A Prospective Multi-Centre Clinical Investigation of the Mamba (Sirolimus Drug Eluting PTCA Balloon) to Investigate Safety and Effectiveness

Name of Study: MIRAGE

PROTOCOL

Contents

PROTOCOL APPROVAL PAGE

Study title: A Multicenter Prospective Clinical Study to Evaluate the Safety and Performance of the Mamba Sirolimus-Coated Drug-Coated Balloon (DCB) for the Treatment of Obstructive Coronary Artery Disease (MIRAGE Study).

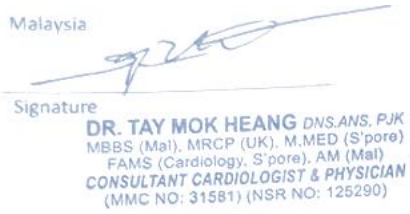
Name of Study: MIRAGE

Protocol version: ECS/FM/030603

We, the undersigned, have read and approved the protocol specified above, and agree to adhere

to its requirements outlined within:

A. Clinical Investigator



01.02.2023

Date

B. Sponsor Representative

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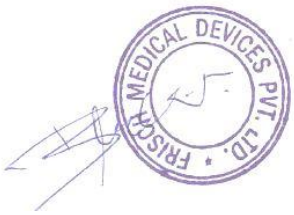


01.02.2023

Signature

Date

PROTOCOL SUMMARY

Protocol No.: ESC/FM/030603

Version: 01

Sponsor: Frisch Medical Devices Private Limited

Device: Mamba Sirolimus Drug-Eluting PTCA Balloon

Study Type: Clinical Investigation to Support Clinical Evaluation Report (CER)

Purpose: Clinical Evaluation for Safety and efficacy of the Sirolimus Coated DCB

Regions: Multicenter – Malaysia, Myanmar

Study Design: Prospective, Non-Randomized, Single-Arm

Study Duration: 12 months follow-up per patient

Study Objectives:

Primary Objective:

To evaluate 30-day MACE following treatment with the Mamba Sirolimus DCB.

Secondary Objectives:

Device success, procedural success, angioplasty outcomes, MACE at 6/12 months, TLR at 6/12 months, SAEs, MACE-free survival.

Endpoints:

Primary Endpoint:
MACE at 30 days.

Secondary Endpoints:
Device success, procedural success, post-usage angioplasty results, MACE at 6/12 months, TLR, TVR, SAEs, MACE-free survival.

Study Population:

Sample Size: 360 subjects

Inclusion/Exclusion criteria:

Inclusion Criteria:

Those subjects eligible for and who met the following inclusion/exclusion criteria were enrolled in this study.

1. Adults ≥18 yrs,
2. Clinical indication for PCI
3. suitable lesion for DCB-only strategy
4. small vessel disease
5. Patient has clinical evidence of ischemic heart disease or a positive functional study
6. Patient and his or her treating physician agree that the patient will comply with all the required post-procedure follow-up.

7. One or more target lesions require treatment

Exclusion Criteria:
Patients were excluded if **ANY** of the following conditions apply:

1. Patient has active infection
2. STEMI <72 hrs, LM disease,
3. heavy calcification, thrombus-rich lesions,
4. mandatory stent requirement,
5. sirolimus allergy, pregnancy,
6. Concurrent medical condition with a life expectancy <1 yr
7. Clinically relevant contraindication to aspirin, heparin, clopidogrel bisulphate, or ticlopidine including thrombocytopenia, neutropenia, or leukopenia
8. Active peptic ulcer or upper gastrointestinal bleeding.
9. Current participation in an investigational drug or device trial that has not completed its primary endpoint follow-up period.
10. Pregnancy or woman of childbearing potential who, in the opinion of the investigator, does not take adequate measures to prevent conception

Study Design:

Comparative Arm: None (no randomization)
Centers**:** Multicenter – Malaysia, Myanmar
Study Duration: 12 months follow-up per patient

Introduction

The Mamba Rapid Exchange Sirolimus Coated Dilatation Catheter is a rapid exchange, PTCA catheter with a balloon located at its end designed for Transluminal angioplasty by percutaneous way. This catheter includes distally two coaxial lumens with a balloon located at the tip. One lumen is used for inflation of the balloon and the other permits the use of guide wire (0.014”max) to facilitate the advancement of the catheter to and through the stenosis to be dilated. The MAMBA Rapid Exchange Sirolimus Coated Dilatation Catheter has flexible distal shaft with a hydrophilic coating on its outer body. The balloon has two Platinum-Iridium radiopaque marker bands, one at each end of the balloon, which represents the approximate balloon working length at nominal pressure for correctly positioning the balloon under fluoroscopy.

