
395603	32/150/FC/SS/3J	395603	III	08863332700062N
395613	32/125/FC/PTFE/3J	395613	III	08863332700042J
395622	32/260/FC/PTFE/3J	395622	III	08863332700042J
395656	35/200/MC/PTFE/3J	395656	III	08863332700142M
395687	35/150/FC/PTFE/HD/ST	395687	III	08863332700262U
395703	35/200/FC/PTFE/ST	395703	III	08863332700052L
395708	35/150/FC/PTFE/3J/LLT	395708	III	08863332700192X
395721	35/145/MC/PTFE/LT/3J	395721	III	08863332700162R
395722	35/200/FC/PTFE/3J	395722	III	08863332700042J
395768	35/175/FC/PTFE/3J	395768	III	08863332700042J

Product Number	Device Name and Description	Product Number	EU Device Class	Basic UDI-DI
395780	35/150/FC/PTFE/7.5J	395780	III	08863332700042J
395787	35/150/FC/PTFE/1.5J	395787	III	08863332700042J
395794	35/260/FC/PTFE/3J	395794	III	08863332700042J
395817	38/200/FC/PTFE/3J	395817	III	08863332700042J
395839	38/260/FC/PTFE/3J	395839	III	08863332700042J
395863	38/150/FC/PTFE/1.5J	395863	III	08863332700042J
395884	28/150/FC/PTFE/ST	395884	III	08863332700052L
395900	32/150/FC/PTFE/1.5J	395900	III	08863332700042J
395919	35/150/FC/PTFE/LT/1.5J	395919	III	08863332700222L
395930E	35/150/FC/PTFE/BEN	395930E	III	08863332700122H
395931	32/150/FC/PTFE/BEN	395931	III	08863332700122H
395933C	38/150/FC/PTFE/BEN	395933C	III	08863332700122H
395961	28/150/FC/PTFE/3J	395961	III	08863332700042J
395979	15/150/FC/SS/MULLINS	395979	III	08863332700012C
395980	17/150/FC/SS/MULLINS	395980	III	08863332700012C
395991	30/150/FC/PTFE/3J	395991	III	08863332700042J
395993	35/150/FC/PTFE/3J/HD	395993	III	08863332700132K
A395231	35/150/FC/PTFE/CLASSIC	A395231	III	08863332700052L
A395282	35/150/FC/PTFE/3J	A395282	III	08863332700042J
A395284	38/150/FC/PTFE/3J	A395284	III	08863332700042J
A395312	35/150/MC/PTFE/3J/HD	A395312	III	08863332700272W
A395369	35/260/FC/PTFE/CLASSIC	A395369	III	08863332700052L
A395482	35/180/FC/PTFE/3J	A395482	III	08863332700042J
A395559	25/150/FC/PTFE/3J	A395559	III	08863332700042J
A395600	32/150/FC/PTFE/3J	A395600	III	08863332700042J
A395613	32/125/FC/PTFE/3J	A395613	III	08863332700042J
A395722	35/200/FC/PTFE/3J	A395722	III	08863332700042J
A395787	35/150/FC/PTFE/1.5J	A395787	III	08863332700042J
A395900	32/150/FC/PTFE/1.5J	A395900	III	08863332700042J

1.7. Year when the first certificate (CE) was issued covering the device:

TF-0001 –Guidewires:

DE certificate number 75616DE02 was issued for the guidewire product family as a Class III medical device on April 24, 2003, when hydrophilic coated guidewires (ArgoGuide) were added to the certificates.

On February 9, 2004, the manufacturing site name was changed from Maxxim Medical to Argon Medical Devices, Inc. DE certificate number 75616DE02 was replaced with the new DE certificate 2029292DE02 issued by KEMA.

In 2011, Argon changed its notified body from KEMA to BSI. The following certificates were issued by BSI:

- Full Quality Assurance Certificate CE 565719
- ISO 13485 Certificate FM 700791

- Design Examination Certificate CE 565721

In 2013, PTFE coated guidewires were added to the DE certificate. The prior representative products AquaTrack and ArgoGuide have been removed from the certificates and are no longer manufactured by Argon.

1.8. Authorized representative name and SRN:

Name:	Emergo Europe B.V.
Address:	Westervoortsedijk 60 6827 AT Arnhem The Netherlands
Website:	www.emergogroup.com
Telephone:	+31 (0)70 345 8570
Fax:	+31 (0)70 346 7299
SRN	NL-AR-000000116

1.9. Notified Body name and single identification number:

Name:	BSI Group the Netherlands B.V.
Address:	Say Building John M. Keynesplein 9 1066 EP Amsterdam The Netherlands
Website:	www.bsigroup.com
Telephone:	+31 (0)20 346 07 80
Fax:	+31 (0)20 346 07 81

Notified Body Number: 2797

2. Intended use of the device

2.1. Intended purpose

The Guidewires are intended to facilitate the percutaneous placement of intravascular devices and non-vascular devices during diagnostic and intervention procedures.

2.2. Indications and Target Populations

The Guidewires are indicated for use in angiographic procedure to introduce and position catheters and interventional devices within the coronary and peripheral vasculature. Guidewires are also intended to facilitate the percutaneous placement of peripheral intravascular and non-vascular devices during diagnostic and intervention procedures. The Guidewires present an indirect benefit to the patient by enabling diagnosis or procedures targeting the heart and the central circulatory system, the peripheral vascular, or non-vascular procedures related to gallbladder or biliary obstruction and percutaneous drainage. The selection of guidewire is based on physician judgement based on the type of procedure being performed.

2.3. Contraindications

There are no known contraindications.

3. Device Description

3.1. Description of the device

The guidewires are single-use surgical instruments for vascular access. The product is intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.

Guidewires are designed to facilitate the passage of catheters and sheath introducers into the vasculature utilizing the Seldinger or Modified Seldinger techniques. These techniques are routinely used but not limited to the placement of sheath introducers, cardiovascular catheters, radiology catheters, central venous catheters, arterial catheters and thermodilution catheters.

The core wire is only welded on the proximal end of the guidewire and ends before reaching the distal end of the guidewire. The safety ribbon is welded at both ends of the guidewire. The coil encloses the entire assembly.

The devices and components in Guidewires are packaged as sterile, single use devices. The wires are sealed in Tyvek pouches and packaged with an IFU. The devices are sterilized using ethylene oxide (EtO) sterilization.

