Mount Sinai Heart

Statistical Analysis Plan

Protocol number: VP-0714rev 1.0

The **SAPPHIRE II PRO** Study

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Statistical Analysis Plan Signature Page

Sapphire II PRO US Clinical Study Protocol Ø1.0mm and 1.25mm
Protocol Number: VP-0714

Sponsor: OrbusNeich Medical

Date: September 25, 2017

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We, the undersigned, have read and approve this Statistical Analysis Plan and agree to its content.

Sponsor Representative

October 17, 2017
Date

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Date

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10/13/2017
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1. Table of Contents

1 Table of Contents 3
2 Abbreviations and Definitions 4
3 Introduction 5
3.1 Study Investigated Device 5
3.2 Purpose of the analyses 5
4 Study Overview (Design/Population/Timeline) 5
4.1 Selection for Entry into the Study 6
4.2 Subject Withdrawal Criteria 6
5 Endpoints 7
5.1 Primary Endpoint 7
5.2 Secondary Endpoints 7
5.2.1 Procedure-Related 7
5.2.2 In-hospital Clinical Safety and Efficacy 8
6 Study Variables 9
7 Analysis Populations 19
7.1 Full Analysis Population 19
8 Summary of Study Data 20
8.1 Listing of tables and mock tables 21

2. Abbreviations and Definitions

AE	adverse event
CEC	Clinical Events Committee
CRF	case report form
FDA	Food and Drug Administration
ICF	informed consent form
ICH	International Committee of Harmonization
IDE	Investigational Device Exemption
IRB	Institutional Review Board
MI	myocardial infarction
PCI	percutaneous coronary intervention
PTCA	Percutaneous Transluminal Coronary Angioplasty
QCA	quantitative coronary angiography
SAE	serious adverse event
TIMI	Thrombolysis In Myocardial Infarction
TLF	target lesion failure
TLR	target lesion revascularization
TVF	target vessel failure
TVR	target vessel revascularization
UADE	unanticipated adverse device event

3.Introduction

3.1Study Investigational Device

The Sapphire® II PRO Coronary Dilatation Catheter is a percutaneous transluminal coronary angioplasty (PTCA) balloon catheter with a working length of 140cm. The proximal shaft is a PTFE coated stainless steel hypotube. Hydrophilic lubricious coatings are applied to the distal section. The semi-compliant balloons are made of Nylon 12, available in diameters from 1.0 and 1.25 mm and lengths from 5-15mm, and can be inflated by injecting dilute contrast media solution through the trailing hub of the catheter. The nominal inflation pressure is 6 ATM and the rated burst pressure is 14 ATM. One radiopaque platinum marker band is centrally located within the balloon segment. The catheter is compatible with 5F or larger guiding catheters. The internal lumen of the catheter accepts a standard 0.014 inch PTCA guidewire. The proximal portion of the guidewire enters the catheter tip and advances coaxially out the catheter proximal port, thereby allowing both coaxial guidance and rapid exchange of catheters with a single standard length guidewire. Two marked sections are located on the hypotube shaft to indicate catheter position relative to the tip of either a brachial or femoral guiding catheter. The design of this dilatation catheter does not incorporate a lumen for distal dye injections or distal pressure measurements.

3.2.Purpose of the analyses

To assess the acute safety and device procedural success of the 1.0 and 1.25mm diameter Sapphire II PRO dilatation catheter in its intended use for the initial dilatation of coronary artery or by-pass graft stenosis (>70% diameter stenosis).

4.STUDY OVERVIEW

Study Plan/Design

A prospective, open label, multi-center, single arm, observational study designed to evaluate the acute safety and device procedural success of the Sapphire II PRO Ø1.0 and 1.25 mm PTCA dilatation catheters in subjects with stenotic coronary arteries or bypass grafts during percutaneous coronary intervention.

Study Population, Sites and Timeline.

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

Sixty (60) subjects will be treated at up to 5 U.S. sites with the Sapphire II PRO Ø 1.0 and 1.25 mm PTCA dilatation catheters to pre-dilate coronary arteries or bypass grafts during their index procedure. All subjects will be screened according to the protocol inclusion and exclusion criteria and will be followed through hospital discharge.