Mamba is a Sirolimus Coated Dilatation Catheter for the treatment of coronary artery disease, indicated for In-Stent Restenosis, Small Vessels and Bifurcation Lesions. Sirolimus Coated Dilatation Catheter (DCB) is a novel device for Percutaneous Coronary Intervention (PCI), which has demonstrated favorable outcome due to its peculiar characteristic of a high-concentration, rapid local delivery of an anti-restenotic drug without the use of a durable polymer or metal stent.

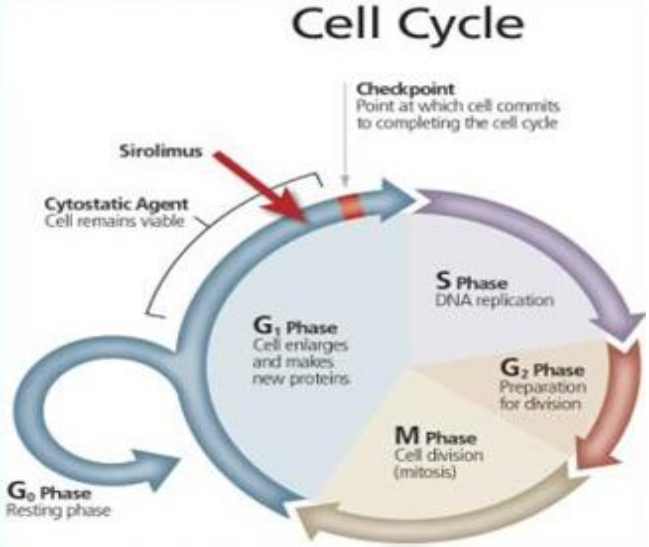
Drug Sirolimus

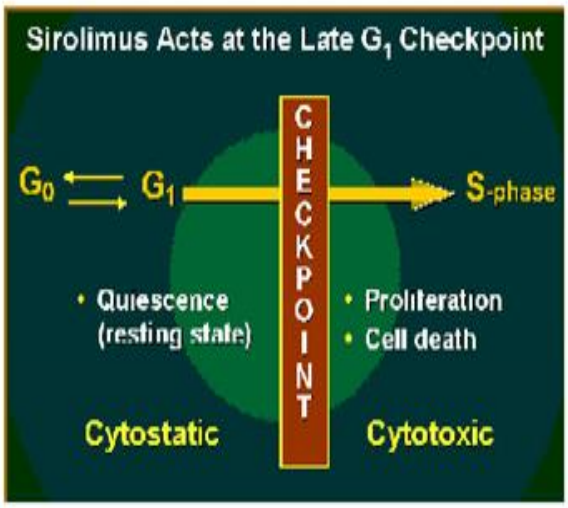
Mamba Sirolimus Drug Eluting PTCA Catheter has a drug loading of 2.75 µg/mm^2 of balloon surface area coated with Sirolimus as the active anti-proliferative agent.

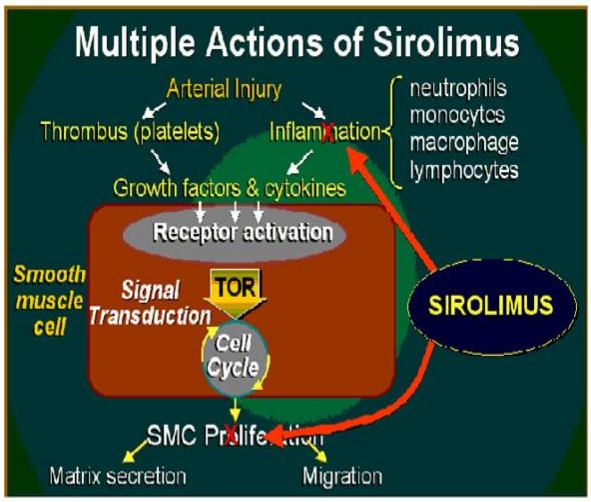
Mechanism of Action for Sirolimus:

The mechanism by which the Sirolimus Coated Dilatation Catheter inhibits neointimal growth as seen in pre-clinical and clinical studies has not been established. At the cellular level, Sirolimus inhibits growth factor-stimulated cell proliferation. At the molecular level, Sirolimus forms a complex with the cytoplasmic protein FKBP-12 (FK 506 Binding Protein). This complex binds to and interferes with FKBP-12 Rapamycin Associated Protein (FRAP), also known as the mammalian target of rapamycin (mTOR), leading to inhibition of cell metabolism, growth, and proliferation by arresting the cell cycle at the late G1 stage.

