Abbott	Statistical Analysis Plan Cover Page

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LIFE-BTK PK Sub-Study
LIFE-BTK (pivotaL Investigation of saFety and Efficacy of BRS treatment-Below The Knee)
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Sponsor Abbott

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Study Number: [redacted]
Document Number: [redacted]

LIFE-BTK (pivotaL Investigation of saFety and Efficacy of BRS treatment-Below The Knee)

Randomized Controlled Trial

Statistical Analysis Plan (SAP)

[redacted]

[redacted]

Statistical Analysis Plan

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[redacted]

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Statistical Analysis Plan

1 SYNOPSIS OF STUDY DESIGN

1.1 Purpose of the Statistical Analysis Plan

This statistical analysis plan (SAP) is to provide a detailed and comprehensive description of the planned methodology and analysis to be used for the LIFE-BTK RCT clinical investigation. [redacted]

1.2 Clinical Investigation Objectives

1.2.1 Clinical Investigation (LIFE-BTK RCT)

The objective of this clinical investigation is to evaluate the safety and efficacy of the Esprit™ BTK, compared to PTA, in the planned treatment of diseased infrapopliteal lesions in patients with critical limb ischemia with up to two *de novo* lesions in separate vessels.

1.2.2 Pharmacokinetics Sub-Study

The objective of the pharmacokinetics (PK) sub-study is to determine the pharmacokinetics of everolimus delivered by the Esprit BTK scaffold in a separate and non-randomized cohort of subjects receiving the Esprit BTK for the planned treatment of narrowed infrapopliteal lesions.

The LIFE-BTK PK sub-study is a prospective, single-arm, open-label, non-blinded, non-randomized sub-study enrolling approximately 7 subjects treated with Esprit BTK at selected clinical trial sites.

A total of 7 subjects will be registered in the PK sub-study, in the United States (US) and outside of US, with a maximum of 5 sites in the US.

The LIFE-BTK PK sub-study subjects will not be included in the primary analysis population of the LIFE-BTK RCT and will not contribute to the determination of the LIFE-BTK RCT primary endpoints.

There are no pre-specified nor powered endpoints for the PK sub-study. The clinical outcomes and data collected for the PK sub-study will be analyzed descriptively. Unless otherwise specified, the planned methodology and analysis in this SAP will be only applied to the LIFE-BTK RCT clinical investigation.

1.3 Clinical Investigation Design

This clinical investigation is designed to evaluate the safety and efficacy of the everolimus eluting Esprit BTK System for the planned treatment of narrowed infrapopliteal lesions.

This is a prospective, randomized, controlled clinical investigation randomizing approximately 225 subjects between Esprit BTK therapy and PTA therapy. Subjects will be randomized in a 2:1 ratio (Esprit BTK:PTA). The clinical investigation will be conducted at approximately 65 clinical sites in the US, Asia, Australia and New Zealand.

One pre-specified interim analysis for sample size re-estimation is planned for this study. Per the planned interim analysis, if this analysis indicates a need for sample size increase, the sample size can be adjusted up to a total of 315 subjects.

Core laboratories will be used for angiography, duplex ultrasound, IVUS, OCT, and wound assessment. Adverse events will be adjudicated by a Clinical Events Committee (CEC), as described in the CEC charter. A Data Monitoring Committee (DMC), also known as Data and Safety Monitoring Board (DSMB), will review cumulative data from the clinical investigation at regular intervals, as described in the DMC charter.
The primary safety endpoint at 6 months and primary efficacy endpoint at 1 year will be evaluated when all subjects have completed their 1-year visit. The primary safety endpoint will be tested for non-inferiority of Esprit BTK to PTA. The primary efficacy endpoint will be tested for superiority of Esprit BTK as compared to PTA.

These primary endpoints will also be analyzed at 1 month, 3, 6 months, and 1, 2, 3, 4 and 5 years. All secondary endpoints will be analyzed at the same time points as the primary endpoints.

Core laboratories will be used for angiography, duplex ultrasound, IVUS, OCT, and wound assessment. Adverse events will be adjudicated by a Clinical Events Committee (CEC), as described in the CEC charter. A Data Monitoring Committee (DMC), also known as Data and Safety Monitoring Board (DSMB), will review cumulative data from the clinical investigation at regular intervals, as described in the DMC charter.