4.1.Selection for Entry into the Study

Once the subjects have signed the Institutional Review Board (IRB) approved study informed consent form (ICF) and research authorization forms (RA/HIPAA) and have met all general inclusion and exclusion criteria shown in the protocol, the subjects will be considered eligible to be enrolled in the study to receive treatment with the either the 1.0 or 1.25 mm diameter Sapphire II PRO dilatation catheter. A subject is considered enrolled in the study upon insertion of the investigational device into a guide catheter. Upon enrolment, a subject identification number will be assigned to each subject in a consecutive manner within each clinical site.

4.2.Subject Withdrawal Criteria

Each enrolled subject shall remain in the study until completion of the required follow-up period, however, a subject's participation in any clinical study is voluntary and the patient has the right to withdraw at any time without penalty or loss of benefit. Conceivable reasons for discontinuation may include, but not be limited to, the following:

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

The reason for subject discontinuation must be documented on the CRF and source documents. The Primary Investigators must also report all subject discontinuations to their IRB, MEC, or HREC as defined by their Institution's procedure.

5.Endpoints

5.1.Primary Endpoint

The study primary end-point shall be defined as Device Procedural Success consisting of a composite of the following parameters:

- 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 related to the study balloon
- Final TIMI flow grade of 3 at the conclusion of the PCI procedure

5.2.Secondary Endpoints

5.2.1.Procedure-Related

The following peri-procedural end-points of study device effectiveness will be determined:

- Successful delivery, inflation, deflation, and withdrawal of the study balloon
- Absence of vessel perforation, flow limiting dissection (grade C or higher, or reduction in TIMI flow from baseline related to the study balloon
- Absence of balloon rupture of the study balloon
- Improvement in Minimum Lumen Diameter (MLD) following pre-dilatation with Sapphire II PRO Ø 1.0 and 1.25 mm PTCA dilatation catheters (measured by QCA)
- And Lesion Success defined as successful PCI in the absence of vessel perforation, flow limiting dissection (grade C or higher, reduction in TIMI flow from baseline related to the study balloon, or clinically significant arrhythmias

5.2.2.In-hospital Clinical Safety and Efficacy

The following end-points will be measured through hospital discharge:

- In-hospital Major Adverse Cardiac Events (MACE), a composite of:

  - All death (cardiac and non-cardiac)
  - Myocardial infarction (MI)
- Target Lesion Revascularization (TLR), clinically indicated
- Individual components of the MACE composite end-point
- In-hospital Target Lesion Failure (TLF) a composite of:
  - Cardiac death
  - Target vessel MI
  - TLR, clinically indicated
- In-hospital stent thrombosis (ST) within the target vessel
- Clinically significant arrhythmias (requiring intervention)

6.Study Variables

The SAPPHIRE II PRO study variables consist of information blocks containing baseline data, information about the procedure, and clinical events up to discharge.

7. Analysis Populations

7.1.Full Analysis Population

This study is designed as a single-arm observational trial. The study sample size is based upon 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.

All analyses will be performed on an intent-to-treat basis. The baseline demographic and lesion characteristics and angiographic and clinical outcomes will be evaluated by descriptive statistics. These calculations will be performed under the assumption that the data are in a normal distribution. All enrolled subjects will be analyzed on an intent-to-treat (ITT) basis as well as per protocol criteria.

7.2 Summary of Study Data

The baseline demographic and lesion characteristics and angiographic and clinical outcomes will be evaluated by descriptive statistics. These calculations will be performed under the assumption that the data are in a normal distribution. All continuous variables will be summarised using the following descriptive statistics: n (non-missing sample size), mean and standard deviation. The frequency and percentages (based on the non-missing sample size) of observed levels will be reported for all categorical measures. Deaths, Serious Adverse Events and other Significant Adverse Events will be reported as number and percentage. All analyses will be performed using SAS version 9.4 (NC, USA).

Lesion related outcomes were assessed using core lab data. Where core lab was not analyzable, site reported data were used. No outcomes were imputed.

8.1. Listing of Tables and mock tables

This section gives details on mock tables.

