COVER PAGE OF STATISTICAL ANALYSIS PLAN

Study title:	**Prospective Observational Study of the PowerPICC Family of Devices and Accessories**
Protocol number.:	**MDS-19PICCEU01**
NCT number:	**NCT04263649**
Statistical Analysis Plan version and date:	**v.5.0, 28-March 2022**

Statistical Analysis Plan
for
interim and final analysis

Version 5.0

Study:	Prospective Observational Study of the Power PICC Family of Devices and Accessories
Study-ID:	MDS-19PICCEU01
Sponsor / Contact:	Becton Dickinson and Company Bard Access Systems 605 North 5600 West Salt Lake City, Utah 84116 United States
Evaluation:	FGK Clinical Research GmbH
FGK code	3558
Version:	5.0 of 28Mar2022 (final)
Previous versions:	4.0 of 28Jul2021 (final) 3.0 of 16Apr2021 (final) 2.0 of 15Apr2021 (final) 1.0 of 23Dec2020 (final)

Revision history

Version	Author	Date	Reason for Revision
2.0	P. Wolf	15Apr2021	Derivation of performance success clarified; title used for all generated TLGs adapted; appendix updated
3.0	P. Wolf	16Apr2021	Assignment of analysis sets to analysis adapted
4.0	P. Wolf	28Jul2021	- Section 4.4.2: derivation of incidence of complications adapted (only non-missing values used for calculation of percentages) - Section 4.4.3: MedDRA version 23.0 added - Section 5 added
5.0	P. Wolf	28Mar2022	- Analysis of safety and performance endpoints adapted to only use non-missing values for the calculation of percentages. - Ease of insertion questionnaire: exception added that specific missing values will be set to not applicable/ not used

Table of Contents

List of Abbreviations

In the following abbreviations are listed as used within this statistical analysis plan or which might occur within the tables, listings and graphs outputs:

AE	Adverse event
BMI	Body mass index
CI	Confidence interval
CRF	Case report form
DRM	Data review meeting
EC	Exclusion Criterion
IC	Inclusion Criterion
ICF	Informed Consent
IFU	Instructions for Use
LLT	Lower level term
MedDRA	Medical dictionary for regulatory activities
N	Number of participants
PICC	Peripherally Inserted Central Catheter
PT	Preferred term
SAE	Serious adverse event
SAP	Statistical analysis plan
SAF	Safety set
SD	Standard deviation
SOC	System organ class
TLG	Tables, listings, graphs
VT	Venous Thrombosis

1 General

This Statistical Analysis Plan (SAP) was defined by the Sponsor and the responsible Statistician. It is based upon the Study Protocol (version 1.0 of 12Dec2019) and contains detailed description of the statistical methods described therein.

The SAP describes prospectively the analyses to be performed on study data for the final analysis as well as for the interim analysis. It was finalized prior to the interim analysis.

1.1 Overall Design

This is a prospective, observational, single arm, post-market study to assess the safety and performance of the PowerPICC family of devices. In the study, only participants who require one of the study devices may be considered for enrollment. The choice of device required for individual participants 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.

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.

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.

Use and Maintenance Procedures

The PowerPICC device will be used for therapy as medically required, according to the Instructions for Use (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 outparticipant). When the participant is treated in an outparticipant 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, peripherally inserted central catheters (PICCs) remaining in place after 180 days will be considered to have completed therapy.

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.

Investigational Sites

Up to 20 sites in the EU will participate in this study. No more than 20% of participants may be enrolled at any one site.

1.2 Sample Size Considerations

The primary safety endpoint of the study is the incidence of venous thrombosis (VT). The expected venous thrombosis rate is about 10% based on literature review. 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.

1.3 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. As all analyses are only exploratory and no confirmatory tests are planned no alpha adjustment for the interim analysis is needed.

1.4 Objectives

The primary safety objective is to assess the incidence of symptomatic venous thrombosis (VT) in patients with PowerPICC, PowerPICC SOLO, and PowerGroshong PICC devices (PICCs) used for both short- and long-term venous access.

The primary performance objective is to assess the rate of therapy completion in PICCs used for both short- and long-term therapy.

2 Safety and Performance Variables

2.1 Primary Safety Variable

The primary safety parameter for this study is the incidence of symptomatic VT defined as any new occurrence of symptomatic VT defined by thrombus presence confirmed by ultrasonography or other imaging.

2.2 Primary Performance Variable

The primary performance parameter for this study is the percent of PICCs that remain in place through the required therapy time period (completion of therapy) (success/failure)

2.3 Secondary Safety Variables

The following secondary safety parameters will be analyzed:

Incidence defined as any new occurrence of:

- Phlebitis
- Extravasation
- Local infection
- Catheter-related bloodstream infection
- Accidental dislodgement
- Vessel laceration
- Vessel perforation

2.4 Secondary Performance Variables

The following secondary performance parameters will be analyzed:

- 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: Ease of insertion - based on a post-insertion survey

2.5 Further Safety Variables

- Adverse events
- Device deficiencies

3 Statistical Analysis Sets

3.1 Enrolled Set

The enrolled set (ES) consists of all participants who sign the ICF.

3.2 Safety Set

The safety set (SAF) consists of all participants who undergo placement of a study device.

3.3 Evaluable Set

The evaluable set (EVS) consists of all participants who undergo successful placement of a study device and receive at least one treatment through it.

3.4 Additional Subgroup Analysis

All analyses will be presented separately for the type of device (PowerPICC, PowerPICC SOLO, and PowerGroshong PICC).

3.5 Assignment of Analysis Sets to Analysis

The evaluable set will be considered the primary analysis set for the primary performance endpoint. Disposition data will be analyzed on the enrolled set. Demographic data and safety analyses are presented using the safety set.

4 Statistical Evaluation

The three types of devices (PowerPICC, PowerPICC SOLO, and PowerGroshong PICC) will be separately tabulated. Total columns will additionally be displayed for all three different types of devices combined.

No inferential assessments will be performed on any analyzed data.

A detailed description of the planned tables, listings and graphs is given in Appendix A (version 5.0).

4.1 Dispositions of Participants and Analysis Sets

Disposition of participants and analysis sets

The disposition of participants and analysis sets, participants per center, participants per country, inclusion and exclusion criteria, and the status at study termination will be shown on the enrolled set.

4.2 Demographics and Other Covariates

Demographic data

Demographic data (age (at signing informed consent), gender, race, body height, body weight, body mass index (BMI)) will be tabulated

Medical history

The proportion of participants with

- implantable devices
- past and/or current use of an artificial heart
- past and/or current anatomical abnormalities of the central venous system
- past and/or current use of an atrial fibrillation or other atrial arrhythmias that affects the p-wave
- known ABSENCE of a p-wave
- abnormalities of the arms
- abnormalities of the chest wall
- history of coagulopathy
- history of hypercoagulopathy
- current treatment with anticoagulants
- central venous access devices
- history of lymph node dissection/ lymphedema
- renal impairment
- treatment with cervical collars or halo traction
- history of phlebitis
- history of venous thrombosis

- history of deep vein thrombosis
- history of catheter related bloodstream infection
- any other relevant medical history

will be tabulated.