The clinical investigation has been designed to involve as little pain, discomfort, fear, and any other foreseeable risk as possible for subjects. Refer to the Risks Analysis section of the clinical investigation plan for details.

For the CIP version [redacted] revision, the primary efficacy endpoint is updated and the sample size is adjusted to approximately 260 subjects.

1.4 Endpoints

1.4.1 Primary Endpoints

Primary Efficacy Endpoint

- Composite of limb salvage and primary patency at 1 year. It includes freedom from: above ankle amputation in index limb, 100% total occlusion of target vessel, binary restenosis of target lesion, and clinically-driven target lesion revascularization (CD-TLR).

This efficacy endpoint was chosen because it allows to assess whether Esprit BTK is efficacious at maintaining patency (CD-TLR and binary restenosis), and at preventing catastrophic limb events such as total vessel occlusion or major amputation.

Primary Safety Endpoint

- Freedom from MALE+POD (Major Adverse Limb Event + Peri-Operative Death). MALE includes above ankle amputation in index limb, major re-intervention on index limb at 6 months and POD includes perioperative (30-day) mortality.

This safety endpoint was chosen because it is a commonly used endpoint to assess the safety of devices used in lower limb treatment, including treatment of lesions below the knee. Additionally, this endpoint assesses whether the device is associated with acute and sub-acute harm such as death and limb loss.

1.4.2 Powered Secondary Endpoints

LIFE-BTK RCT has two powered secondary endpoints. The first powered secondary endpoint is binary restenosis of the target lesion at 1 year. This endpoint was added to better evaluate the device performance as binary restenosis can be used as a marker for disease progression over time.

The second powered secondary endpoint is a composite endpoint including freedom from: above ankle amputation in index limb, 100% total occlusion of target vessel and clinically-driven target lesion revascularization (CD-TLR) at 1 year.

1.4.3 Descriptive Secondary Endpoint

The following secondary endpoints will be evaluated during the course of the clinical trial:

Procedural:

- Acute procedure success
- Device success – for Esprit BTK arm only
- Technical success
- Clinical success
- Angiographic acute gain (in-segment)
- Angiographic acute gain (in-device) – for Esprit BTK arm only

Clinical endpoints evaluated at 1 month, 3 months, 6 months, 1 year and annually through 5 years are:

- Composite of limb salvage and primary patency (primary efficacy endpoint)
- Freedom from MALE+POD (primary safety endpoint)
- Freedom from: above ankle amputation in index limb, 100% total occlusion of target vessel and clinically-driven target lesion revascularization (CD-TLR)
- Freedom from major amputation and clinically-driven target lesion revascularization (CD-TLR)
- Freedom from above ankle amputation
- Freedom from restenosis
- Binary restenosis of the target lesion (first powered secondary endpoint)
- Amputation-free survival[§]
- All-cause death
- Arterial thrombosis
- Major re-intervention on index limb

- Primary assisted patency
- Secondary patency
- Clinically-driven target lesion revascularization (CD-TLR)
- Clinically-driven target vessel revascularization (CD-TVR)
- Clinically-driven target vessel revascularization distal to the target lesion
- Clinically-driven target vessel revascularization proximal to the target lesion
- Index wound assessment for healing (14 days, 30 days, 42 days, 90 days, 180 days and 1 year)*
- Index Wound assessment for infection (14 days, 30 days, 42 days, 90 days, 180 days and 1 year)*
- Rutherford Becker clinical category, and change from baseline for the treated limb
- Occurrence of new wound†
- Acute limb ischemia
- Peripheral embolization

Note: Patency by duplex ultrasound will be assessed 30 ± 14 days post-procedure, and at 6 months, 1, 2 and 3 years.

§Amputation-free survival includes freedom from above ankle amputation and death.
*Index wound assessment for healing and infection will be assessed by the core laboratory through 90 days (14 days, 30 days, 42 days and 90 days). For index wounds that are not healed by 90 days, the index wound will be assessed by the core laboratory at 180 days. If the index wound is not healed by 180 days, index wound assessment by the core laboratory will be carried out at 1 year. Index wounds that have healed by 90 days will not be assessed by the core laboratory at 180 days and 1 year.
†New wound is defined as wound below the knee in the index limb that was not identified at the time of the index procedure or wound that has recurred in the same location following the healing of the index wound. The new wound will be assessed firstly by the wound assessment core laboratory for etiology. Subsequently, the new wound will be evaluated by the site per protocol until the wound is healed through the 5-year follow-up. If a new wound is first observed at 5-year follow-up, a picture will be taken for etiology assessment by the core laboratory. As this will be the final patient visit for the trial, no additional pictures of the new wound will be required following the initial picture submitted to the core laboratory