It inhibits growth factor & cytokine-stimulated cell proliferation. DNA damage checkpoint (G1 check):chk1-kinase inactivation before DNA replication and also inactivation of cdk2- cyclin a protein (growth factor).







Balloon

A balloon is made up of nylon material having PTFE coated stainless steel hypo tube shaft. Two radiopaque markers located underneath the balloon, fluoroscopically mark the working length of the balloon.

Available Sirolimus Drug Eluting PTCA Catheter Sizes

Diameters (mm)	Available Lengths (mm)									
1.50	06	08	10	12	15	20	25	30	35	40
2.00	06	08	10	12	15	20	25	30	35	40
2.25	06	08	10	12	15	20	25	30	35	40
2.50	06	08	10	12	15	20	25	30	35	40
2.75	06	08	10	12	15	20	25	30	35	40
3.00	06	08	10	12	15	20	25	30	35	40
3.50	06	08	10	12	15	20	25	30	35	40
4.00	06	08	10	12	15	20	25	30	35	40

Study rationale

This is a multi-center; prospective study aimed at evaluating the safety and effectiveness of the Mamba Sirolimus Drug Eluting PTCA Catheter in reducing neointimal hyperplasia and decreasing restenosis during PCI of stenotic coronary artery disease as well as intermediate-term outcomes. High Radial Strength, Excellent conformability, and Sirolimus eluting characteristics. A Drug Eluting PTCA Catheter of this type is expected to decrease restenosis following PCI and thereby improve Clinical Outcomes.

Study Procedure:

Baseline evaluation, index PCI procedure, device success, procedural success, post-angioplasty results. Follow-up at 1, 6, 12 months (clinical only).

Screening and eligibility check
Informed consent
Baseline assessment (demographics, ECG, labs, angina class)
Index DCB procedure (balloon angioplasty using Sirolimus-coated DCB)

Pre-dilatation of the target lesion with an appropriate semi-compliant or non-compliant balloon is mandatory. Only lesions with successful pre-dilatation—defined as TIMI 3 flow, no flow-limiting dissection, and ≤30% residual stenosis—are eligible for DCB deployment."
No stent implantation unless medically necessary (bailout)
Discharge as per hospital protocol
Follow-up visits at 1, 6, and 12 months for clinical evaluation, ECG, and adverse event assessment

Follow-Up Schedule:

Timepoint	Visit Type	Assessments
Day 0	Baseline	Demographics, consent, eligibility, angina class, ECG, labs
Day 1	Procedure	DCB implantation, procedural outcomes
1 Month	Clinic visit	MACE, adverse events, ECG, medication adherence
6 Months	Clinic/Tele	MACE, TLR, adverse events, angina class
12 Months	Final visit	MACE, TLR, SAE reporting, device durability

Data Management and Monitoring:

Use of Electronic Data Capture (EDC)
On-site and remote monitoring
Centralized adjudication of endpoints by Clinical Events Committee (CEC)
Safety reviewed periodically by an independent Data Monitoring Committee (DMC) if required

Ethics and Regulatory Compliance:

Conforms to ISO 14155:2020 and Declaration of Helsinki
Ethics Committee/IRB approvals mandatory at each site
Adverse events reported to regulatory bodies per local laws
Fully anonymized patient data to protect confidentiality

Statistical Analysis Plan (SAP):

ITT and PP populations.
Descriptive statistics for baseline and outcome data
95% CI for MACE. Kaplan–Meier for survival
Exploratory subgroup analysis.
No formal hypothesis testing due to non-comparative design

Subgroup analysis

No subgroup analyses are planned.

Withdrawal, discontinuation, and/or replacement of subjects

All patients have the right to withdraw at any point during the period of the clinical study. It will be documented whether or not each patient completed the clinical study Every attempt should be made to collect follow-up information. Discontinued patients will not be replaced.

Safety Reporting

AE, SAE, and device deficiency reporting according to ISO 14155.

Adverse Events Reporting

Definitions

At each evaluation, the investigator will determine whether any adverse events (AEs) have occurred. For the purpose of this protocol, an adverse event is any undesirable clinical occurrence in a subject that can be attributed to the device, Sirolimus Drug Eluting PTCA Catheter, procedure, or medications required by this protocol (i.e., Aspirin, Clopidogrel Bisulfate [Plavix®], or other antiplatelet medication).