Further details of medical history and details of other relevant medical history will be listed.

Baseline information

The primary and secondary diagnosis for current admission and the reason for PICC placement as well as the intended access duration will be tabulated.

Demographics and other covariates will be presented for the safety set.

4.3 Catheter insertion, Maintenance and Removal

Catheter insertion

The location of procedure performance (bedside/ interventional radiology) will be tabulated.

The following information regarding catheter insertion will be tabulated:

- Was the catheter tip repositioned?
- What device was placed?
- What guidewire was used to facilitate insertion?
- Where was the catheter placed?
- Which vein was accessed for the procedure?
- Was an assessment of the vessel/catheter ratio done prior to insertion?
- How many insertion attempts were made?
- Was local anaestesia used?
- Was the catheter length trimmed?
- Was the insertion of the catheter done using tunneling?
- Was a Sherlock TLS used for placement?
- Was a Sherlock 3CG used for placement?
- What method was used to confirm catheter tip positioning?
- What stabilization method was used?
- What dressing type was used?
- Was the catheter inserted as per the instructions for use?
- Was a second implanted line vascular access device present (together with location and type of second device)?

Basic statistics for the duration between start and PICC is secured and the duration between start and tip position confirmation will be displayed. All catheter insertion data will be presented on the safety set.

Use and Maintenance

All information about participant location will be listed.

Removal

The proportion of participants with study PICC still in place, the reason for PICC removal, the proportion of participants with skin condition around the catheter site normal at removal and the specification of abnormal skin condition, and the use of the PICC line during the study period will be tabulated. Removal data will be presented for the evaluable set.

4.4 Safety Analysis

All primary and secondary safety parameters will be analyzed using descriptive methods. For proportions exact two-sided 95% Clopper-Pearson confidence intervals will be calculated where appropriate. All safety analyses will be based on the safety set.

4.4.1 Analysis of Primary Safety Variable

The primary safety endpoint for this study is the incidence of symptomatic VT defined as any new occurrence of symptomatic VT defined by thrombus presence confirmed by ultrasonography or other imaging.

The incidence rate of symptomatic VT will be calculated as the number of participants with symptomatic VT incidence (as ticked on the AE CRF page) divided by the total number of participants with non-missing data on symptomatic VT in the safety set and displayed using frequency tables. 95% confidence interval for the incidence rate will be additionally presented.

4.4.2 Analysis of Secondary Safety Variables

Complications

For each complication listed as a secondary endpoint, the incidence will be calculated by dividing the number of participants experiencing the event by the total number of participants with non-missing data on the corresponding complication in the safety set and displayed using frequency tables. 95% confidence interval for the incidence will be additionally presented.

The following complications will be analyzed:

- Phlebitis (Preferred term (PT): “Catheter site phlebitis” / Lower level term (LLT): “Catheter site phlebitis”)
- Extravasation (PT: “Catheter site extravasation” / LLT: “Catheter site extravasation”)
- Local infection (as ticked on the adverse event (AE) case report form (CRF) page)
- Catheter-related bloodstream infection (as ticked on the AE CRF page)
- Accidental dislodgement (System organ class (SOC): “Product issues” / PT: “Device dislocation” / LLT: “Catheter dislodgment”)
- Vessel laceration (as recorded on the catheter insertion CRF page)
- Vessel perforation (as recorded on the catheter insertion CRF page)

For local infections additionally the number of participants with local infections confirmed according to protocol (presence of pus at the exit site and/or culture confirmed site infection) by type of device and overall will be displayed in a footnote.

4.4.3 Further Safety Variables

Adverse events (AEs)

AEs will be coded by using the Medical dictionary for regulatory activities version 23.0 (MedDRA).

AEs will be tabulated by SOC and PT (MedDRA). The number of entries, as well as the number and rate of affected participants will be reported for each type of device. Additionally, AEs will be presented by severity.

SAEs, non-serious AEs, and AEs which are related to device (adverse device effects [ADEs]), SADEs, AEs which are related to procedure, or related to accessories will be presented separately.

All AEs will be listed together with study day of AE (start date of AE – insertion date) as well as duration of AE for AEs with complete dates.

AEs are considered being related to device/procedure/accessories, if relationship is at least likely or relationship assessment is missing.

Device deficiencies

Details regarding device deficiencies will be listed.

4.5 Performance Analysis

All primary and secondary performance parameters will be analyzed using descriptive methods. For proportions two-sided exact 95% Clopper-Pearson confidence intervals will be calculated where appropriate.

4.5.1 Analysis of Primary Performance Variable

The primary performance parameter for this study is the percent of PICCs that remain in place through the required therapy time period (completion of therapy) (success/failure). A success will be defined as follows:

- subjects which still have the study peripherally inserted central line catheter in place
- subjects who did not have the study peripherally inserted central line catheter in place with the reason for peripherally inserted central line catheter removal:
    - “therapy completed / end of useful medical use (catheter stayed in place through the required therapy time)” or
    - “therapy changed or cancelled”.

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 devices with non-missing data on success/failure in the evaluable set and displayed using frequency tables. 95% confidence interval will be calculated.

4.5.2 Analysis of Secondary Performance Variables

Percent of patent catheters

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 with non-missing data on patency in the evaluable set and displayed using frequency tables. 95% confidence intervals will be additionally calculated.

Percent of placement success in single insertion attempt

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 with non-missing data on placement success and number of attempts and displayed using frequency tables. 95% confidence intervals will be additionally calculated. Data will be presented on the safety set.

Usability: Ease of insertion - based on a post-insertion survey

The usability of guidewires/stylets will be analyzed based on a composite score of performance questions administered in a post-insertion survey.

The results of the insertion user questionnaire will be tabulated. For each question, the individual results will be tabulated. Additionally, for all scores, a numerical score will be applied (5 = very easy / strongly agree; 1 = very difficult / strongly disagree) and basic statistics will be additionally presented. Data will be presented on the safety set. Cases where the use of Sherlock TLS or 3CG is documented with “No” and no documentation is available in the ease of insertion data (“empty CRF documentation”) for the respective question, will be displayed as “not applicable/not used” for the corresponding question.

4.6 Other Analysis

Protocol deviation

Details regarding protocol deviations will be listed.

4.7 Missing Values

No missing value imputation methods will be applied. During the data review meeting (DRM) all participants will be reviewed regarding their occurrence of missing data on safety and performance endpoints.

