A prospective, post-marketing, non-randomized, multi-center, single-arm clinical study to collect additional information about the safety and effectiveness of the NIRxcell™ Stent System in the treatment of *de novo* stenotic lesions in native coronary arteries in the US population

NIRTRAKS – (NIRxcell TRial for a post mArKet Study)

Clinical Investigation Protocol No: CV103-02
Version 3.0

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Statistical Analysis Plan
Final Version 3.2 Jun. 15, 2020

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DOCUMENT HISTORY:

Revision	Author	Date Reviewed/Revised	Changes	Reason for Changes
Draft Version 1.0	Yuyin Liu	July 8, 2015	New SAP	N/A
Draft Version 2.0	Yuyin Liu	July 28, 2015	Add tipping point analysis to Section 4.4.2; Multiple updates to several sections	Incorporate internal reviewer's comments
Draft Version 2.1	Yuyin Liu	October 18, 2016	Update the definition of procedure success	Incorporate sponsor's comments
Draft Version 3.0	Yuyin Liu	October 25, 2017	1. Reduction of the number of subjects to be enrolled to this study, as per FDA's approval, dated 10-Feb-2017. 2. No formal test will be performed on the primary endpoint. This will be a descriptive study. 3. Replacement of "Harvard Clinical Research Institute" with "Baim Institute for Clinical Research" throughout the document.	Per FDA's approval
Draft Version 3.1	Liyan Dong	December 4, 2017	Update the visit windows: 1. 1-year: changes from 360 ± 30 days to 365 ± 30 days; 2. 2-year: changes from 720 ± 30 days to 730 ± 30 days; 3. 3-year: changes from 1080 ± 30 days to 1095 ± 30 days;	Per sponsor's comments
Final Version 3.2	Qi Gao	June 15, 2020	Revise the table shell, keep the TLGs picked by sponsor.	Incorporate sponsor's comments

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1 INTRODUCTION

The purpose of the Statistical Analysis Plan for this study is to provide a framework in which answers to the protocol objectives may be achieved in a statistically rigorous fashion, without bias or analytical deficiencies. Specifically, this Plan has the following purposes:
To prospectively outline the types of analyses and presentations of data that will form the basis for conclusions to be reached that will 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 the medical device industry.
This statistical analysis plan (SAP) contains definitions of analysis populations, derived variables and statistical methods for the analysis of the NIRTRAKS – NIRxcell Trial for a post mArKet Study. This SAP specifies the pre-planned analyses and serves as the base for the clinical study report.

2 STUDY OBJECTIVES AND DESIGN

2.1 Overall Study Objectives

The purpose of this study is to collect and analyze additional information about the safety and effectiveness of the NIRxcell stents in the treatment of *de novo* stenotic lesions in native coronary arteries. Data will be collected at 30 days, 9 months and 1, 2 and 3 years post–index stenting procedure. The primary objective is to assess the incidence of TVF within 3 years after treatment with the NIRxcell Stent System.

The long-term safety of the stenting procedure, including the occurrence of complications, will be evaluated through clinical data obtained before, during and after stent placement. Initial effectiveness of stent placement will be evaluated by determining acute success, including device success, lesion success and procedure success. The primary clinical outcome of TVF at 3 years post–index stenting procedure as well as a number of secondary outcomes will be used to

determine the long-term clinical effectiveness of treating native coronary artery lesions with the investigational product.

The NIRTRAKS Post-Market Study will be performed according to the World Medical Association Declaration of Helsinki, and FDA regulation 21 Code of Federal Regulations (CFR) parts 803, 812, 50 & 54. The data collected will be used to support the post-market requirements for the NIRxcell Stent System.

2.2 Study Design

This is a prospective, post-marketing, non-randomized, multi-center, single-arm clinical study to collect additional information about the safety and effectiveness of the NIRxcell Stent System in the treatment of *de novo* stenotic lesions in native coronary arteries in the US population. A total of 65 subjects will be enrolled in up to 15 sites in the US. Clinical follow-up for all subjects will occur at 30 days, 9 months and 1, 2 and 3 years post–index stenting procedure. An unscheduled follow up may be conducted as clinically warranted.

2.2.1 Clinical Centers

The study will be conducted at a maximum of 15 centers in the United States.

2.2.2 Number of Subjects

This study will enroll 65 subjects.

2.2.3 Control of Systematic Error/Bias

By the nature of the type of the proposed study, blinding of the investigator and/or subject is not possible. However, several measures will be implemented for minimization of systematic error/bias:

- Basic screening will be completed by investigational sites of all potential candidates. Subjects who fail to meet the *clinical* inclusion and exclusion criteria will not be included in this study. Subjects who have met all the clinical inclusion and exclusion criteria will then be screened for angiographic eligibility criteria.
- All subjects who undergo angiographic screening will be entered onto the screening log. The screening log will include all subjects who have signed the informed consent.
- Measurements made by angiography will be standardized by use of an angiographic core laboratory. The core laboratory measurements will be used in all cases for purposes of data analysis.

  In determining subject eligibility for the study, the investigator's assessment of pre-procedure angiographic parameters will be used. However, the angiographic core laboratory will provide feedback to the sponsor concerning accuracy of assessments in relation to inclusion criteria such as lesion parameters and anatomic location.
- Electrocardiogram (ECG) tracings analysis will be standardized by use of an ECG core laboratory. The ECG core laboratory readings will be used in all cases for purposes of data analysis.
- Clinical monitors will verify subjects' data and ensure compliance with Good Clinical Practice (GCP), clinical protocol and other study requirements, according to the guidelines set forth in Baim Institute's monitoring standard operating procedures (SOP).
- An independent clinical events committee (CEC) will adjudicate all clinical endpoint events and investigator-reported adverse events that have the potential to be a clinical endpoint event. The CEC adjudication results will be used in all cases for purposes of data analysis.

2.2.4 Eligibility, Exclusions and Subject Discontinuations

All subjects presented to the angiographic suite for possible coronary artery revascularization are potential study candidates and will be screened for eligibility, and consented for possible inclusion. Every effort will be made to establish eligibility of the participants prior to enrollment. Prior to enrollment, subjects will have screening clinical laboratory, medical history and physical exams to verify qualification into the study. If conducted within the appropriate time windows,

and the subjects meet the pre-angiography inclusion and exclusion criteria, the screening results will also serve as baseline parameters. Angiographic eligibility will be based solely on angiography performed at the time of index procedure. Once a subject has signed the informed consent, angiographic eligibility has been confirmed, and the NIRxcell Stent System introduced into the subject's body, the subject is considered to be enrolled. Subjects who do not meet **all** inclusion (general and angiographic) criteria or meet **any** of the exclusion criteria should not be enrolled in the study. All subjects enrolled will be evaluated, regardless of sequence of treatment that ensues.

Once a subject has been enrolled in the study, he/she may withdraw his/her consent to participate in the study at any time without prejudice. Participation in this clinical investigation is entirely voluntary.