A biocompatibility assessment has been completed for Guidewires, 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 Worker and Amplatz Guidewires is externally communicating, circulating blood and limited contact duration (≤24 hours).

Figure 1: Stainless Steel Guidewires

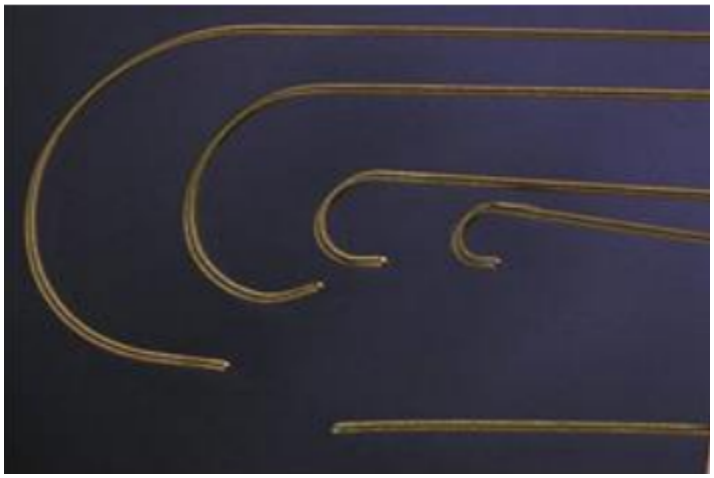

Figure 2: PTFE Coated Stainless Steel Guidewires

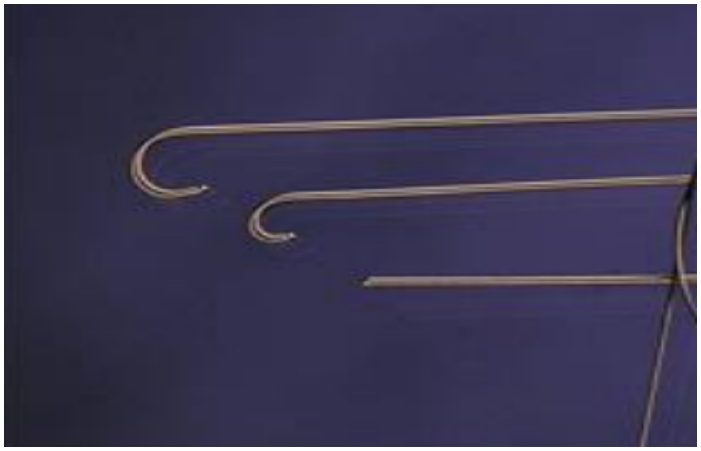

Table 3.1.-1: Guidewires variations

Trade names	Stainless Steel	Stainless Steel, PTFE Coated	Nitinol, Platinum Coil
Coating	Stainless Steel	PTFE Coated	Nitinol
Primary purpose	General intravascular use to assist with catheter placement	General intravascular use to assist with catheter placement PTFE coating facilitates the catheter passing over a guidewire	General intravascular use to assist with catheter placement
Diameter	.015” - .038”	.018” - .038”	.018”
Length	40cm - 150cm	50cm - 260cm	45cm
Shaft stiffness	Standard	Standard	Standard
Core	Fixed or Movable	Fixed or Movable, HD	Nitinol mandrel w/ Platinum Coil
Core taper	1.5cm – 9.0cm	3.5cm – 16cm	4.8cm

Trade names	Stainless Steel	Stainless Steel, PTFE Coated	Nitinol, Platinum Coil
Coating	Stainless Steel	PTFE Coated	Nitinol
Tip styles	1.5mm J, 3mm J, Straight (ST), Classic Double Ended, Mullins	1.5mm J, 3mm J, 6mm J, 7.5mm J, Extendable (EXT), Z, XTB, Classic, LT, LLT Straight (ST), Bentson Type (BEN), Double Ended (DE), Mullins	Straight

3.2. Previous Variants and their Differences

None

3.3. Accessories, Compatible Devices, and Other Products Used in Combination

The Guidewires are compatible with medical devices with a lumen larger than the diameter size listed on the label and shorter than the labelled length. Physician judgement required to select the appropriate guidewire compatible with other medical devices to be used.

4. Risks and Warnings

4.1. Residual Risks and Undesirable Side Effects

The Argon Risk Management process is conducted in accordance with EN ISO 14971:2019. Individual residual risk summary and assessment was conducted by review of clinical literature on the subject device and state of the art (SOA) in CER-001 Rev E. The search period covered 01 January 2017 to 31 July 2022. Adverse events identified in the literature are presented in the table below.

Table 4.1.-1: Potential Adverse Events for the Guidewires found in literature.

Potential Adverse Events
Potential complications associated with use of the Guidewires include, but are not limited to: • Vessel Perforation • Vessel Dissection • Thrombus/Occlusion • Myocardial Infarction • Perforation of non-intended organs • Tissue damage • Infection

Table 4.1.-2: Adverse Events Reported in the Literature

Adverse Event	Guidewires in this scope n/N (%)	Guidewires n/N (%)
Peripheral Vascular		
Vessel Perforation	0/24 (0%)	17/3069 (0.6%)
Vessel Dissection	0/24 (0%)	85/3265 (2.6%)
Thrombus/Occlusion	0/24 (0%)	2/289 (0.7%)
Total	**0/24 (0%)**	**104/3561 (2.9%)**
Non-Vascular		
Perforation of non-intended organs	0/59 (0%)	42/3203 (1.3%)
Tissue damage	0/59 (0%)	-
Infection	1/59 (1.7%)	93/3203 (2.9%)
Total	**1/59 (1.7%)**	**135/3203 (4.2%)**
Coronary		
Vessel Perforation	-	861/20682 (4.2%)
Vessel Dissection	-	39/5054 (0.8%)
Thrombus/Occlusion	-	59/15794 (0.4%)
Myocardial Infarction	-	236/17435 (1.4%)
Total	**-**	**1195/24861 (4.8%)**

*Note: All time points are periprocedural
**Note: n= # of occurrence's, N= total sample size for all studies where "n" was observed

The current knowledge and state of the art in the percutaneous placement of intravascular and non-vascular devices during diagnostic and interventional procedures by ancillary and standard of care guidewire devices. The literature was assessed for information related to the target population, available alternatives, benchmark, and competitor devices to present a state of the art landscape analysis. Performance and safety outcomes with currently available devices were established from the state current knowledge/state of the art in the field and from a review of published literature on competitor devices to define acceptance criteria. The comparison of acceptance criteria to outcomes with the subject devices demonstrates that the Guidewire Families are considered to be within the current state of the art when used as intended.

