COVER PAGE OF STUDY PROTOCOL

Study title:	**Prospective Observational Study of the PowerPICC Family of Devices and Accessories**
Protocol number.:	**MDS-19PICCEU01**
NCT number:	**NCT04263649**
Protocol version and date:	**v.1.0, 12-December 2019**

TITLE PAGE

Protocol Title: Prospective Observational Study of the Power PICC Family of Devices and Accessories

Protocol Number: MDS-19PICCEU01

Version Number: 1.0

Study Device: Power PICC Family of Devices

Study Type: Prospective, Observational, Multi-Center, Post-Market

Short Title: Power PICC Prospective Observational PMCF Study

Acronym: **PICC PMCF**

Sponsor Name: Becton Dickinson, & Company

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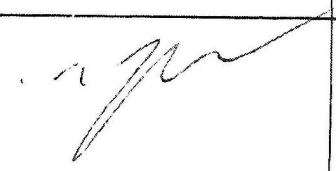
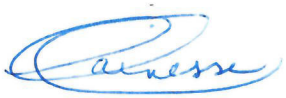
Regulatory Agency Identifier Number(s): TBD

Approval Date: 12DEC2019

Version History

Version Number	Date	Type
1.0	12 December 2019	Original

SPONSOR PROTOCOL APPROVAL

Signature below indicates approval of the protocol as written.			
Function	**Name**	**Signature**	**Date**
Medical Affairs	Klaus Hoerauf, MD Vice President, MPS Medical Affairs		13-DEC-2019
Study Statistician	Wen Yue Senior Statistician, Global Clinical Development		13Dec2019
Regulatory Affairs	Roya Borazjani Vice President, VAD Regulatory Affairs		
Project Manager	Audrey Lainesse Sr Clinical Project Manager, Global Clinical Development		13DEC 2019

SPONSOR PROTOCOL APPROVAL

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Study Statistician	Wen Yue Senior Statistician, Global Clinical Development		
Regulatory Affairs	Roya Borazjani Vice President, VAD Regulatory Affairs		Dec/13/19
Project Manager	Audrey Lainesse Sr Clinical Project Manager, Global Clinical Development		

PRINCIPAL INVESTIGATOR AGREEMENT PAGE

Investigator Responsibilities

1. Prior to participation in this study, the Investigator or Institution must sign the Clinical Study Agreement (CSA) and obtain written approval from the appropriate Institutional Review Board (IRB)/Ethics Committee (EC).
2. The Investigator must receive BD-sponsored training prior to site activation. The Investigator is responsible for ensuring that all Sub-Investigators and clinical staff are adequately trained prior to performing any data collection or study-related procedures.
3. The Principal Investigator shall ensure that the study is conducted in accordance with the study protocol, any modifications as requested by the IRB/EC, the signed CSA, the ethical principles of the Declaration of Helsinki, Good Clinical Practice (ICH E6) / ISO 14155), EU MDR (Council Regulation 2017/745 of 5 April 2017), and applicable national/regional regulations and laws.
4. If applicable, ensure that written informed consent is obtained from each participant prior to the conduct of any study activity, using the current IRB/EC approved Informed Consent Form.

I have read and understand the contents of this study protocol. I agree to follow and abide by the requirements set forth in this document. I agree to conduct the trial in accordance with the study protocol, the signed Clinical Study Agreement, and Good Clinical Practice (GCP) as well as applicable ISO regulations (e.g., ISO 14155:2011E). I agree to participate in BD-Sponsored training prior to performing any data collection or study-related procedures.

Agreed to by (Investigator):

_____
Printed Name – Investigator

_____
Signature – Investigator

_____
Site Name and Number

_____
Date

SUB-INVESTIGATOR AGREEMENT PAGE

Sub-Investigator Responsibilities

1. The Sub-Investigator must receive study specific training prior to performing any data collection or study-related procedures.
2. The Sub-Investigator shall conduct the study in accordance with the study protocol, any modifications as requested by the IRB/EC, the signed CSA, the ethical principles of the Declaration of Helsinki, Good Clinical Practice (ICH E6) / ISO 14155), EU MDR (Council Regulation 2017/745 of 5 April 2017), and applicable national/regional regulations and laws.
3. If applicable, ensure that written informed consent is obtained from participants prior to the conduct of any study activity, using the current IRB/EC approved Informed Consent Form.

I have read and understand the contents of this study protocol. I agree to follow and abide by the requirements set forth in this document. I agree to conduct the trial in accordance with the study protocol, the signed Clinical Study Agreement, and Good Clinical Practice (GCP) as well as applicable ISO regulations (e.g., ISO 14155:2011E). I agree to participate in study-specific training prior to performing any data collection or study-related procedures.

Agreed to by (Sub-Investigator):

_____
Printed Name – Sub-Investigator

_____
Signature – Sub-Investigator

_____
Site Name and Number

_____
Date

Abbreviations

AE	Adverse event
Bard	C. R. Bard, Inc.
BD	Becton Dickinson and Company
CE	Certification mark
CFR	Code of Federal Regulations
CI	Confidence Interval
CRA	Clinical Research Associate
CRF	Case Report/Record Form
CRO	Contract Research Organization
CT	Computed tomography
CVC	Central venous catheter
CVP	Central venous pressure
EU	European Union
FDA	Food and Drug Administration
FT	Fit for Veins
GCP	Good Clinical Practice
HF	High Flow
HIPAA	Health Insurance Portability and Accountability Act
ICH	International Council for on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
IV	Intravenous
IRB/EC	Institutional or Independent Review Board/Ethics Committee
PICC	Peripherally Inserted Central Catheter
PIV	Peripheral intravenous catheter
SAE	Serious Adverse Event
SD	Standard Deviation
SoA	Schedule of Activities
SOP	Standard Operating Procedure
SV	Small Veins
TMF	Trial Master File
VAD	Vascular access device
VT	Venous Thrombosis

1 PROTOCOL SUMMARY

1.1 Synopsis

Protocol Title	Prospective Observational Study of the Power PICC Family of Devices and Accessories	
Short Title	Power PICC Prospective Observational PMCF Study	
Rationale	This study is designed to collect prospective data related to the safety and performance of the Power PICC family of devices and its accessories in a real-world setting. Only patients who require one of the study devices may be considered for enrollment. The choice of device required for individual patients is left to the discretion of the clinician.	
Objectives and Endpoints* *Note: Clinical endpoints are gathered from information collected as part of the participants' routine care. No study specific procedures will be performed.	Objective(s)	Endpoint(s)
	Primary Safety • To assess the incidence of symptomatic venous thrombosis (VT) in patients with PowerPICC, PowerPICC SOLO2, and PowerGroshong PICC devices (PICCs) used for both short- and long-term venous access.	Primary Safety • Incidence defined as any new occurrence of symptomatic VT defined by thrombus presence confirmed by ultrasonography or other imaging
	Primary Performance • To assess the rate of therapy completion in PICCs used for both short- and long-term therapy	Primary Performance • Percent of PICCs that remain in place through the required therapy time period (completion of therapy) (success/failure)
	Secondary Safety • To assess the incidence of select complications in patients with PICCs used for both short- and long-term venous access while in-situ and during insertion.	Secondary Safety • Incidence defined as any new occurrence of: o Phlebitis o Extravasation o Local infection o Bloodstream infection o Accidental dislodgement o Vessel laceration o Vessel perforation