The following **Anticipated Events** have been
identified as possible complications of Sirolimus Drug Eluting PTCA Catheter procedure:

1. Allergic/immunologic reaction to anticoagulant and/or antithrombotic therapy
2. agents or contrast medium
3. Aneurysm
4. Arrhythmia’s (bradycardia, rhythmical disturbances)
5. Arterial perforation
6. Bleeding complications
7. Cardiac tamponade
8. Cardiogenic shock
9. Death
10. Dissection

11. Drug reactions to antiplatelet agents/ anticoagulation agents/contrast medium
12. Emboli (tissue, air or thrombic emboli)
13. Embolization
14. Emergency CABG
15. Entry site complications
16. Fever
17. Fistulization
18. Heart Failure
19. Hemorrhage (hematoma)
20. Hypotension/hypertension
21. Infection (and pain at insertion site)
22. Myocardial infarction
23. Myocardial ischemia
24. Nausea and vomiting
25. Occlusion
26. Palpitations
27. Perforation or rupture
28. Pericardial effusion
29. Prolonged angina
30. Pseudoaneurysm
31. Renal failure
32. Respiratory Failure
33. Restenosis of the stented segment
34. Rupture of native coronary artery
35. Shock/pulmonary oedema
36. Stroke
37. Thrombosis (acute, subacute or late)
38. Unstable Angina Pectoris
39. Vascular complications, which may require vessel repair
40. Ventricular fibrillation
41. Vessel spasm

The following **Anticipated Events** have been identified as possible complications of Sirolimus coating:

1. Allergic/immunologic reaction to drug coating
2. Alopecia
3. Anemia
4. Blood product transfusion
5. Gastrointestinal symptoms
6. Hematologic dyscrasia (including leukopenia, neutropenia, thrombocytopenia)
7. Hepatic enzyme changes
8. Histologic changes in vessel wall, including inflammation, cellular damage or necrosis
9. Myalgia/Arthralgia

10. Peripheral neuropathy

The following **Anticipated Events** have been identified as possible complications of the medicine Sirolimus:

1. Change in taste
2. Change in color of the nails
3. Change in normal bowel habits for more than 2 days
4. Chest pain
5. Chills
6. Cough
7. Difficulty swallowing
8. Dizziness
9. Facial flushing
10. Fatigue
11. Fever
12. Loss of appetite
13. Mouth blistering
14. Nausea and vomiting
15. Pain in the joints of the arms or legs lasting 2-3 days
16. Pain, redness, or swelling at the injection site
17. Severe exhaustion
18. Shortness of breath
19. Skin rash
20. Sore throat
21. Tingling in the hands or toes
22. Thinned or brittle hair
23. Unusual bruising or bleeding

Unanticipated Adverse Device Effects (ADEs) are defined as adverse effects on health or safety or any life-threatening problem or death caused by or associated with a device, if that effect, problem, or death was not previously identified in nature, severity or degree of incidence in the investigational plan or IDE application, or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of patients.

Adverse Event (AE): An adverse event is defined as any undesirable clinical event occurring to a subject, during a clinical study, whether or not considered related to the investigational product(s).

Serious Adverse Event (SAE): an adverse event is defined as serious, whenever the adverse event results in the patient's death, is life-threatening, results in permanent or remarkable disability/dysfunction, requires in-patient hospitalization or prolongation of hospitalization, results in fetal death or distress, is a congenital anomaly/birth defect and in cases of cancer/malignancy or required surgical or medical intervention to prevent permanent impairment.

Reporting of (Serious) Adverse Events

All AEs and SAEs since randomization must be recorded in the CRF and source documents. All SAEs or unanticipated adverse device effects (ADE) must be reported to Frisch Medical immediately (within 24 hours) by email.

Follow-up of SAEs

All adverse events occurring during the study are to be followed up in accordance with good clinical practice until resolved or judged no longer clinically significant, or in case of a chronic condition until fully characterized. All follow-up results are to be reported to Frisch Medical Devices Private Limited.

Organization

Sponsor

Frisch Medical Devices PVT LTD.

B 303, Titanium Square, Thaltej Cross Roads

Ahmedabad

Gujarat. India

Clinical Investigator:

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MBBS (MaI), MRCP (UK), M.MED (S'pore)
FAMS (Cardiology, S'pore), AM (MaI)
Consultant Cardiologist & Physician
Sunway Heart & Vascular Institute, Malaysia
(MMC No.: 31581) (NSR No: 125290)

Quality Control and Quality Assurance

Monitoring

Monitoring visits, source verification, query resolution.