4.2. Warnings and Precautions

Guidewires IFU PMT-35-2000-99AM:

Warnings

- This device was designed, tested and manufactured for single use only. Reuse or reprocessing has not been evaluated and may lead to its failure and subsequent patient illness, infection, or other injury. Do not reuse, reprocess or re-sterilize this device.
- Inspect the package integrity before use.
- Do not use if package appears open or if the expiry date has been exceeded.

- Do not advance the wire against resistance until the cause of the resistance has been determined by fluoroscopy. Excess force against resistance may result in damage to guidewire, or catheter, or vessel perforation.
- Do not excessively torque the guidewire.
- Do not entrap or over-rotate the distal tip of the guidewire, it can lead to wire rupture.
- Do not excessively bend the guidewire, it may result in wire fracture.
- Guidewire placement should be monitored during placement and manipulation using fluoroscopic or suitable imaging method.
- Do not withdraw a guidewire through a needle. Straighten the guidewire in order to withdraw the needle.

Precautions

- Twisting or entanglement of the guidewires may occur when more than one wire is being used simultaneously. This can be prevented by carefully isolating and marking the proximal end of the wires.

4.3. Other relevant aspects of safety, including a summary of any field safety corrective action (FSCA including FSN)

There have been no field safety corrective actions or field notifications for the Guidewires.

5. Summary of clinical evaluation and post-market clinical follow-up (PMCF)

5.1. Summary of clinical data related to equivalent device, if applicable

Not applicable, as no equivalence is being claimed for the Guidewires.

5.2. Summary of clinical data from conducted investigations of the device before the CE-marking, if applicable

Not applicable. There were no clinical investigations of the Guidewires prior to CE marking.

5.3. Summary of clinical data from other sources, if applicable

Clinical data supporting the safety and performance of the Guidewires have been derived from the following sources:

- PMCF activities of the Guidewires Families including customer surveys
  - Survey Report – Worker Guidewire Product Family (January 2018 to September 2019)
  - Survey Report –Guidewires (01 September 2017 through 01 September 2020)
- The Medline and EMBASE databases were used for the literature search for the period from 01 January 2017 to 31 July 2022. It contains comprehensive datasets of

ongoing clinical investigations, peer reviewed scientific publications, current guidelines and recommendations released by medical associations, as well as the systematic literature reviews conducted to establish these recommendations.

The PMCF activities are documented in the PMCFP-0027 Rev C

Table 5.3.-1: PMCF Study Summary

Name of the Activity	Description of Activity	Aim of Activity	Rationale and Known Limitations of Activity	Date of Completion/ Estimated Timeline
Post-Market Clinical Follow Up Survey Report-the Argon Guidewires (N=36)	**Customer Feedback Surveys** Survey from health care professional/user	To capture the feedback on end users' satisfaction regarding a particular product's performance, end users' concerns in a particular product's safety and potential risk, overall user satisfaction regarding the product category and user profile and their chosen of similar products.	The sample size is relatively small for three of the product families evaluated:	18 November 2020
WORKER GUIDEWIRE PRODUCT FAMILY CUSTOMER SURVEY (N=53)	**Customer Feedback Surveys** Survey from health care professional/user	To obtain clinicians feedback related to the clinical safety and performance objectives of the Worker Guidewire devices.	The goal is to reach a minimum 85% acceptability/positive feedback from the end-users	September 2019

Survey Report – Worker Guidewire Product Family

The objective of this survey was to obtain clinicians feedback related to the clinical safety and performance objectives of the Worker Guidewire devices.

The survey was submitted via paper format and online to end-users (physicians/clinicians) of the product line. The research approach was qualitative (yes/no answers) rather than quantitative (e.g., performing a laboratory measurement on a parameter of interest). The relevance of the Yes/No style questions are based on the simplistic nature of each objective. There were 10 questions on the survey that applied to all the Worker guidewire variants. Argon Medical had intended to analyze the survey data after collecting at least 35 surveys; however, more surveys were received, and that data was incorporated. Qualitative analyses require a smaller sample size than the quantitative analyses.

A total of 53 respondents completed the survey. A minimum of 85% acceptability/positive feedback from the end-users was achieved except for Question #3 which was at 81% due to 6 of the 33 responses indicated that, the flexible tip of the Amplatz guidewire did not provide atraumatic navigation within the vessels. All the 6 responses were provided by the clinicians from the same hospital referencing one complaint issue that had just occurred at that facility. There were no new risks or concerns identified.

Survey Report Guidewires

The product-specific variants the Guidewires being surveyed are Bentson, Double ended, Movable core, Stainless Steel Fixed Core (SS Fixed Core) and PTFE Fixed Core.

The survey is an end user self-administrated survey conducted via paper form or online interactive format consisted of Yes/No questions and open-ended questions related to patient safety, product quality, as well as the user profile regarding use of other guidewires from other manufacturers. In closing, respondents were asked to provide any other feedback on the products evaluated.

The customer feedback survey consisted of five domains and was divided into three sections:

- Product-Specific Safety and Performance
- General Satisfaction and User Profile
- Respondent Information.

The survey domains are as follows:

- Product-Specific Safety & Performance. This domain includes product-specific metrics and questions like trackability, torqueability, flexibility, crossability, supportability and tactile feedback.
- Additional patient safety concerns related to the use of the device
- General satisfaction regarding the quality of the guidewires
- General product performance
- User profile.

The target survey population was the end users of the guidewires who are clinicians performing vascular procedures using any of the product families within the the guidewire product line for its intended uses.

The customer survey was sent to all global end users in various medical institutions through the company's sales network of distributors and direct sales representatives.

A total of 36 surveys were completed by end users who used at least one families of the guidewires products between 10 September 2020 through 13 November 2020. The end users were radiology technicians (n=6) and physicians (n=30).

The guidewires usage by respondents is shown below in Table 5.3.-2. A total of 30/36 (83.3%) respondents used one type of the guidewires, 5/36 respondents (13.9%) used 2 types of guidewires, and 1/36 respondent (2.8%) used all guidewire types.