<table>
<tr><td>Protocol Title</td><td colspan="2">Prospective Observational Study of the Power PICC Family of Devices and Accessories</td></tr>
<tr><td></td><td>Secondary Performance
• To assess the incidence of select performance measures in PICCs used for both short- and long-term therapy</td><td>Secondary Performance
• Percent of patent catheters (number of functional catheters through therapy/total number of catheters)
• Percent of placement success in single insertion attempt (placement success defined as single insertion attempt, proper tip location, and patent catheter) (successful placement / total insertions)
• Usability
o Ease of insertion - based on a post-insertion survey</td></tr>
<tr><td>Design and Overview</td><td colspan="2">This is a prospective, observational, single arm study to assess the safety and performance of the PowerPICC family of devices. In the study, only patients who require one of the study devices may be considered for enrollment. The choice of device required for individual patients is left to the discretion of the clinician.

Information will be collected on the study participants and devices before, during, and after catheter insertion, while the device is indwelling, and during device removal to assess both safety and performance. Both short- and long-term use of the PowerPICC devices will be assessed as part of the study.</td></tr>
</table>

Protocol Title	Prospective Observational Study of the Power PICC Family of Devices and Accessories
Study Devices	The full range of CE-marked devices marketed in the EU will be available for use in this study. These devices include: • PowerPICC • PowerPICC SV (Small Vein) • PowerPICC FT (Fit for Veins) • PowerPICC HF (High Flow) • PowerPICC SOLO2, • PowerPICC SOLO2 FT • PowerPICC SOLO2 HF • PowerGroshong PICC Catheters • Accessory Guidewires • Accessory Stylets PowerPICC. PowerPICC SOLO2, and PowerGroshong PICC devices are intended for both short- (<30 days) and long-term (≥30 days) peripheral access to the central venous system for intravenous (IV) therapy, blood sampling, infusion, or therapy, and power injection of contrast media. PowerPICC and PowerPICC SOLO2 catheters may also be used for central venous pressure measurements. Guidewires and Stylets: Guidewires and Stylets must retain integrity within the vasculature system and facilitate placement of the catheter. All devices used in this study will be used in a manner consistent with their labelled indications.

Protocol Title	Prospective Observational Study of the Power PICC Family of Devices and Accessories
Participants	Approximately 150 participants for each category of device (PowerPICC, PowerPICC SOLO2, and PowerGroshong PICC) will be enrolled in the study. In order to be eligible to participate in this study, an individual must meet all of the following criteria: 1. Any patient, regardless of age or gender, for which the investigator has decided that one of the PowerPICC study devices for either short-or long-term venous access should be inserted as standard of care 2. Expected to be available for observation through the duration of PICC therapy (including outpatient therapy, if applicable) 3. Provision of signed and dated informed consent form (Note: Consent of guardian or parent may be required for patients under the age of 18 years; participant assent may be required as well.) Participants are excluded from the study if any of the following criteria apply: 1. Presence of any device-related infection, bacteremia, or septicemia is known or suspected 2. Body size is insufficient to accommodate the size of implanted device 3. Known or suspected to be allergic to materials contained in the device 4. History of irradiation of prospective insertion site 5. Previous episode(s) of venous thrombosis or vascular surgical procedures at the prospective placement site 6. Local tissue factors which would prevent proper device stabilization and/or access

Protocol Title	Prospective Observational Study of the Power PICC Family of Devices and Accessories
Intervention(s)/Procedure(s)	After screening against inclusion/exclusion criteria, potential participants will be provided with detailed information about the study. If the potential participant, or parent/guardian in the case of those under 18 years of age, provides written informed consent, he/she will be enrolled in the study. Participant baseline and demographic information will be documented, including, but not limited to age, gender, primary diagnosis, limited medical history, reason for PICC insertion, and expected duration of therapy. At the time of study device placement, information about the insertion procedure will be documented, including, but not limited to: date and time of insertion, catheter type, size, and length, insertion location, insertion procedure (e.g., components/accessories used), number of insertion attempts, stabilization method, dressing type, and total procedure time. Additionally, limited information about the clinician performing the procedure will be collected (e.g., years of experience, estimated number of PICCs inserted, education level). Lastly, to assess overall ease of insertion, the inserting clinician will complete a brief survey describing their experience with the procedure. Once the PICC is in place and is accessed for use, data about the use of the catheter will be collected including, but not limited to: catheter maintenance procedures , types of IV therapy (e.g., antimicrobial, TPN, blood products), blood sampling, CVP monitoring, and injection of contrast. While the participant is in the acute care setting, the PICC will be assessed daily, as part of the participant's routine care, until the catheter is discontinued or until they are discharged, whichever comes first. If the participant is discharged with the PICC in-situ, assessments will be performed at each therapy visit, as part of the participant's routine care. Assessments will continue as scheduled until the line is discontinued or until 180 days (± 14 days) post-insertion, whichever comes first. For the purposes of endpoint calculations, PICCs remaining in place after 180 days will be considered to have completed therapy. At the time of catheter removal, date and time of removal, reason for removal, and site condition will be documented.
Investigational Sites	Up to 20 sites in the EU will participate in this study. No more than 20% of subjects may be enrolled at any one site.
Data Monitoring Committee	A Data Monitoring Committee will not be used in this study.

Protocol Title	Prospective Observational Study of the Power PICC Family of Devices and Accessories
Regulatory Status	This is a post-market study of CE-marked devices currently sold in the EU (CE 551344 and CE 551348).

1.2 Schedule of Activities

Procedure / Study Phase	Screening/ Enrollment	Insertion	Use and Maintenance	Removal / Last Study Visit* (End of Study)	Notes
Inclusion and exclusion criteria	X				
Informed Consent	X				
Baseline and demography	X				
Medical history	X				
Catheter insertion		X			
Ease of insertion survey		X			
Use and maintenance assessment			X		
Removal assessment				X	
AE monitoring		X	X	X	
Device deficiency monitoring		X	X	X	

*Participants will be followed through device removal or 180 ± 14 days post-insertion, whichever comes first.

