RADIANCY
STATISTICAL ANALYSIS PLAN

Title:	**Evaluation of Safety and Efficacy of the S.M.A.R.T. RADIANZ™ Vascular Stent System in the Treatment of Iliac and Femoropopliteal Lesions via Transradial Access**
Short Title:	**Radiancy**
Protocol Number:	**P21-7701**
Products:	**S.M.A.R.T. RADIANZ™ Vascular Stent System** **BRITE TIP RADIANZ™ Guiding Sheath** **SABERX RADIANZ™ PTA Balloon Catheter**
Sponsor:	**Cordis US Corp.** **14201 NW 60th Avenue** **Miami Lakes, FL 33014, USA**
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Signed: Carleton Southworth *Electronically signed by: Carleton Southworth Reason: Author Date: Nov 25, 2024 09:01 EST* Date: 25-Nov-2024

Carleton Southworth, Consultant

Signed: Nusrath Sultana *Electronically signed by: Nusrath Sultana Reason: Approved Date: Nov 25, 2024 15:57 PST* Date: 25-Nov-2024

Nusrath Sultana, MD
Sr. Director Clinical Affairs

LIST OF ABBREVIATIONS

Acronym / Abbreviation	Term
ACM	All-cause mortality
AE	Adverse Event
AP	Anterior/Posterior
BID	Twice Daily
BP	Blood Pressure
CEC	Clinical Events Committee
CFA	Common Femoral Artery
CFR	Code of Federal Regulations
CI	Confidence Interval
Cm	Centimeter
COV	Closeout Visit
CRF	Case Report Form
CRO	Contract Research Organization
CSR	Clinical Study Report
CT	Computerized Axial Tomography Scan
DSMB	Data and Safety Monitoring Board
ECeCRF	Ethics Committee Electronic Case Report Form
EDC	Electronic Data Capture
EQ-5D	EuroQOL-5 Dimension
EU	European Union
FDA	Food and Drug Administration
Fr	French (sizing unit for devices)
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
GFR	Glomerular Filtration Rate
IB	Investigator Brochure
ICF	Informed Consent Form
ICH	International Council on Harmonization
IFU	Instructions for Use
IMV	Interim Monitoring Visits
ISO	International Organization for Standardization
ITT	Intent-to-treat
MAE	Major Adverse Event
mm	Millimeter
mmHg	Millimeters of mercury (unit of pressure)
mSv	Millisievert
NCA	National Competent Authorities
PPA	Proximal popliteal artery
PTA	Percutaneous transluminal angioplasty
PAD	Peripheral Arterial Disease
QD	Once Daily
RVD	Reference Vessel Diameter
SAE	Serious adverse event
SF-36	Short-Form 36
SFA	Superficial femoral artery
SOP	Standard Operating Procedures
TFA	Transfemoral Artery
TFATIA	Transfemoral Arterial
TIA	Transient Ischemic Attack
TLR	Target lesion(s) revascularization

Acronym / Abbreviation	Term
TRA	Transradial Arterial
USADE	Unanticipated Serious Adverse Device Effect

TABLE OF CONTENTS

1 INTRODUCTION

This document outlines the detailed statistical analysis methods to provide the appropriate clinical information on the "Evaluation of Safety and Efficacy of the S.M.A.R.T. RADIANZ™ Vascular Stent System in the Treatment of Iliac and Femoropopliteal Lesions via Transradial Access"

2 STUDY OBJECTIVE

The primary objective of this clinical investigation is to evaluate the safety and efficacy of the S.M.A.R.T. RADIANZ™ Vascular Stent System (S.M.A.R.T. RADIANZ), when used with the BRITE TIP RADIANZ™ Guiding Sheath (BRITE TIP RADIANZ) and SABERX RADIANZ™ PTA Balloon Catheter (SABERX RADIANZ) to deploy the S.M.A.R.T.™ Nitinol Stent (S.M.A.R.T. stent) for the treatment of patients with iliac and/or femoropopliteal [which includes the superficial femoral artery (SFA) and proximal popliteal artery (PPA)] lesions via transradial artery access.

3 STUDY DESIGN

This is a multi-center, single-arm, non-randomized, prospective, pivotal (pre-market) clinical study enrolling approximately 159 subjects at 15 sites with obstructive iliac or femoropopliteal arterial disease.