Table 5.3.-2: Number and Type of Argon Products Used

Manufacturer	Number of Respondents (n=36)	Percent (%)
Single Product	30	83.3
Bentson	13	36.1
PTFE Fixed Core –J-tip	11	30.6
PTFE Fixed Core –Straight -tip1	5	13.9
Double-Ended	1	2.8

Manufacturer	Number of Respondents (n=36)	Percent (%)
Two Products	5	13.9
Bentson, Movable Core	1	2.8
Bentson, PTFE Fixed Core _Jtip	2	5.6
Bentson, SS Fixed Core – J-tip	1	2.8
PTFE Fixed Core –J-tip, SS Fixed Core – J-tip	1	2.8
All Seven Products	1	2.8

The response rate was 100% for all metrics in all families except for trackability (89%) in Bentson family. The customer feedback survey results by product were presented in Table 5.3.-3.

Table 5.3.-3: Customer Feedback Survey Results by Product

Guidewires Type	# of Users	Flexibility	Trackability	Torqueability	Control of Stiffness/ Flexibility	Tactile Feedback	Crossability
Bentson	18	18 (100%)	16 (89%)	N/A	N/A	N/A	N/A
Double-Ended	2	2 (100%)	2 (100%)	2 (100%)	N/A	N/A	N/A
Movable Core	2	N/A	N/A	2 (100%)	2 (100%)	N/A	N/A
PTFE Fixed Core 1	20	2 (100%)	2 (100%)	2 (100%)	N/A	N/A	N/A
SS Fixed Core 2	3	3 (100%)	3 (100%)	3 (100%)	N/A	3 (100%)	2 (100%)

Note: 1. There were 14 PTFE J-Tip users, 5 Straight Tip, and 1 used both. 2. There were 2 SS J-Tip users and 1 used both SS J-tip and Straight Tip. 3. One user did not answer this item.

The overall clinical experience withthe Guidewires is presented in Table 5.3.-4

Table 5.3.-4: General Product Satisfaction

Item	Number of Respondents	Yes	No
Additional Safety Concerns	35	1 (3%)	34 (97%)
Product Package Acceptable	36	36 (100%)	0
Overall Quality Acceptable	36	36 (100%)	0
Overall Performance Acceptable [1]	36	35 (97%)	1 (3%)
Product Tolerated by the Patient	28	28 (100%)	
Product Support Introduction and Placement of Interventional Devices Within the Vasculature [1]	35	34 (97%)	1 (3%)
Use Guidewires from a Different Manufacturer	36	33 (92%)	3 (8%)

[1] One user (#001) indicated the overall product performance was not acceptable and responded that the product does not support introduction and placement of interventional devices within the vasculature. The remark for both survey questions is 'shaft is too flexible for sufficient trackability.

A total of 35 respondents indicated that no additional patient safety concerns related to the use of theGuidewires, while 1 respondent indicated that the tip of the Bentson guidewire is very stiff, and it could inadvertently puncture a vessel if placed forcefully. A total of 28 (100%) respondents indicated that the products were tolerated by all patients. The overall product quality was acceptable by all 36 (100%) respondents while the product performance was acceptable to 35 (97%) of the 36 respondents. The Guidewires support introduction and placement of interventional devices within the vasculature was supported by 34/36 (97%) respondents. A total of 33 (91.7%) respondents indicated the use of guidewires from Terumo (16/33, 48.5%), Boston Scientific (15/33, 45.5), Merit (7/33, 21.2%), Cook/Cook Medical (6/33, 18.2%) and Abbott (3/33, 9.1%).

A total of 36 respondents (100%) are satisfied with guidewires with respect to overall product quality, patient tolerability and product packaging; and all except one (97%) of them are satisfied with overall product performance, safety, and product support introduction and placement of interventional devices within the vasculature. There were no new risks or concerns identified.

Appraisal and Data Extraction of Relevant Clinical Literature

A total of 147 subject device articles were identified in the systematic literature search for this initial MDR CER-001 Rev E, and 3 articles met the inclusion criteria. Summary of the clinical data from the 3 included articles are presented below.

Article 1. Teoh AYB, Serna C, Penas I, et al. Endoscopic ultrasound-guided gallbladder drainage reduces adverse events compared with percutaneous cholecystostomy in patients who are unfit for cholecystectomy. Endoscopy. 2017;49(2):130-138.[127]

Device/Configuration	0.035" Amplatz guidewire (Argon Medical Devices, Inc.)
Application/Indication	ACC, on-label
Anatomical location	Gall bladder
Appraisal	D1 A1 P1 R1 T1 O1 F1 S1 C1
Article Level	1
Subject device /subject device configuration (n)	0.035" Amplatz guidewire (Argon Medical Devices, Inc.) (n=59)
Competitor/other device (n)	NR
CER objective follow-up duration	Periprocedural
CER objectives: Safety	
Tissue Damage	0/59 (0%)
Perforation/puncture (of non-intended organs)	0/59 (0%)
Infection	Sepsis: 1/59 (1.69%) Urinary tract infection: 0/59 (0%)
CER objectives: Performance	
Technical success	59/59 (100%)
Procedural success	56/59 (94.9%)[1]
New AE or device issues identified	No

[1]Considered based on clinical success. However, complications occurred a day after the procedure was performed
NR-Not Reported

Objective: To compare endoscopic ultrasound-guided gallbladder drainage (EGBD) with percutaneous cholecystostomy as a definitive management approach for acute cholecystitis in patients who are unfit for surgery.

Patients and Methods: Between November 2011 and August 2014, in a multicenter, retrospective, 1:1 matched cohort study of 118 patients, 59 acute cholecystitis patients (males, n=30; females, n=29) of mean age: 81.2±10.4 years, underwent percutaneous cholecystostomy. The outcomes were matched for age, sex, and American Society of Anaesthesiologists grade.

A 0.035" inch Amplatz guidewire (Argon Medical Devices Inc., USA) was inserted through the needle and securely coiled inside the gallbladder lumen followed by serial tract dilations. Once the tract had been adequately dilated, a suitable size of pigtail drainage catheter was inserted into the gallbladder lumen over the guidewire.

The outcome measures included the technical and clinical success rates, adverse event rates, hospital stay, the number of unplanned admissions, and mortality. Technical success was defined as the ability to access and drain the gallbladder by placement of a drainage tube or stent with immediate drainage of bile. Clinical success was defined as improvement in clinical symptoms and decreasing white cell counts within 5 days after the procedure.