2 INTRODUCTION

The PowerPICC family of devices was introduced to the European market beginning in 2008 for use in patients requiring short- or long-term peripheral access to the central venous system for intravenous (IV) therapy, blood sampling, infusion, or therapy, power injection of contrast media, or central venous pressure measurements. Guidewires and stylets, typically packaged with the PICCs, facilitate placement of the catheter.

2.1 Background

Long-term intravascular catheters, also known as vascular access devices (VADs) are divided into two major groups based on the entry site: those that are introduced into the central venous system via the subclavian, jugular or femoral vein and known as central venous catheters (CVCs) and those introduced via the peripheral vessels and known as peripherally inserted central catheters (PICCs). PICCs, used for both long and short-term intravascular access, are often chosen over CVCs to avoid or minimize the risks associated with placement of subclavian vascular access devices, specifically pneumothorax and other pulmonary complications. PICCs are also used in patients who may require therapy over prolonged dwell times to reduce the number of venipunctures than typically associated with peripheral intravenous catheters (PIVs) replacements/ changes. Today, PICCs are used for a wide variety of uses including delivery of total parenteral nutrition, antimicrobials, blood components, chemotherapy, and other infusates, blood sampling, and for central venous pressure monitoring in both critical/ acute care and alternate care settings.

In the mid-1990s, catheters made of polyurethane were developed to satisfy clinician requests for greater durability and improved flow rates than were available with the original silicone catheters. In addition to standard usage, patients who received a PICC catheter may also require an injection of contrast media, typically administered with a power injector, for enhanced computed tomography (CT). For these patients, being able to administer contrast media through their PICC may be beneficial. This need led C. R. Bard, Inc. to develop and launch the PowerPICC family of devices, indicated for the standard uses noted above as well as for administration of contrast media using a power injector.

2.2 Rationale

While there is clinical data available on the PowerPICC family of devices, it is limited in scope. This study is being conducted to assess the overall safety and performance of these devices in a real-world setting.

2.3 Risk/Benefit Assessment

Due to the observational nature of the study and the fact that only patients requiring use of one of the study devices as part of their standard medical care, there are no anticipated risks associated with participation in the study other than those associated with device usage. More detailed information about the known and expected benefits and risks and reasonably expected adverse events of PowerPICC devices may be found in their respective Instructions for Use (IFUs).

2.3.1 Risk Assessment

Note: Potential risks for the PowerPICC devices are based on complications noted in the Instructions for Use and are not unique to this study.

Potential Risk of Clinical Significance	Summary of Data/Rationale for Risk	Mitigation Strategy
Study Intervention (s): PowerPICC Device		
• Air embolism • Bleeding • Brachial plexus injury • Cardiac arrhythmia • Cardiac tamponade • Catheter erosion through skin • Catheter embolism • Catheter occlusion • Catheter related sepsis • Endocarditis • Exit site infection • Exit site necrosis • Extravasation • Fibrin sheath formation • Hematoma • Heparin induced thrombocytopenia (PowerPICC or SOLO devices only) • Hypersensitivity, anaphylactic or anaphylactic-like reaction during placement, positioning, flushing of catheter or cleaning of catheter exit site (PowerPICC or SOLO devices) • Intolerance reaction to implanted device • Laceration of vessels or viscus • Myocardial erosion • Perforation of vessels or viscus • Phlebitis • Spontaneous catheter tip malposition or retraction • Thromboembolism	See device-specific Instructions for Use for additional information.	Only patients requiring a PowerPICC device as part of their standard medical care will receive a device. The treating physician will select the most appropriate device for the patient based on their specific needs.

Potential Risk of Clinical Significance	Summary of Data/Rationale for Risk	Mitigation Strategy
• Venous thrombosis • Vessel erosion • Risks normally associated with local or general anesthesia, surgery and post-operative recovery		
Study Procedures		
No study-specific risks identified		
Other		
Not applicable		

2.3.2 Benefit Assessment

There is no direct benefit for study participation for an individual patient other than the placement of one of the study devices which is otherwise required as part of their standard medical care.

2.3.3 Overall Benefit: Risk Conclusion

Due to the observational nature of this study, there is no anticipated benefit to an individual patient. Likewise, because a participating patient will receive a study device regardless of their participation in the study, there are no anticipated study-specific risks regardless of the participant's age or medical condition.

3 OBJECTIVES AND ENDPOINTS

Note: Clinical endpoints are gathered from information collected as part of the participants' routine care. No study specific procedures will be performed.

Objectives	Endpoints
Primary Safety	
• To assess the incidence of symptomatic venous thrombosis (VT) in patients with PowerPICC, PowerPICC SOLO2, and PowerGroshong PICC devices (PICCs) used for both short- and long-term venous access.	• Incidence defined as any new occurrence of symptomatic VT defined by thrombus presence by ultrasonography or other imaging

Primary Performance	
• To assess the rate of therapy completion in PICCs used for both short- and long-term therapy.	• Percent of PICCs that remain in place through the required therapy time period (completion of therapy) (success/failure)
Secondary Safety	
• To assess the incidence of select complications during catheter insertion and while the catheter is in-situ in patients with PICCs used for both short- and long-term venous access.	• Incidence defined as any new occurrence of: o Phlebitis – inflammation of the cannulated vessel identified by redness, swelling, warmth, tenderness, and/or cord formation o Extravasation – accidental infiltration of a vesicant or chemotherapeutic drug into the tissue around the catheter o Local infection - presence of pus at the exit site and/or culture confirmed site infection o Catheter-related bloodstream infection - positive blood culture(s) with a microorganism not related to another source (e.g., UTI) OR positive blood culture(s) with microorganism matching catheter tip culture OR blood cultures from peripheral venous puncture and PICC positive with the same microorganism o Accidental dislodgement – catheter accidentally dislodged the extent to which it requires replacement o Vessel laceration – a tear in the tissue of the vessel o Vessel perforation – a hole formed in the vessel
Secondary Performance	
• To assess the incidence of select performance measures in PICCs used for both short- and long-term therapy.	• Percent of patent catheters (number of functional catheters through therapy/total number of catheters) • Percent of placement success in single insertion attempt (placement success defined as single insertion attempt, proper tip location, and patent catheter) (successful placement / total insertions) • Usability o Ease of insertion - composite score of guidewire/stylet performance based on post-insertion survey

4 STUDY DESIGN

4.1 Overall Design

This is a multi-center, single-arm, prospective, observational, post-market study of the PowerPICC family of devices used for both short- and long-term therapy. Only participants requiring the use of a study device as part of their standard medical care may be enrolled in the study. Study enrollment is expected to take 6 – 12 months.