Possible reasons for subject discontinuation include but are not limited to the following:

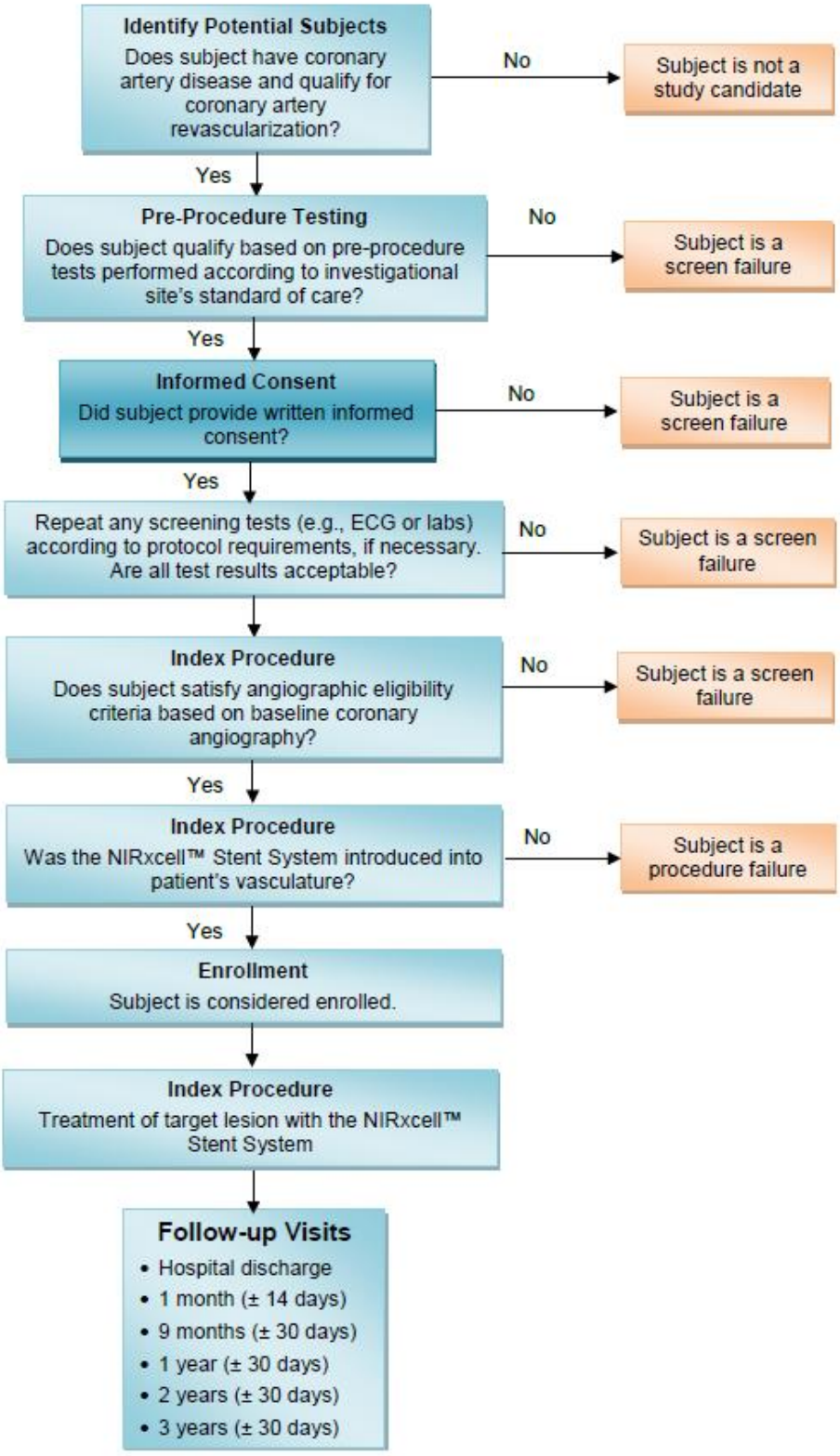
- Subject death
- Subject voluntary withdrawal
- Subject withdrawal by physician as clinically-indicated
- Subject lost-to follow-up as described below

Subjects withdrawn after treatment will not be required to undergo follow-up after withdrawal; however, they will still be considered part of the subject cohort.

All subjects enrolled in the study are considered eligible for follow-up and will be required to adhere to the follow-up schedule outlined in Section 2.2.6. If a subject cannot be contacted for a follow-up assessment and follow-up information cannot be obtained, he/she will be counted as "missed contact" for that specific schedule. Attempts shall be made to contact the subject in next follow-up schedule. A subject will be considered "lost to follow-up" only after the last scheduled follow-up assessment for that subject (3 years). If a subject is lost to follow-up, the methods used to attempt to contact the subject should be documented. At least 3 attempts should be made to contact the subject through all available routes, and a certified letter should be sent to the permanent address in file.

Figure 1 summarizes the above steps and follow-up period.

Figure 1: Study Flowchart



2.2.5 Scheduled Study Procedures

Table 1: Summary of Study Procedures from Screening through End of Follow-Up

Study Requirement	Screening		Procedure	Post-Procedure						
	Within 7 Days Prior to Procedure	24 Hours Prior to Procedure		Hospital Discharge	30 Days (±2 Weeks)	9 Months (±1 Month)	1 Year (±1 Month)	2 Years (±1 Month)	3 Years (±1 Month)	Unscheduled Visit /Phone
Informed consent	X									
Medical history	X									
Clinical assessment and physical exam	X			X						X(7)
Telephone assessment					X	X	X	X	X	X
CBC w/differential (1)	X									
Serum creatinine	X									
INR, APTT	X									X(7)
Pregnancy test	X(2)									
CK/CK-MB/ troponin		X(3)		X(6)						X(7)
12-lead ECG		X(4)								X(7)
Record of relevant medications (5)		X		X	X	X	X	X	X	X
Coronary angiography			X							
Stenting			X							
Record of adverse events			X	X	X	X	X	X	X	X

APTT: activated partial thromboplastin time; CBC: complete blood count; CK: creatinine kinase; CK-MB: creatinine kinase myocardial band; ECG: electrocardiogram; INR: international normalized ratio

(1) Collection of CBC differentials during the index hospitalization should be done as per the respective institutions standard of care. However, if the white blood count (WBC) is abnormal, it is recommended to perform the CBC differential before and after the procedure.

(2) For females of childbearing potential.

(3) Pre-procedure cardiac enzymes: CK, CK-MB or troponin performed within 24 hours prior to the procedure may be used as the baseline cardiac enzymes provided there have been no signs or symptoms of myocardial ischemia between the time of cardiac enzymes test and the time of arterial access.

(4) Pre-procedure 12-lead ECG: an ECG performed within 7 days prior to the procedure may be used as the baseline ECG provided there have been no signs or symptoms of myocardial ischemia between the time of ECG and the time of arterial access.

(5) Relevant medications: statins, angiotensin converting enzyme inhibitors (ACE-I), angiotensin receptor blockers (ARB), beta-blockers and anti-platelets.

(6) CK and CK-MB will be measured at 6- 8 hours post procedure, 12-16 hours post procedure and 20-24 hours post procedure (or upon discharge, whichever comes first). If any CK elevation (CK above ULN) is noted post procedure, CK and CK-MB measurements will continue to be performed every 8 hours for 24 hours starting from when the first elevation is noted and recorded on the appropriate eCRF. If total CK values are within normal ranges, CK-MB measurements may not be performed (per hospital standards). However, it is strongly encouraged that CK-MB measurements are obtained with every total CK drawn, even if CK values are within normal limits. It is also recommended that sites collect CK and CK-MB preferentially over troponin in the peri-procedural period subsequent to the index procedure. In the case where CK and CK-MB are not available, troponin can be used.

(7) These assessments and tests will be performed only if clinically warranted.

2.2.6 Follow-up Assessments

Follow-up will be conducted at 30 days, 9 months, and 1, 2, and 3 years post-procedure via telephone call. Refer to the text below for details. Additional unscheduled follow up visits/phone calls may occur as clinically warranted.

The window for the 30-day follow-up contact will be ±2 weeks. For the 1-, 2- and 3-year contacts, the window will be ±1 month.

1. **30-Day (±2 Weeks) Contact**
   - Record of relevant medications.
   - Record of all AEs that occurred since last subject contact.

2. **9-Month (±1 Month) Contact**
   - Record of relevant medications.
   - Record of all AEs that occurred since last subject contact.

