STATISTICAL ANALYSIS PLAN

A Prospective, Open Label, Multi-center, Single Arm, Observational Study Designed to Evaluate the Safety and Device Procedural Success of the Scoreflex NC Scoring PTCA Catheter in Subjects with Stenotic Coronary Arteries during Percutaneous Coronary Intervention

Short Title:	Scoreflex NC – Scoring PTCA Catheter
Protocol No:	VP-0730
Clinical Trials Identifier:	NCT03763747
Name of Test Device:	Scoreflex NC Scoring PTCA catheter

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1. SIGNATURE PAGE

Protocol Title:	A Prospective, Open Label, Multi-center, Single Arm, Observational Study Designed to Evaluate the Safety and Device Procedural Success of the Scoreflex NC Scoring PTCA Catheter in Subjects with Stenotic Coronary Arteries during Percutaneous Coronary Intervention
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2. STUDY SYNOPSIS

Protocol Number	VP-0730
Title	A Prospective, Open Label, Multi-center, Single Arm, Observational Study Designed to Evaluate the Safety and Device Procedural Success of the Scoreflex NC Scoring PTCA Catheter in Subjects with Stenotic Coronary Arteries during Percutaneous Coronary Intervention
Study Devices	Scoreflex NC Scoring PTCA catheter
Objective(s)	The objective of this study is to assess the acute safety and device procedural success of the Scoreflex NC scoring PTCA catheter in its intended use for the dilatation of coronary artery stenosis (≥70% diameter stenosis).
Design	Prospective, open label, multi-center, single arm, observational study
Study Population	Subjects with evidence of ischemia and clinically indicated for one- or two-vessel revascularization procedures by percutaneous coronary intervention
Sample Size	Two-hundred (200) subjects will be enrolled at up to 15 U.S. sites
Inclusion Criteria	**General Inclusion Criteria** 1. Subject is ≥ 18 years of age 2. Subject or a legally authorized representative must provide written informed consent prior to any study related procedures 3. Subject must agree not to participate in any other clinical study during hospitalization for the index procedure that would interfere with the endpoints of this study 4. Subjects must have a single or double vessel coronary artery disease and clinical evidence of ischemic heart disease, such as CAD, stable / unstable angina or silent ischemia
Angiographic Inclusion Criteria	5. Subject must have de novo or restenotic lesion(s) in native coronary arteries, including in-stent restenosis suitable for percutaneous coronary intervention. 6. A maximum of two lesions, including at least one target lesion, in up to two coronary arteries. 7. Target lesion must have a reference vessel diameter (RVD) between 1.75 and 4.0 mm by visual estimation.

	8. Target lesion(s) must have a diameter stenosis of ≥70% by visual estimation and may include chronic total occlusions (CTO). 9. The non-target lesion must be located in different coronary artery from the Target lesion. 10. Treatment of non-target lesion, if any, must be completed prior to treatment of target lesion and must be deemed a clinical angiographic success as visually assessed by the physician
Exclusion Criteria	**General Exclusion Criteria** 1. Subject with a known hypersensitivity or contraindication to aspirin, heparin, bivalirudin, anti-platelet medications, or sensitivity to contrast media which cannot be adequately premedicated 2. Subject with known diagnosis of STEMI or NSTEMI at index presentation or within 7 days of study screening 3. Subject with known pregnancy or is nursing. Women of child-bearing potential should have a documented negative pregnancy test within 7 days before index procedure 4. Planned or actual target lesion treatment with an unapproved device, atherectomy, laser, cutting balloon or thrombectomy during the index procedure 5. A serum creatinine level > 2.0 mg/dl within 7 days prior to index procedure 6. Cerebrovascular accident (CVA) within the past 6 months 7. Active peptic ulcer or active gastrointestinal (GI) bleeding within the past 6 months 8. Subject has a known left ventricular ejection fraction (LVEF) <30% (LVEF may be obtained at the time of the index procedure if the value is unknown, if necessary) 9. Target lesion located within an arterial or saphenous vein graft or graft anastomosis
Angiographic Exclusion Criteria	10. More than two lesions requiring treatment. 11. Target lesion longer than 30 mm by visual estimation. 12. Extreme angulation (90º or greater) proximal to or within the target lesion. 13. Previous percutaneous intervention of lesions in a target vessel (including side branches) conducted within 9 months before the study procedure and located within 10 mm from the current target lesion. 14. Target lesion demonstrating severe dissection prior to planned deployment of the Scoreflex NC device 15. Unprotected left main coronary artery disease. (Greater than