Results: Technical success was achieved in all patients and clinical success was achieved in 56/59 (94.9%) patients. There were no instances of any tissue damage, perforation/puncture (of non-intended organs), urinary tract infection. One patient (1.69%) experienced severe sepsis that led to acute renal failure and death.

The overall adverse event rate was 44/59, (74.6%). The 30-day adverse events occurred in 10/59 (16.9%) patients and severe adverse events were observed in 44/59, (74.6%) patients. The unplanned admissions related to the intervention were observed in 4 42/59, (71.2%) patients and recurrent acute cholecystitis occurred in 4/59, (6.8%) patients, and no intraprocedural adverse events were encountered, respectively.

Conclusion: The authors concluded that, the percutaneous cholecystostomy technique was an effective means of achieving gallbladder drainage in acute cholecystitis patients unfit for surgery.

Article 2. Yip HK, Youssef AA, Chang WN, et al. Feasibility and safety of transradial arterial approach for simultaneous right and left vertebral artery angiographic studies and stenting. Cardiovasc Intervent Radiol. 2007;30(5):840-846[128]

Device/Configuration	J-tip Teflon guide wire (Argon Medical Devices, Inc.)
Application/Indication	Vertebral angiography and stenting/ carotid artery angiography in patients with vertebral artery stenosis/carotid artery stenosis; on-label
Anatomical location	Circulatory vasculature/peripheral arterial vasculature
Appraisal	D1 A1 P1 R1 T1 O1 F1 S1 C1
Article Level	1
Subject device /subject device configuration (n)	J-tip Teflon guide wire (N=24 patients)
Competitor/other device (n)	NR
CER objective follow-up duration	Periprocedural
CER objectives: Safety	
Vessel Perforation	0/24 (0%)
Vessel Dissection	0/24 (0%)
Thrombus/Occlusion	0/24 (0%)
CER objectives: Performance	
Technical success	24/24 (100%)
Procedural success	24/24 (100%)[1]
New AE or device issues identified	No

[1]Considered based on technical success. However, complications occurred a day after the procedure was performed.

NR; Not Reported
Objective: To study the safety and effectiveness of the transradial artery (TRA) approach using a 6-French (F) Kimny guiding catheter for right VA angiographic study and stenting.

Patients and Methods: This is a prospective study of 24 consecutive patients with VA stenosis/carotid artery stenosis who underwent vertebral and carotid artery angiography followed by VA stenting between November 2004 and December 2006 were included in this study. The baseline characteristics and comorbidities were as follows: mean age: 68.7±9.5 years, males: 22/24 (91.7%), hypertension: 21/24 (87.5%), diabetes mellitus: 11/24 (45.8%), current smoking: 11/24 (45.8%), prior MI: 3/24 (8.3%) and, prior TIA: 10/24 (41.7%). For this VA angiographic study, a combination of the ipsilateral and retrograde-engagement technique, which involved a looping 6-F Kimny guiding catheter along with the 0.035-inch J-tip Teflon guidewire (Argon Medical Devices), was utilized. For VA stenting, an ipsilateral TRA approach with either a Kimny guiding catheter or a left internal mammary artery guiding catheter was utilized in 22 patients and retrograde-engagement technique in 2 patients. A ≥50% stenosis in either the carotid artery, the vertebral artery, or the main intracranial artery was defined as a significant obstruction of these vessels. Severe obstruction was defined as ≥70% stenosis.

Results: The left TRA approach was used in most cases. Significant coronary artery obstruction was found in 83.3% and significant stenosis of extracranial carotid arteries was found in 33.3% of the study patients. Technical success of the procedure was reported 100% in all patients, including left VA stenting in 15 patients and right VA stenting in 9 patients. Procedure-related neurological complications were reported in 1 patient (4.2%). There were no vascular or wound complications and procedure related deaths reported.

Conclusion: Authors concluded that TRA approach for both cerebral and coronary angiographic studies and VA stenting is safe and effective. In patients unsuited for femoral arterial access, it can be considered as a simple and useful clinical tool.

Article 3. Alqahtani S, Kandeel AY, Rolf T, Frederic G, Qanadli SD. Case report: an unusual combined retrograde and antegrade transpedal subintimal recanalization of the infrainguinal arteries. J Vasc Interv Radiol. 2012;23(10):1325-1329.[129]

Device/Configuration	POINTER nitinol guide wire (Angiotech/Medical Device Technologies, Inc.)
Application/Indication	Combined retrograde and antegrade transpedal subintimal recanalization of infrainguinal vessels [SFA, popliteal artery, tibioperoneal trunk, peroneal artery]/CLI, on-label
Anatomical location	Infrainguinal vessels (SFA, popliteal artery, tibioperoneal trunk, peroneal artery)
Appraisal	D1 A1 P1 R1 T2 O1 F1 S2 C1
Article Level	1
Subject device /subject device configuration (n)	POINTER nitinol guide wire (N=1 patient)
Competitor/other device (n)	NR
CER objective follow-up duration	Periprocedural
CER objectives: Safety	
Vessel Perforation	NR
Vessel Dissection	NR
Thrombus/Occlusion	NR
CER objectives: Performance	
Technical success	1/1*
Procedural success	1/1
New AE or device issues identified	No

NR; Not Reported

*Difficulty of pushing guidewire was due to the extensive calcification however, the balloon angioplasty and stenting were performed, and blood flow was restored.

Objective: To describe a novel technique for retrograde recanalization of the infrainguinal arteries, even when no patent arteries can be identified at or below the level of the knee joint.

Patients and Methods: The authors described a case of a 66-year-old male patient with a past medical history of diabetes, ischemic cardiomyopathy, and right hemiplegia. He presented with a 3-month-old nonhealing ulcer of the dorsum of the left foot associated with left foot pain at rest for past 1-month. CT angiography showed complete occlusion of the superficial femoral, popliteal, infrapopliteal arteries and calcified stenosis in the left common femoral artery (CFA) extending into the profunda femoris artery. Endarterectomy with patch angioplasty of the left CFA and profunda femoris was unsuccessful for which, antegrade recanalization was performed and was unsuccessful. Finally, retrograde approach through the left dorsalis pedis artery was performed which resulted in recanalization of the totally occluded anterior tibial, popliteal, and superficial femoral arteries subintimally until CFA was reached.