Table Listings

Number	Table Title	Summary Statistics
1	Primary end-point	n (%)
2	Secondary end-points	n (%)
3	Summary of baseline patient characteristics	n, mean, SD, Median, min, max, n (%)
4	Summary of discharge patient data	n, mean, SD, Median, min, max, n (%)
5	Summary of procedural patient characteristics	n, mean, SD, Median, min, max, n (%)
6	Summary of site reported lesion level Data	n, mean, SD, Median, min, max, n (%)
7	Core lab lesion level data	n, mean, SD, Median, min, max, n (%)
8	Lesion level study outcomes	n, mean, SD, Median, min, max, n (%)
9	In-hospital patient level outcomes	n (%)

Table 1: Primary End-Point:

	Overall population N = patients
Primary Endpoint	
Successful balloon delivery to the target lesion	
No	
Yes	
Successful inflation at the target lesion	
No	
Yes	
Successful deflation and withdrawal of the study balloon	
No	
Yes	
Vessel Perforation	
No	
Yes	
Flow limiting dissection (Grade C or Higher)	
No	
Yes	
No reduction in TIMI flow from baseline related to the study balloon (i.e. TIMI>=0)	
No	
Yes	
Final TIMI flow grade of 3 at the conclusion of the PCI procedure	
No	
Yes	

Table 2: Secondary End-Points:

	Overall population N = patients
Successful balloon delivery to the target lesion	
No	
Yes	
Successful inflation at the target lesion	
No	
Yes	
Successful deflation and withdrawal of the study balloon	
No	
Yes	
Vessel Perforation	
No	
Yes	
Flow limiting dissection (Grade C or Higher)	
No	
Yes	
No reduction in TIMI flow from baseline related to the study balloon (i.e. TIMI>=0)	
No	
Yes	
Final TIMI flow grade of 3 at the conclusion of the PCI procedure	
No	
Yes	
Balloon rupture of the study balloon	
No	
Yes	
Improvement in Minimum Lumen Diameter	
No	
Yes	
Lesion success	
No	
Yes	
Vessel Perforation	
No	
Flow limiting dissection (Grade C or Higher)	
No	
Yes	
No reduction in TIMI flow from baseline related to the study balloon (i.e. TIMI>=0)	
No	
Yes	

	Overall population N = patients
Clinically Significant Arrythmia	
No	
Yes	

Table 3: Baseline patient characteristics:

	Overall population N = patients
CLINICAL CHARACTERISTICS	
Age (Years)	
N, N Missing	
Mean ± Std	
Min , Max	
Median (IQR)	
Gender	
Female	
Male	
Race	
Asian	
Black	
White	
BMI (kg/m^2)	
N, N Missing	
Mean ± Std	
Min , Max	
Median (IQR)	
Diabetes Mellitus	
No	
Yes	
Diabetes Treatment	
Diet	
Insulin	
None	
Oral Medication	
Current Cigarette smoking (within 30 days)	
No	
Yes	
Hypercholesterolemia (requiring treatment)	
No	
Yes	
Hypertension (requiring treatment)	
No	
Yes	
Peripheral arterial disease (arms, legs, renal, mesenteric, aneurysm)	
No	
Yes	
Previous history of stroke more than 6 months prior	

	Overall population N = patients
No	
Yes	
Prior myocardial infarction	
No	
Yes	
Previous PCI	
No	
Yes	
Previous CABG	
No	
Yes	
Left ventricular ejection fraction	
30-40%	
>40%	
Unknown	
Angina status	
Asymptomatic	
NSTEMI	
Stable angina	
Unstable angina	
CCS Class	
0	
I	
II	
III	
IV	
Heart failure NYHA class III or IV	
No	
Yes	
Extent of coronary artery disease (number of vessels with CAD >= 50%)	
1	
2	
3	
BASELINE MEDICATIONS	
ACE inhibitors or ARB	
No	
Yes	
Beta-blockers	
No	
Yes	
Calcium channel blockers	

	Overall population N = patients
No	
Yes	
Long-acting nitrate	
No	
Yes	
Ranexa	
No	
Yes	
Oral Anticoagulation	
No	
Yes	
Statins	
No	
Yes	
Proton pump inhibitor	
No	
Yes	
Aspirin	
No	
Yes	
P2Y12 inhibitor	
Clopidogrel	
None	
Prasugrel	
Ticagrelor	
BASELINE LABS	
Creatinine	
N, N Missing	
Mean ± Std	
Min , Max	
Median (IQR)	
Hemoglobin	
N, N Missing	
Mean ± Std	
Min , Max	
Median (IQR)	
White cell count (10^9/L)	
N, N Missing	
Mean ± Std	
Min , Max	
Median (IQR)	

	Overall population N = patients
Platelets	
N, N Missing	
Mean ± Std	
Min , Max	
Median (IQR)	
Troponin	
N, N Missing	
Mean ± Std	
Min , Max	
Median (IQR)	
CKMB	
N, N Missing	
Mean ± Std	
Min , Max	
Median (IQR)	
BASELINE ECG	
12-lead electrocardiogram performed	
No	
Yes	
Rhythm	
AF/flutter	
Other	
Sinus Rhythm	
Q wave	
No	
Yes -Existing	
ST-segment depression or elevation	
No	
Yes - Existing	
Yes - New	