	50% diameter stenosis) 16. Coronary artery spasm of the target vessel in the absence of a significant stenosis. 17. Target lesion with angiographic presence of probable or definite thrombus. 18. Target lesion involves a bifurcation requiring treatment with more than one stent or pre-dilatation of a side branch >2.0 mm in diameter. 19. Non-target lesion to be treated during the index procedure meets any of the following criteria: • Located within a bypass graft (venous or arterial) • Left main location • Chronic total occlusion • Involves a bifurcation (e.g., bifurcations requiring treatment with more than 1 stent) • Treatment not deemed a clinical angiographic success
Subject screening and enrollment process	A subject is considered enrolled in the study following provision of informed consent and upon insertion of the investigational device into a guide catheter.
Study Duration/Follow-Up Period	Subjects will be followed through hospital discharge.
Primary Effectiveness Endpoint	Device procedural success consisting of the following: • Successful delivery, inflation, deflation, and withdrawal of the study balloon • No evidence of vessel perforation, flow limiting dissection (grade C or higher) or reduction in TIMI flow from baseline as related to the Scoreflex NC study balloon • Final TIMI flow grade of 3 at the conclusion of the PCI procedure
Secondary Endpoints	Angiographic Procedural efficacy: • Final diameter stenosis ≤ 50% in at least one of the Scoreflex NC attempted lesions following completion of the interventional procedure, including adjunctive stenting The following clinical endpoints will be measured through hospital discharge: • In-hospital Major Adverse Cardiac Events (MACE), a composite of: o All death (cardiac and non-cardiac) o Myocardial infarction (MI)

	○ Target Lesion Revascularization (TLR), clinically indicated ○ In-hospital stent thrombosis (ST) within the target vessel ○ Clinically significant arrhythmias (requiring intervention)
Statistical Considerations	A sample size of two-hundred (200) subjects has been chosen in order to characterize the performance of the device. Statistical analyses will be performed for the primary, secondary endpoints, and additional analyses based on analysis populations that are defined below. *Primary Analysis Set:* The primary analysis set is the Intent-to-Treat (ITT) population. The ITT population includes all consented and enrolled subjects. *Secondary Analysis Set:* The secondary analysis set is the Per-Protocol (PP) population. The PP population is defined as all enrolled subjects who received a Scoreflex NC device with availability of data of the primary endpoint and without any major protocol violations including the violation of inclusion or exclusion criteria
Lesions	A maximum of two lesions, including at least one target lesion, may be treated during the index procedure. Non-target lesion should be treated first and deemed a clinical angiographic success by visual assessment prior to treatment of the target lesion. The lesion identified as the target lesion is intended to be treated during the index procedure with a Scoreflex NC study device. ***Non-Target Lesion*** • A maximum of one non-target lesion (in addition to one target lesion in a target vessel) may be treated in a non-target vessel with a commercial treatment during the index procedure and must occur prior to treatment of target lesion.

	• Treatment of non-target lesion must be deemed a clinical angiographic success for subjects to be eligible for enrollment into the study. • Target and non-target lesions must be located in different coronary arteries. ***Target Lesion*** • Lesion that is to be treated with the Scoreflex NC study device during the index procedure. • Target lesions (maximum of 2) may be located in the same or different coronary arteries. • Target lesion composed of multiple focal lesions that can be covered with one stent will be considered as a single lesion. *Note:* A separate Scoreflex NC study device must be used for treatment of each target lesion.