The 0.014-inch guidewire was exchanged with a 0.018 inch, 300-cm POINTER nitinol guide wire (Angiotech Medical Device Technologies) which was pushed with difficulty into the true lumen of the

proximal tibioperoneal trunk due to extensive calcification in the artery. Antegrade balloon angioplasty of the peroneal and tibioperoneal arteries followed by balloon dilatation of popliteal and SFA was performed. Extensive calcification was noted for which two self-expanding stents were deployed into the proximal SFA to upper part of the popliteal artery.

Results: Control angiography revealed recanalization of the SFA, popliteal, tibioperoneal trunk and peroneal arteries with flow restoration to the foot through plantar arch. Pain at rest disappeared immediately after the procedure. Improvement of the distal flow was documented on follow-up ultrasound studies performed on the same day and on the day after the procedure. On day 10, the patient was discharged with aspirin and clopidogrel medication. Complete healing of the ulcer was noted seven weeks post-procedure. At 6-month follow-up visit, the patient remained well, without any presence of pain at rest or a new foot ulcer.

Conclusion: Authors concluded that in selected patients with CLI who have occlusion of all infrapopliteal arteries and are at high surgical risk or in whom a previous antegrade approach has failed, retrograde subintimal recanalization of chronically occluded infrainguinal vessels through an occluded dorsalis pedis artery access is a feasible and useful approach.

Table 5.3.-5: Classification, Assessment, and Appraisal of Subject Devices Literature – Peripheral Vascular

Reference	Device	Study Design	Appraisal Criteria for Suitability				Appraisal Criteria for Data Contribution					LOE
Yip et al., 2007[128]	J-tip Teflon guide wire (Argon Medical Devices, Inc.) Diameter: 0.035 inches Length: 260 cm	Prospective study November 2004 to December 2006	D1	A1	P1	R1	T2	O1	F1	S1	C1	1
Alqahtani et al., 2012[129]	POINTER nitinol guide wire (Angiotech Medical Device Technologies) Diameter: 0.018 inches Length: 300 cm	Case report	D1	A1	P1	R1	T2	O1	F1	S2	C1	1

Note: All time points are periprocedural

Table 5.3.-6: Classification, Assessment, and Appraisal of Subject Devices Literature – Non-Vascular

Reference	Device	Study Design	Appraisal Criteria for Suitability				Appraisal Criteria for Data Contribution					LOE
Teoh et al., 2016[127]	Amplatz guidewire (Argon Medical Devices) Diameter: 0.035 inches	Multi-center, retrospective, cohort study November 2011 and August 2014	D1	A1	P1	R1	T2	O1	F1	S1	C1	1

Note: All time points are periprocedural

Table 5.3.-7: Rates of Safety and Performance Outcome Measures Reported from Subject Devices Analysis – Peripheral Vascular

Reference	Safety			Performance	
	Vessel Perforation n/N (%)	Vessel Dissection n/N (%)	Thrombus/Occlusion n/N (%)	Technical Success n/N (%)	Procedural Success n/N (%)
Yip et al., 2007[128]	0/24 (0%)	0/24 (0%)	0/24 (0%)	24/24 (100%)	24/24 (100%)
Alqahtani et al., 2012[129] [a]	NR	NR	NR	1/1	1/1
Overall Range	0%	0%	0%	100%	100%
Acceptance Criteria	**Less than 2.4%**	**Less than 2.9%**	**Less than 1.9%**	**Greater than 81.8%**	**Greater than 83.3%**
All Datasets Meet Acceptance Criteria (Yes/No)	Yes	Yes	Yes	Yes	Yes

[a] As this a case report, the article was not considered for overall range as we do not analyze case reports for overall S&P analysis.
Note: All time points are periprocedural
NR: Not reported.

Table 5.3.-8: Rates of Safety and Performance Outcome Measures Reported from Subject Devices Analysis – Non-Vascular

Reference	Safety			Performance	
	Tissue Damage n/N (%)	Perforation or puncture of non-intended organs n/N (%)	Infection n/N (%)	Technical Success n/N (%)	Procedural Success n/N (%)
Teoh et al., 2016[127]	0/59 (0%)	0/59 (0%)	1/59 (1.7%)	59/59 (100%)	59/59 (100%)
Overall Range	0%	0%	1.7%	100%	100%
Acceptance Criteria	**Less than 3.12%**	**Less than 3.2%**	**Less than 9.1%**	**Greater than 77.1%**	**Greater than 87.1%**
All Datasets Meet Acceptance Criteria (Yes/No)	Yes	Yes	Yes	Yes	Yes

Note: All time points are periprocedural

Conclusions of the Clinical Literature Review

A total of 147 articles were identified in the subject device literature search conducted all years until 31 July 2022 with 3 articles being included after the literature review. Of these 3 studies, 2 were related to the peripheral vasculature[128,129], and 1 was within the non-vascular indication.[127] However, one of the studies related to the peripheral vasculature[129] was not considered for overall range as case reports are not analyzed for overall safety and performance analysis. There were no articles included that represent the coronary vasculature application. J-tip Teflon guidewire, POINTER nitinol guidewire, and Amplatz guidewire were each reported. Overall, the literature safety and performance analysis included 24 patients with J-tip Teflon guidewire indicated for vertebral angiography and stenting/ carotid artery angiography, and 59 patients with Amplatz guidewire indicated for ACC. Performance and safety outcomes with currently available devices, established from the current knowledge/sate of art in the fields and from a review of published literature on competitor devices used to define acceptance criteria and were compared to the rates reported in the literature. The analysis of safety objectives demonstrated consistent clinical outcomes with the current acceptance criteria rates with 100% technical and procedural success rates with no unanticipated adverse events observed. The safety and performance objectives reported from the subject device literature search analysis met the predefined acceptance criteria, therefore, suggesting the subject devices continue as standard of care devices.

5.4. An overall summary of the clinical performance and safety

The Guidewire Families demonstrated well known safety and clinical performance using robust SOA with clinical guidelines from the SOA calling the devices standard of care with bench studies and biocompatibility testing providing evidence that the Guidewire Families are standard of care devices. The Guidewire Families are used as ancillary devices in well-established procedures in the vasculature (central / peripheral) and in non-vascular applications as. The use of guidewires during the procedure reflects the current standard of care. The Guidewire Families incorporate technical characteristics that are common to guidewires and have well established clinical performance and safety characteristics in vascular and non-vascular. Multiple configurations and differences in material are available to provide specific characteristics required in these procedures. Based on the simplicity and conservation of the overall design of guidewires, and similarity of performance requirements across similar clinical applications, benchtop testing standards may apply to multiple guidewires in scope. Therefore, the outcomes of benchtop testing may support performance characteristics of guidewires within the group sharing the same technical or performance requirements. Similarly, biocompatibility assessments can support guidewires sharing the same materials and used in similar applications, e.g., vascular.