Table 4: Discharge patient data

	Overall population N = patients
DISCHARGE	
Did any complications occur before discharge	
No	
Did the patient complete all study related activities at the time of discharge?	
No	
Yes	
Was there a protocol deviation?	
No	
Yes	
DISCHARGE CARDIAC ENZYMES	
Troponin	
N, N Missing	
Mean ± Std	
Min , Max	
Median (IQR)	
CKMB (Immediately after procedure)	
N, N Missing	
Mean ± Std	
Min , Max	
Median (IQR)	
CKMB (6-12h after PCI)	
N, N Missing	
Mean ± Std	
Min , Max	
Median (IQR)	
CKMB (18-24h after PCI or prior to discharge)	
N, N Missing	
Mean ± Std	
Min , Max	
Median (IQR)	
POST PCI LABS	
Lowest Hemoglobin value	
N, N Missing	
Mean ± Std	
Min , Max	
Median (IQR)	
Highest Creatinine value	
N, N Missing	
Mean ± Std	

	Overall population N = patients
Min , Max	
Median (IQR)	
Patient required new hemodialysis post-PCI	
Missing	
No	
POST PCI ECG	
12-lead electrocardiogram performed	
No	
Yes	
Rhythm	
AF/flutter	
Other	
Sinus Rhythm	
Q wave	
No	
Yes - Existing	
ST-segment depression or elevation	
No	
Yes - Existing	
POST PCI MEDICATIONS	
ACE inhibitors or ARB	
No	
Yes	
Beta-blockers	
No	
Yes	
Calcium channel blockers	
No	
Yes	
Long-acting nitrate	
No	
Yes	
Ranexa	
No	
Yes	
Oral Anticoagulation	
No	
Yes	
Statins	
No	
Yes	

	Overall population N = patients
Proton pump inhibitor	
No	
Yes	
Aspirin	
No	
Yes	
P2Y12 inhibitor	
Clopidogrel	
None	
Prasugrel	
Ticagrelor	

Table 5: Procedural patient characteristics

	Overall population N = patients
PROCEDURAL CHARACTERISTICS	
Number of lesions per patients	
Multiple	
Single	
Extent of coronary artery disease (number of vessels with CAD >= 50%)	
1	
2	
3	
Presence of Left main disease >= 50%	
No	
Yes	
Total contrast volume used (diagnostic and intervention) (ml)	
N, N Missing	
Mean ± Std	
Min , Max	
Median (IQR)	
Procedure duration (min)	
N, N Missing	
Mean ± Std	
Min , Max	
Median (IQR)	
Total fluroscopy time (min)	
N, N Missing	
Mean ± Std	
Min , Max	
Median (IQR)	
Specify arterial sheath access	
Femoral	
Radial	
Procedural medication (within 72 hours of PCI)	
Bivalirudin	
Low molecular weight heparin	
Unfractionated heparin	
Heart rate(beats per min)	
N, N Missing	
Mean ± Std	
Min , Max	
Median (IQR)	

	Overall population N = patients
Systolic Blood Pressure(mmHg)	
N, N Missing	
Mean ± Std	
Min , Max	
Median (IQR)	
Diastolic Blood Pressure(mmHg)	
N, N Missing	
Mean ± Std	
Min , Max	
Median (IQR)	

Table 6: Lesion level data (Site reported)

	Overall population N = lesions
LESION CHARACTERISTICS	
SAPPHIRE II PRO Device size	
1.0 x 10 mm	
1.0 x 15 mm	
1.0 x 8 mm	
1.25 x 10 mm	
1.25 x 15 mm	
1.25 x 5 mm	
1.25 x 8 mm	
Vessel treated	
Bypass graft	
Diagonal branch of LAD	
LAD	
LCx	
Marginal branch of LCx	
Posterior descending branch of RCA	
RCA	
Lesion location	
Distal	
Mid	
Ostial	
Prox	
Number of inflations per lesion	
0	
1	
2	
3	
Successful baloon delivery to the target lesion	
Yes	
Successful baloon inflation and deflation at the target lesion	
No	
Yes	
Inflation pressure (atm)	
N, N Missing	
Mean ± Std	
Min , Max	
Median (IQR)	
Number of inflations per lesion	
01	