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3. LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

Abbreviation	Definition
AE	Adverse Event
CRF	Case Report Form
CSR	Clinical Study Report
CTO	Chronic Total Occlusions
CVA	Cerebrovascular Accident
EDC	Electronic Data Capture
GCP	Good Clinical Practice
GI	Gastrointestinal
ICH	International Conference on Harmonization
IRB	Institutional Review Board
ISO	International Organization for Standardization
ITT	Intent to Treat
LVEF	Left Ventricular Ejection Fraction
MACE	Major Adverse Cardiac Event
MI	Myocardial infarction
MLD	Minimum Lumen Diameter
PCI	Percutaneous Coronary Intervention
PP	Per Protocol
PTCA	Percutaneous Transluminal Coronary Angioplasty
QCA	Quantitative Coronary Angiography
RVD	Reference Vessel Diameter
SAP	Statistical Analysis Plan
SAS	Statistical Analysis System
ST	Stent thrombosis
US	United States

4. INTRODUCTION

The Scoreflex NC Scoring PTCA Catheter is a coronary dilatation catheter designed with a short rapid-exchange tip distal to the dilation balloon and an external integral wire on the outside of the balloon, such that the guide wire and the integral wire act as scoring elements external to the balloon when the balloon is inflated. The presence of the external scoring elements outside the angioplasty balloon create a focal stress pattern which allows for opening of lesions at lower pressures using a concept of Focused Force Angioplasty.

The target study population is subjects with evidence of ischemia and clinically indicated for one- or two-vessel revascularization procedures by percutaneous coronary intervention.

The statistical analysis plan (SAP) is intended to prospectively (*a priori*) outline the analyses and presentations of data that will form the basis for conclusions to be reached to answer the study objectives outlined in the protocol, and to explain in detail how the data will be handled and analyzed, adhering to commonly accepted standards and practices of biostatistical analysis in clinical trials. Results obtained from the analyses outlined in this document will be the basis for the clinical study report (CSR) for this study. This plan is based on Revision 1 of the study protocol, dated 30 November 2018.

5. STUDY OBJECTIVES

As stated in the protocol, the objective of this study is to assess the acute safety and device procedural success of the Scoreflex NC scoring PTCA catheter in its intended use for the dilatation of coronary artery stenosis (≥70% diameter stenosis).

6. INVESTIGATIONAL PLAN

6.1. Overall Study Design and Plan

This is a prospective, open label, multi-center, single arm, observational study designed to evaluate the acute safety and device procedural success of the Scoreflex NC scoring PTCA catheter in subjects with stenotic coronary arteries during percutaneous coronary intervention.

Two-hundred (200) subjects are treated at up to 15 U.S. sites with the Scoreflex NC catheter during their index procedure. All subjects are screened according to the protocol inclusion and exclusion criteria and are followed through hospital discharge.

6.1.1. *Choice of Control Groups*

There is no control group in this study because this is a single-arm study.

6.1.2. *Method of Assigning Subjects to Treatment Groups*

Assignment to treatment groups is not applicable because this is a single-arm study. All subjects will receive the Scoreflex NC Scoring PTCA catheter.

6.1.3. *Blinding*

The study is an open-label observational study. Therefore, there is no blinding procedure applied in this study.

6.2. Description of study hypotheses and endpoints

There are no hypotheses defined in this study.

6.2.1. *Primary Safety and Efficacy Endpoint*

The primary endpoint is a successful procedure based on the following composite components on a per-patient level:

- Successful delivery, inflation, deflation, and withdrawal of the study balloon
- No evidence of vessel perforation, flow limiting dissection (grade C or higher) or reduction in TIMI flow from baseline as related to the Scoreflex NC study balloon
- Final TIMI flow grade of 3 at the conclusion of the PCI Procedure

A patient's procedure is considered a success if all three components are achieved.

Each component of the primary endpoint measures will be reported as individual components as well..