Trained and qualified personnel from the Sponsor will monitor the study throughout its duration by means of One personal visit to the Investigator's facilities and by other communication.
- the progress of the study,
- verify whether the reported clinical study data are accurate, complete, and verifiable from source documents,
- Whether the protocol and applicable amendments are being followed.

Record retention

The investigator should maintain the essential clinical study documents (including CRFs, source documents, device disposition records, adverse event reports, and other regulatory documents) as required by the applicable regulatory requirements. The investigator should take adequate measures to prevent accidental or premature destruction of these documents. Essential clinical study documents should be retained for a

minimum of two years after the last approval of the marketing application, or at least five years after formal discontinuation of clinical development of the investigational product. These documents should be retained for a longer period, however, if required by the applicable regulatory requirements or by an agreement with the Sponsor.

If the investigator retires, relocates, or for other reasons withdraws from the responsibility of keeping the study records, custody must be transferred to a person who will accept responsibility.

Publication policy

The Sponsor and Investigators are committed to the publication and widespread dissemination of the results of the study. This study represents a joint effort between the Sponsor and Investigators, and as such, the parties agree that the recommendation of any party concerning manuscripts or text shall be taken into consideration in the preparation of final scientific documents for publication or presentation. All proposed publications and presentations by Sponsor and Investigators or their personnel and associates resulting from or relating to the study must be submitted to the Steering Committee for review and approval before submission for publication or presentation. If any such proposed publication or presentation contains patentable subject matter which in Sponsor's sole discretion, warrants intellectual proprietary protection, Sponsor may delay any publication or presentation for up to thirty (30) days after Steering Committee approval to pursue such protection.

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APPENDIX I - DEFINITIONS AND ACRONYMS

Acute gain: post-procedure minimal lumen diameter (MLD) minus the pre-procedure MLD measured by Quantitative Coronary Angiography (QCA).

ADE (Adverse Device Effect): Adverse effects on health or safety or any life-threatening problem or death caused by or associated with a device, if that effect, problem, or death was not previously identified in nature, severity or degree of incidence in the investigational plan or IDE application, or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of patients.

AE (Adverse Event): Any undesirable clinical event occurring to a subject, during a clinical Registry, whether or not considered related to the investigational product(s).

Angiographic Thrombosis/Occlusion: Angiographic thrombosis is defined as the angiographic documentation of either a complete occlusion (TIMI flow 0 or 1) or an angiographic documentation of a flow limiting thrombus (TIMI flow 1or 2). A Subacute Occlusion is defined as occurring after removal of the guiding catheter, before 30 days follow-up.

ASA: Acetylsalicylic acid: Chemical name for aspirin; a drug having antiplatelet, anti-inflammatory, analgesic, and antipyretic effects.

Bleeding complications: Bleeding will be considered major if:

1. it leads to death;
2. it leads to permanent disability;
3. it is clinically suspected or proven to be intracranial (see stroke)
4. it produces a fall in hemoglobin of at least 3 mmol/l;
5. it leads to transfusion of 2 or more units of whole blood of packed cells;
6. Peripheral vascular surgery is necessary.

All other bleeding will be considered as minor.

Braunwald classification of unstable angina

Severity

Class 1: New onset of severe or accelerated angina. Patients with new onset (<2 months in duration) exertional angina pectoris that is severe or frequent (<3 episodes/day) or patients with chronic stable angina who develop accelerated angina (that is, angina distinctly more frequent, severe, longer in duration, or precipitated by distinctly less exertion than previously) but who have not experienced pain at rest during the preceding 2 months.

Class 2: Angina at rest, subacute. Patients with one or more episodes of angina at rest during the preceding month but not within the preceding 48 hours.

Class 3: Angina at rest, acute. Pts with one or more episodes of angina at rest within the preceding 48 hours.

Clinical circumstances in which unstable angina occurs:

Class A: Secondary unstable angina. Patients in whom unstable angina develops secondary to a clearly identified condition extrinsic to the coronary vascular bed that has intensified myocardial ischemia. Such conditions reduce myocardial oxygen supply or increase myocardial oxygen demand and include anemia, fever, infection, hypotension, uncontrolled hypertension, tachyarrhythmia, unusual emotional stress, thyrotoxicosis, and hypoxemia secondary to respiratory failure.

Class B: Primary unstable angina. Patients who develop unstable angina pectoris in the absence of an extra cardiac condition that have intensified ischemia, as in class A.