In conclusion, it has been shown that Guidewires are established standard of care devices with similarities between them that do not affect the safety or performance of the devices.

Benefit / Risk Assessment

The benefits and risks of the Guidewire are discussed in CER-001 Rev E. As it was objectively demonstrated that clinical data on the subject devices demonstrate that the subject devices are safe and perform as intended when used according to their IFUs, therefore, continue to be standard of care devices that are essential for assisting catheter devices during diagnostic and intervention procedures.

Based on the review of the current knowledge/SOA, the clinical outcome parameters relevant to examine clinical safety and performance of the Guidewire Families were identified in Table 5.4.-1 & Table 5.4.-2 below.

Table 5.4.-1: The Guidewire Families Safety and Performance Objectives Identified from Clinical Data Sources – Peripheral Vascular

Outcome	Subject Device Clinical Literature %	Safety and Performance Acceptance Criteria %	All data sets meet acceptance criteria?
Safety			
Vessel perforation	**0%**	**Less than 2.4%**	**Yes**
Vessel dissection	**0%**	**Less than 2.9%**	**Yes**
Thrombus/occlusion	**0%**	**Less than 1.9%**	**Yes**
Performance			
Technical success	**100%**	**Greater than 81.8%**	**Yes**
Procedural success	**100%**	**Greater than 83.3%**	**Yes**

Note: All time points are periprocedural

Table 5.4.-2: The Guidewire Families Safety and Performance Objectives Identified from – Non-Vascular

Outcome	Subject Device Clinical Literature %	Safety and Performance Acceptance Criteria %	All data sets meet acceptance criteria?
Safety			
Tissue damage	**0%**	**Less than 3.12%**	**Yes**
Perforation or puncture of non-intended organs	**0%**	**Less than 3.2%**	**Yes**
Infection	**1.7%**	**Less than 9.1%**	**Yes**
Performance			
Technical success	**100%**	**Greater than 77.1%**	**Yes**
Procedural success	**100%**	**Greater than 87.1%**	**Yes**

Note: All time points are periprocedural

As standard of care devices, a lower level of clinical evidence for the Guidewire Families can be justified to be sufficient for the confirmation of conformity with relevant GSPRs. The clinical data was further evaluated to demonstrate sufficient clinical evidence in support of conformity to the GSPRs with an assessment per MDCG 2020-6. Table 5.4.-3 summarizes the ranking of each data set.

Clinical evidence demonstrating the safety and performance of Class III devices (Guidewire Families) consists of scientific literature (Rank 4 and 6), proactive PMS data – customer survey data (Rank 8), complaint data (Rank 7) and bench testing (Rank 12). This meets the recommendation of demonstrating sufficient clinical evidence for Class III devices.

Therefore, there are sufficient data sets to support the safety and performance of the Guidewire Families as standard of care devices.

Table 5.4.-3: Clinical Evidence Supporting the Guidewire Families

Data Source	Device / Quantity	Rank per MDCG 2020-6
State of the Art	**Evaluation of state of the art, including evaluation of clinical data from competitor devices**	**6**

Proactive PMS data Customer Survey Data	**Worker Guidewire Product Family-33 surveys Worker Guidewires-53 surveys**	**8**
Literature Articles (n=2) Outcomes from studies with potential methodological flaws but where data can still be quantified, and acceptability justified	**J-tip Teflon guide wire, 24 patients Amplatz guidewire, 59 patients**	**4**
Literature Articles (n=1) Individual case reports on the subject device	**POINTER nitinol guide wire, 1 patient**	**9**
Complaint Data and vigilance data	**Guidewires - 1,406,760 complaints Worker Guidewires - 142,514 complaints**	**7**
	Lunderquist Stainless Steel Guidewires, WORKER Guidewires, POINTER Nitinol Guidewires, Access Guidewires - 46,108 complaints	**7**
Bench Testing	**Mechanical testing for strength and endurance, biological safety, usability**	**12**

Clinical Benefits/Performance Analysis

Clinical benefits encompass any claims about clinical safety and performance outcomes and include the ability of the Guidewires Families to achieve their intended purpose as claimed. As a clinical benefit, the subject devices may provide percutaneous placement of intravascular or non-vascular devices during diagnostic and interventional procedures. Therefore, the clinical benefits of the Guidewire Families have been substantiated based on objective evidence from the appraised data–- either clinical, non-clinical, or both.

Clinical Risks and Safety Analysis

The risk management process is conducted according to procedures defined in CAQ-QA-013. Risk Management in accordance with principles of ISO14971: 2019 Medical devices — Application of Risk Management to Medical Devices.

The Guidewires Families are reviewed for risk and undergo a failure modes and effects analysis (FMEA) and/or Hazard Analysis. Risk assessment reports are reviewed at defined time intervals and updated based on data from literature and commercial complaints.

5.5. Ongoing or planned post-market clinical follow-up.

As documented in the PMS plan (PMSP-0008), PMCF is a key subset of the PMS and shall have its own governing plan (PMCFP-0027). The primary objectives of these PMCF plans are to specify the methods and procedures for proactively collecting and evaluating clinical data to support the safety and performance of the Guidewires Families and continuously gain knowledge of use related to:

- Confirm the safety and performance throughout the expected lifetime of the Guidewire Families by ensuring compliance of the device to the GSPRs.
- Previously unknown side effects

- Side effects and contraindications
- New or emergent risks, based on factual evidence.