6.2.2. *Secondary Endpoints*

The secondary endpoints consist of angiographic procedural efficacy, clinical, and peri-procedural endpoints.

The secondary angiographic procedural efficacy endpoint is measured and defined as follow:

- Final diameter stenosis ≤ 50% in at least one of the Scoreflex NC attempted lesions following completion of the interventional procedure, including adjunctive stenting

The secondary clinical endpoints which are measured through hospital discharge are as follows:

- In-hospital Major Adverse Cardiac Events (MACE), a composite of the following:
  - All death (cardiac and non-cardiac)
  - Myocardial infarction (MI)
  - Clinically indicated Target Lesion Revascularization (TLR)
- In-hospital stent thrombosis (ST) within the target vessel
- Clinically significant arrhythmias (requiring intervention)

The secondary peri-procedural endpoints are measured through hospital discharge and defined as follows:

- Occurrence of Scoreflex NC study balloon rupture
- Improvement in Minimum Lumen Diameter (MLD) following use of Scoreflex NC coronary dilatation catheters (measured by QCA)

Both MI and ST are to be determined by the Academic Research Consortium (ARC) classification criteria. MI will be classified into various types including the 99th percentile upper reference limit (URL) decision limits for biomarkers employed.

Myocardial Infarction will be defined as:

- Q-Wave MI: Development of new (i.e., not present on the subject's ECG before allocation) pathological Q-waves in 2 or more leads lasting 0.04 seconds with post-procedure CK-MB levels elevated above normal.
- Non–Q-Wave MI: Elevation of post-procedure CK-MB levels to >3.0 times ULN without new Q-waves.

For subjects undergoing bypass surgery, a peri-operative MI will be defined as follows:
a) Total CK-MB >5× ULN.
or
b) Presence of new pathologic Q-waves as defined above.

7. DATA QUALITY ASSURANCE AND COMPUTING ENVIRONMENT

Case report forms (CRFs) for data collection were created on an Electronic Data Capture (EDC) system specifically for this study and were used to record data. The forms were completed by the study site personnel, overseen and approved by the Investigators. All procedures for the handling and analysis of data were conducted using Good Clinical Practices (GCP) meeting the International Organization for Standardization (ISO) 14155 and the International Conference on Harmonization (ICH) guidelines and the US Food and Drug Administration regulations for the handling and analysis of data for Clinical Investigations.

All statistical analyses will be performed using the Statistical Analysis System (SAS) Software package, Version 9.4 or higher (SAS Institute, Cary, NC).

8. SUBJECT POPULATIONS

The following analysis populations are defined for the purpose of analysis: an Intent to Treat (ITT) population, and a Per Protocol (PP) population. The primary endpoint analysis and all other secondary endpoint analyses will be carried out on both ITT and PP populations unless otherwise stated in the final clinical summary report. The analyses of adverse events will be carried out on the ITT population.

8.1. Analysis Populations

The primary analysis set is the ITT population. The ITT population includes all consented and enrolled subjects.

The PP population is defined as all enrolled subjects who received a Scoreflex NC device with availability of data of the primary endpoint and without any major protocol violations including the violation of inclusion or exclusion criteria as shown below. The PP population will be used for confirmatory analysis of efficacy endpoints. Categories of Major protocol deviations are defined in Section 8.2.

The following are inclusion and exclusion criteria.

Inclusion Criteria

1. Subject is ≥ 18 years of age
2. Subject or a legally authorized representative must provide written informed consent prior to any study related procedures.
3. Subject must agree not to participate in any other clinical study during hospitalization for the index procedure that would interfere with the endpoints of this study.
4. Subjects must have a single or double vessel coronary artery disease and clinical evidence of ischemic heart disease, such as CAD, stable / unstable angina or silent ischemia

Angiographic Inclusion Criteria

5. Subject must have de novo or restenotic lesion(s) in native coronary arteries, including in-stent restenosis suitable for percutaneous coronary intervention.
6. A maximum of two lesions, including at least one target lesion, in up to two coronary arteries.
7. Target lesion must have a reference vessel diameter (RVD) between 1.75 and 4.0 mm by visual estimation.
8. Target lesion(s) must have a diameter stenosis of ≥70% by visual estimation and may include chronic total occlusions (CTO).