Class C: Post infarction unstable angina. Patients who develop unstable angina within the first 2 weeks after a documented acute myocardial infarction

CABG: Coronary Artery Bypass Graft.

CCS (Canadian Cardiovascular Society) classification

Class I: Ordinary physical activity, such as walking and climbing stairs, does not cause angina. Angina with strenuous, rapid, or prolonged exertion at work or recreation.

Class II: Slight limitation of ordinary activity. Walking or climbing stairs rapidly, walking up hill, walking or stair climbing after meals, in cold, in wind, or when under emotional stress or during the first few hours after awakening may cause pain. Walking more than two blocks on the level and climbing more than one flight of stairs at a normal pace and in normal conditions.

Class III: Marked limitation of ordinary physical activity. Walking one-two blocks on a level and climbing one flight of stairs at normal pace results in angina.

Class IV: Inability to carry on any physical activity without discomfort. Anginal syndrome may be present at rest.

De novo lesion: A coronary lesion not previously treated.

Dissection NHLBI classification National Heart Lung and Blood Institute:

A – Intraluminal radiolucent defect

B – Extraluminal "cap" (without staining)

C – Extraluminal "cap" with persistence of dye (staining)

D – Spiral defects

E – Persistent filling defect

F – Filling defect with total occlusion

Note: Types E & F dissections may be caused by thrombus

DS (Diameter Stenosis):

Percent DS – Value calculated as 100 * (1 –(MLD/RVD). A 100 %DS is imputed for total occlusions.

Late loss:

Late lumen loss is defined as the difference in minimal lumen diameter (MLD) between post-procedural and follow-up in mm

MACE (Major Adverse Cardiac Events):

Composite of Death (Both Cardiac & Non-Cardiac Death), MI (Q-wave and Non-Q-wave), (emergent) CABG or clinically driven Target Lesion Revascularization (TLR).

Major vascular complications:

All pseudoaneurysms, vascular access site bleeding associated with a decrease in hemoglobin ^{3}3.0 mmol/L as well as vascular events which required surgical repair or transfusion of > 2 units within 30 days of the procedure.

MI (Myocardial Infarction):

Necrosis of the myocardium, as a result of interruption of the blood supply to the area, as in coronary thrombosis.

MI, non-Q-Wave:

Elevation of post-procedure CK levels to >2 times normal with elevated CK-MB in the absence of pathological Q waves. If no assay for CK-MB was performed, elevation of CK levels to >2 times normal without new Q waves is also considered a non-Q-wave MI.

MI, Q-Wave:

MI, Q-Wave Development of new, pathological Q waves in 2 or more contiguous leads (as assessed by the investigator and confirmed by the Clinical Endpoint Committee) with post-procedure CK-MB levels elevated above normal.

MLD (Minimal Lumen Diameter):

MLD (Minimal Lumen Diameter) Mean Minimal Lumen Diameter (mm).

Procedure success rate: Percentage of patients with angiographic success and without the occurrence of MACE during the index hospitalization.

QCA (Quantitative Coronary Angiography, off-line):

Off-line refers to assessment at the Angiographic Core Laboratory. The method is a quantitative estimate obtained with a digital angiographic computer utilizing an automatic edge detection algorithm.

RVD (Reference Vessel Diameter):

Interpolated reference diameter.

SAE (Serious Adverse Event):

An adverse event is defined as serious, whenever the adverse event is fatal, life-threatening, results in persistent or significant disability/incapacity, requires inpatient hospitalization or prolongation of hospitalization, results in fetal death or distress, is a congenital anomaly/birth defect and in cases of cancer/malignancy.

Stroke:

A focal neurological deficit, resulting from a vascular cause involving the CNS, of sudden onset that is not reversible within 24 hours (including death) and which is not due to a readily identifiable cause (i.e. brain tumor, trauma).

TLR (Target Lesion Revascularization):

Any repeat treatment of the stented segment including 5 mm proximal and 5 mm distal from the edge of the stent.

TVF (Target Vessel Failure):

Cardiac Death, MI (Q-wave and non-Q-wave) or Target Vessel Revascularization (TVR) that could not be clearly attributed to a vessel other than the target vessel.

TVR (Target Vessel Revascularization):

Revascularization of any segment of the index coronary artery, which was in physical contact with any component (guiding catheter, guidewire, balloon catheter, etc.) of the angioplasty hardware during the initial procedure

TWS (Technician's Work Sheet):

Part of the CRF used to specify the details of the angiographic procedure and the angiographic observations.