4.8 Interim Analysis

All parameters captured on CRF pages belonging to data of participants needed for the interim analysis will be checked, as specified in the data validation plan and all queries will be resolved. The interim analysis will be performed at the time when 50% of the patients are enrolled. A cut-off date for the interim analysis will be fixed and all assessments done until the cut-off date will be entered in the eCRF and cleaned for the interim analysis. Only these data will be used for the interim analysis. Further unclean data entered in the eCRF will be cut and not used for the interim analysis.

As all analyses are only exploratory and no confirmatory tests are planned no alpha adjustment for the interim analysis is needed.

4.9 Data Base Closure and Data Review

A data base closure will be performed prior to the final analysis. All parameters will be checked, as specified in the data validation plan, and all queries resolved before data base closure and final analysis.

A data snapshot will be done for the interim analysis.

A data review will be conducted prior to the interim and final analysis on all data to allocate the participants to the analysis sets. At least the following items will be discussed:

- Successful placement of a study device [listing 3.1]
- Receipt of at least one treatment through study device [listing 3.5]

These evaluations and assessments will be done together and in agreement with the Sponsor, however FGK will provide the Sponsor with the appropriate participant listings (as defined in appendix A). Data review can be done via a telephone conference or in writing.

The affiliation of participants to the analysis sets will be done prior to the analysis.

Data analysis will be done after data base closure and data review has been conducted and data review minutes have been signed by both the Sponsor and FGK.

4.10 Miscellaneous

The description of the tables in Appendix A determines the general format of the tables. The real design will be determined by the technical possibilities within SAS and may not look identical to the provided example. However, all information as displayed will be included.

For qualitative variables frequency tables (absolute and relative values) will be presented. For frequency tables, all missing values (including user-defined missing values) will be displayed in one combined category “missing”, but not included in the calculation of percentages. Percentages will be presented to one decimal place. Quantitative parameters will be described by declaring the mean value, standard deviation, minimum, first quartile, median, third quartile, and maximum. In general, minimum and maximum will be presented to the same level of precision as the raw data; means and medians, and quartiles will be presented to one further decimal place; standard deviations will be printed out to one additional place further. In basic statistics tables the overall number of missing values (including user-defined missing values as “not done”, “unknown”, “not applicable”, “not documented”) will be given.

The listings are always sorted by type of device, center, and participant. If a different sorting order should be used for some listings this will be remarked separately. The variables for the special listings are explicitly given in the description of listings. All listings will be presented for the safety set and an indicator if the patient is also in the evaluable set will be added to all listings, if not stated differently.

Enrolled participants without placement of device will be considered in tables and listings describing disposition of participants, analysis sets, and inclusion and exclusion criteria. Protocol deviations will be listed for enrolled patients.

The following title will be used for all generated tables, listings, and graphs for the interim/ final analysis:

Becton Dickinson Page # of #
Protocol: MDS-19PICCEU01 - <Interim/Final> Analysis

<Table/Listing/Graph NNN >
<Description of contents>
<Subtitle for description of contents - if applicable>
<Analysis set>

The numbering NNN of the tables/listings/graphs will be stated in the detailed description (Appendix A).
Following footnote will be used for all generated tables, listings, and graphs:

Program name: <Name of program> Date: <Actual date(DDMMMYYYY:hhmmss)>

All tables, listings, and graphs will be generated in A4 paper format.
The statistical evaluation will be performed using SAS version 9.4 or higher.

5 Changes from Protocol

In the protocol the calculation of percentages for the safety and performance endpoints is described as dividing the numbers of participants with events by the total number of participants. This was corrected in the SAP to dividing by the number of participants with non-missing data for the respective endpoints only.

6 Signatures

This SAP will be signed electronically in the eTMF.

Statistician:
Petra Wolf Senior Statistician FGK Clinical Research GmbH Heimeranstr. 35 80339 München Germany

Sponsor:
Gloria Viti Clinical Project Manager Becton Dickinson and Company Via Enrico Cialdini, 16 20161 Milan Italy

Sponsor:
Rachel Gao Senior Statistician Becton Dickinson and Company 1 Becton Drive, Franklin Lakes, New Jersey 07417 United States

Statistical Analysis Plan
Appendix A

List of generated summary tables, listings, and graphs

Version 5.0

Tables and listing needed for the interim analysis are marked with (*)

Table of Contents

1 Disposition of Participants

1.1 Disposition of Participants / Analysis Sets

- Table 1.1.1: Participants per Type of Device and Analysis Set

Enrolled Set

	Type of Device									
	PowerPICC		PowerPICC SOLO		PowerGroshong PICC		Device Not Assigned		Total	
	(N=XXX)		(N=XXX)		(N=XXX)		(N=3)		(N=XXX)	
Enrolled Set (ES)	**N**	**%**	**N**	**%**	**N**	**%**			**N**	**%**
no										
yes										
Overall (non-missing)										

	Type of Device									
	PowerPICC		PowerPICC SOLO		PowerGroshong PICC		Device Not Assigned		Total	
	(N=XXX)		(N=XXX)		(N=XXX)		(N=3)		(N=XXX)	
Safety Set (SAF)	**N**	**%**	**N**	**%**	**N**	**%**			**N**	**%**
no										
yes										
Overall (non-missing)										

	Type of Device									
	PowerPICC		PowerPICC SOLO		PowerGroshong PICC		Device Not Assigned		Total	
	(N=XXX)		(N=XXX)		(N=XXX)		(N=3)		(N=XXX)	
Evaluable Set (EVS)	**N**	**%**	**N**	**%**	**N**	**%**			**N**	**%**
no										
yes										
Overall (non-missing)										

Footnote 1: For the subsequent tables, listings, and graphs, only the short labels for the statistical analysis sets (given in brackets) are used.

- Table 1.1.2: Participants per Analysis Set and Center

  Enrolled Set

	Analysis Set					
	Enrolled Set (N=XXX)		Evaluable Set (N=XXX)		Safety Set (N=XXX)	
Center	**N**	**%**	**N**	**%**	**N**	**%**
1						
2						
3						
4						
…						
Overall (non-missing)						

- Table 1.1.3: Participants per Analysis Set and Device

  Enrolled Set

	Analysis Set					
	Enrolled Set (N=XXX)		Evaluable Set (N=XXX)		Safety Set (N=XXX)	
Device	**N**	**%**	**N**	**%**	**N**	**%**
missing						
PowerPICC						
PowerPICC SOLO						
PowerGroshong PICC						
Device Not Assigned						
Overall (non-missing)						

- Table 1.1.4: Participants per Analysis Set and Country

  Enrolled Set

	Analysis Set					
	Enrolled Set (N=XXX)		**Evaluable Set (N=XXX)**		**Safety Set (N=XXX)**	
Country	**N**	**%**	**N**	**%**	**N**	**%**
…						
…						
…						
Overall (non-missing)						