3. **1-Year (±1 Month) Contact**
   - Record of relevant medications.
   - Record of all AEs that occurred since last subject contact.

4. **2-Year (±1 Month) Contact**
   - Record of relevant medications.
   - Record of all AEs that occurred since last subject contact.

5. **3-Years (±1 Month) Contact**
   - Record of relevant medications.
   - Record of all AEs that occurred since last subject contact.

6. **Unscheduled visit/Phone follow up**
   - Record of relevant medications.
   - Record of all AEs that occurred since last subject contact.
   - Additional assessments and tests may be performed if clinically warranted.

During each specified evaluation, the corresponding electronic case report form (eCRF) must be completed per the written instructions provided by the sponsor. Although not anticipated, should the appropriate authorized regulatory bodies request additional follow-up, the physicians and subjects will be requested to adhere accordingly.

3 ENDPOINTS

The following study endpoints will be evaluated in all subjects enrolled in the NIRTRAKS Post-Market Study.

3.1 Primary Endpoint

The primary endpoint for this study is TVF, which is defined as a composite of cardiac death, target vessel MI, or clinically driven TVR by percutaneous or surgical methods within 3 years post-procedure.

3.2 Secondary Endpoints

1. **TVF** at 9 Months

2. **All Cause Death** at 30 Days, and 1, 2 and 3 Years

3. **Cardiac Death** at 30 Days, and 1, 2 and 3 Years
   Cardiac death is defined as any death due to proximate cardiac cause (e.g. MI, low-output failure, fatal arrhythmia), unwitnessed death and death of unknown cause, and all procedure-related deaths, including those related to concomitant treatment.

4. **All Cause MI** at 30 Days, and 1, 2 and 3 Years
   MI is defined using the Academic Research Consortium (ARC) definitions.

5. **Target Vessel MI** at 30 Days, and 1, 2 and 3 Years
   Target vessel MI is defined as any MI attributed to the target vessel.

6. **Clinically Driven TLR** at 30 Days, and 1, 2 and 3 Years
   Clinically-driven target lesion revascularization (TLR) is defined as any revascularization at the target lesion that is associated with positive functional ischemia study or ischemic symptoms AND an angiographic minimal lumen diameter stenosis ≥50% by quantitative coronary angiography (QCA), or revascularization of a target lesion with diameter stenosis ≥70% by QCA without either angina or a positive functional study.

7. **Clinically Driven TVR** at 30 Days, and 1, 2 and 3 Years
   Clinically-driven target vessel revascularization (TVR) is defined as any revascularization in the target vessel that is associated with positive functional ischemia study or ischemic symptoms AND an angiographic minimal lumen diameter stenosis ≥50% by quantitative coronary angiography (QCA), or revascularization of a target vessel with diameter stenosis ≥70% by QCA without either angina or a positive functional study.

8. **Acute Success Rates**
   Device success is defined as the attainment of <50% final residual stenosis of the target lesion using only the NIRxcell Stent System.
   Lesion success is defined as the attainment of <50% final residual stenosis of the target lesion using any percutaneous method.
   Procedure success is defined as attainment of <50% residual stenosis of the target lesion and no in-hospital death, MI or TLR.

9. **Stent Thrombosis at Discharge, 30 Days, and 1, 2 and 3 Years**
   Acute stent thrombosis is defined as a thrombotic event occurring between 0 and 24 hours after stent implantation.
   Subacute stent thrombosis is defined as a thrombotic event occurring between 1 and 30 days after stent implantation.
   Late stent thrombosis is defined as a thrombotic event occurring between 30 days to 1 year after stent implantation.

4 STATISTICAL CONSIDERATIONS AND ANALYSIS PLAN

This is a prospective, multi-center, non-randomized, single-arm clinical study designed to collect additional information on the safety and efficacy of the NIRxcell Stent Systems in the treatment of *de novo* stenotic lesions in native coronary arteries in the US population. The primary endpoint to be evaluated in this study is TVF at 3 years, defined as a composite of cardiac death, target vessel MI, or clinically driven TVR by percutaneous or surgical methods within 3 years

post-procedure. The study will be conducted at a maximum of 15 centers in the United States, and will enroll 65 subjects. All analyses will be descriptive, as noted in Section 4.3.

4.1 Sample Size Determination

Per agreement with the FDA (FDA decision letter dated 2017 February 10, following review of supplement P110004/S021), a sample size of 65 subjects was deemed adequate to provide sufficient information about the study device. By accounting for approximately 7.0% loss to follow-up per-year, approximately 52 evaluable subjects will be available for analysis after 3 years.

4.2 Analysis Sets

4.2.1 Intention-to-Treat

The primary analysis set will be based on the principle of intention-to-treat. All statistical analyses in this study will be performed on the ITT population with each enrolled subject analyzed regardless of the actual treatment received.

4.2.2 Per-Protocol

Per-protocol (PP) analysis will also be conducted. Per-protocol is defined as all subjects who sufficiently comply with the study protocol. Compliance covers treatment received, availability of follow-up data (follow-up of at least 3 years, allowing for a visit window of 3 years ± 1 month), and absence of major protocol deviations.

4.3 Methods of Analyses

Descriptive statistics will be used to present the data and to summarize the results. Categorical variables will be presented using counts and percentages. Proportions will be calculated using known non-missing values. Continuous variables will be summarized by presenting the number of observations (N), mean, two-sided 95% confidence interval of the mean, standard deviation,

median, minimum and maximum values. Unless otherwise indicated, all statistical tests and/or confidence intervals will be performed at $\alpha = 0.05$ (two-sided).

For adverse event reporting, which includes the primary and secondary safety endpoints, the primary analysis will be based on subject counts, not event counts. A subject with more than one event will be counted only once toward the event rate based on the total number of subjects with adverse events. Additionally, an event rate based on event counts will also be presented in the adverse event tables. Unless specified otherwise, statistical significance will be declared if the two-sided p-value is < 0.05.

All statistical analyses will be performed using Statistical Analysis System (SAS) for Windows (version 9.4 or higher, SAS Institute Inc. Cary, NC) or other widely accepted statistical or graphical software. In general, data for all study subjects will be combined and presented. Individual data will be presented in subject listings.

4.3.1 Analysis of Demographics and Procedural Characteristics

Descriptive statistics will be generated for baseline demographics, procedural characteristics, and follow-up data collected. Categorical variables will be analyzed using frequency, incidence and event rate. For continuous variables collected in the study, analysis will include mean, median, standard deviation and range.

4.3.2 Analysis of Primary Endpoint

The primary endpoint for this study is TVF, which is defined as a composite of cardiac death, target vessel MI, or clinically driven TVR by percutaneous or surgical methods within 3 years post-procedure.

No formal statistical test will be performed, as this study is descriptive only. The TVF rate at 3 years and the exact two-sided 95% confidence intervals will be provided. In addition, the TVF at 3 years will be estimated for all ITT subjects by generating the two-sided 95% confidence

interval of the Kaplan-Meier estimate of the primary endpoint rate; subjects not experiencing the endpoint will be censored at 3 years post-procedure or day of withdrawal, whichever is earlier. Finally, the same analysis will be carried out on the PP population (secondary analysis).

4.3.3 Analysis of Secondary Endpoints

All secondary endpoints (listed below) are dichotomous variables. Secondary endpoints will be presented as the number and percentage of subjects experiencing the outcome, along with two-sided exact 95% confidence intervals of the percentages. Included in the denominators for each outcome will be patients experiencing the event within the period (e.g., 30 days for 30-day time point, 270 days for 9-month time point, 365 days for 1-year time point, 730 days for 2-year time point, and 1095 days for 3-year time point) or who have adequate follow-up (e.g., at least 16 days for 1-month time point, at least 240 days for the 9-month time point, at least 335 days for the 1-year time point, at least 700 days for 2-year time point, and at least 1065 days for 3-year time point).
In addition, a Kaplan-Meier (K-M) estimate of the event-free survival rate and its corresponding standard error will be presented for cardiac death, target vessel MI, clinically driven TLR and TVR, with a corresponding K-M curve.