Approximately 129 of the 159 enrolled subjects will be studied to demonstrate the safety and effectiveness of the new S.M.A.R.T. RADIANZ™ Vascular Stent System for delivery of the S.M.A.R.T.™ stent to obstructive iliac or femoropopliteal lesions by radial artery access.

A subgroup of approximately 30 subjects, consisting of the first two (2) enrolled subjects at each study site (as applicable), will constitute the "roll-in" cohort for the study. Such subjects will be pre-specified as "roll-in" subjects prior to their enrollment and must meet all criteria for enrollment. Roll-in subjects will be followed and evaluated to 30 days post-procedure for safety only, and not included in any endpoint analyses.

All enrolled subjects (including those in the "roll-in" cohort) will be followed up to 30 days post-procedure. To adequately assess the efficacy and safety of both iliac and

femoropopliteal artery treatment under study, a minimum of 30 subjects will be required for each of the two indications (femoropopliteal and iliac). A goal of this study is to collect data on 30 uses of the SABERX RADIANZ device. Ideally, those uses will be evenly distributed across the iliac and femoropopliteal arteries.

4 ENDPOINTS

4.1 Safety Endpoints

The primary safety endpoint is the occurrence rate of CEC-adjudicated, major radial access site complications attributed to study device or procedure through time of hospital discharge.

The secondary safety endpoints include:

- Through time of hospital discharge:
  - Rate of non-access site-related complications (adverse events)
- Peri-procedural (within 30 days post-index procedure):
  - Rate of device deficiencies for each of the three (3) devices
  - Rate of adverse events
  - Rates of death, index limb amputation and target lesion revascularization
  - Rate of procedural complications

4.2 Effectiveness Endpoints

The primary efficacy endpoint is technical success at the conclusion of the index procedure, defined as successful insertion of the S.M.A.R.T. RADIANZ™ Vascular Stent System into the peripheral vasculature through the radial artery, successful deployment of the study device (S.M.A.R.T.™ stent) at the intended location, and successful withdrawal of the delivery system without conversion from radial to femoral artery access.

The secondary effectiveness endpoints include:

- Technical success associated with use of the BRITE TIP RADIANZ™ Guiding Sheath, defined as successful insertion of the device into the peripheral vasculature through the radial artery (allowing for introduction of interventional and/or diagnostic devices) and successful withdrawal of the device.

- Procedural success associated with use of the SABERX RADIANZ™ PTA Balloon Catheter for pre-dilation and/or post-deployment stent dilatation (whenever applicable), defined as successful insertion of the device into the peripheral vasculature through the radial artery, successful inflation and deflation of the balloon,

successful withdrawal of the device, and achievement of a final residual diameter stenosis of < 30% at the conclusion of the index procedure.

4.3 Additional Data Points

Data will be collected to evaluate the following health economics outcomes:

- Fluoroscopy time and procedural time, defined as the time of sheath introduction to time of vascular closure.
  - Time to achieve hemostasis, defined as the time elapsed from removal of the BRITE TIP RADIANZ Guiding Sheath to the time that hemostasis was first observed.
- Time to ambulation, defined as when the subject can stand up and walk any distance
- Time to hospital discharge
- Time to hospital discharge eligibility (when physician examines and if all is well, gives discharge orders).
- Method to achieve closure of the transradial artery access site

Quality of Life Assessments: Data will be also collected to evaluate health-related, quality-of-life in all subjects by administering both the SF-36 and the EuroQOL-5 Dimension (EQ-5D) standardized, validated questionnaires to assess general and disease-specific outcomes.

- The SF-36 is a patient-reported survey of general health and well-being. It consists of 36 items grouped in these dimensions: physical functioning, physical and emotional limitations, social functioning, bodily pain, general and mental health. Higher scores indicate better health status.
- The EQ-5D questionnaire is used for the assessment of health state utility and visual analog rating, which is a quantitative measure of overall health status. It consists of five (5) dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression.