- Table 1.1.5: Inclusion and Exclusion Criteria

Enrolled Set

	Type of Device									
	PowerPICC		PowerPICC SOLO		PowerGroshong PICC		Device Not Assigned		Total	
	(N=xxx)		(N=xxx)		(N=xxx)		(N=3)		(N=xxx)	
All inclusion criteria met	**N**	**%**	**N**	**%**	**N**	**%**			**N**	**%**
no										
yes										
Overall (non-missing)										

	Type of Device									
	PowerPICC		PowerPICC SOLO		PowerGroshong PICC		Device Not Assigned		Total	
	(N=xxx)		(N=xxx)		(N=xxx)		(N=3)		(N=xxx)	
None of the exclusion criteria met	**N**	**%**	**N**	**%**	**N**	**%**			**N**	**%**
no										
yes										
Overall (non-missing)										

	Type of Device									
	PowerPICC		PowerPICC SOLO		PowerGroshong PICC		Device Not Assigned		Total	
	(N=xxx)		(N=xxx)		(N=xxx)		(N=3)		(N=xxx)	
All inclusion criteria and none of the exclusion criteria met	**N**	**%**	**N**	**%**	**N**	**%**			**N**	**%**
no										
yes										
Overall (non-missing)										

- Listing 1.1.1: Disposition of Participants and Analysis Sets

  Enrolled Set
  Variables: Type of device, Center, Country, Participant, ICF version date, Date/Time ICF signed, All IC and EC met (yes/no), Violated IC^, Violated EC^, Agreed to use the study data for further research, Subject status, EVS (yes/no), SAF (yes/no)
  Footnote 1: ^ Numbers (eCRF) of violated IC or EC.
  Note: Type of device will be displayed as “by-variable” within a subtitle.

1.2 Discontinuation

- Table 1.2.1: Status at End of Study (*)

Safety Set

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Completion status (CRF)	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
completed (removal and/or 180 days)								
withdrawal								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Reason for withdrawal	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
withdrawal of consent								
lost to follow up								
death								
AE								
device deficiency								
other								
Overall (non-missing)								

Note 1: Reason for withdrawal only displayed for patients with study withdrawal.

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Completion status	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
completed (removal and/or 180 days)								
death								
lost to follow up								
withdrawal								
Overall (non-missing)								

- Listing 1.2.1: Study Termination

  Safety Set
  Variables: Type of device, Participant, Date of study completion, Completion status, Reason for withdrawal, Specification of other reason, Date of death, EVS (yes/no), SAF (yes/no)
  Note: Type of devices will be displayed as “by-variable” within a subtitle.

2 Demographic Data and Other Covariates

- Table 2.1: Participant Demographics – Frequencies

Safety Set

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Gender	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
male								
female								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Race	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
White								
Asian								
Black or African American								
other								
unknown								
Overall (non-missing)								

- Table 2.2: Participant Demographics – Basic Statistics

Safety Set

		Type of Device			Total (N=xxx)
		PowerPICC (N=xxx)	PowerPICC SOLO (N=xxx)	PowerGroshong PICC (N=xxx)	
Age [years]^	N				
	missing				
	mean				
	SD				
	minimum				
	1st quartile				
	median				
	3rd quartile				
	maximum				

Footnote 1: ^ Age at signing informed consent.

		Type of Device			Total (N=xxx)
		PowerPICC (N=xxx)	PowerPICC SOLO (N=xxx)	PowerGroshong PICC (N=xxx)	
Body height [cm]	N				
	missing				
	mean				
	SD				
	minimum				
	1st quartile				
	median				
	3rd quartile				
	maximum				

Body weight [kg]	N				
	missing				
	mean				
	SD				
	minimum				
	1st quartile				
	median				
	3rd quartile				
	maximum				

BMI [kg/m^2]	N				
	missing				
	mean				
	SD				
	minimum				
	1st quartile				
	median				
	3rd quartile				
	maximum				

- Listing 2.1: Participant Demographics

  Safety Set
  Variables: Type of device, Participant, Age [years]^, Gender, Race (including specification of other race), Body height [cm], Body weight [kg], BMI [kg/m2], Evaluable Set (yes/no)
  Footnote 1: ^ Age at signing informed consent.
  Note: Type of devices will be displayed as “by-variable” within a subtitle.

- Table 2.3: Medical History

Safety Set

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Implantable devices	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
no								
yes								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Past and/or current use of an artificial heart	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
no								
yes								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Past and/or current anatomical abnormalities of the central venous system	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
no								
yes								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Past and/or current use of an atrial fibrillation or other atrial arrhythmias that affects the p-wave	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
no								
yes								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Known absence of a p-wave	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
no								
yes								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Abnormalities of the arms	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
no								
yes								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Abnormalities of the chest wall	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
no								
yes								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
History of coagulopathy	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
no								
yes								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
History of hypercoagulopathy	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
no								
yes								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Current treatment with anticoagulants	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
no								
yes								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Central venous access devices	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
no								
yes								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
History of lymph node dissection/ lymphedema	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
no								
yes								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Renal impairment	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
no								
yes								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Treated with cervical collars or halo traction	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
no								
yes								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
History of phlebitis	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
no								
yes								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
History of venous thrombosis	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
no								
yes								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
History of deep vein thrombosis	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
no								
yes								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
History of catheter related bloodstream infection	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
no								
yes								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Other relevant Medical History	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
no								
yes								
Overall (non-missing)								

- Listing 2.2: Medical History

  Safety Set
  Variables: Type of device, Participant + all variables on medical history-form, Evaluable Set (yes/no)
  Note: Type of devices will be displayed as “by-variable” within a subtitle.

- Listing 2.3: Other Medical History

  Safety Set
  Variables: Type of device, Participant, Sequence No., Term/Description, Start date, End date, Status (ongoing), Evaluable Set (yes/no)
  Footnote 1: Only participants with at least one entry in 'Other Medical History' form are displayed.

- Table 2.4: Baseline Information

Safety Set

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
	N	%	N	%	N	%	N	%
Primary diagnosis for current admission								
missing								
cardiac								
orthopedic								
…								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
	N	%	N	%	N	%	N	%
Secondary diagnosis for current admission								
missing								
cardiac								
orthopedic								
…								
Overall (non-missing)								

	Type of Device											
	PowerPICC			PowerPICC SOLO			PowerGroshong PICC			Total		
	(N=xxx)			(N=xxx)			(N=xxx)			(N=xxx)		
	Number of Reasons	Number of Part. with Reason	Part. with Reason	Number of Reasons	Number of Part. with Reason	Part. with Reason	Number of Reasons	Number of Part. with Reason	Part. with Reason	Number of Reasons	Number of Part. with Reason	Part. with Reason
	(N#)	(N)	(%)	(N#)	(N)	(%)	(N#)	(N)	(%)	(N#)	(N)	(%)
Reason for PICC placement												
limited peripheral access												
IV therapy/pain management												
…												
Total												

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
	N	%	N	%	N	%	N	%
Intended access duration								
missing								
short-term (<30 days)								
long-term (>= 30 days)								
Overall (non-missing)								

- Listing 2.4: Baseline Information

  Safety Set
  Variables: Type of device, Participant, Primary diagnosis for current admission / Specification of other, Secondary diagnosis for current admission / Specification of other, Reason for PICC placement / Specification of other reason, Intended access duration, Evaluable Set (yes/no)
  Note: Type of devices will be displayed as “by-variable” within a subtitle.