	Overall population N = lesions
02	
03	
04	
05	
06	
Was there balloon rupture?	
No	
Yes	
Successful withdrawal of the balloon from the target lesion	
Yes	
Was any post-dilation performed with stent implantation?	
No	
Not applicable	
Yes	
Was post procedural TIMI flow <3 at any lesion?	
No	
Yes	
Stent type implanted	
Biodegradable polymer stent (eg. Synergy)	
None	
Other	
Resolute	
Xience	
Stent implanted	
No	
Yes	

Table 7: Core lab lesion level data

	Overall population N = lesions
CASS Segment	
N, N Missing	
Mean ± Std	
Min , Max	
Median (IQR)	
CORE LAB	
Lesion location	
Missing	
Distal	
Mid	
Ostial	
Prox	
Lesion Length analyzable	
Missing	
No	
Lesion length (mm)	
N, N Missing	
Mean ± Std	
Min , Max	
Median (IQR)	
Eccentricity	
Missing	
Concentric	
Eccentric	
Thrombus	
Missing	
No	
Yes	
Tortuosity	
Missing	
None	
Calcification	
Missing	
Mod	
None	
Not-analyzable	
Severe	
Ulceration	
Missing	

	Overall population N = lesions
No	
Yes	
Aneurysm	
Missing	
No	
Intimal Flap	
Missing	
No	
Pre TIMI	
Missing	
0	
1	
2	
3	
Number of frames	
N, N Missing	
Mean ± Std	
Min , Max	
Median (IQR)	
Bifurcation	
Missing	
No	
Yes	
Prox Main branch	
Missing	
No	
Not-analyzable	
Yes	
Distal Main branch	
Missing	
No	
Not-analyzable	
Yes	
Side branch	
Missing	
No	
Not-analyzable	
Yes	
Branch diameter stenosis analyzable	
Missing	
No	

	Overall population N = lesions
Yes	
Branch diameter stenosis, %	
N, N Missing	
Mean ± Std	
Min , Max	
Median (IQR)	
Prox Normal analyzable	
Missing	
No	
Prox Normal(mm)	
N, N Missing	
Mean ± Std	
Min , Max	
Median (IQR)	
Distal Normal analyzable	
Missing	
No	
Distal Normal(mm)	
N, N Missing	
Mean ± Std	
Min , Max	
Median (IQR)	
MLD analyzable	
Missing	
No	
MLD(mm)	
N, N Missing	
Mean ± Std	
Min , Max	
Median (IQR)	
Prox Normal analyzable	
Missing	
No	
Yes	
Prox Normal(mm)	
N, N Missing	
Mean ± Std	
Min , Max	
Median (IQR)	
Distal Normal analyzable	
Missing	

	Overall population N = lesions
No	
Yes	
Distal Normal(mm)	
N, N Missing	
Mean ± Std	
Min , Max	
Median (IQR)	
MLD analyzable	
Missing	
No	
Yes	
MLD(mm)	
N, N Missing	
Mean ± Std	
Min , Max	
Median (IQR)	
CORONARY DILATATION CATHETER	
Aneurysm	
Missing	
No	
Not-analyzable	
Post TIMI	
1	
2	
3	
Number of frames analyzable	
Missing	
No	
Yes	
Number of frames	
N, N Missing	
Mean ± Std	
Min , Max	
Median (IQR)	
No Reflow	
Missing	
No	
Not-analyzable	
Abrupt closure	
Missing	
No	

	Overall population N = lesions
Not-analyzable	
Dissection	
0	
Stalning	
Missing	
Not-analyzable	
Dissection Length analyzable	
Missing	
No	
Dissection Length (mm)	
N, N Missing	
Mean ± Std	
Min , Max	
Median (IQR)	
Branch % stenosis analyzable	
Missing	
No	
Yes	
Branch % Stenosis	
N, N Missing	
Mean ± Std	
Min , Max	
Median (IQR)	
Distal embolus	
Missing	
No	
Not-analyzable	
Perforation	
No	
Spasm	
Missing	
No	
Not-analyzable	
PROJECTION #1	
Prox Normal analyzable	
Missing	
No	
Yes	
Prox Normal(mm)	
N, N Missing	
Mean ± Std	