5 SAMPLE SIZE

Effectiveness Endpoint:

It is assumed that the technical success rate will be 98%, which is derived from other studies using radial access procedures. The performance goal was also based on a literature review and was set at 93%. Using a one-sided exact 95% confidence interval calculated using the Clopper-Pearson method, a sample size of 129 limbs provides 88% power to demonstrate that the observed technical success rate is greater than the performance goal of 93%. Given the acute, in-hospital nature of the endpoint, no adjustment for attrition was made.

Safety Endpoint:

It is assumed that the in-hospital device or procedure-related radial artery complications will be 2% which is derived from other studies using radial access procedures. The performance goal was also based on a literature review and was set at 7%. Using a one-sided exact 95% confidence interval calculated using the Clopper-Pearson method, a sample size of 129 subjects provides 88% power to demonstrate that the observed complication rate is less than the performance goal of 7%. No adjustment for attrition was made.

Other Considerations:

To adequately assess the efficacy and safety of both iliac and femoropopliteal artery treatment under study a minimum of 30 subjects will be required for each artery treatment, i.e., a minimum of 30 iliac and minimum of 30 femoropopliteal arteries.

In order to characterize the safety and efficacy of the SABERX RADIANZ device, it is a goal of this study to collect information on 30 distinct uses of the device. This is a goal and not a minimum since use of the SABERX RADIANZ device is dictated by the attending physician. Ideally, the 30 uses will be evenly distributed between the iliac and femoropopliteal arteries.

Study Sample Size:

The sample size for effectiveness and safety are approximately equal. The effectiveness endpoint is based on a per limb analysis since bilateral subjects are allowed in this trial. Safety is based on a per subject analysis since some adverse events may not be assignable to a particular limb. Given this, the sample size for the safety endpoint, 129 subjects will be used. Overall enrollment is planned as approximately 159 subjects, which includes the 30 roll-in subjects.

6 ANALYSIS POPULATION

Analyses for the endpoints will be performed using the intent-to-treat (ITT) population. The ITT population will consist of all subjects enrolled in the study, excluding roll-ins, and for whom a device insertion was attempted, regardless of the treatment actually received.

The per-protocol analysis population is defined as a sub-group of the ITT population consisting of subjects without protocol deviations that could possibly affect the primary endpoints. Primary endpoint analysis using this population is supportive in nature.

7 RANDOMIZATION

This is a non-randomized, single arm study.

8 STATISTICAL METHODS OF ANALYSIS

8.1 General Considerations

Except where otherwise specified, the following general principles apply to the planned statistical analyses. All descriptive statistical analyses will be performed using SAS version 9.4 or higher, unless otherwise noted (SAS Institute Inc., Cary, NC) or other widely accepted statistical or graphical software as required. Derived variables will be independently verified by an independent programmer / statistician.

In general, for categorical variables, the numerator, denominator, rate (%) and exact 95% CI will be calculated. For continuous variables, the median, mean, standard deviation, interquartile range, number of observations, minimum and maximum values, and 95% CI, as appropriate, will be presented.

For each parameter, the baseline value will be defined as the last non-missing value collected at the time closest to but before treatment with the investigational device.

Statistical tests of the primary endpoints will be performed at the one-sided 0.05 significance level.

8.2 Subject Disposition

Subject accountability will be summarized in tabular form.

8.3 Subject Demographics and Baseline Variables

All baseline variables will be summarized using descriptive statistics. Continuous variables will be summarized using the mean, standard deviation, N, minimum, and maximum. Categorical variables will be summarized as frequencies and proportions. Baseline variables for all enrolled subjects will be summarized, however roll-in subjects will be summarized separately.

8.4 Analyses of Safety Endpoints

8.4.1 Primary Safety Endpoint Analysis

The primary safety endpoint is the occurrence rate of device or procedure-related complications associated with transradial artery access through the time of hospital discharge.

The safety hypothesis being tested is:

Ho: $\pi \geq 0.07$
Vs
Ha: $\pi < 0.07$

where π is the proportion of subjects experiencing a radial access related complication.

A one-sided upper exact 95% CI for device or procedure-related radial artery complications rate will be calculated using the Clopper-Pearson method. The upper bound will be compared to the performance goal of 7%. If the upper bound is less than the performance goal, then this endpoint will have been successfully achieved.

Even though some subjects may contribute bilateral lesions, the safety analysis will be analyzed on a per subject basis.