The secondary endpoints that will be reported are as follows:

1. **TVF** at 9 Months.
2. **All cause death** at 30 days, and 1, 2 and 3 years.
3. **Cardiac death** at 30 days, and 1, 2 and 3 years.
4. **All cause MI** at 30 days, and 1, 2 and 3 years.
5. **Target vessel MI** at 30 days, and 1, 2 and 3 years.
6. **Clinically driven TLR** at 30 days, and 1, 2 and 3 years.
7. **Clinically driven TVR** at 30 days, and 1, 2 and 3 years.
8. **Acute success rates**

   Device success: Attainment of <50% final residual stenosis of the target lesion using the NIRxcell Stent System only.

Lesion success: Attainment of <50% final residual stenosis of the target lesion using any percutaneous method.

Procedure success: Attainment of <50% residual stenosis of the target lesion and no in-hospital death, MI or TLR.

9. **Stent thrombosis** at hospital discharge, at 30 days, and 1, 2 and 3 years.

4.4 Adverse Events

A Treatment Emergent Adverse Event (TEAE) is an event that emerges, or a pre-existing event that worsens, any time during or after stent implantation. Adverse events will be coded by the MedDRA system version 18.1 or later. The per-event and per-patient incidence of TEAEs will be presented overall and by MedDRA system organ class and preferred term. This will be repeated for serious TEAEs.

5 TABLES, FIGURES, and LISTINGS

Table 1.1a Primary Endpoints – Intention-to-Treat Analysis Set

Primary Endpoint	ITT Subjects with Available Data (N=xx subjects)	Two-sided Binomial Exact 95% CI
TVF at 3 years	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Cardiac Death	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Target Vessel MI	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Clinically-driven TVR	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]

Note: Events defined for the period of 3 year post-procedure follow up are reported for patients with at least 1050 days of follow-up or with event to 3 years (1080 days).

Table 1.1b Primary Endpoints – Per-Protocol Analysis Set

Table 1.2 Secondary Endpoints – Intention-to-Treat Analysis Set

	ITT Subjects (N=xx subjects)	Two-sided Binomial Exact 95% CI
TVF at 9 months	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
All Cause Death		
30-day	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
1-year	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
2-year	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
3-year	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Cardiac Death		
30-day	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
1-year	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
2-year	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
3-year	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
All Cause MI		
30-day	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
1-year	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
2-year	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
3-year	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Target Vessel MI		
30-day	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
1-year	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
2-year	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
3-year	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Clinically-driven TLR		
30-day	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
1-year	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
2-year	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
3-year	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Clinically-driven TVR		
30-day	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]

1-year	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
2-year	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
3-year	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Device Success[1]	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Lesion Success[2]	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Procedure Success[3]	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Stent Thrombosis		
Discharge	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
30-day	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
1-year	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
2-year	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
3-year	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]

1 Device success is defined as attainment of <50% final residual stenosis of the target lesion using only the NIRxcell Stent System.

2 Lesion success is defined as attainment of <50% final residual stenosis of the target lesion using any percutaneous method.

3 Procedure success is defined as attainment of <50% residual stenosis of the target lesion and no in-hospital death, MI, or TLR.

Events in this table have been adjudicated by the CEC.

Denominators for 30-day events will reflect the number of patients with an adjudicated event in 30 days or follow-up through 16 days.

Denominators for 9-month events will reflect the number of patients with an adjudicated event in 270 days or follow-up through 240 days.

Denominators for 1-year events will reflect the number of patients with an adjudicated event in 365 days or follow-up through 335 days.

Denominators for 2-year events will reflect the number of patients with an adjudicated event in 730 days or follow-up through 700 days.

Denominators for 3-year events will reflect the number of patients with an adjudicated event in 1095 days or follow-up through 1065 days.

Table 2 Enrollment by Site

Site	Site Name	Site Location	ITT Subjects (N=xx subjects)	Per Protocol Subjects (N=xx subjects)
001			xx	xx
002			xx	xx
Total			xx	xx

Table 3 Compliance Table -- Intention-to-Treat Analysis Set

Site	Index Procedure Form (received/expected, %)	30-Day Contact[1] (received/expected, %)	9-Month Contact[2] (received/expected, %)	1-Year Contact[3] (received/expected, %)	2-Year Contact[4] (received/expected, %)	3-Year Contact[5] (received/expected, %)
001	xx.xx% (xx/xx)	xx.xx% (xx/xx)	xx.xx% (xx/xx)	xx.xx% (xx/xx)	xx.xx% (xx/xx)	xx.xx% (xx/xx)
002	xx.xx% (xx/xx)	xx.xx% (xx/xx)	xx.xx% (xx/xx)	xx.xx% (xx/xx)	xx.xx% (xx/xx)	xx.xx% (xx/xx)
…		…	…	…	…	…
014						
015						
Total	xx.xx% (xx/xx)	xx.xx% (xx/xx)	xx.xx% (xx/xx)	xx.xx% (xx/xx)	xx.xx% (xx/xx)	xx.xx% (xx/xx)

1 Denominator for 30-Day contact includes patients who had 30-day visit form filled or patients who have reached 44 (30+14) days after procedure (data export date - procedure date) and excludes patients who died or withdrew before 44 days.

2 Denominator for 9-Month contact includes patients who had 9-month visit form filled or patients who have reached 300 (270+30) days after procedure (data export date - procedure date) and excludes patients who died or withdrew before 300 days.

3 Denominator for 1-year contact includes patients who had 1-year visit form filled or patients who have reached 395 (365+30) days after procedure (data export date - procedure date) and excludes patients who died or withdrew before 395 days.

4 Denominator for 2-year contact includes patients who had 2-year visit form filled or patients who have reached 760 (730+30) days after procedure (data export date - procedure date) and excludes patients who died or withdrew before 760 days.

5 Denominator for 3-year contact includes patients who had 3-year visit form filled or patients who have reached 1125 (1095+30) days after procedure (data export date - procedure date) and excludes patients who died or withdrew before 1125 days.

Table 4 Patient Disposition

	ITT Subjects (N=xx subjects) n (%)	Per Protocol Subjects (N=xx subjects) n (%)
Enrolled	xx (xx.xx%)	xx (xx.xx%)
Completed the study	xx (xx.xx%)	xx (xx.xx%)
Not completed all required follow-up visits	xx (xx.xx%)	xx (xx.xx%)
Primary reason for not completed		
Withdrew consent	xx (xx.xx%)	xx (xx.xx%)
Lost to follow-up	xx (xx.xx%)	xx (xx.xx%)
Adverse event	xx (xx.xx%)	xx (xx.xx%)
Death	xx (xx.xx%)	xx (xx.xx%)
Lack of efficacy	xx (xx.xx%)	xx (xx.xx%)
Protocol violation	xx (xx.xx%)	xx (xx.xx%)
Physician decision	xx (xx.xx%)	xx (xx.xx%)
Study cancelled	xx (xx.xx%)	xx (xx.xx%)
Other	xx (xx.xx%)	xx (xx.xx%)