Exclusion Criteria

General Exclusion Criteria

1. Subject with a known hypersensitivity or contraindication to aspirin, heparin, bivalirudin, anti-platelet medications, or sensitivity to contrast media which cannot be adequately premedicated

2. Subject with known diagnosis of STEMI or NSTEMI at index presentation or within 7 days of study screening
3. Subject with known pregnancy or is nursing. Women of child-bearing potential should have a documented negative pregnancy test within 7 days before index procedure
4. Planned or actual target lesion treatment with an unapproved device, atherectomy, laser, cutting balloon or thrombectomy during the index procedure
5. A serum creatinine level > 2.0 mg/dl within 7 days prior to index procedure
6. Cerebrovascular accident (CVA) within the past 6 months
7. Active peptic ulcer or active gastrointestinal (GI) bleeding within the past 6 months
8. Subject has a known left ventricular ejection fraction (LVEF) <30% (LVEF may be obtained at the time of the index procedure if the value is unknown, if necessary).
9. Target lesion located within an arterial or saphenous vein graft or graft anastomosis

Angiographic Exclusion Criteria

10. More than two lesions requiring treatment.
11. Target lesion longer than 30 mm by visual estimation.
12. Extreme angulation (90º or greater) proximal to or within the target lesion.
13. Previous percutaneous intervention of lesions in a target vessel (including side branches) conducted within 9 months before the study procedure and located within 10 mm from the current target lesion.
14. Target lesion demonstrating severe dissection prior to planned deployment of the Scoreflex NC device
15. Unprotected left main coronary artery disease. (Greater than 50% diameter stenosis)
16. Coronary artery spasm of the target vessel in the absence of a significant stenosis.
17. Target lesion with angiographic presence of probable or definite thrombus.
18. Target lesion involves a bifurcation requiring treatment with more than one stent or pre-dilatation of a side branch >2.0 mm in diameter.
19. Non-target lesion to be treated during the index procedure meets any of the following criteria:
    - Located within a bypass graft (venous or arterial)
    - Left main location
    - Chronic total occlusion
    - Involves a bifurcation (e.g., bifurcations requiring treatment with more than 1 stent)
    - Treatment not deemed a clinical angiographic success

8.2. Protocol Deviations

Protocol deviations will be categorized as Major and Minor.

Major deviations include those that involve the informed consent process, and the inclusion/exclusion criteria of the study.

Minor deviations include all other noted deviations, i.e. Missed Assessment, Assessment not done in the required timeframe, and other.

9. STATISTICAL METHODS

9.1. Determination of Sample Size

The study sample size of 200 patients is based on treatment of a reasonable number of subjects with the study device to provide a reliable and meaningful assessment of device performance, rather than based upon any statistical hypothesis of an endpoint.

9.2. General Considerations

9.2.1. *General Methods*

All descriptive statistical analyses will be performed using SAS (Version 9.4 or higher), unless otherwise noted. Derived variables will be programmed by the study programmer/statistician, and then verified by an independent programmer/statistician (e.g., age or height conversions). The program review also will include a check whether analyses conform to specifications of the SAP. All output will be incorporated into Microsoft Word files and formatted as to the appropriate page size(s).

All primary and secondary endpoints will be evaluated using descriptive statistics only. No hypothesis tests will be performed.

Statistics for continuous outcomes will include N, mean, median, standard deviation, minimum, and maximum. Binary outcomes will be summarized using frequencies, percentages and two-sided exact 95% confidence intervals for the primary and secondary endpoints. For categorical variables, the number and percentage within each category of the parameter will be calculated.

The baseline demographic and clinical characteristics, lesion characteristics, procedure information will be summarized by descriptive statistics for the ITT population.