1.5 Randomization

Subjects will be randomized 2:1 in the primary analysis (test device: Esprit BTK vs. control device/treatment strategy: PTA). Randomization will be performed after all eligibility criteria have been met, all in-flow and non-target lesion(s) have been treated successfully, and the guidewire successfully crossed the target lesion. For laboratory assessments where multiple values for that test are present, it will be up to the physician's discretion to determine which value will be used to assess subject eligibility, as long as one of the laboratory values is within the eligibility range. In cases where two target lesions are being treated, there needs to be strong assurance that both target lesions can be successfully crossed by the guidewire. Randomization will occur after successful crossing of the first lesion.

Once randomization is completed and a treatment is assigned, crossover to the other treatment group is not permitted. Regardless of the actual device the subject received, the subject will be included in the ITT population per the original randomization assignment. An Esprit BTK may never be used in a subject randomized to PTA. However, if the subject is randomized to Esprit BTK and the scaffold cannot be delivered, any device approved for BTK in that geography may be used as per label indication. If a complication occurs in a patient randomized to Esprit BTK, such as dissection, another BVS may be

used (first choice), or any other approved device in the geography, as necessary in the best interests of the subject.

Randomization assignments will be given through the Oracle EDC system.

The subject is considered to be successfully registered in this study and considered in the ITT population at the point of randomization.

1.6 Blinding

This is a single-blinded clinical investigation. [redacted]

2 ANALYSIS CONSIDERATIONS

2.1 Analysis Populations

2.1.1 Intent-to-Treat Population (ITT)

[redacted]

2.1.2 As-Treated Population (AT)

[redacted]

2.1.3 Per-Protocol Population (PP)

[redacted]

- [redacted]
  - [redacted]
  - [redacted]
  - [redacted]
  - [redacted]
  - [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

This is the secondary analysis population for the primary endpoint analysis.

2.2 Statistical Methods

Descriptive analysis will be performed to summarize baseline, clinical and safety event data. Depending on the type of data (e.g., continuous or categorical), statistical methods described in the following sections will be used.

2.2.1 Descriptive Statistics for Continuous Variables

For continuous variables (e.g., age, etc.), results within treatment arm will be summarized with the numbers of observations, means, and standard deviations, with quartiles, minimums, maximums, and 95% confidence intervals for the means. Differences between the treatment arms, where specified, will be summarized with differences of the two means, and 95% confidence intervals for the difference between the means.

2.2.2 Descriptive Statistics for Categorical Variables

For binary or categorical variables (e.g. gender, diabetic status, etc.), results within treatment arm will be summarized with subject counts and percentages/rates, and where applicable, with exact 95% Clopper-Pearson[1] confidence intervals. Differences between the two treatment arms, when specified, will be summarized with the difference in percent and the Newcombe[2] score 95% confidence interval for the difference of two percentages.

For events of interest, relative risks (i.e., the ratio of rates), confidence interval for the relative risks, the difference in rates and the confidence interval for difference in rates, and p-values may also be presented for hypothesis generating purposes. The p-values will be based on either Pearson's Chi-square test or Fisher's exact test by checking the expected frequency for each cell in the 2x2 contingency table against Cochran's rule[3], i.e., if the expected frequencies for all cells in the contingency table are ≥ 5, then Pearson's Chi-square test will be used, otherwise Fisher's exact test will be used.

For a 2-by-2 contingency table as below

	Esprit BTK	PTA	Row Total
Success	O_{11}	O_{12}	R_1
Failure	O_{21}	O_{22}	R_2
Column Total	C_1	C_2	N

The Pearson Chi-square test statistic is calculated as $\sum_{i=1}^{2}\sum_{j=1}^{2}\frac{(O_{ij}-E_{ij})^2}{E_{ij}}$, where O_{ij} are the observed counts and E_{ij} is $(R_i \times C_j)/N(N$ is the grand total). Under no treatment effect, the Pearson Chi-square test statistic follows a Chi-square distribution with 1 degree of freedom.