Table 5 Demographic and Medical History – Intention-to-Treat Analysis Set

Characteristics	ITT Subjects (N=xx subjects)	95% CI
Demographics		
Age (yrs)		
Mean±SD (N)	xx.xx±xx.xx (xx)	[xx.xx, xx.xx]
Median (Q1, Q3)	xx.xx (xx.xx, xx.xx)	
Range (min, max)	(xx.xx, xx.xx)	
Male	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Ethnicity		
Hispanic or Latino	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Not Hispanic or Latino	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Race		
American Indian or Alaska Native	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Asian	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Black or African American	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Native Hawaiian or Other Pacific Islander	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
White	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Other	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Medical History/Risk Factor		
Previous MI	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Previous PCI	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Previous CABG	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Previous TIA	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Previous CVA	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Congestive Heart Failure	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Family History of Premature Coronary Artery Disease (CAD)	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]

Atrial Fibrillation	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Chronic Lung Disease/COPD	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Cancer	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Mental Illness	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Active GI Bleed	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Diabetes Mellitus	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Diet	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Insulin	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Oral Hypoglycemics	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Peripheral Vascular Disease	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Hypertension	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Hypercholesterolemia	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Chronic Renal Disease	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Receiving Dialysis	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Current Smoking Status		
Current Smoker	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Former Smoker	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Never Smoked	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
LVEF at most recent evaluation prior to index procedure		
Mean±SD (N)	xx.xx±xx.xx (xx)	[xx.xx, xx.xx]
Median (Q1, Q3)	xx.xx (xx.xx, xx.xx)	
Range (min, max)	(xx.xx, xx.xx)	

Table 6 Procedural Characteristic – Intention-to-Treat Analysis Set

Characteristics	ITT Subjects (N=xx subjects)	95% CI
Procedural Characteristic		
Time of Procedure (min)		
Mean±SD (N)	xx.xx±xx.xx (xx)	[xx.xx, xx.xx]
Median (Q1, Q3)	xx.xx (xx.xx, xx.xx)	
Range (min, max)	(xx.xx, xx.xx)	
Vascular Access Site		
Femoral	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Radial	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Other	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Number of Non-target Lesion treated		
0	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
1	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
2	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
3	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Other Devices used for the Target Lesion		
Atherectomy Device	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Laser Device	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Cutting Balloon	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Brachytherapy Device	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Thrombectomy	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Other	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Vascular Closure Device used	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Bailout Procedure Performed	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Lesion Characteristic		
Target Vessel Location		
LMCA	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]

LAD	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
LCX	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
RCA	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Target Lesion treated	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Native/*de novo* Lesion	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Pre-Procedure Diameter Stenosis (%)		
Mean±SD (N)	xx.xx±xx.xx (xx)	[xx.xx, xx.xx]
Median (Q1, Q3)	xx.xx (xx.xx, xx.xx)	
Range (min, max)	(xx.xx, xx.xx)	
Post-Procedure Diameter Stenosis (%)		
Mean±SD (N)	xx.xx±xx.xx (xx)	[xx.xx, xx.xx]
Median (Q1, Q3)	xx.xx (xx.xx, xx.xx)	
Range (min, max)	(xx.xx, xx.xx)	
Lesion Length (mm)		
Mean±SD (N)	xx.xx±xx.xx (xx)	[xx.xx, xx.xx]
Median (Q1, Q3)	xx.xx (xx.xx, xx.xx)	
Range (min, max)	(xx.xx, xx.xx)	
Reference Vessel Diameter (mm)		
Mean±SD (N)	xx.xx±xx.xx (xx)	[xx.xx, xx.xx]
Median (Q1, Q3)	xx.xx (xx.xx, xx.xx)	
Range (min, max)	(xx.xx, xx.xx)	
Tortuosity		
None	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Mild	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Moderate	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Severe	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Final Dissection Grade		
0	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
A	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
B	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
C	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
D	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]

E	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
F	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Pre-Procedure TIMI		
0	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
1	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
2	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
3	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Post-Procedure TIMI		
0	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
1	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
2	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
3	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Device Characteristics		
Reason for Deployment the study stent		
Treatment of Target Lesion	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Treatment of Non-target Lesion	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Treatment of complication (bailout)	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Other	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Pre-dilatation performed	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Maximum Balloon Diameter (mm)		
Mean±SD (N)	xx.xx±xx.xx (xx)	[xx.xx, xx.xx]
Median (Q1, Q3)	xx.xx (xx.xx, xx.xx)	
Range (min, max)	(xx.xx, xx.xx)	
Maximum Balloon Length (mm)		
Mean±SD (N)	xx.xx±xx.xx (xx)	[xx.xx, xx.xx]
Median (Q1, Q3)	xx.xx (xx.xx, xx.xx)	
Range (min, max)	(xx.xx, xx.xx)	
Maximum Balloon Pressure (atm)		
Mean±SD (N)	xx.xx±xx.xx (xx)	[xx.xx, xx.xx]
Median (Q1, Q3)	xx.xx (xx.xx, xx.xx)	
Range (min, max)	(xx.xx, xx.xx)	
Stent Location Relative to Lesion		

At Target Lesion	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Proximal to the Target Lesion	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Distal to the Target Lesion	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Other	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Post-dilatation performed	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Maximum Balloon Diameter (mm)		
Mean±SD (N)	xx.xx±xx.xx (xx)	[xx.xx, xx.xx]
Median (Q1, Q3)	xx.xx (xx.xx, xx.xx)	
Range (min, max)	(xx.xx, xx.xx)	
Maximum Balloon Length (mm)		
Mean±SD (N)	xx.xx±xx.xx (xx)	[xx.xx, xx.xx]
Median (Q1, Q3)	xx.xx (xx.xx, xx.xx)	
Range (min, max)	(xx.xx, xx.xx)	
Maximum Balloon Pressure (atm)		
Mean±SD (N)	xx.xx±xx.xx (xx)	[xx.xx, xx.xx]
Median (Q1, Q3)	xx.xx (xx.xx, xx.xx)	
Range (min, max)	(xx.xx, xx.xx)	
Outcome of Stent Deployment		
Stent Deployed	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Failed Delivery/Misplaced Stent	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Device Package opened, but not used	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Maximum Stent Deployment Pressure		
Mean±SD (N)	xx.xx±xx.xx (xx)	[xx.xx, xx.xx]
Median (Q1, Q3)	xx.xx (xx.xx, xx.xx)	
Range (min, max)	(xx.xx, xx.xx)	
Second Stent placed at the Target Lesion	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Overlapped with the Previous Stent	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]

Table 7 Stent Implanted by Diameter and Length - Intention-to-Treat Analysis Set

Any Stent

Characteristics	ITT Subjects (N=xx subjects, S=xx stents)	95% CI
Any Stent		
Diameter of Stent (mm)		
2.5	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
2.75	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
3.0	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
3.5	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
4.0	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Length of Stent (mm)		
8	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
12	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
17	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
20	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
24	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
28	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
33	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]

Any Stent	**Diameter (mm)**					
Length (mm)	**2.5**	**2.75**	**3.0**	**3.5**	**4.0**	**Total**
8	**xx**	**Xx**	**Xx**	**xx**	**xx**	**xx**
12	**xx**	**Xx**	**Xx**	**xx**	**xx**	**xx**
17	**xx**	**Xx**	**Xx**	**xx**	**xx**	**xx**
20	**xx**	**Xx**	**Xx**	**xx**	**xx**	**xx**
24	**xx**	**Xx**	**Xx**	**xx**	**xx**	**xx**
28	**xx**	**Xx**	**Xx**	**xx**	**xx**	**xx**
33	**xx**	**Xx**	**Xx**	**xx**	**xx**	**xx**
Total	**xx**	**Xx**	**Xx**	**xx**	**xx**	**xx**

Study Stent

Characteristics	ITT Subjects (N=xx subjects, S=xx stents)	95% CI
Study Stent		
Diameter of Stent (mm)		
2.5	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
2.75	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
3.0	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
3.5	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
4.0	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Length of Stent (mm)		
8	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
12	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
17	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
20	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
24	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
28	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
33	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]