Argon will conduct the following activities in post-market, including general and specific methods/procedures, for the Class III guidewires. A summary table of the different PMCF activities foreseen by the manufacturer is provided below:

Activity ID	Description of activity	Aim of the activity	Rationale and known limitations of the activity	Timelines
1	General: Scientific Literature Review	Confirm the safety and performance of the subject devices. Ensure the continued acceptability of the benefit-risk ratio. Identify possible systematic misuse or off-label use	Allows evaluation of information on current knowledge and state of the art. Limitations: Clinical data limited to published data from literature	Annual review within the calendar year
2	General: Complaint Trending and Analysis	Confirming the safety of the medical device Identifying previously unknown side-effects (related to the procedures or to the medical devices). Monitoring the identified side-effects and contraindications	All complaints related to marketed products are captured in our QMS from clinician users and/or distributors of the subject devices. Limitations: Without knowing the sales volumes of the similar devices, it may be difficult to compare the adverse event occurrence rates, but the overall numbers of events and the types of events can be compared.	Annual review within the calendar year
3	Specific: PMCF study to obtain real world data on the use of guidewires in the coronary vasculature, peripheral vasculature, and non-vascular applications.	Confirm safety and performance. Identify previously unknown side-effects and monitor the identified side effects and contraindications	Observational study intended to collect quantitative data regarding performance of the subject devices for each indication. Limitations: Data quality and availability	Study will be executed within the certification period of the devices up to renewal (2023-2028).

6. Possible Diagnostic or Therapeutic Alternatives

The alternative to the use of Guidewires is traditional open surgery and inserting catheters blindly. But the emergence of the medical guidewire enabled accurate placement of therapeutic device or access to target lesions decreased medical cost burden and improved treatment efficiency. Guidewires may be best positioned when tracked by fluoroscopy.

7. Suggested profile and training for users

These devices are intended to be used by trained medical personnel in a clinical setting.

8. Harmonized Standards / Common Specifications

Argon Compliance Date/Version	Standards Title
Labelling	
BS EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical devices. labels, labelling and information to be supplied - Part 1: General requirements.
EN ISO 20417:2021	Terminology, Symbols and Information Provided with Medical Devices: Information Supplied by the Manufacturer with Medical Devices
General Standards – Sterilization	
BS EN ISO 11070:2014/A1:2018	Sterile, single-use intravascular catheter introducers, guidewires and dilators
ISO 10555-1:2013	Intravascular catheters -- Sterile and single-use catheters -- Part 1: General requirements
BS EN 556-1:2001	Sterilization of medical devices. Requirements for medical devices to be designated STERILE. Requirements for terminally sterilized medical devices
BS EN 1422:2014	Sterilizers for medical purposes - Ethylene oxide sterilizers - Requirements and test methods
EN ISO 11135:2019	Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
AAMI TIR28:2016	Product Adoption and Process Equivalence for Ethylene Oxide Sterilization
EN ISO 14644-1:2015	Classification of Air Cleanliness, Clean rooms & Associated Controlled Environments. Part 1: Classification of air cleanliness
EN ISO 14644-2:2015	Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
BS EN ISO 11737-1:2018	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products
BS EN ISO 10993-7:2022	Biological evaluation of medical devices. Ethylene oxide sterilization residuals
NSI/AAMI ST72:2019	Bacterial Endotoxins Test
General Standards – Quality Systems	
EN ISO 13485:2016	Medical devices. Quality management systems. Requirements for regulatory purposes
Risk Management	

Argon Compliance Date/Version	Standards Title
EN ISO 14971:2019	Medical Devices - Application of Risk Management to Medical Devices
Biological Safety	
BS EN ISO 10993-1:2020 + LC:2021	Biological Evaluation of Medical Devices – Part 1: Evaluation and testing
BS EN ISO 10993-3:2014	Biological evaluation of medical devices -- Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
BS EN ISO 10993-4:2017	Biological evaluation of medical devices -- Part 4: Selection of tests for interactions with blood
BS EN ISO 10993-5:2009	Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
BS EN ISO 10993-10:2013	Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
BS EN ISO 10993-11:2018	Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity
BS EN ISO 10993-12:2021	Biological Evaluation of Medical Devices – Part 12: Sample preparation and reference materials
BS EN ISO 10993-18:2020	Biological evaluation of medical devices — Part 19: Physico-chemical, morphological and topographical characterization of materials
BS EN ISO 10993-19:2020	Standard Guide for Biocompatibility of Medical Device Packaging Materials
Clinical Evaluation	
MEDDEV 2.7/1 Rev4	Clinical evaluation: Guide for manufacturers and notified bodies
Design Control	
EN ISO 14971	Medical devices - Application of risk management to medical devices
Usability	
IEC 62366-1:2015 & IEC 62366-1:2015/COR1:2016	Medical Devices – Application of usability engineering to medical devices
Packaging	
EN ISO 11607-1:2020	Packaging for Terminally Sterilized Medical Devices. Part 1: Requirements for materials, sterile barrier systems, and packaging systems.
EN ISO 11607-2:2020	Packaging for Terminally Sterilized Medical Devices. Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 2233:2001	Packaging -- Complete, filled transport packages and unit loads -- Conditioning for testing
ASTM D4169 :2022	Standard Practice for Performance Testing of Shipping Containers and Systems -
ASTM F2096 – 2011 (R2019)	Standard Test Method for Detecting Gross Leaks in Medical Packaging by Internal Pressurization (Bubble Test) - ASTM F 2096-11 (2019)
ASTM F1929 - 15	Standard Test Method for Detecting Seal Leaks in porous. Medical Packaging by Dye Penetration - ASTM F 1929

Argon Compliance Date/Version	Standards Title
ASTM F88 / F88M - 2021	Standard Test Method for Seal Strength of Flexible Barrier Materials - ASTM F88
ASTM F1980 - 2021	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices - ASTM F1980
Post Market Clinical Follow-Up	
MEDDEV 2.12/2 Rev2	Post Market Clinical Follow-up studies
Vigilance	
MEDDEV 2.12/1 Rev8	Guidelines on a Medical Devices Vigilance System

9. Revision History

Revision	Date Issued	Change Description	Revision validated by the Notified Body?
A	22 August, 2022	Initial Release	☐ Yes Validation language: ☐ No (only applicable for class IIa or some IIb implantable devices for which the SSCP is not yet validated by the NB)
B	27 July, 2023	Removed Worker Guidewires class III devices per BSI response. SSCP-0003 will contain only Argon GW Class III devices per EU MDR 2017/746.	☐Yes Validation language: English ☐ No (only applicable for class IIa or some IIb implantable devices for which the SSCP is not yet validated by the NB)
C	19 Feb 2024	Harmonize the device name and Intended Purpose per the Declaration of Conformity	☒Yes Validation language: English
D	01 November, 2024	Updating BSI approved IFU numbers and revision numbers, there is no content update.	Not required as content of the SSCP is not being updated.