[redacted]

- [redacted]

[redacted]

- [redacted]

[redacted]

2.2.3 Survival Analyses

Survival analysis will be conducted to analyze time-to-event variables. Subjects without events will be censored at their last known event-free time point. Subjects who withdrew from the study will be censored at the date of withdrawal. Survival curves will be constructed using Kaplan-Meier[4] estimates. Summary tables for endpoints will include event (failure) rates, Greenwood standard error and confidence interval for the event rates.

2.3 Endpoint Analysis

2.3.1 Primary Endpoint(s)

The primary efficacy endpoint, a composite of limb salvage and primary patency at 1 year will be evaluated using the difference in endpoint rates in the ITT population. The hypothesis test is designed to show superiority of Esprit BTK to PTA for the primary efficacy endpoint with one-sided alpha of 0.025. The null (H_0) and alternative (H_1) hypotheses are:

$$H_0: P_{BTK} - P_{PTA} \leq 0$$
$$H_1: P_{BTK} - P_{PTA} > 0$$

where P_{BTK} and P_{PTA} are the primary efficacy endpoint rates for the Esprit BTK arm and PTA arms respectively.

The primary efficacy endpoint events will be adjudicated by CEC. If the CEC adjudication data are not available, the primary patency such as 100% total occlusion of target vessel or binary restenosis of target lesion at 1 year will be based on core laboratory imaging data. If both angiogram and Duplex Ultrasound (DUS) core laboratory imaging data are available, the angiogram data will be used for the primary efficacy endpoint analysis. If the core laboratory imaging data at 1-year are not available, valid and diagnostic repeat core laboratory imaging data beyond 1 year will be used for the primary analysis.

A sensitivity analysis for the primary efficacy endpoint will be performed for the AT, modified AT and PP populations.

The primary safety endpoint will be evaluated using the difference in endpoint rates in the AT population. The hypothesis test is designed to show non-inferiority of Esprit BTK to PTA for the primary safety endpoint with one-sided alpha of 0.025. The null (H_0) and alternative (H_1) hypotheses are:

$$H_0: q_{BTK} - q_{PTA} \leq \delta$$
$$H_1: q_{BTK} - q_{PTA} > \delta$$

where q_{BTK} and q_{PTA} are the primary safety endpoint rates for the Esprit BTK and PTA arms respectively. The non-inferiority margin of δ is set at -0.1.

A sensitivity analysis for the primary safety endpoint will be performed for the modified AT, ITT and PP populations. In addition, landmark Kaplan-Meier analyses will be performed for the primary safety and efficacy endpoints from 0 to 30 days, 30 days to 6 months, and 30 days to 1 year.

[redacted]

2.3.2 Powered Secondary Endpoints

<u>The first powered secondary endpoint</u>

Binary restenosis of target lesion at 1 year will be evaluated using the difference in endpoint rates in the ITT population. The hypothesis test is designed to show superiority of Esprit BTK to PTA with one-sided alpha of 0.025.

The null (H_0) and alternative (H_1) hypotheses are:

$$H_0: R_{BTK} - R_{PTA} \geq 0$$
$$H_1: R_{BTK} - R_{PTA} < 0$$

where R_{BTK} and R_{PTA} are the first powered secondary endpoint rates for the Esprit BTK and PTA arms respectively.

The second powered secondary endpoint

A composite endpoint of freedom from the above ankle amputation in index limb, 100% total occlusion of target vessel and CD-TLR at 1 year will be evaluated using the difference in endpoint rates in the ITT population. The hypothesis test is designed to show superiority of Esprit BTK to PTA with one-sided alpha of 0.025.

The null (H_0) and alternative (H_1) hypotheses are:

$$H_0: S_{BTK} - S_{PTA} \leq 0$$
$$H_1: S_{BTK} - S_{PTA} > 0$$

where S_{BTK} and S_{PTA} are the second powered secondary endpoint rates for the Esprit BTK and PTA arms respectively.

[redacted]

[redacted]

2.3.3 Descriptive Secondary Endpoint(s)

Analyses on secondary endpoints will be descriptive in nature. If p-values are generated, they are for hypothesis generation only.