4.2 Scientific Rationale for Study Design

This study is designed to assess the real-world safety and efficacy of the PowerPICC family of devices used in an on-market fashion. The observational design will ensure that study activities have no direct impact on the endpoints being assessed and that they represent outcomes typically associated with standard medical use of the study devices.

4.2.1 Participant Input into Design

Participant input was not sought while designing the study; however, similar published studies were reviewed.

4.3 End of Study Definition

A participant is considered to have completed the study if he/she has completed all phases of the study including study device removal or achievement of 180 ± 14-day dwell time (last study assessment). Data collection will cease for the study participant at this point regardless of whether or not the device remains in place.

The end of the study is defined as the date of the last study assessment of the last participant in the study.

5 STUDY POPULATION

Participants will be recruited from the patient population treated at the investigational sites. Sites may choose to limit recruitment to specific areas of the hospital and/or to patients treated by specific healthcare providers.

5.1 Inclusion Criteria

In order to be eligible to participate in this study, an individual must meet all of the following criteria:

1. Any patient, regardless of age or gender, for which the investigator has decided that one of the PowerPICC study devices for either short-or long-term venous access should be inserted as standard of care
2. Expected to be available for observation through the duration of PICC therapy (including outpatient therapy, if applicable)
3. Provision of signed and dated informed consent form (Note: Consent of guardian or parent may be required for patients under the age of 18 years; participant assent may be required as well.)

5.2 Exclusion Criteria

Participants are excluded from the study if any of the following criteria apply:

1. Presence of any device-related infection, bacteremia, or septicemia is known or suspected
2. Body size is insufficient to accommodate the size of implanted device
3. Known or suspected to be allergic to materials contained in the device
4. History of irradiation of prospective insertion site
5. Previous episode(s) of venous thrombosis or vascular surgical procedures at the prospective placement site
6. Local tissue factors which would prevent proper device stabilization and/or access

5.3 Lifestyle Considerations

Because of the real-world design of this study, there are no study-specific restrictions other than those typically associated with use of a study device (e.g., keeping the insertion area clean and dry).

5.4 Screen Failures

Screen failures are not anticipated due to the observational nature of the study.

6 STUDY INTERVENTION

6.1 Investigational/Test Device

Peripherally inserted central catheters (PICCs) are a group of single-, double-, or triple-lumen central venous access catheters composed of silicone elastomer or polyurethane, typically 40 cm to 70 cm in usable length and 2F to 6F in diameter, whose tips terminate centrally in the Superior Vena Cava (SVC). Because these devices are placed centrally, they can be used to deliver a wide variety of parenteral therapies that can potentially cause chemical phlebitis or other vessel damage or irritation when infused through Peripheral intravenous catheters (PIVs) or midline catheters whose tips are not located in the SVC. PICCs can be either open- or closed-ended. Open-ended PICCs typically

require a clamp attached to their extension tubing to prevent blood from back up into the catheter or tubing. A closed-ended PICC has a valve at the distal end that prevents blood reflux into the catheter lumen. The valve remains closed unless exposed to pressure changes such as those exerted at the catheter hub to withdraw or infuse fluids through the catheter lumen.

The PowerPICC family of catheters are indicated for short- or long-term peripheral access to the central venous system for intravenous therapy, power injection of contrast media, and allows for central venous pressure monitoring. For blood sampling, infusion, or therapy a 4 French or larger catheter should be used. The maximum recommended infusion rate is 5mL/sec for power injection of contrast media. For central venous pressure monitoring, a catheter lumen of 20 gauge or larger be used. Table 6.1 provides an overview of the device variants available for use.

Table 6.1 Device Variants

Type	Design	Material	Lumens	Size(s)	Length(s) (cm)
PowerGroshong PICC	Closed-ended	Silicone	Single	5F	40/45/55
PowerPICC	Open-ended	Polyurethane	Single	4F, 5F	55
			Double	5F, 6F	55
			Triple	6F	55
PowerPICC FT	Open-ended	Polyurethane	Double	5F	55
PowerPICC HF	Open ended	Polyurethane	Double	5F	55
PowerPICC SV	Open-ended	Polyurethane	Single	3F	45
			Double	4F	45
PowerPICC SOLO	Open-ended; pressure-activated proximal hub valve	Polyurethane	Single	4F, 5F	55
			Double	5F, 6F	55
			Triple	6F	55
PowerPICC SOLO FT	Open-ended; pressure-activated proximal hub valve	Polyurethane	Double	5F	55
PowerPICC SOLO HF	Open-ended; pressure-activated proximal hub valve	Polyurethane	Triple	5F	55

See device specific IFUs for more detailed information (References 2 – 16).

6.2 Control Device/Standard of Care

This is a single-arm study; no control device will be used.

6.3 Ancillary Devices/Products

The PowerPICC family of devices are available in multiple tray (kit) configurations. These trays typically contain ancillary materials used during catheter insertion procedures. These trays may contain one or more of the following components:

- Microintroducer
- Scalpel
- Introducer needles
- End cap
- Syringes
- StatLock Stabilization Device
- Measuring tape
- Filter straw
- Wound closures
- Transparent dressing
- Drape, fenestrated
- Drape, full body, fenestrated
- Bouffant cap
- Surgical gown
- Towel, absorbent
- Poly underdrape
- Tourniquet
- Face mask
- Surgical tape
- Scissors
- Surgical gloves, sterile
- Antiseptic skin preparation
- Lidocaine
- Saline
- Gauze pads

6.4 Device Labeling

This study will utilize shelf-stock devices. As such, no special labelling is required.

6.5 Treatment Allocation and Measures to Minimize Bias

In this single-arm study, the choice of the specific device type, size, number of lumens, and length required for an individual patient is left to the discretion of the clinician.

7 STUDY PROCEDURES AND ASSESSMENTS

- Study activities and their timing are summarized in the Schedule of Activities (SoA), Section 1.2.
- Protocol waivers or exemptions are not allowed.
- Adherence to the study design requirements, including those specified in the SoA, is essential and required for study conduct.
- All inclusion/exclusion criteria must be reviewed to confirm that potential participants meet all eligibility criteria.

7.1 Screening and Enrollment

After screening against inclusion/exclusion criteria, potential participants will be provided with detailed information about the study. If the potential participant, or parent/guardian in the case of those under 18 years of age, provides written informed consent, he/she will be enrolled in the study.

7.2 Medical History / Baseline Assessments

After enrollment, participant baseline and demographic information will be documented, including, but not limited to:

- Age
- Gender
- Primary diagnosis
- Limited medical history (e.g., vascular disease, coagulopathy, anticoagulant therapy)
- Reason for PICC insertion
- Expected duration of PICC use (i.e., short- vs. long-term)

7.3 Index Procedure

Choice of the specific PowerPICC type, size, number of lumens, and length required for an individual patient is left to the discretion of the clinician. The device and insertion site will be prepared according to the device specific IFU. The device will be inserted, and catheter tip location will be confirmed according to standard medical practice and according to the device specific IFU. Once proper placement is confirmed, the procedure will be completed, the catheter aspirated and flushed, and secured/stabilized according to the device specific IFU. The insertion site will be dressed according to the IFU and hospital-specific protocols.