9.2.2. *Adjustments for Covariates*

No adjustment for covariates will be made.

9.2.3. *Handling of Dropouts or Missing Data*

Only enrolled subject data which are collected will be included in the analysis. All efforts will be made to reduce missing data. In general, missing data will not be imputed in this study unless partial dates for special variables as described in Section 9.2.3.1. Details of imputing partial dates are described next.

9.2.3.1. *Partial Date Imputation*

The following table shows partial date imputation for some special cases.

Table 9.3.2.1. Partial Date Imputation in Some Special Cases

Type of Date/Time	**Day is missing**	**Month is missing**	**Both Month and Day are missing**
concomitant medication start date	the day of treatment start date[1] if medication occurs in the same month and the same year as the subject's in treatment start date, otherwise, the first day of month	the month of treatment start date if medication occurs in same year as the in-treatment start date, otherwise, the first month of year	treatment start date if medication occurs in the same year as the in-treatment start date, otherwise, no imputation
concomitant medication end date	day of study end date if medication occurs in the same year and the same month as the subject's in-study end date, otherwise, last day of month	month of study end date if medication occurs in the same year as the subject's in-study end date, otherwise, December	treatment end date if medication occurs in the same year as the subject's in-study end date, otherwise, no imputation, considered ongoing
medical history or prior medication start date	first day of month	first month of year	study start date if it occurs in the same year as the one in study start date, otherwise, January 1
end date for medical history or prior medication	day of study end date if it occurs in the same year and the same month as ones in study end date, otherwise, last day of month	month of study end date if it occurs in same year as one in study end date, otherwise, December	study end date if it occurs in the same year as one in study end date, otherwise, December 31

[1] Treatment start date: date of procedure or device implantation

Table 8.3.2.1. Partial Date Imputation in Some Cases (continued)

Type of Dates	Day is missing	Month is missing	Both Month and Day are missing
AE start date	day of treatment start date[1] if AE occurs in the same year and same month as ones in treatment start date, otherwise, last day of month	month of treatment start date if AE occurs in the same year as one in treatment start date, otherwise, January	treatment start date if AE occurs in the same year as treatment start date, otherwise, as January 1
AE end date	same day as study end date if AE occurs in the same year and the same month as study end date, otherwise, last day of month	same month of study end date if AE occurs in the same year as one in study end date, otherwise, December	study end date if AE occurs in the same year as one in study end date, otherwise, December 31

[1] Treatment start date: date of procedure

9.2.4. *Interim Analysis*

No interim analysis is planned for this study.

9.2.5. *Multicenter Studies*

There are up to 15 sites enrolling 200 subjects in the single arm study, data across all sites will be pooled to perform all primary and secondary analyses. No stratification analysis by sites will be performed.

9.2.6. *Multiple Comparisons/Multiplicity*

This is a prospective, multi-center, single-arm study. No comparisons will be performed. Therefore, no multiple comparisons or multiplicity will be conducted.

9.2.7. *Use of an Efficacy Subset of Patients*

It is not applicable to this study.

9.2.8. *Active Control Studies Intended to Show Equivalence*

It is not applicable to this study.

9.2.9. *Examination of Subgroups*

Primary endpoint will be analyzed by reasons for use of Scoreflex NC device.

9.2.10. *Analysis Windows and Definitions*

Analysis windows and definitions are not applicable as the subjects are complete at discharge. No follow up is conducted for this protocol.

9.3. Patient Disposition, Demographics and Other Baseline Characteristics

A tabulation of subject disposition will be presented including the number enrolled, the number of patients who received procedure, the number of major protocol violators, number of patients with available data of the primary endpoint, and the number of withdrawals, including reasons for withdrawal as documented on the CRF.

Baseline demographic characteristics will be summarized for ITT population. Other baseline characteristics will be reported as well.

9.3.1. *Listing of Individual Data*

A by-subject listing of demographic, endpoint event as well as angiographic core lab data will be provided.