2.4 Sample Size Calculations

2.4.1 Primary Endpoint

For the primary efficacy endpoint [redacted]

[redacted]
The power calculation is based on the statistical hypotheses and the following assumptions:

$$H_0: P_{BTK} - P_{PTA} \leq 0$$
$$H_1: P_{BTK} - P_{PTA} > 0$$

- One-sided type I error rate = 0.025
- Randomization ratio is 2:1 (Esprit BTK vs. PTA)
- [redacted]
- Superiority test

[redacted]

For the primary safety endpoint [redacted] The power calculation is based on the statistical hypotheses and the following assumptions:

$$H_0: q_{BTK} - q_{PTA} \leq \delta$$
$$H_1: q_{BTK} - q_{PTA} > \delta$$

- One-sided non-inferiority test
- One-sided type I error rate = 0.025
- Randomization ratio is 2:1 (Esprit BTK vs. PTA)
- [redacted]
- Non-inferiority margin (δ) of -10%

[redacted]

2.4.2 Powered Secondary Endpoints

For the first powered secondary endpoint of target lesion binary restenosis at 1 year, the binary restenosis will be determined as the presence of a hemodynamically significant restenosis ≥ 50% by angiography, or PSVR ≥ 2.0 by duplex ultrasound.

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The power calculation is based on the statistical hypotheses and the following assumptions:

$$H_0: R_{BTK} - R_{PTA} \geq 0$$
$$H_1: R_{BTK} - R_{PTA} < 0$$

- One-sided type I error rate = 0.025
- Randomization ratio is 2:1 (Esprit BTK vs. PTA)
- [redacted]
- Superiority test

[redacted]

For the second powered secondary endpoint of freedom from above ankle amputation in index limb, 100% total occlusion of target vessel and CD-TLR at 1 year, [redacted]

The power calculation is based on the statistical hypotheses and the following assumptions:

$$H_0: S_{BTK} - S_{PTA} \leq 0$$
$$H_1: S_{BTK} - S_{PTA} > 0$$

- One-sided type I error rate = 0.025
- Randomization ratio is 2:1 (Esprit BTK vs. PTA)
- [redacted]
- Superiority test

[redacted]

[redacted]

[redacted]

2.5 Interim Analysis

[redacted]

2.6 Timing of Analysis

The primary endpoint analysis will be performed when all subjects in ITT population have completed their 1-year follow-up visit and the clinical investigation becomes unblinded.

2.7 Study/Trial Success

[redacted]

2.8 Subgroups for Analysis

The treatment comparisons for the primary endpoints will be analyzed within each of the subgroups below. In addition, the treatment by subgroup interaction for the primary endpoints will be evaluated [redacted]. The following subgroups will be evaluated for the ITT. The treatment comparisons in these analyses are not powered for hypothesis testing and are not meant for confirmatory inference.

Gender:

- Males
- Female

Race:

- White

- Black or African American
- Other

Age:
- Age < 65
- Age ≥ 65

Country:
- US
- OUS

2.9 Handling of Missing Data

All analyses will be based on available data with missing data excluded. Any unused or spurious data will be noted as appropriate in the final report [redacted]

[redacted]

2.10 Poolability Assessment

This study will have up to 65 sites. For the analysis of center effect, data from smaller sites with limited registration will be removed from analysis. [redacted]

To evaluate the center effect on the primary endpoints, interaction effect between treatment and center on the primary endpoints will be tested against an alpha level of 0.15. [redacted]

In addition, region effect (US, Asia, Australia and New Zealand) and US versus OUS (outside US) effect will be assessed [redacted]

2.11 Multiplicity Assessment

[redacted]

[redacted]

2.12 Sensitivity Analysis

The following sensitivity analyses of the primary endpoints and the first powered secondary endpoint of binary restenosis at 1 year may be performed for the ITT population:

Tipping Point Analysis for Primary Endpoints

A tipping point analysis will be performed by searching for a point that reverses the study conclusion. A tipping point analysis will include all randomized subjects in the denominator of the primary endpoint rate.

[redacted]

Multiple Imputation for Primary Endpoints

[redacted]

Binary Restenosis of Target Vessel Using PSVR Cutoff of 2.0

To evaluation the impact of the binary restenosis of target vessel on the primary efficacy and the first powered secondary endpoint, two sensitive analyses will be carried out, using the PSVR cutoff of 2.0:

- One is using the binary restenosis of **target vessel** to replace the component of the binary restenosis of target lesion, for the primary efficacy endpoint for the composite endpoint defined as freedom from: above ankle amputation in index limb, 100% total occlusion of target vessel, binary

restenosis of **target vessel**, and clinically-driven target lesion revascularization (CD-TLR), at 1 year.