The same analysis will be completed on the per-protocol analysis population if that population is different from the ITT population.

8.4.2 Secondary Safety Endpoint Analysis

Secondary safety endpoints will be summarized using the statistical methods described in section 8.1. All secondary safety endpoints will be summarized on a per subject basis. In particular, each of the rates outlined in section 4.1 will be estimated and presented with a two-sided 95% confidence interval that is calculated using the Clopper-Pearson method in addition to the other descriptive statistics.

No formal hypothesis testing will be done on the secondary safety endpoints.

8.5 Analyses of Effectiveness Endpoints

8.5.1 Primary Effectiveness Endpoint Analysis

The primary efficacy endpoint is technical success at the conclusion of the index procedure defined as successful insertion of the S.M.A.R.T. RADIANZ™ Vascular Stent System through the vasculature, successful deployment of the study device (S.M.A.R.T.™ stent) at the intended location, and successful withdrawal of the delivery system without conversion to femoral access.

The hypothesis being tested is:

Ho: $\pi \leq 0.93$
Vs
Ha: $\pi > 0.93$

where π is the proportion of limbs successfully treated with one or more S.M.A.R.T. RADIANZ™ Vascular Stent Systems.

A one-sided lower exact 95% CI for technical success rate will be calculated using the Clopper-Pearson method. The lower bound will be compared to the performance goal of 93%. If the lower bound is greater than the performance goal then this endpoint will have been successfully achieved.

This analysis will be done on a per limb basis since some subjects enrolled in the trial have bilateral lesions. Each lesion can be treated with up to two stents. In the case that two stents are used, success is based on successful insertion of each of the S.M.A.R.T. RADIANZ™ Vascular Stent System through the radial artery, successful deployment of both stents at the intended location and the successful withdrawal of both systems with no conversion to femoral access. While some subjects will present with bilateral lesions, the actual number of those subjects will be small. As such, each limb will be considered an independent observation for the purpose of analysis of this endpoint.

The same analysis will be completed on the per-protocol analysis population if that population is different from the ITT population.

8.5.2 Secondary Effectiveness Endpoint Analysis

The secondary endpoint of technical success of the BRITE TIP RADIANZ™ Guiding Sheath will be summarized on a per subject basis since the guiding sheath would not be completely removed between lesion treatments of a bilateral subject. The number of successfully inserted BRITE TIP RADIANZ guiding sheaths will be counted and divided by the number of BRITE TIP RADIANZ guiding sheaths with attempted insertions to estimate the technical success. A two-sided 95% exact confidence interval will be constructed about the technical success rate. The confidence interval will be calculated using the Clopper-Pearson method.

Procedural success of the SABERX RADIANZ™ PTA Balloon Catheter will be summarized on a per limb basis. In the case where pre-dilation and post-dilatation are performed and/or more than one SABERX RADIANZ balloon was used to treat a lesion, each device must be successfully inserted into the peripheral vasculature through the radial artery, successfully inflated and deflated, and successful withdrawn with the achievement of a final residual diameter stenosis of < 30% for the treated lesion. The number of successful procedures using the SABERX RADIANZ™ PTA Balloon Catheter will be calculated for each limb. A two-sided 95% exact confidence interval will be constructed about the procedural success rate. The confidence interval will be calculated using the Clopper-Pearson method.

No formal hypothesis testing will be done on the secondary effectiveness endpoints.

8.6 Adverse Events

In addition to the adverse event rates estimated for the secondary safety endpoint, all adverse events (AE), serious adverse events (SAE), major adverse events (MAE), and unanticipated adverse device effects (UADE) will be tabulated (or listed). The table or listing will contain the term or description, start and end dates, severity, outcome, and causality or association to the investigational product or procedures. These summary tables will present descriptive statistics. No formal testing will be done.

8.7 Additional Endpoints

The additional data points of fluoroscopy time, procedural time, time to achieve hemostasis, time to ambulation, time to hospital discharge, time to hospital discharge eligibility, method to achieve closure, and the scoring of the EQ-5D and SF-36 will be completed on a per subject basis.

Estimates of each of the endpoints related to time will be summarized with a mean, standard deviation, median, and a range expressed as a minimum and maximum. For each estimate, a two-sided 95% confidence interval will be calculated using normal approximation methods.