9.4. Primary Endpoint Analysis

The primary endpoint is a device procedural success endpoint based on a composite of the following components:

- Successful delivery, inflation, deflation, and withdrawal of the study balloon
- No evidence of vessel perforation, flow limiting dissection (grade C or higher) or reduction in TIMI flow from baseline as related to the Scoreflex NC study balloon
- Final TIMI flow grade of 3 at the conclusion of the PCI Procedure

A patient's procedure is considered a success if all of three components are successful.

Number and percentages of each component above and the overall composite primary endpoint will be calculated and presented, by both patient level and lesion level, with two-sided 95% confidence intervals at index procedure, based on the Intent-to-Treat (ITT) and Per-Protocol (PP) population, respectively.

Because this study is a prospective, open label, multi-center, single arm, observation study, no formal hypothesis testing will be performed.

9.5. Secondary Endpoint Analyses

The secondary endpoints consist of angiographic procedural efficacy, clinical, and peri-procedural endpoints.

Binary secondary endpoint will be summarized using frequency, percentage, and two sided exact 95% confidence interval through hospital discharge based on the Intent-to-Treat (ITT) and Per-Protocol (PP) population, respectively.

For the continuous binary endpoint, i.e. Improvement in Minimum Lumen Diameter, the simple statistic description such as mean, median, and standard deviation will be presented.

9.6. Concomitant Medications and Medical History

The medical history and concomitant medication will be summarized in the subject demographic and discharge data.

9.7. Adverse Events

For adverse event (AE) analyses, summary tables and detailed patient listings will be provided for all major adverse cardiac events (MACE). Adverse Events will be summarized by relationship to the procedure, to the study device, and by seriousness. MACE will be reported on a per-patient level as a percent (%) of subjects whom experience at least one MACE. If a patient has more than one MACE, only one of MACEs will be used to calculate to percent of subjects who experienced at least one event. Except where indicated, a subject reporting the same MACE more than once will be counted once when calculating the number and percentage of subjects with that particular event.

A listing for MACE will be provided. All safety analyses will be based on the ITT Population.

9.8. Supportive Analyses

Additional analyses may be performed per sponsor's requests.

10. CHANGES TO ANALYSES PLANNED IN THE PROTOCOL

There were no changes to the analyses planned in the protocol.

11. REFERENCES

The Study Protocol (Study Protocol: VP-0730 Version 1), 2018. A Prospective, Open Label, Multi-center, Single Arm, Observational Study Designed to Evaluate the Safety and Device Procedural Success of the Scoreflex NC Scoring PTCA Catheter in Subjects with Stenotic Coronary Arteries during Percutaneous Coronary Intervention.

Clinical Trials Identifier: NCT03763747

12. CHANGES TO THE STATISTICAL ANALYSIS PLAN

Any changes to the planned statistical analyses made prior to the analysis of the primary endpoints will be documented in an amended SAP, which will be approved prior to performing the analyses. Any unanticipated changes from the planned statistical methods after analyzing the primary endpoint data will be documented in the clinical study report with a reason for the deviation.

Version/Date	Page(s)	Old Version	New Version	Reason for change
1.0/13JAN2020	N/A	N/A	N/A	
2.0/28MAY2020	25	1.0	2.0	Shell updates

13. STATISTICAL TABLES TO BE GENERATED

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Table 3. Baseline Patient Medical History - ITT Population
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Table 8. Scoreflex NC Device Usage (Lesion based) -ITT Population
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Table 10.1.1. Summary of Primary Endpoint Analysis by Subcomponents at Patient Level -ITT Population
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14. DATA LISTINGS TO BE GENERATED

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Listing 4.2 Angiographic Core Lab at Post-Scoreflex NC Coronary Dilation Catheter -ITT Population
Listing 4.3 Angiographic Core Lab at Post Procedure -ITT Population
Listing 5. Medical History -ITT Population

15. FIGURES TO BE GENERATED

No Figures will be produced.