3 Catheter Insertion, Maintenance and Removal

- Table 3.1: Catheter Insertion: Procedure Details

Safety Set

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
	N	%	N	%	N	%	N	%
Location of procedure performance								
missing								
bedside								
interventional radiology								
other								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
	N	%	N	%	N	%	N	%
Catheter tip repositioning								
missing								
no								
yes								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
	N	%	N	%	N	%	N	%
Device placement successful								
missing								
no								
yes								
Overall (non-missing)								

- Table 3.2: Catheter Insertion: Duration

Safety Set

		Type of Device			Total (N=xxx)
		PowerPICC (N=xxx)	PowerPICC SOLO (N=xxx)	PowerGroshong PICC (N=xxx)	
Duration between start and PICC is secured [min]	N				
	missing				
	mean				
	SD				
	minimum				
	1st quartile				
	median				
	3rd quartile				
	maximum				

		Type of Device			Total (N=xxx)
		PowerPICC (N=xxx)	PowerPICC SOLO (N=xxx)	PowerGroshong PICC (N=xxx)	
Duration between start and tip position confirmation [min]	N				
	missing				
	mean				
	SD				
	minimum				
	1st quartile				
	median				
	3rd quartile				
	maximum				

- Listing 3.1: Catheter Insertion: Procedure Details

  Safety Set
  Variables: Type of device, Participant, Where was the procedure performed / Specification, Insertion date, Procedure start time/stop time, Time of tip location confirmation, Duration between start and PICC is secured [min], Duration between start and tip position confirmation [min], Catheter tip repositioned, Device placement successful, Evaluable Set (yes/no)
  Note: Type of devices will be displayed as “by-variable” within a subtitle.

- Table 3.3: Catheter Insertion: Device

Safety Set

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Device	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
PowerGroshong PICC-Single - 5F- 40 cm								
PowerGroshong PICC-Single - 5F- 45 cm								
…								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Guidewire	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
BD nitinol 70 cm								
BD nitinol 135 cm								
…								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Placement of catheter	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
right arm								
left arm								
other								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Vein	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
basilic								
cephalic								
…								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Vessel/catheter ratio done prior to insertion	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
no								
yes								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Number of insertion attempts	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
1								
2								
..								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Local anaesthesia used	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
no								
yes								
Overall (non-missing)								

- Listing 3.2: Catheter Insertion: Device

  Safety Set
  Variables: Type of device, Participant, What device was placed, What guidewire was used / Specification, Kit / tray catalog number, Kit / tray lot number, Kit / tray expiration date, More than 1 kit used , Where was catheter placed / Specification, Which vein was accessed / Specification, Assessment of the vessel/catheter ratio done, Vessel diameter, Vessel to catheter ratio, No. of insertion attempts, Local anaesthesia used, Evaluable Set (yes/no)
  Note: Type of devices will be displayed as “by-variable” within a subtitle.

- Listing 3.3: Catheter Insertion: Additional Kits

  Safety Set
  Variables: Type of device, Participant, Sequence No., Kit / tray catalog number, Kit / tray lot number, Kit / tray expiration date, Implanted catheter from this kit, Guidewire used from this kit, Evaluable Set (yes/no)
  Note: Type of devices will be displayed as “by-variable” within a subtitle.

- Table 3.4: Catheter Insertion: Insertion

Safety Set

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Catheter length trimmed	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
no								
yes								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Tunneling used	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
no								
yes								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Sherlock TLS used	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
no								
yes								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Sherlock 3CG used	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
no								
yes								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Method used for catheter tip positioning confirmation	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
x-ray								
Sherlock 3CG								
Sherlock 3CG+								
other								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Stabilization method	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
StatLock								
SecurAcath								
…								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Dressing	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
transparent semi-permeable membrane								
gauze								
other								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Inserted as per the instructions for use	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
no								
yes								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Second implanted line vascular access device present	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
no								
yes								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Location of second implanted line	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
contralateral								
ipsilateral								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Type of second device	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
subclavian CVC								
IJ CVC								
...								
Overall (non-missing)								

- Listing 3.4: Catheter Insertion: Insertion (*)

  Safety Set
  Variables: Type of device, Participant, Catheter length trimmed, Catheter length [cm], External length [cm], Tunneling used, Sherlock TLS used, Sherlock 3CG used, Method to confirm catheter tip positioning / Specification, Stabilization method / Specification, Dressing type / Specification, Inserted as per IFU / Description, Vein lacerated, Vein perforated, Upper arm circumference [cm], Second implanted line present, Location, Type of device / Specification, Comment, Evaluable Set (yes/no)
  Note: Type of devices will be displayed as “by-variable” within a subtitle.

- Listing 3.5: Participant Location

  Safety Set
  Variables: Type of device, Participant, Sequence No., Participant location / Specification of ward / Specification of other, From / To, Expected maintenance interval for specific location (unit), Expected maintenance interval for dressing change (unit), Expected maintenance interval for catheter insertion site assessment (unit), Device maintained as per site procedure / Description of change, Dressing changed as per site procedure / Description of change, Evaluable Set (yes/no)
  Note: Type of devices will be displayed as “by-variable” within a subtitle.