Study Stent	**Diameter (mm)**					
Length (mm)	**2.5**	**2.75**	**3.0**	**3.5**	**4.0**	**Total**
8	**xx**	**Xx**	**Xx**	**xx**	**xx**	**xx**
12	**xx**	**Xx**	**Xx**	**xx**	**xx**	**xx**
17	**xx**	**Xx**	**Xx**	**xx**	**xx**	**xx**
20	**xx**	**Xx**	**Xx**	**xx**	**xx**	**xx**
24	**xx**	**Xx**	**Xx**	**xx**	**xx**	**xx**
28	**xx**	**Xx**	**Xx**	**xx**	**xx**	**xx**
33	**xx**	**Xx**	**Xx**	**xx**	**xx**	**xx**
Total	**xx**	**Xx**	**Xx**	**xx**	**xx**	**xx**

Non-Study Stent

Characteristics	ITT Subjects (N=xx subjects, S=xx stents)	95% CI
Non-Study Stent		
Diameter of Stent (mm)		
2.5	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
2.75	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
3.0	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
3.5	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
4.0	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Length of Stent (mm)		
8	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
12	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
17	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
20	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
24	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
28	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
33	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]

Non-Study Stent	**Diameter (mm)**					
Length (mm)	**2.5**	**2.75**	**3.0**	**3.5**	**4.0**	**Total**
8	**xx**	**Xx**	**Xx**	**xx**	**xx**	**xx**
12	**xx**	**Xx**	**Xx**	**xx**	**xx**	**xx**
17	**xx**	**Xx**	**Xx**	**xx**	**xx**	**xx**
20	**xx**	**Xx**	**Xx**	**xx**	**xx**	**xx**
24	**xx**	**Xx**	**Xx**	**xx**	**xx**	**xx**
28	**xx**	**Xx**	**Xx**	**xx**	**xx**	**xx**
33	**xx**	**Xx**	**Xx**	**xx**	**xx**	**xx**
Total	**xx**	**Xx**	**Xx**	**xx**	**xx**	**xx**

Table 8 Baseline Angiographic Findings -- Intention-to-Treat Analysis Set

	ITT Subjects (N=xx subjects)	95% CI
Lesion Location		
Prox	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Mid	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Distal	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Ostial	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Lesion Length (mm)		
Mean±SD (N)	xx.xx±xx.xx (xx)	[xx.xx, xx.xx]
Median (Q1, Q3)	xx.xx (xx.xx, xx.xx)	
Range (min, max)	(xx.xx, xx.xx)	
Eccentric	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Bend		
< 45 degrees	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
>= 45 degrees and <90 degrees	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
>= 90 degrees	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Thrombus	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Tortuosity		
Mild	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Moderate	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Severe	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Calcification		
Mild	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Moderate	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Severe	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Ulcerated	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Aneurysm	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Intimal Flap	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Ectasia	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]

Pre TIMI		
0	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
1	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
2	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
3	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Bifurcation	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Medina Bifurcation		
(1, 1, 1)	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
(1, 1, 0)	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
(1, 0, 1)	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
(0, 1, 1)	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
(1, 0, 0)	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
(0, 1, 0)	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
(0, 0, 1)	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Branch % Diameter Stenosis		
Mean±SD (N)	xx.xx±xx.xx (xx)	[xx.xx, xx.xx]
Median (Q1, Q3)	xx.xx (xx.xx, xx.xx)	
Range (min, max)	(xx.xx, xx.xx)	

Data presented in this table is from the Angiographic Core Laboratory.

Table 9 Quantitative Angiographic Findings – Intention-to-Treat Analysis Set

	ITT Subjects (N=xx subjects)	95% CI
Baseline		
Reference Vessel Diameter (mm)		
Mean±SD (N)	xx.xx±xx.xx (xx)	[xx.xx, xx.xx]
Median (Q1, Q3)	xx.xx (xx.xx, xx.xx)	
Range (min, max)	(xx.xx, xx.xx)	
MLD (mm)		
Mean±SD (N)	xx.xx±xx.xx (xx)	[xx.xx, xx.xx]
Median (Q1, Q3)	xx.xx (xx.xx, xx.xx)	
Range (min, max)	(xx.xx, xx.xx)	
% Diameter Stenosis		
Mean±SD (N)	xx.xx±xx.xx (xx)	[xx.xx, xx.xx]
Median (Q1, Q3)	xx.xx (xx.xx, xx.xx)	
Range (min, max)	(xx.xx, xx.xx)	
Final		
Reference Vessel Diameter (mm)		
Mean±SD (N)	xx.xx±xx.xx (xx)	[xx.xx, xx.xx]
Median (Q1, Q3)	xx.xx (xx.xx, xx.xx)	
Range (min, max)	(xx.xx, xx.xx)	
In-Segment MLD (mm)		
Mean±SD (N)	xx.xx±xx.xx (xx)	[xx.xx, xx.xx]
Median (Q1, Q3)	xx.xx (xx.xx, xx.xx)	
Range (min, max)	(xx.xx, xx.xx)	
In-Segment % Diameter Stenosis		
Mean±SD (N)	xx.xx±xx.xx (xx)	[xx.xx, xx.xx]
Median (Q1, Q3)	xx.xx (xx.xx, xx.xx)	
Range (min, max)	(xx.xx, xx.xx)	

In-Stent MLD (mm)		
Mean±SD (N)	xx.xx±xx.xx (xx)	[xx.xx, xx.xx]
Median (Q1, Q3)	xx.xx (xx.xx, xx.xx)	
Range (min, max)	(xx.xx, xx.xx)	
In-Stent % Diameter Stenosis		
Mean±SD (N)	xx.xx±xx.xx (xx)	[xx.xx, xx.xx]
Median (Q1, Q3)	xx.xx (xx.xx, xx.xx)	
Range (min, max)	(xx.xx, xx.xx)	
Prox Edge MLD (mm)		
Mean±SD (N)	xx.xx±xx.xx (xx)	[xx.xx, xx.xx]
Median (Q1, Q3)	xx.xx (xx.xx, xx.xx)	
Range (min, max)	(xx.xx, xx.xx)	
Prox Edge % Diameter Stenosis		
Mean±SD (N)	xx.xx±xx.xx (xx)	[xx.xx, xx.xx]
Median (Q1, Q3)	xx.xx (xx.xx, xx.xx)	
Range (min, max)	(xx.xx, xx.xx)	
Distal Edge MLD (mm)		
Mean±SD (N)	xx.xx±xx.xx (xx)	[xx.xx, xx.xx]
Median (Q1, Q3)	xx.xx (xx.xx, xx.xx)	
Range (min, max)	(xx.xx, xx.xx)	
Distal Edge % Diameter Stenosis		
Mean±SD (N)	xx.xx±xx.xx (xx)	[xx.xx, xx.xx]
Median (Q1, Q3)	xx.xx (xx.xx, xx.xx)	
Range (min, max)	(xx.xx, xx.xx)	

Data presented in this table is from the Angiographic Core Laboratory.

Table 10 Final Angiographic Findings – Intention-to-Treat Analysis Set

	ITT Subjects (N=xx subjects)	95% CI
Thrombus	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Aneurysm	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Final TIMI		
0	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
1	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
2	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
3	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
No Reflow	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Abrupt Closure	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Spasm	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Dissection		
0	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
A	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
B	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
C	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
D	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
E	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
F	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Staining	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Distal Embolism	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Perforation	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Branch % Diameter Stenosis		
Mean±SD (N)	xx.xx±xx.xx (xx)	[xx.xx, xx.xx]
Median (Q1, Q3)	xx.xx (xx.xx, xx.xx)	
Range (min, max)	(xx.xx, xx.xx)	

Data presented in this table is from the Angiographic Core Laboratory.