7.3.1 Procedure Data

After the PICC is in place, information about the insertion procedure will be documented, including, but not limited to:

- Date and time of insertion
- Catheter type, size, and length
- Insertion location
- Insertion procedure (e.g., components/accessories used including guidewires/stylets)
- Number of insertion attempts
- Stabilization method/securement method
- Dressing type
- Total procedure time
- Adverse events/complications (including but not limited to study endpoints such as laceration/perforation of vessel)
- Device deficiencies/failures
- Inserting clinician experience (e.g. years of experience, estimated number of PICCs inserted, education level)

7.3.2 Ease of Insertion Procedure Survey

After the catheter is inserted and procedure data is recorded, the inserting clinician will complete a short survey to assess the performance of the guidewire/stylet.

7.4 Use and Maintenance Procedures

The PowerPICC device will be used for therapy as medically required, according to the IFU and hospital protocol. The device will be maintained (i.e., flushing, fluid locking, cleansing) and the site maintained (i.e., cleansing, dressing) according to the device specific IFU, standard medical practice, and hospital protocols.

When the participant is treated in an acute-care setting, the catheter/site will be assessed daily until the device is removed or until they are discharged with the device in place (then treated as an outpatient). When the participant is treated in an outpatient setting, the catheter/site will be assessed at each therapy visit until the device is removed, or until 180 days post-insertion (±14 days), whichever comes first. For the purposes of endpoint calculations, PICCs remaining in place after 180 days will be considered to have completed therapy.

7.4.1 Use and Maintenance Data

Device assessments will be conducted as part of the participant's routine medical care. Information from these assessments about the use and maintenance of the PICC will be documented, including, but not limited to:

- Catheter patency
- Performance of catheter/site maintenance procedures
- Type of use (i.e., IV therapy (e.g., antimicrobial, TPN, blood products), blood sampling, CVP monitoring, injection of contrast media)

- Adverse events/complications (including but not limited to study endpoints such as extravasation, VT, phlebitis, infection, etc.)
- Device deficiencies/failures (including but not limited to accidental dislodgement and occlusion)

7.5 Device Removal Procedure

The study device will be discontinued/removed when it is deemed medically appropriate by the participant's treating clinician (e.g., no longer needed, no longer functioning). Removal of the device will be performed according to the device specific IFU, standard medical practice, and hospital protocols.

7.5.1 Device Removal Data

At the time of device removal, the following data will be collected:

- Date and time of device removal
- Reason for removal (e.g., completion of therapy, device failure)
- Site condition

Note: Should the catheter remain in place through 180 days without removal, day 180, or the last study visit occurring 180 ± 14 days, will be documented as the final catheter day for the purposes of dwell-time calculations.

8 PARTICIPANT DISCONTINUATION/WITHDRAWAL

8.1 Discontinuation/Withdrawal

- A participant may withdraw from the study at any time at his/her own request or may be withdrawn at any time at the discretion of the investigator or sponsor for safety, behavioral, compliance, or administrative reasons. This is expected to be uncommon.
- At the time of discontinuing from the study, no further data will be collected for the participant.
- If the participant withdraws consent for disclosure of future information, the sponsor may retain and continue to use any data collected before such a withdrawal of consent.
- Participants who withdraw or discontinue the study early (e.g., prior to PICC insertion) may be replaced.

8.2 Lost to Follow-Up

A participant will be considered lost to follow-up if he or she repeatedly fails to return for/complete therapy visits and is unable to be contacted by the study site.

9 ADVERSE EVENTS AND DEVICE DEFICIENCIES

9.1 Definitions of Events

9.1.1 Adverse Events (AEs)

An AE is defined as any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other persons, whether or not related to the investigational medical device. In this study, AE collection will be limited to those occurring in the arm in which the device is inserted or upper torso, as well as any other undesirable clinical event judged to be related or likely related to the PowerPICC device or the suture or stabilization method used for securement of the device, regardless of anatomical region, that in the opinion of the investigator warrants reporting.

Pre-existing conditions should be considered as part of the participant's medical history and should not be reported as an AE unless there is a substantial increase in severity or frequency of the condition, which has not been attributed to natural history. Exacerbation of an existing condition should be reported as an AE if the event meets the protocol definition of an AE.

The clinical course of the event will be followed according to accepted standards of medical practice until the event resolves, stabilizes, or in the opinion of the Investigator, is no longer considered clinically significant. The Investigator must supply the Sponsor with information concerning the follow up and/or resolution of the AE.

9.1.2 Serious Adverse Events (SAEs)

A serious adverse event is defined by ISO 14155 as an adverse event that:

a. led to death,
b. led to serious deterioration in the health of the subject, that either resulted in
   1) a life-threatening illness or injury, or
   2) a permanent impairment of a body structure or a body function, or
   3) in-patient or prolonged hospitalization, or
   4) medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function,
c. led to foetal distress, foetal death or a congenital abnormality or birth defect

NOTE: Planned hospitalization for a pre-existing condition, without serious deterioration in health, is not considered a serious adverse event. Likewise, conditions in the medical history leading to elective hospital stays (e.g. chemotherapy treatment) should not be considered as serious adverse events.

9.1.3 Adverse Device Effect (ADE) / Serious Adverse Device Effect (SADE)

An adverse device effect is defined as any adverse event that is considered to be related to the use of an investigational medical device. This definition includes any event resulting from insufficiencies or inadequacies in the instructions for use, deployment, implantation, or operation or any malfunction of the investigational device (study device) and includes any event that is a result of a user error.

A serious adverse device effect (SADE) is defined as an ADE that has resulted in any of the consequences characteristic of an SAE.

9.1.4 Unanticipated (Serious) Adverse Device Effect (UADE/USADE)

An unanticipated (serious) adverse device effect (UADE/USADE) is any (serious) adverse device effect on health or safety or any life-threatening problem or death caused by, or associated with, a study device, which by its nature, incidence, severity, or outcome has not been identified in the current instructions for use and/or current version of the risk analysis report, or any other unanticipated serious problem associated with a device that relates to the rights, safety or welfare of participants (see Section 2.3.1).

UADEs/USADEs will be reported to FDA as required by 21 CFR Part 812 and to the appropriate governing body per ISO 14155:2011(E).

9.2 Severity of Adverse Events

Each AE shall be assessed for its severity, or the intensity of an event, experienced by the participant according to the criteria below.