The method of vascular closure will be reported as the percent of subjects falling into closure categories.

The EQ-5D will be reported as the proportion of subjects falling within the scale for each domain at three time points; Screening, Discharge, and 30 day follow-up. Each domain is a rank-order scale in which lower numbers represent outcomes superior to those represented by higher numbers (i.e. “1” is best and “5” is worst) for each time point. Overall health score, however, is reported as a mean and standard deviation at each time point. For the SF-36, results within each subscale will be summarized with a mean and standard deviation at three time points: screening, discharge and 30-day follow-up.

8.8 Sub-Group Analysis

A sub-group analysis will be completed for the primary safety and primary efficacy endpoints. This analysis is not powered and is strictly for information purposes. The sub-groups are:

- Sex (females vs. males)
- Artery treated (iliac vs. femoropopliteal)

The same analysis outlined above for the primary safety and efficacy endpoints will be completed within each sub-group separately (e.g. separately for males and females).

8.9 Analysis of Roll-in Subjects

Roll-in subjects will be summarized separately using descriptive statistics (mean, standard deviation, median, minimum and maximum values for interval level data). These subjects will be evaluated for safety only. The primary and secondary safety endpoints will be estimated for these subjects, however no formal hypothesis testing will be done.

8.10 Protocol Deviations

Protocol deviations will be listed by category. Descriptive statistics will be used to summarize the number of times a deviation happened over the course of the trial.

9 STUDY SITE POOLABILITY

Study site poolability for the primary effectiveness endpoint of technical success will be tested using a Pearson Chi-square statistic. A table whose rows are the individual study sites and the two columns are technical success (yes and no) will be used for the analysis. If the p-value for the Pearson Chi-square statistic is greater than 0.15, then the study site data can be pooled for this endpoint.

Study site poolability for the primary safety endpoint will be assessed in the same fashion as the primary effectiveness endpoint, but here the columns will be the number of subjects who did or did not experience a major, CEC-adjudicated, device or procedure-related complication associated with transradial artery access. Again, if the p-value for the Pearson Chi-square statistic is greater than 0.15, then the study site data can be pooled for the safety endpoint.

10 INTERIM ANALYSIS

No interim analysis is planned for this study.

11 HANDLING OF MISSING DATA

For both primary endpoints, a sensitivity analysis will be done where missing data is imputed using a worst-case scenario. Specifically, for the efficacy endpoint (technical success), missing data will be imputed as “unsuccessful.” Likewise, missing safety data will be imputed to indicate that the subject experienced a radial access-related AE.

If after imputing the missing data with the worst-case scenario, the interpretation of the analysis changes, then each missing data point will be imputed one at a time and the analysis re-run each time in order to see how many failed data points were needed to change the interpretation.

12 PLANNED TESTS AND EXPECTED RESULTS

Planned a priori analyses and expected results, where applicable, are shown in Table 1.

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Table 1. A Priori Planned Statistics

Variable	Analysis	Expected Result	Cohort			
			ITT	PP	Non-Roll-in	Roll-in
Technical Success (Primary) Non-Roll-in Subjects Only	One-Sided Lower Exact 95% CI	Confidence Interval does not include 93%	X		X	
Technical Success (Primary) Roll-in Subjects Only	One-Sided Lower Exact 95% CI	Exploratory	X			X
Technical Success (Primary) Non-Roll-in, Per Protocol Subjects Only	One-Sided Lower Exact 95% CI	Confidence Interval does not include 93%		X	X	
Sensitivity Analysis for Primary Technical Success. Non Roll-in Subjects Only	One-Sided Lower Exact 95% CI	N/A	X		X	
Subgroup analysis for Primary Efficacy Variables by Gender and Lesion Type (Iliac and Femoral/Popliteal)	One-sided Lower Exact 95% Confidence Interval	Confidence Interval Does Not Include 93%			X	X
Major Radial Access Site Complications Attributed to Device or Procedure Through Discharge (Primary) Non-Roll-in Subjects Only	One-Sided Lower Exact 95% CI, w/wo	Confidence Interval Does Not Include 7%	X		X	