	Overall population N = lesions
Min , Max	
Median (IQR)	
Distal Normal analyzable	
Missing	
No	
Yes	
Distal Normal(mm)	
N, N Missing	
Mean ± Std	
Min , Max	
Median (IQR)	
MLD analyzable	
Missing	
No	
Yes	
MLD(mm)	
N, N Missing	
Mean ± Std	
Min , Max	
Median (IQR)	
PROJECTION #2	
Prox Normal analyzable	
Missing	
No	
Yes	
Prox Normal(mm)	
N, N Missing	
Mean ± Std	
Min , Max	
Median (IQR)	
Distal Normal analyzable	
Missing	
No	
Yes	
Distal Normal(mm)	
N, N Missing	
Mean ± Std	
Min , Max	
Median (IQR)	
MLD analyzable	
Missing	

	Overall population N = lesions
No	
Yes	
MLD(mm)	
N, N Missing	
Mean ± Std	
Min , Max	
Median (IQR)	
FINAL POST-PROCEDURE	
Thrombus	
Missing	
No	
Not-analyzable	
Aneurysm	
Missing	
No	
Not-analyzable	
Post TIMI	
0	
3	
Number of frames analyzable	
Missing	
No	
Yes	
Number of frames	
N, N Missing	
Mean ± Std	
Min , Max	
Median (IQR)	
No Reflow	
Missing	
No	
Abrupt closure	
Missing	
No	
Yes	
Dissection	
Missing	
0	
Staining	
Missing	
Not-analyzable	

	Overall population N = lesions
Dissection Length analyzable	
Missing	
Yes	
Dissection Length(mm)	
Missing	
Branch % stenosis analyzable	
Missing	
No	
Yes	
Distal embolus	
Missing	
Yes	
Perforation	
Missing	
No	
Spasm	
Missing	
No	
PROJECTION #1	
Prox Normal analyzable	
Missing	
No	
Prox Normal(mm)	
N, N Missing	
Mean ± Std	
Min , Max	
Median (IQR)	
Distal Normal analyzable	
Missing	
No	
Distal Normal(mm)	
N, N Missing	
Mean ± Std	
Min , Max	
Median (IQR)	
MLD analyzable	
Missing	
No	
MLD(mm)	
N, N Missing	
Mean ± Std	

	Overall population N = lesions
Min , Max	
Median (IQR)	
PROJECTION #2	
Prox Normal analyzable	
Missing	
No	
Yes	
Prox Normal(mm)	
N, N Missing	
Mean ± Std	
Min , Max	
Median (IQR)	
Distal Normal analyzable	
Missing	
No	
Yes	
Distal Normal(mm)	
N, N Missing	
Mean ± Std	
Min , Max	
Median (IQR)	
MLD analyzable	
Missing	
No	
Yes	
MLD(mm)	
N, N Missing	
Mean ± Std	
Min , Max	
Median (IQR)	

Table 8: Lesion level study outcomes

	Overall population N = lesions
Device related primary endpoint composite	
Successful delivery, inflation, deflation and withdrawal of the study balloon	
No	
Yes	
Successful delivery	
No	
Yes	
Inflation	
No	
Yes	
Withdrawal of the study balloon	
No	
Yes	
No evidence of vessel perforation, flow limiting dissection (grade C or higher) or reduction in TIMI	
No	
Yes	
Vessel perforation	
No	
Yes	
Lesion Success	
No	
Yes	
Vessel perforation	
No	
Yes	
Flow limiting dissection (grade C or higher)	
No	
Yes	
Flow limiting dissection (grade C or higher)	
No	
Yes	
Clinically significant arrhythmia	
No	
Yes	
No reduction in TIMI flow from baseline related to the study balloon (i.e. TIMI>=0)	
No	
Yes	
No reduction in TIMI flow from baseline related to the study balloon (i.e. TIMI>=0)	
No	

	Overall population N = lesions
Yes	
Change in Minimum lumen diameter, pre and post balloon dilation	
N, N Missing	
Mean ± Std	
Min , Max	
Median (IQR)	
Final TIMI flow grade of 3 at the conclusion of the PCI procedure	
No	
Yes	
Improvement in Minimum Lumen Diameter	
No	
Yes	
Balloon rupture	
No	
Yes	

Table 9: In-hospital patient level outcomes

	Overall population N = patients
MACE, composite of all death, MI or clinically indicated TLR	
Death	
MI	
Clinically indicated TLR	
Target lesion failure, composite of cardiac death, target vessel MI or clinically indicated TLR	
Stent thrombosis within the target vessel	
Clinically significant arrhythmias requiring intervention	
Device related Primary composite endpoint	