Severity Rating	Description
Mild	Event, signs, or symptoms that do not interfere with the participant's daily activity, are usually considered self-limiting, can be treated with non-prescription type medications, and do not require medical intervention
Moderate	Event may interfere or cause low level inconvenience with the participant's daily activity. Requires medical intervention and/or treatment; however, unlikely to require hospitalization or be considered potentially life-threatening in nature
Severe	Event may cause significant discomfort to the participant and/or interferes with the participant's daily activity. Requires medical intervention and/or treatment to preclude a permanent impairment; may be life threatening and/or require hospitalization

9.3 Relationship of Adverse Event to Device(s)/Procedure

Each AE will be assessed for its relationship to the study device or procedure according to the following guidelines.

A. Assess each AE for its relationship to the device or procedure.

- Device Related: This category should be restricted to AEs directly attributable to the study device used.

- Procedure: A procedure includes any activity performed with the study device

B. The following categories shall be used for assigning the certainty of the relatedness.

Relatedness	Description
Not Related	Event is independent of study intervention and/or evidence exists that the event is related to another etiology. There must be an alternative etiology documented by the clinician.
Unlikely Related	Event in which the temporal relationship to study intervention makes a causal relationship improbable (e.g., the event did not occur within a reasonable time of the study device use) and in which underlying disease provides plausible explanations (e.g., the participant's clinical condition other concomitant treatments).
Likely Related	Event in which there is evidence to suggest a causal relationship and the influence of other factors is less likely. The event occurs within a reasonable time after use of the study device and is less likely to be attributed to concurrent disease.
Related	Event in which there is clear evidence to suggest a causal relationship and other possible contributing factors can be ruled out. The event occurs in a plausible time relationship to use of the study device and cannot be explained by concurrent disease.

9.4 Reporting of Events

For all adverse collected events, all sections of the appropriate Case Report Form (CRF) must be completed.

- All SAEs, SADEs, and/or UADEs/USADEs must be reported to the Sponsor via the electronic CRF without unjustified delay and within three (3) working days of the site/investigator becoming aware of the event.

- De-identified copies of all requested relevant documentation should be submitted to the Sponsor within 72 hours of knowledge, as appropriate.

It is the responsibility of the Investigator or their designee to report adverse events to individual Institutional Review Boards (IRBs)/Ethics Committees (ECs). The Sponsor or their designee is responsible for reporting AEs to regulatory authorities according to the local regulations in each participating country.

9.5 Safety Committees

There will be no Safety Committee used in this study.

9.6 Device Deficiencies

The Investigator will record, without unjustified delay, a device deficiency if a device used failed to meet its performance specifications whether due to mechanical failure, malfunction, or defect. Device deficiencies also include use errors and inadequate labeling. This applies to: devices used to treat the participant, or devices in which the package was opened, but the device was not used for treatment, or devices with which treatment was attempted, but the device did not remain through the entire study period.

All mechanical failures, malfunctions, missing components, and defects of the study devices will be recorded on the appropriate Case Report Form and will be promptly reported to the Sponsor. The device(s) should be returned to the Sponsor if requested.

If the device deficiency was associated with an AE, the reporting provisions for AEs, ADEs, SAEs, SADEs and UADEs/USADEs apply.

Reported deficiencies will be investigated and reported as required by appropriate national laws and regulations. The site may be contacted to provide additional information to allow the Sponsor to conduct a thorough investigation.

It is the responsibility of the Investigator, or their designee, to notify the IRB/EC of such device deficiencies in accordance with the IRB/EC and/or local regulations.

10 STATISTICAL METHODS

The statistical analysis plan will be finalized prior to the interim analysis and will include a more technical and detailed description of the statistical analyses described in the following sections. This section includes a summary of the planned statistical analyses of the most important endpoints including primary and key secondary endpoints.

10.1 Overview of Study Design

This is a multi-center, single-arm, prospective, observational study to assess the overall safety and performance of the PowerPICC family of devices.

10.2 Sample Size Considerations

The primary safety endpoint of the study is the incidence of venous thrombosis. The expected venous thrombosis rate is about 10% based on literature review.[1] The statistical rationale of the sample size is based on precision of the point estimates of the primary endpoint, as well as the ability to observe rare adverse events or complications. Assuming the primary endpoint of VT incidence is 10% for a specific type of device, with a sample size of 150, the precision of the point estimate is 4.8% (i.e. the 95% confidence interval is the point estimate plus/minus 4.8%).

Additionally, with a sample size of 150, the probability of observing at least one rare AE/complication with a 1% rate is 78% and the probability of observing at least one rare AE/complication with a 2% rate is 95%.

A sample size of 150 is proposed for each type of device (PowerPICC, PowerPICC SOLO, and PowerGroshong PICC) for a total of 450 participants in the study.

10.3 Analysis Population

The following populations are defined:

Population	Description
Enrolled	All participants who sign the ICF
Evaluable	All participants who undergo successful placement of a study device and receive at least one treatment through it

10.4 Primary Endpoint(s)

10.4.1 Safety

Venous thrombosis will be defined as the presence of symptomatic thrombus confirmed by ultrasonography or other imaging. The incidence rate of symptomatic VT will be calculated as the number of participants with symptomatic VT incidence divided by the total number of participants; 95% confidence interval will be calculated.

10.4.2 Performance

The percentage of PICCs that remain in place through the completion of therapy (success) will be calculated by dividing successful cases by the total number of cases (total number of participants completing therapy with single PICC / total number of participants); 95% confidence interval will be calculated.

10.5 Secondary Endpoint(s)

Secondary endpoints will be analyzed in the following manner:

- For each complication listed as a secondary endpoint, the incidence of each complication will be calculated by dividing the number of participants experiencing the event by the total number of participants; 95% confidence intervals will be calculated where appropriate.
- The percent of patent catheters will be calculated by dividing the number of catheters remaining functional through completion of therapy by the total number of catheters; 95% confidence intervals will be calculated where appropriate.
- The percent of placement success in a single insertion attempt will be calculated by dividing the number of catheters that are placed in a single attempt with proper tip location, and catheter patency by the total number of insertions; 95% confidence intervals will be calculated where appropriate.
- The usability of guidewires/stylets will be analyzed based on a composite score of performance questions administered in a post-insertion survey where 1 represents the best possible score and 5 represents the worst possible score. Scores for individual survey questions will be analyzed separately as well.

Summary statistics for categorical variables will include frequency counts and proportions and for continuous variables mean, standard deviation, minimum, median and maximum. Further details will be included in the final Statistical Analysis Plan (SAP).

10.6 Interim Analysis

An interim analysis, to assess study progress, will be targeted when 50% of the subjects have completed the study, or sooner, based on reporting requirements. Details of the analysis will be defined in the statistical analysis plan.