- Table 3.5: Removal

Evaluable Set

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Study PICC still in place	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
no								
yes								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Reason for PICC removal	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
therapy completed								
therapy changed or cancelled								
…								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Skin condition around the catheter site normal at removal	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing	51		75		54		180	
no	5	8.8	11	15.3	0	0.0	16	11.5
yes	51	89.5	38	52.8	7	70.0	96	69.1
unknown	1	1.8	23	31.9	3	30.0	27	19.4
Overall (non-missing)	57	100.0	72	100.0	10	100.0	139	100.0

	Type of Device								
	PowerPICC			PowerPICC SOLO			Total		
	(N=xxx)			(N=xxx)			(N=xxx)		
	No. of Events (N#)	No. of Part. with Event (N)	Part. with Event (%)	No. of Events (N#)	No. of Part. with Event (N)	Part. with Event (%)	No. of Events (N#)	No. of Part. with Event (N)	Part. with Event (%)
Specification of abnormal skin condition									
erythema									
MARSI									
…									
Total									

	Type of Device											
	PowerPICC (N=xxx)			PowerPICC SOLO (N=xxx)			PowerGroshong PICC (N=xxx)			Total (N=xxx)		
	No. of Purposes (N#)	No. of Part. with Purpose (N)	Part. with Purpose (%)	No. of Purposes (N#)	No. of Part. with Purpose (N)	Part. with Purpose (%)	No. of Purposes (N#)	No. of Part. with Purpose (N)	Part. with Purpose (%)	No. of Purposes (N#)	No. of Part. with Purpose (N)	Part. with Purpose (%)
Use of PICC during the study period												
pain management												
limited peripheral access												
…												
Total												

- Listing 3.6: Removal (*)

  Safety Set
  Variables: Type of device, Participant, Study PICC still in place, Removal date and time, Reason for removal / Specification of other, Skin condition around the catheter site normal, Specification of abnormal skin condition, Specification of other, Use of PICC line during the study period, Specification of other, Device success, Evaluable Set (yes/no)
  Note: Type of devices will be displayed as “by-variable” within a subtitle.

- Listing 3.7: Removal: Complications and Performance (*)

  Safety Set
  Variables: Type of device, Participant, PICC always patent, Experience of: Venous thrombosis, Phlebitis, Extravasation, Local infection, Catheter related bloodstream infection, Evaluable Set (yes/no)
  Note: Type of devices will be displayed as “by-variable” within a subtitle.

4 Safety

4.1 Primary Safety Variable

- Table 4.1.1: Incidence of Symptomatic Venous Thrombosis (*)

  Safety Set

Type of Device	Symptomatic VT	Number of Participants (N)	Participants (%)	Lower 95% Confidence Bound (%)	Upper 95% Confidence Bound (%)
PowerPICC (N=xxx)	missing				
	no				
	yes				
PowerPICC SOLO (N=xxx)	missing				
	no				
	yes				
PowerGroshong PICC (N=xxx)	missing				
	no				
	yes				
Total (N=xxx)	missing				
	no				
	yes				

4.2 Secondary Safety Variables

4.2.1 Complications

- Table 4.2.1.1: Complications (*)

Safety Set

Type of Device	Phlebitis	Number of Participants (N)	Participants (%)	Lower 95% Confidence Bound (%)	Upper 95% Confidence Bound (%)
PowerPICC (N=xxx)	missing				
	no				
	yes				
PowerPICC SOLO (N=xxx)	missing				
	no				
	yes				
PowerGroshong PICC (N=xxx)	missing				
	no				
	yes				
Total (N=xxx)	missing				
	no				
	yes				

Type of Device	Extravasation	Number of Participants (N)	Participants (%)	Lower 95% Confidence Bound (%)	Upper 95% Confidence Bound (%)
PowerPICC (N=xxx)	missing				
	no				
	yes				
PowerPICC SOLO (N=xxx)	missing				
	no				
	yes				
PowerGroshong PICC (N=xxx)	missing				
	no				
	yes				
Total (N=xxx)	missing				
	no				
	yes				

Type of Device	Local Infection*	Number of Participants (N)	Participants (%)	Lower 95% Confidence Bound (%)	Upper 95% Confidence Bound (%)
PowerPICC (N=xxx)	missing				
	no				
	yes				
PowerPICC SOLO (N=xxx)	missing				
	no				
	yes				
PowerGroshong PICC (N=xxx)	missing				
	no				
	yes				
Total (N=xxx)	missing				
	no				
	yes				

Footnote 1: * In total a/b, in PowerPICC c/d, in PowerPICC SOLO e/f, and in PowerGroshong PICC g/h local infections were confirmed according to protocol by presence of pus at the exit site and/or culture confirmed site infection.

Type of Device	Bloodstream Infection	Number of Participants (N)	Participants (%)	Lower 95% Confidence Bound (%)	Upper 95% Confidence Bound (%)
PowerPICC (N=xxx)	missing				
	no				
	yes				
PowerPICC SOLO (N=xxx)	missing				
	no				
	yes				
PowerGroshong PICC (N=xxx)	missing				
	no				
	yes				
Total (N=xxx)	missing				
	no				
	yes				

Type of Device	Accidental Dislodgment	Number of Participants (N)	Participants (%)	Lower 95% Confidence Bound (%)	Upper 95% Confidence Bound (%)
PowerPICC (N=xxx)	missing				
	no				
	yes				
PowerPICC SOLO (N=xxx)	missing				
	no				
	yes				
PowerGroshong PICC (N=xxx)	missing				
	no				
	yes				
Total (N=xxx)	missing				
	no				
	yes				

Type of Device	Vein Laceration	Number of Participants (N)	Participants (%)	Lower 95% Confidence Bound (%)	Upper 95% Confidence Bound (%)
PowerPICC (N=xxx)	missing				
	no				
	yes				
PowerPICC SOLO (N=xxx)	missing				
	no				
	yes				
PowerGroshong PICC (N=xxx)	missing				
	no				
	yes				
Total (N=xxx)	missing				
	no				
	yes				

Type of Device	Vein Perforation	Number of Participants (N)	Participants (%)	Lower 95% Confidence Bound (%)	Upper 95% Confidence Bound (%)
PowerPICC (N=xxx)	missing				
	no				
	yes				
PowerPICC SOLO (N=xxx)	missing				
	no				
	yes				
PowerGroshong PICC (N=xxx)	missing				
	no				
	yes				
Total (N=xxx)	missing				
	no				
	yes				

4.3 Further Safety Variables

4.3.1 Adverse Events

- Table 4.3.1.1: Number of Participants with (S)AEs, (S)ADEs, and Related AEs

Safety Set

	Type of Device											
	PowerPICC (N=xxx)			PowerPICC SOLO (N=xxx)			PowerGroshong PICC (N=xxx)			Total (N=xxx)		
	Number of AEs	Number of Part. with AE	Part. with AE	Number of AEs	Number of Part. with AE	Part. with AE	Number of AEs	Number of Part. with AE	Part. with AE	Number of AEs	Number of Part. with AE	Part. with AE
	(N#)	(N)	(%)	(N#)	(N)	(%)	(N#)	(N)	(%)	(N#)	(N)	(%)
Any AEs												
Any SAEs												
Any ADEs												
Any SADEs												
Any AEs related to procedure												
Any AEs related to accessories												

- Table 4.3.1.2: AEs by System Organ Class

  Safety Set

		Type of Device											
		PowerPICC (N=xxx)			PowerPICC SOLO (N=xxx)			PowerGroshong PICC (N=xxx)			Total (N=xxx)		
		Number of AEs	Number of Part. with AE	Part. with AE	Number of AEs	Number of Part. with AE	Part. with AE	Number of AEs	Number of Part. with AE	Part. with AE	Number of AEs	Number of Part. with AE	Part. with AE
		(N#)	(N)	(%)	(N#)	(N)	(%)	(N#)	(N)	(%)	(N#)	(N)	(%)
System Organ Class (MedDRA)	**Preferred Term (MedDRA)**												
Blood and lymphatic system disorders	Anaemia												
	Thrombocytopenia												
	Total												
Cardiac disorders	Tachycardia												
	Total												
…	…												
Total	Total												

Footnote 1: Each participant is counted at most once for the line total. MedDRA version <xx.x> was used for coding.