Table 11a Combined In and Out-of-Hospital Complications to xx days– Intention-to-Treat Analysis Set

	ITT Subjects (N=xx subjects)	95% CI
To 30-day		
TVF (Cardiac death, Target Vessel MI, and Clinically-driven TVR)	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Death	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Cardiac Death	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Non-Cardiac Death	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
All Cause MI (ARC)	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Peri-Procedural PCI		
Peri-Procedural CABG	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Spontaneous	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Silent	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Sudden Death	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Reinfarction	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Q wave MI	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Non-Q wave MI	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Target Vessel MI	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Target Vessel Q wave MI	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Target Vessel Non-Q wave MI	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Non-Target Vessel MI	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Non-Target Vessel Q wave MI	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Non-Target Vessel Non-Q wave MI	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
All Revascularization	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
PCI	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
CABG	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Clinically-driven Revascularization	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
PCI	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]

CABG	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Non-Clinically-driven Revascularization	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
PCI	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
CABG	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
All TLR	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
PCI	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
CABG	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Clinically-driven TLR	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
PCI	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
CABG	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Non-Clinically-driven TLR	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
PCI	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
CABG	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
All TVR	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
PCI	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
CABG	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Clinically-driven TVR	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
PCI	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
CABG	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Non-Clinically-driven TVR	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
PCI	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
CABG	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
All Non-TVR	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
PCI	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
CABG	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Stent Thrombosis	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Acute (0-24 hours)	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Subacute (1-30 days)	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
Late (31 days-1 year)	xx.xx% (xx/xx)	[xx.xx%, xx.xx%]
To 9-month		
To 1-year		
To 2-year		

To 3-year

Denominators for 30-day events will reflect the number of patients with an adjudicated event in 30 days or follow-up through 16 days.
Denominators for 9-month events will reflect the number of patients with an adjudicated event in 270 days or follow-up through 240 days.
Denominators for 1-year events will reflect the number of patients with an adjudicated event in 365 days or follow-up through 335 days.
Denominators for 2-year events will reflect the number of patients with an adjudicated event in 730 days or follow-up through 700 days.
Denominators for 3-year events will reflect the number of patients with an adjudicated event in 1095 days or follow-up through 1065 days.

Table 11b Combined In and Out-of-Hospital Complications to xx days– Per-Protocol Analysis Set

Table 12 Adverse Events – Intention-to-Treat Analysis Set

Adverse Events	**Number of Events**	**ITT Subjects (N=xx subjects)**
Any Adverse Event	xx	xx.xx% (xx/xx)
System Organ Class Term	xx	xx.xx% (xx/xx)
Preferred Term	xx	xx.xx% (xx/xx)

Table 13 Serious Adverse Events – Intention-to-Treat Analysis Set

Serious Adverse Events	**Number of Events**	**ITT Subjects (N=xx subjects)**
Any Serious Adverse Event	xx	xx.xx% (xx/xx)
System Organ Class Term	xx	xx.xx% (xx/xx)
Preferred Term	xx	xx.xx% (xx/xx)

Table 14 Device Malfunction, Failure or Misuse Issues – Intention-to-Treat Analysis Set

Device malfunction, failure, or misuse issue	Device-based (D=xx devices)	Subject-based (N=xx subjects)
Unable to cross lesion with device and removed	xx	xx.xx% (xx/xx)
Stent detachment	xx	xx.xx% (xx/xx)
Failure to deploy device	xx	xx.xx% (xx/xx)
Inability to retrieve catheter	xx	xx.xx% (xx/xx)
Dislodgement of device	xx	xx.xx% (xx/xx)
Device deployed at unintended site	xx	xx.xx% (xx/xx)
Balloon burst	xx	xx.xx% (xx/xx)
Other balloon failure	xx	xx.xx% (xx/xx)
Device opened but not used	xx	xx.xx% (xx/xx)
Physician decision not to use the study device	xx	xx.xx% (xx/xx)
Device explanted or removed	xx	xx.xx% (xx/xx)
Inadequate labeling	xx	xx.xx% (xx/xx)
Other	xx	xx.xx% (xx/xx)

Table 15 Protocol Deviation by Type – Intention-to-Treat Analysis Set

Protocol Deviations	ITT Subjects (N=xx subjects)
Informed Consent Violation	
Not obtained prior to study screening	xx.xx% (xx/xx)
Wrong version used	xx.xx% (xx/xx)
Expired version used	xx.xx% (xx/xx)
Not dated	xx.xx% (xx/xx)
Not signed	xx.xx% (xx/xx)
General Inclusion Criteria Violation	xx.xx% (xx/xx)
Angiographic Inclusion Criteria Violation	xx.xx% (xx/xx)
General Exclusion Criteria Violation	xx.xx% (xx/xx)
Angiographic Exclusion Criteria Violation	xx.xx% (xx/xx)
Follow-up Compliance Violation	
30-day visit out of window	xx.xx% (xx/xx)
30-day visit data obtained by medical records only	xx.xx% (xx/xx)
30-day visit not done	xx.xx% (xx/xx)
1-year visit out of window	xx.xx% (xx/xx)
1-year visit data obtained by medical records only	xx.xx% (xx/xx)
1-year visit not done	xx.xx% (xx/xx)
2-year visit out of window	xx.xx% (xx/xx)
2-year visit data obtained by medical records only	xx.xx% (xx/xx)
2-year visit not done	xx.xx% (xx/xx)
3-year visit out of window	xx.xx% (xx/xx)
3-year visit data obtained by medical records only	xx.xx% (xx/xx)
3-year visit not done	xx.xx% (xx/xx)
Lab Value Violation	
Pregnancy test (female subjects) not done	xx.xx% (xx/xx)
CBC not done	xx.xx% (xx/xx)
Chemistry not done	xx.xx% (xx/xx)
INR not done	xx.xx% (xx/xx)

aPTT not done	xx.xx% (xx/xx)
Baseline CK not done	xx.xx% (xx/xx)
Baseline CK-MB not done	xx.xx% (xx/xx)
Baseline troponin not done	xx.xx% (xx/xx)
Serial CK not done	xx.xx% (xx/xx)
Serial CK-MB not done	xx.xx% (xx/xx)
Clinical Assessment Violation	
Baseline 12-lead ECG not done	xx.xx% (xx/xx)
Baseline 12-lead ECG done out of window	xx.xx% (xx/xx)
Baseline ECG not 12-lead	xx.xx% (xx/xx)
Baseline ECG data not available	xx.xx% (xx/xx)
Baseline physical exam not done	xx.xx% (xx/xx)
Discharge physical exam not done	xx.xx% (xx/xx)
Procedural Angiography not done	xx.xx% (xx/xx)
Procedural Assessments Violation	
Pre-dilation not performed	xx.xx% (xx/xx)
Inappropriate size stent used	xx.xx% (xx/xx)
Inappropriate size balloon used for pre-dilatation	xx.xx% (xx/xx)
Unacceptable other therapies used	xx.xx% (xx/xx)
Treatment of target lesion not attempted	xx.xx% (xx/xx)
Target lesion not treated with NIRxcell	xx.xx% (xx/xx)
Target lesion treated not native/*de novo* lesion	xx.xx% (xx/xx)
Treatment of an additional lesion	xx.xx% (xx/xx)
Medication Violation	
Information regarding relevant medication not collected	xx.xx% (xx/xx)
Pre-procedure ASA dose not per protocol	xx.xx% (xx/xx)
ASA temporarily interrupted	xx.xx% (xx/xx)
ASA discontinued prior to study completion	xx.xx% (xx/xx)
ASA not taken at all	xx.xx% (xx/xx)
Pre-procedure Thienopyridine dose not per protocol	xx.xx% (xx/xx)
Thienopyridine temporarily interrupted prior to 1-month follow-up	xx.xx% (xx/xx)
Thienopyridine discontinued prior to 1-month follow-up	xx.xx% (xx/xx)