11 DATA COLLECTION AND RECORD MAINTENANCE

11.1 Case Report Forms

The Investigator is responsible for ensuring the completeness and accuracy of all study documentation.

All required clinical data will be collected/documented in sponsor-provided electronic Case Report Forms (CRFs). Applicable national and local regulations are followed on the handling of electronic data. Modification of the CRFs will only be made if deemed necessary by the Sponsor and/or the appropriate regulatory body.

Site numbers and participant numbers will be used to track participant information throughout the study. Participant personal information will be pseudonymized/de-identified.

11.2 Source Documentation

Original or certified copies of all relevant clinical findings, observations, and other activities throughout the clinical investigation must be recorded and maintained in the medical and/or study file of each enrolled participant. Where there is no prior written or electronic record of data, such as clinical surveys, these data may be recorded directly on the CRF(s) and the CRF is then considered to be the source. In this study, the following CRFs will serve as original source documents: Insertion Procedure Details and Ease of Insertion Survey.

11.3 Data Management

Data management is the responsibility of the Sponsor or their designee. Data from completed CRFs will be managed in a secured, controlled database. A Data Management Plan (DMP) will be developed that outlines the procedures used for data review, database cleaning and issuing/resolving data queries. Procedures for validations and data storage will also be contained within the DMP.

11.4 Record Retention

The Investigator shall retain all study records for a minimum of two (2) years after the date on which the study is terminated/completed. Study records may be stored longer if required by national law or other local rules. The data for some of these records may be available in computerized form but the final responsibility for maintaining study records remains with the Investigator.

The Investigator may withdraw from the responsibility to maintain records for the period required by transferring custody of the records to any other person who will accept responsibility for retaining them. Notice of a transfer shall be given to the Sponsor not later than ten (10) working days after the transfer occurs.

12 QUALITY CONTROL AND ASSURANCE

12.1 Control of Study Products

In this observational, real-world study, shelf-stock of study devices will be used. Clinicians may choose and use any study device that is available for use in their institution and that is medically appropriate for use in study participant. No special controls are required in this study.

12.2 Monitoring

The Sponsor or their designee will designate trained and qualified personnel to monitor the progress of this clinical study in accordance with established standard operating procedures and the study-specific Monitoring Plan.

Prior to study start, a study initiation visit (SIV) will be conducted to review with the Investigator(s) and staff the provisions and proper conduct of this study. This visit will include a detailed review of this protocol, verification that all necessary documents are on file at the investigational site and confirmation of IRB/EC approvals.

During the study, routine monitoring visits (RMVs) will be conducted to assure the site continues to adhere to the protocol, the investigator agreement, and regulations regarding conduct of clinical studies. The Sponsor-Clinical Research Associate (CRA) will confirm that the ICF to be used is the version approved by the IRB/EC, confirm the applicable national privacy laws have been followed, verify that all necessary documents are on file at the investigational site and confirm that there are provisions to continue and maintain all documents and records throughout the study as required by applicable regulations. These monitoring visits will assess continued protocol compliance, adequate participant enrollment, accurate data reporting, monitoring of participant safety through identification and/or review of any device-related AEs, UADEs, or SAEs, device accountability, continued maintenance and calibration of study-specific equipment (if applicable), and continued IRB/EC acceptance of the study.

At the completion of the study, the Sponsor-CRA will conduct a final close-out visit or COV. The purpose of this visit may include but is not limited to collecting all outstanding study data documents, confirming that the Investigator's files are accurate and complete, reviewing the record retention requirements with the Investigator and ensuring that all applicable requirements for closure of the study are met.

12.3 Audits and Inspections

If the study is selected for audit by the Sponsor or if there is an inspection by the appropriate regulatory authorities, the Investigator and his team will make themselves available during the visit. The Investigator must agree to the inspection of all study related records and give the auditor/inspector direct access to source documents for verification of data on CRFs. The participant's anonymity must be ensured, and data checked during the audit must remain confidential.

As soon as the Investigator is aware of an upcoming inspection/audit by the regulatory authorities, he/she will promptly inform the Sponsor. As agreed with the Investigator, Sponsor personnel may be present at the site during the inspection.

12.4 Protocol Deviations

A protocol deviation is defined as an event where the Investigator or site personnel did not conduct the study according to the protocol.

Except when necessary to protect the life or physical well-being of a participant, protocol deviations are not permitted. The Sponsor and the investigational site's IRB/EC must be notified immediately if an emergency situation arises in which the safety of a participant may require immediate intervention different than that defined in the protocol. This must

be followed by written confirmation that describes the emergency action and outcomes, within five (5) working days from the date of the emergency action in accordance with the governing IRB/EC's requirement.

It is the Investigator's responsibility to ensure that there are no deviations from the Protocol. Except in an emergency, a protocol deviation requires Sponsor approval. Any and all deviations must be recorded on the appropriate CRF regardless of whether medically justifiable or Sponsor approved. Upon evaluation by the Sponsor, actions may be required to prevent additional deviations, such as retraining of the site, implementation of additional site procedures, and more frequent monitoring. If these steps fail, more serious measures, up to and including termination of enrollment at the site may be considered.

13 ADMINISTRATIVE REQUIREMENTS

13.1 Investigator and Site Selection

The Investigator must be of good standing as an Investigator and knowledgeable in relevant areas of clinical research to ensure adherence to the requirements of this protocol, including the protection of human participants. Other site personnel must have appropriate research experience and infrastructure to ensure adherence to this protocol and enrollment of sufficient numbers of evaluable participants. The curriculum vitae (CV) of the Investigator(s), Sub-Investigator(s) and Study Coordinator(s) will be maintained in the Sponsor's files as documentation of qualification by training and experience.

The Principal Investigator will sign the Investigator Agreement pages of this protocol, agreeing to comply with all applicable regulations and the requirements of this study as per the clinical study agreement.

Any site that is deactivated prior to initial enrollment, either by the Sponsor or by the individual site itself, may be replaced.

13.2 Training

Each Investigator and appropriate site personnel will be trained on this protocol and study requirements during the Site Initiation Visit. All training will be documented and filed at the investigational site and with the Sponsor.

13.3 Required Documents

An Investigator may not screen or enroll participants until authorized to do so by the Sponsor. At a minimum, the following documentation should be received by the Sponsor prior to the commencement of study activities:

- Fully executed Non-disclosure Agreement (NDA) between PI/site and Sponsor;

- CVs, signed and dated within 2 years of study start for the PI and Sub-Investigator(s)]
- CVs for Study Coordinator(s);
- Signed CSA by PI/site (or designee);
- Signed Investigator Agreement Page by PI and Sub-Investigator(s);
- Signed Financial Disclosure Statement by PI and Sub-Investigator(s);
- Completed and Signed Training Log by PI and Sub-Investigator(s);
- Study Personnel Identification list;
- Written approval from the IRB/EC of both the protocol and ICF, and any other
- applicable protocol specific material; and
- IRB/EC Membership List, Assurance of Compliance Form, or equivalent.