- Table 4.3.1.3: AEs by System Organ Class and Severity

  Safety Set

			Type of Device											
			PowerPICC (N=xxx)			PowerPICC SOLO (N=xxx)			PowerGroshong PICC (N=xxx)			Total (N=xxx)		
			Number of AEs	Number of Part. with AE	Part. with AE	Number of AEs	Number of Part. with AE	Part. with AE	Number of AEs	Number of Part. with AE	Part. with AE	Number of AEs	Number of Part. with AE	Part. with AE
			(N#)	(N)	(%)	(N#)	(N)	(%)	(N#)	(N)	(%)	(N#)	(N)	(%)
System Organ Class (MedDRA)	**Preferred Term (MedDRA)**	**Severity**												
Blood and lymphatic system disorders	Anaemia	mild												
		moderate												
		severe												
	Thrombocytopenia	mild												
		moderate												
		severe												
	Total	mild												
		moderate												
		severe												
…	…	…												
Total	Total	mild												
		moderate												
		severe												

Footnote 1: Each participant is counted at most once for the line total. MedDRA version <xx.x> was used for coding.

- Table 4.3.1.4: Serious AEs by System Organ Class

  Safety Set
  Note: The same table layout as used for table AEs by system organ class will be used. Only serious AEs will be tabulated.
  Footnote 1: Adverse events documented as serious on the AE form are tabulated.
  Footnote 2: Each participant is counted at most once for the line total. MedDRA version <xx.x> was used for coding.

- Table 4.3.1.5: Non-serious AEs by System Organ Class

  Safety Set
  Note: The same table layout as used for table AEs by system organ class will be used. Only non-serious AEs will be tabulated.
  Footnote 1: Adverse events documented as non-serious on the AE form are tabulated.

  Footnote 2: Each participant is counted at most once for the line total. MedDRA version <xx.x> was used for coding.

- Table 4.3.1.6: Adverse Device Effects by System Organ Class

  Safety Set
  Note: The same table layout as used for table AEs by system organ class will be used.

  Footnote 1: Adverse events documented as related to device on the AE form are tabulated.
  Footnote 2: Each participant is counted at most once for the line total. MedDRA version <xx.x> was used for coding.

- Table 4.3.1.7: Serious Adverse Device Effects by System Organ Class

  Safety Set
  Note: The same table layout as used for table AEs by system organ class will be used. Only serious AEs will be tabulated.

  Footnote 1: Serious adverse events documented as related to device on the AE form are tabulated.
  Footnote 2: Each participant is counted at most once for the line total. MedDRA version <xx.x> was used for coding.

- Table 4.3.1.8: AEs Related to Procedure by System Organ Class

  Safety Set
  Note: The same table layout as used for table AEs by system organ class will be used. Only AEs related to procedure will be tabulated.
  Footnote 1: Adverse events documented as related to procedure on the AE form are tabulated.
  Footnote 2: Each participant is counted at most once for the line total. MedDRA version <xx.x> was used for coding.

- Table 4.3.1.9: AEs Related to Accessories by System Organ Class

  Safety Set
  Note: The same table layout as used for table AEs by system organ class will be used. Only AEs related to Accessories will be tabulated.
  Footnote 1: Adverse events documented as related to accessories on the AE form are tabulated.
  Footnote 2: Each participant is counted at most once for the line total. MedDRA version <xx.x> was used for coding.

- Listing 4.3.1.1: Adverse Events (*)

  Safety Set
  Variables: Type of device, Participant + all variables on AE-form + Preferred term and system organ class, Study day of AE, Duration of AE, Evaluable Set (yes/no)
  Note: Type of devices will be displayed as “by-variable” within a subtitle.

- Listing 4.3.1.2: Serious Adverse Events - AE Form

  Safety Set
  Variables: Type of device, Participant + all variables on AE-form + Preferred term and system organ class, Study day of AE, Duration of AE, Evaluable Set (yes/no)
  Footnote 1: Adverse events documented as serious on the AE form are listed only.
  Note: Type of devices will be displayed as “by-variable” within a subtitle.

- Listing 4.3.1.3: Serious Adverse Events - SAE Form

  Safety Set
  Variables: Type of device, Participant + all variables on SAE-form as entered by the investigator, Evaluable Set (yes/no)
  Note: Type of devices will be displayed as “by-variable” within a subtitle.

4.3.2 Device Deficiencies

- Listing 4.3.2.1: Device Deficiencies

  Safety Set
  Variables: Type of Device, Participant + all variables on device deficiency-form, Evaluable Set (yes/no)
  Note: Type of devices will be displayed as “by-variable” within a subtitle.

5 Performance Analysis

5.1 Analysis of Primary Performance Variable

- Table 5.1.1: PICCs that remain in place through completion of therapy (*)

  Evaluable Set

Type of Device	PICCs that remain in place through completion of therapy	Number of Participants (N)	Participants (%)	Lower 95% Confidence Bound (%)	Upper 95% Confidence Bound (%)
PowerPICC (N=xxx)	missing				
	no				
	yes				
PowerPICC SOLO (N=xxx)	missing				
	no				
	yes				
PowerGroshong PICC (N=xxx)	missing				
	no				
	yes				
Total (N=xxx)	missing				
	no				
	yes				

5.2 Analysis of Secondary Performance Variables

- Table 5.2.1: Patent Catheters (*)

  Evaluable Set

Type of Device	Patent Catheter	Number of Catheters (N)	Catheters (%)	Lower 95% Confidence Bound (%)	Upper 95% Confidence Bound (%)
PowerPICC (N=xxx)	missing				
	no				
	yes				
PowerPICC SOLO (N=xxx)	missing				
	no				
	yes				
PowerGroshong PICC (N=xxx)	missing				
	no				
	yes				
Total (N=xxx)	missing				
	no				
	yes				

- Table 5.2.2: Placement Success in Single Insertion Attempt (*)

  Safety Set

Type of Device	Placement Success in a Single Insertion Attempt	Number of Catheters (N)	Catheters (%)	Lower 95% Confidence Bound (%)	Upper 95% Confidence Bound (%)
PowerPICC (N=xxx)	missing				
	no				
	yes				
PowerPICC SOLO (N=xxx)	missing				
	no				
	yes				
PowerGroshong PICC (N=xxx)	missing				
	no				
	yes				
Total (N=xxx)	missing				
	no				
	yes				