Thienopyridine not taken at all	xx.xx% (xx/xx)
Heparin/Bivalirudin not given per protocol	xx.xx% (xx/xx)
Nitroglycerin not given per protocol	xx.xx% (xx/xx)
Serious Adverse Event not reported within the Protocol required time frame	xx.xx% (xx/xx)
Other	xx.xx% (xx/xx)

Listing 1 Patient-based Listing

Site	Patient	Demographic Characteristics	Medical Historic Characteristics	Acute Success
xxx	Xxx	*Refer to Table 5*	*Refer to Table 5*	*Refer to Table 1.2*

Listing 2 Lesion-based Listing

Site	Patient	Lesion Length	Eccentric	Thrombus	Calcification	Baseline RVD	Baseline MLD	Baseline % DS	Final RVD	Final In-Segment MLD	Final In-Segment % DS	Final In-Stent MLD	Final In-Stent % DS
xxx	xxx												

Listing 3 Device Malfunction, Failure or Misuse Issues

Site	Patient	Stent Type	Stent location to lesion	Device malfunction, failure, or misuse issue
xxx	xxx	xxx	xxx	*Refer to Table 14*

Figure 1 Flow Chart – Intention-to-Treat Analysis Set

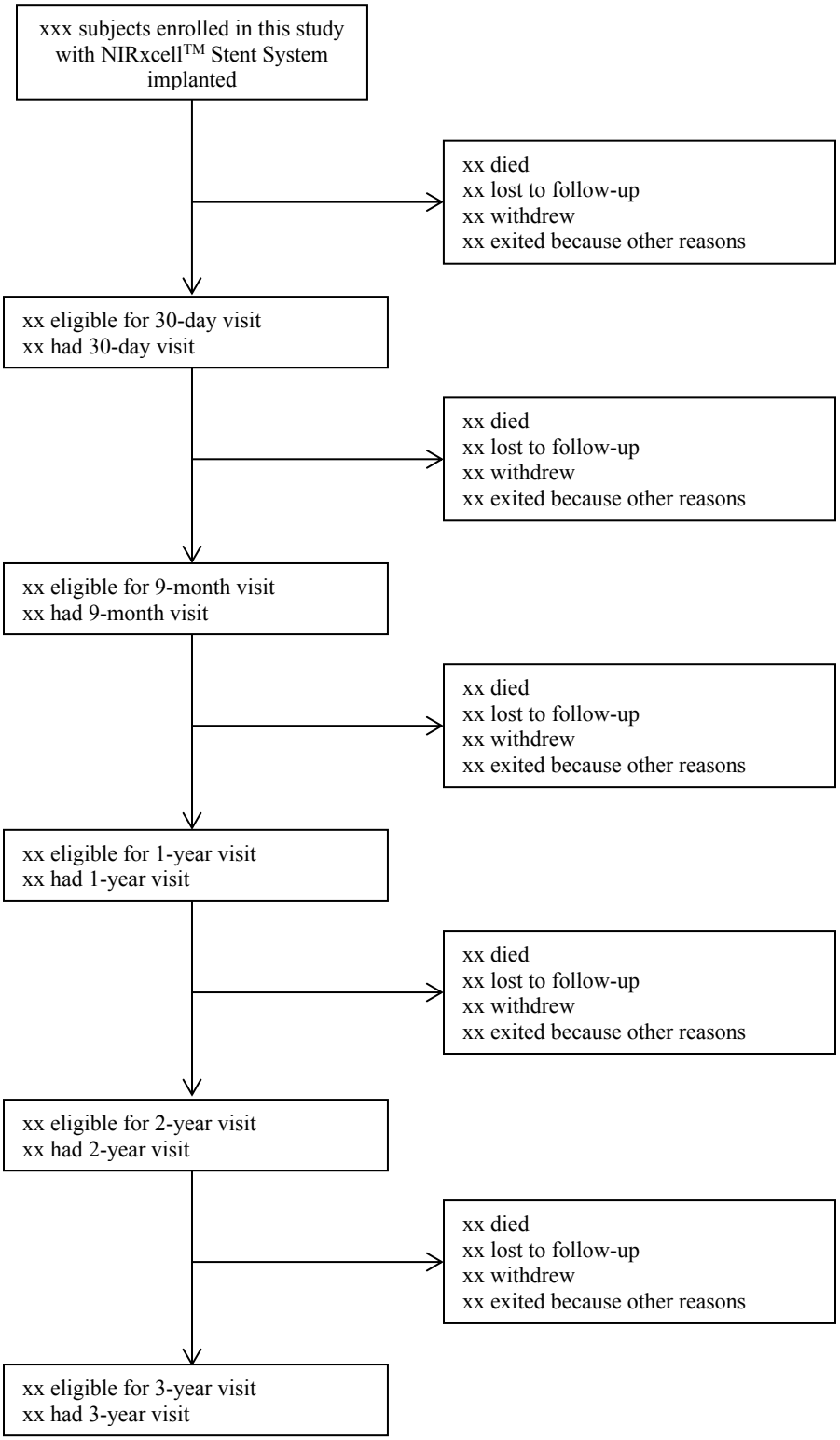


Figure 2 Kaplan-Meier Survival from TVF from Procedure to xx Days – Intent- to-Treat Analysis Set

	Time after Procedure (days)						
TVF	0	1-180	181-360	361-540	541-720	721-900	901-1080
# At Risk							
# Censored							
# Events							
% Survived							
SE							

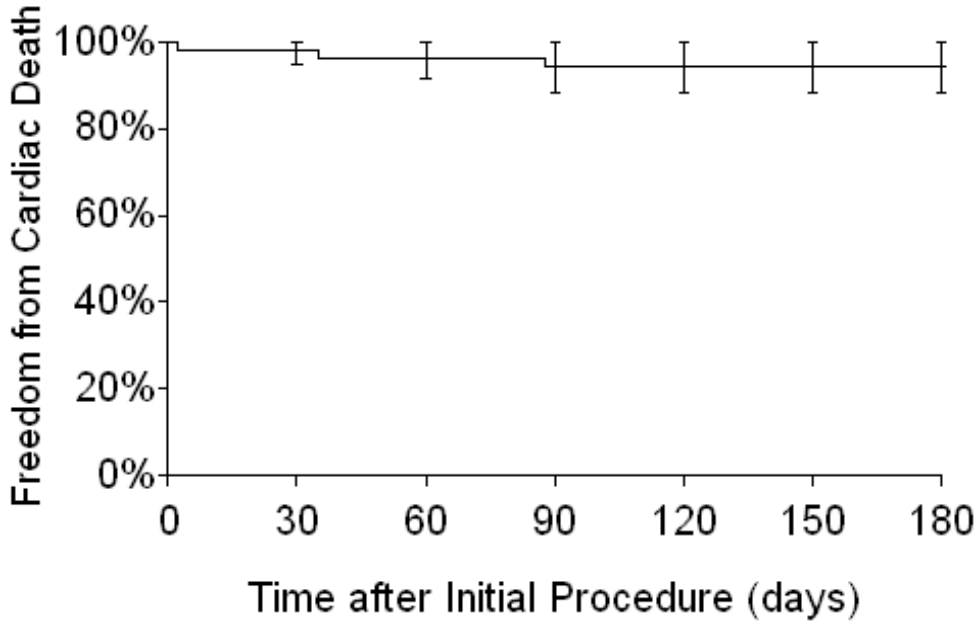


Figure 3 Kaplan-Meier Survival from Stent Thrombosis from Procedure to xx Days – Intention-to-Treat Analysis Set