Major Radial Access Site Complications Attributed to Device or Procedure Through Discharge (Primary) Roll-in Subjects Only	One-Sided Lower Exact 95% CI	Confidence Interval Does Not Include 7%		X	X	
Major Radial Access Site Complications Attributed to Device or Procedure Through Discharge (Primary) Roll-in Subjects Only	One-Sided Lower Exact 95% CI	Exploratory	X			X
Sensitivity Analysis for Major Radial Access Site Complications Attributed to Device or Procedure Through Discharge (Primary) Non-Roll-in Subjects Only	One-Sided Lower Exact 95% CI, w/wo	N/A	X		X	
Subgroup Analysis for Major Radial Access Site Complications Attributed to Device or Procedure Through Discharge (Primary) by Gender and Lesion Type (Iliac and Femoral/Popliteal)	One-Sided Lower Exact 95% Confidence Interval	Confidence Interval Does Not Include 7%			X	X
Rate of Brite Tip Radianz Guiding Sheath Deficiencies Non-Roll-in Subjects	Two-sided Exact 95% Confidence Interval (one or more per procedure, w/wo)	Exploratory			X	
Rate of Brite Tip Radianz Guiding Sheath Deficiencies Roll-in Subjects	Two-sided Exact 95% Confidence Interval (one or more per procedure, w/wo)	Exploratory				X
Rate of SaberX Radianz PTA Balloon Catheter Deficiencies Non Roll-in Subjects Only	Two-sided Exact 95% Confidence Interval (one or more per procedure, w/wo)	Exploratory			X	

Rate of SaberX Radianz PTA Balloon Catheter Deficiencies Roll-in Subjects Only	Two-sided Exact 95% Confidence Interval (one or more per procedure, w/wo)	Exploratory				X
Rate of S.M.A.R.T Radianz Vascular Stent System Deficiencies Non-Roll-in Subjects	Two-sided Exact 95% Confidence Interval (one or more per procedure, w/wo)	Exploratory			X	
Rate of S.M.A.R.T Radianz Vascular Stent System Deficiencies Roll-in Subjects Only	Two-sided Exact 95% Confidence Interval (one or more per procedure, w/wo)	Exploratory				X
Subgroup analysis for Secondary Safety Variables by Gender and Lesion Type (Iliac and Femoral/Popliteal)	Two-sided Exact 95% Confidence Interval (one or more per procedure, w/wo)	Exploratory			X	X
Rate of AEs; Run Separately for Non-Roll-in and Roll-in Subjects	Two-sided Exact 95% Confidence Interval (one or more per procedure)	Exploratory			X	X
Rate of Death	Two-sided Exact 95% Confidence Interval (one or more per procedure)	Exploratory			X	X
Rate of Index Limb Amputation	Two-sided Exact 95% Confidence Interval (one or more per procedure)	Exploratory			X	X
Rate of Target Lesion Revascularization	Two-sided Exact 95% Confidence Interval (one or more per procedure)	Exploratory			X	X
Rate of Procedural Complications, Separately for Non-Roll-in and Roll-in Cohorts	Two-sided Exact 95% Confidence Interval (one or more per procedure)	Exploratory			X	X
Additional Variables						
Fluoroscopy Time	Mean, 95% CI	Exploratory			X	X
Procedure Time	Mean, 95% CI	Exploratory			X	X
Time to Hospital Discharge, Minutes	Mean, 95% CI	Exploratory			X	X

Time to Hospital Discharge Eligibility, Minutes	Mean, 95% CI	Exploratory			X	X
Method of Transradial Artery Access Site Closure	Tabulation with Percentages	Exploratory			X	X
SF-36 Subscale Results	Mean, Standard Deviation and 95% CI for Each Domain	Exploratory			X	X
EQ-5D Subscale Results	Tabulations by Dimensions with Percentages for Each Domain	Exploratory			X	X
Descriptive Statistics-Age/Gender/Lesion Type (Mean, SD, Median, Min and Max or Tabulation for Categorical Variables)	Run Poolability Analysis Separately by Site	Exploratory			X	X

All variables that are measured by procedure—and without—will be listed comprehensively with details. The analyses indicated as being performed on a per procedure basis will be analyzed this way to assure statistical independence, but all results will be reported. Therefore, for example, if there is more than one procedural complication in a given procedure, all complications will be listed.

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