- The other is using the binary restenosis of the target vessel to replace the binary restenosis of target lesion, for the first powered secondary endpoint at 1 year.

Binary Restenosis of Target Lesion using PSVR Cutoff of 2.4

To evaluation the impact of the PSVR cutoff of 2.4 on the binary restenosis of target lesion, two sensitive analyses will be carried out:

- One is using the PSVR cutoff of 2.4 for the component of binary restenosis of target lesion for the primary efficacy endpoint defined as freedom from: above ankle amputation in index limb, 100% total occlusion of target vessel, binary restenosis of target lesion, and clinically-driven target lesion revascularization (CD-TLR), at 1 year,

- The other is using the PSVR cutoff of 2.4 for the binary restenosis of the target lesion at 1 year.

COVID-19 Analyses

Abbott will collect COVID-19 test result and symptom status in a log form as well as review and identify COVID-19 related protocol deviations through the course of the study. The CEC will assess COVID-19 relatedness for specified adverse events.

[redacted]

- [redacted]
- [redacted]

[redacted]

3 DESCRIPTIVE ENDPOINTS AND ADDITIONAL DATA

3.1 Baseline and Demographic Characteristics

The following baseline and demographic variables will be summarized based on the ITT population: gender, age, height, weight, baseline risk factors, medical history, morphology, imaging data, procedural characteristics, device usage, and quality of life etc.

3.2 Adverse Events

All of the adverse device effects, serious adverse device effects, UADEs will be summarized for all subjects who enrolled in this trial in terms the number of events, the percentage of subjects with events.

All CEC adjudicated adverse events will also be summarized for all subjects who registered in the trial by treatment arms based on the ITT population in terms the number of events, the percentage of subjects with events.

3.3 Subject Early Termination

Subject early termination reasons including deaths, withdrawals, lost-to-follow-up, etc. will be summarized by treatment arms at the primary endpoint follow-up visit.

3.4 Protocol Deviation

Protocol deviations will be summarized by category for subjects in whom a protocol deviation was reported. Number of protocol deviations and number of subjects with deviation will be summarized by deviation categories.

3.5 Informational Endpoints or Additional Data

Sites using IVUS for vessel sizing will be asked to provide their IVUS images in addition to their angiographic images, to the core laboratory. Analysis will be conducted to determine offset in vessel diameter sizing between IVUS and visual estimation using angiography.

Patient Reported Outcomes:

The following Patient Reported Outcomes will be analyzed as informational endpoints at baseline, 30 days, 3 months, 6 months and 1 year:

- Overall health status using the EQ-5D-5L (EuroQoL-5D-5L) questionnaire
- Walking capacity using WIQ (Walking Impairment Questionnaire)
- Disease-specific health status using PAQ (Peripheral Artery Questionnaire)

[redacted]

Cost-Effectiveness

Cost per quality adjusted life year (QALY) and cost per clinical event avoided will be evaluated using standardized methods[14].

[redacted]

4 DOCUMENTATION AND OHER CONSIDERATIONS

All analyses will be performed using SAS® for Windows, version 9.3 or higher.

5 ACRONYMS AND ABBREVIATIONS

Acronym or Abbreviation	Complete Phrase or Definition
ABT	Abbott
AE	Adverse Event
AT	As-Treated Population
BTK	Below-The-Knee
BVS	Bioresorbable Vascular Scaffold
CEC	Clinical Events Committee
CIP	Clinical Investigation Plan
CRF	Case Report Form
DSMB	Data Safety Monitoring Board
EDC	Electronic Data Capture
EQ-5D-5L	EuroQoL-5 Dimensions-5 Levels
GFR	Glomerular Filtration Rate
ITT	Intent-to-Treat Population
IVUS	Intravascular ultrasound
MALE	Major Adverse Limb Event
NG	Next Generation
OCT	Optical Coherence Tomography
POD	Peri-Operative Death
PP	Per-Protocol Population
QALY	Quality Adjusted Life Year
RVD	Reference Vessel Diameter
SAE	Serious Adverse Event
SAP	Statically Analysis Plan
UADE	Unanticipated Adverse Device Event

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