13.4 Publication Policy

The sponsor believes that results of applicable clinical studies should be published in peer-reviewed literature in a timely, accurate, complete and balanced manner, regardless of study outcomes, whenever possible. As such, at the conclusion of this study, an article may be prepared for publication in a reputable scientific journal. Formal presentation(s) or publication(s) of data collected from this study will be considered as a joint publication by the investigator(s) and the appropriate personnel of the Sponsor. Authorship will be based on generally accepted criteria of the ICMJE (International Committee of Medical Journal Editors) and determined by mutual agreement.

The publication of the principal results from any single-center experience within the study is not allowed until the preparation and publication of the multicenter results. Exceptions to this rule require the prior approval of the Sponsor. The analysis of other pre-specified and non-pre-specified endpoints will be performed by the Sponsor or its designee. Such analyses, as well as other proposed investigations or manuscripts will require the approval of the Sponsor.

13.5 Study Registration

This is a not an Applicable Clinical Trial and does not meet the FDA Amendments Act of 2007 (FDAAA) criteria for clinical study registration; however, to ensure transparency, the study will be registered on www.clinicaltrials.gov. The study will also be registered on applicable local registries.

13.6 Termination of Study

The Sponsor reserves the right to suspend enrollment or terminate the study at any time for any reason. The Sponsor may suspend enrollment or terminate the study at a specific investigational site for reasons including, but not limited to, inadequate data collection, low participant enrollment rate, achievement of the total enrollment, conditions imposed by the reviewing IRB/EC and/or non-compliance with this protocol or other clinical research requirements. Written notice will be submitted to the Investigator in advance of such termination.

In the event of study suspension or termination, the Sponsor will send a report outlining the circumstances to the IRB/EC, and all Investigators and Regulatory Authorities as required by regulation.

14 ETHICAL AND REGULATORY CONSIDERATIONS

14.1 IRB/EC Approval

Investigators or designees must submit the study protocol, Informed Consent Form (and pediatric assent form if applicable), and all other locally required documentation to an appropriate IRB/EC and obtain study-specific written approval (favorable opinion) before being allowed to participate in the study. Before commencement of the study, the Investigator or designee must provide the Sponsor with written documentation of such approval. The IRB/EC must give written renewal of the original approval at least annually to continue the study. A copy of the written renewal must be provided to the Sponsor.

The IRB/EC will be notified of any amendments to the protocol, as well as possible associated information and consent form changes, where applicable, and written approval (favorable opinion) will be obtained prior to implementation, as applicable.

The Investigator or designee is responsible for fulfilling any conditions of approval imposed by the IRB/EC, such as regular safety reporting, study timing, etc. The Investigator or designee will provide the Sponsor with copies of such reports.

14.2 Informed Consent and Confidentiality

Prior to any study activity, the Investigator (or designee) must explain to each participant in layman's terms, the nature of the study, its purpose, expected duration, and the risks and benefits of study participation. Also, participant will be informed of uses and disclosures of their medical information for research purposes, and their rights to access information about them. All applicable national privacy laws (e.g., GDPR requirements in the E.U.) will be followed in this study. The participants must be informed of their right to withdraw from the study at any time and for any reason without sanction, penalty, or loss of benefits to which they are otherwise entitled, and that withdrawal from the study will not jeopardize their future medical care. Participants will be informed of their right to new information and/or findings relating to the clinical study, and the process by which this information is made available. After this explanation, given sufficient time to decide whether to participate before entering the study, the participant must voluntarily provide consent in accordance with ISO 14155:2011(E). The participant will receive a copy of his/her signed ICF.

14.2.1 Confidentiality

Participant confidentiality must be strictly held in trust by the Investigator, study staff, and the Sponsor. Participant confidentiality and anonymity will be

maintained by removal of identifiers from any data, documentation, or clinical samples submitted to the Sponsor.

Any data collected meeting the definition of protected/confidential health information or personal identifying information will be collected and maintained using the designated authorizations and following privacy procedures as specified in the applicable regulatory authority regulations including the European Union General Data Protection Regulation (GDPR).

The Sponsor-CRA, authorized representatives of the sponsor, and/or applicable regulatory authorities may inspect all documents and records required to be maintained by the Investigator. The Investigator/Site will permit access to such records.

14.3 Regulatory Status

The study devices are CE marked and will be studied in a post-market fashion in Europe.

14.4 Statement of Compliance

This clinical investigation will be conducted in compliance with the protocol and following regulatory requirements:

- ISO14155:2011 (Good Clinical Practice);
- EU MDR (Council Regulation 2017/745 of 5 April 2017);
- Ethical principles of the Declaration of Helsinki, in its current revision; and
- Applicable sections of the national laws and regulations.

The clinical investigation will not commence at a clinical site until approval (favorable opinion) from the respective IRB/EC has been received. All additional requirements imposed by the IRB/EC(s) will be followed. Involvement of the national competent authorities (e.g. by notification, seeking authorization) will be accomplished as required by national laws and regulations.

15 REFERENCES

1. Chopra, V. Peripherally inserted central catheter (PICC)-related venous thrombosis. UpToDate, 2019. www.uptodate.com Referenced 05 August 2019.
2. PowerPICC, Gravity Flow and Power Injection Insert (BAW0741905)
3. PowerPICC, Microintroducer, Interventional Radiology IFU (BAW0740757)
4. PowerPICC, Microintroducer, Nursing IFU (BAW0740756)
5. PowerPICC SV, Microintroducer, Interventional Radiology IFU (BAW0743785)
6. PowerPICC SV, Microintroducer, Nursing IFU (BAW0743784)
7. PowerPICC SOLO, Gravity Flow and Power Injection Insert (BAW0741906)
8. PowerPICC SOLO, Microintroducer, Interventional Radiology IFU (BAW0740759)
9. PowerPICC SOLO, Microintroducer, Nursing IFU (BAW0740758)
10. PowerGroshong, Gravity Flow and Power Injection Insert (BAW0743526)
11. PowerGroshong, Sherlock TLS Stylet IFU (BAW0736702)
12. PowerGroshong, Sherlock 3CG IFU (BAW0738512)
13. PowerGroshong, Microintroducer IFU (BAW0748151)
14. Supplement IFU, PICC and Midline (BAW0728690)
15. Sherlock 3CG IFU (BAW0741868)
16. Power Injection Insert (BAW0743752)