- Table 5.2.3: Usability: Ease of Insertion – Guidewire (*)

Safety Set

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Difficulty to use the guidewire	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
very difficult								
difficult								
…								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Force to advance the guidewire acceptable	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
no								
yes								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Difficulty to withdraw/remove the guidewire	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
very difficult								
difficult								
…								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Force to withdraw/remove the guidewire acceptable	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
no								
yes								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Agreement on Integrity	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
strongly disagree								
disagree								
…								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Agreement on Guidewire facilitated placement	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
strongly disagree								
disagree								
…								
Overall (non-missing)								

- Table 5.2.4: Usability: Ease of Insertion – Guidewire – Basic Statistics (*)

Safety Set

		Type of Device			Total (N=xxx)
		PowerPICC (N=xxx)	PowerPICC SOLO (N=xxx)	PowerGroshong PICC (N=xxx)	
Difficulty to use the guidewire	N				
	missing				
	mean				
	SD				
	minimum				
	1st quartile				
	median				
	3rd quartile				
	maximum				

		Type of Device			Total (N=xxx)
		PowerPICC (N=xxx)	PowerPICC SOLO (N=xxx)	PowerGroshong PICC (N=xxx)	
Difficulty to withdraw/remove the guidewire	N				
	missing				
	mean				
	SD				
	minimum				
	1st quartile				
	median				
	3rd quartile				
	maximum				

		Type of Device			Total (N=xxx)
		PowerPICC (N=xxx)	PowerPICC SOLO (N=xxx)	PowerGroshong PICC (N=xxx)	
Agreement on Integrity	N				
	missing				
	mean				
	SD				
	minimum				
	1st quartile				
	median				
	3rd quartile				
	maximum				

		Type of Device			Total (N=xxx)
		PowerPICC (N=xxx)	PowerPICC SOLO (N=xxx)	PowerGroshong PICC (N=xxx)	
Agreement on Guidewire facilitated placement	N				
	missing				
	mean				
	SD				
	minimum				
	1st quartile				
	median				
	3rd quartile				
	maximum				

- Table 5.2.5: Usability: Ease of Insertion – Stylet (*)

Safety Set

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Difficulty to use the stylet	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
1 = very difficult								
2 = difficult								
…								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Force to advance the stylet/catheter acceptable	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
no								
yes								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Difficulty to withdraw/remove the stylet/catheter	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
1 = very difficult								
2 = difficult								
…								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Force to withdraw/remove the guidewire acceptable	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
no								
yes								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Agreement on Integrity								
missing								
no								
yes								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Stylet/catheter facilitated placement	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
1 = strongly disagree								
2 = disagree								
…								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Sherlock 3CG Pre-Loaded question answered	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
yes								
not applicable / not used								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Sherlock 3CG Pre-Loaded stylet aided	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
1 = strongly disagree								
2 = disagree								
…								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Sherlock Tip Location System (TLS) Pre-Loaded stylet question answered	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
yes								
not applicable / not used								
Overall (non-missing)								

	Type of Device							
	PowerPICC (N=xxx)		PowerPICC SOLO (N=xxx)		PowerGroshong PICC (N=xxx)		Total (N=xxx)	
Sherlock Tip Location System (TLS) Pre-Loaded stylet aided	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
missing								
1 = strongly disagree								
2 = disagree								
…								
Overall (non-missing)								

- Table 5.2.6: Usability: Ease of Insertion – Stylet – Basic Statistics (*)

Safety Set

		Type of Device			Total (N=xxx)
		PowerPICC (N=xxx)	PowerPICC SOLO (N=xxx)	PowerGroshong PICC (N=xxx)	
Difficulty to use the stylet	N				
	missing				
	mean				
	SD				
	minimum				
	1st quartile				
	median				
	3rd quartile				
	maximum				

		Type of Device			Total (N=xxx)
		PowerPICC (N=xxx)	PowerPICC SOLO (N=xxx)	PowerGroshong PICC (N=xxx)	
Difficulty to withdraw/remove the stylet/catheter	N				
	missing				
	mean				
	SD				
	minimum				
	1st quartile				
	median				
	3rd quartile				
	maximum				

		Type of Device			Total (N=xxx)
		PowerPICC (N=xxx)	PowerPICC SOLO (N=xxx)	PowerGroshong PICC (N=xxx)	
Agreement on stylet/catheter facilitated placement	N				
	missing				
	mean				
	SD				
	minimum				
	1st quartile				
	median				
	3rd quartile				
	maximum				

		Type of Device			Total (N=xxx)
		PowerPICC (N=xxx)	PowerPICC SOLO (N=xxx)	PowerGroshong PICC (N=xxx)	
Sherlock 3CG Pre-Loaded Stylet aided	N				
	missing				
	mean				
	SD				
	minimum				
	1st quartile				
	median				
	3rd quartile				
	maximum				

		Type of Device			Total (N=xxx)
		PowerPICC (N=xxx)	PowerPICC SOLO (N=xxx)	PowerGroshong PICC (N=xxx)	
Sherlock Tip Location System (TLS) Pre-Loaded Stylet aided	N				
	missing				
	mean				
	SD				
	minimum				
	1st quartile				
	median				
	3rd quartile				
	maximum				

- Listing 5.2.1: Usability: Ease of Insertion – Guidewire (*)

  Safety Set
  Variables: Type of device, Participant, Difficulty to use the guidewire / Explanation, Force acceptable to advance the guidewire / Explanation, Difficulty to withdraw/remove the guidewire / Explanation, Force to withdraw/remove the guidewire acceptable / Explanation, Agreement on: Integrity / Explanation, Guidewire facilitated placement / Explanation, Evaluable Set (yes/no)
  Note: Type of devices will be displayed as “by-variable” within a subtitle.

- Listing 5.2.2: Usability: Ease of Insertion – Stylet (*)

  Safety Set
  Variables: Type of device, Participant, Difficulty to use the stylet / Explanation, Force to advance the stylet/catheter acceptable / Explanation, Difficulty to withdraw/remove the stylet/catheter / Explanation, Force to withdraw/remove the stylet/catheter acceptable / Explanation, Agreement on: Integrity / Explanation, Stylet/catheter facilitated placement / Explanation, Sherlock 3CG Pre-Loaded Stylet aided / Explanation, Sherlock Tip Location System (TLS) Pre-Loaded Stylet aided / Explanation
  Note: Type of devices will be displayed as “by-variable” within a subtitle.

6 Protocol Deviations

- Listing 6.1: Protocol Deviations (eCRF)

  Enrolled Set
  Variables: Type of Device, Participant, Sequence No., Category (including specification of other), Date of deviation, Description, Action / outcome, Evaluable Set (yes/no)
  Note: Type of devices will be displayed as “by-variable” within a subtitle.