Revision 4.0

Medtronic **Statistical Analysis Plan**	
Clinical Investigation Plan Title	**Onyx ONE Clear Study: A Single Arm Study with Resolute Onyx in ONE-Month DAPT for High-Bleeding Risk Patients Who Are Considered One-Month Clear**
Clinical Investigation Plan Identifier	MDT18015RES008
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1. Version History

Version	Summary of Changes	Author(s)/Title
1.0	Initial release	Te-Hsin Lung Principal Statistician
2.0	1. Section 3.1 removed definition of one-month clear because it is also defined in section 6.1 2. Section 6.1 additional details for the one-month clear definition, clarifications for as treated one-month clear definition as primary analysis population. Added intent-to-treat (ITT) set for one-month clear and definition of pivotal date 3. Section 6.2 added ITT set and moved the comparison between Onyx arm and BioFreedom to section 6.8 where all comparisons between Onyx arm and BioFreedom are in the same section. 4. Section 6.4.4 removed secondary analysis and analysis on the Per Protocol (PP) set as critical analyses are already covered by multiple populations: intent-to-treat, as treated, one month clear, and as treated one month clear. 5. Section 6.4.5 clarification of section by removing "although only cardiac death and myocardial infarction occurring on or before one year will count toward the primary endpoint" 6. Section 6.5.1 to be consistent with Section 6.1, replaced PP set with ITT and removed the sentences "the acute success will be analyzed on the AT set, the AT one-month clear population, and PP set." and "For publication purpose, the secondary endpoints analysis may also be performed based on ITT set" 7. Section 6.6 added landmark analysis 8. Section 6.7 added subgroups and subgroup analyses of secondary endpoint, AT set. Removed SAPT compliance at 2 months, SAPT compliance at 6 months, and SAPT compliance at 12 months 9. Section 6.8 added analysis for extension of Onyx One Global RCT study to include baseline demographic and clinical data and cumulative analysis and landmark analysis that will compare Onyx arm to BioFreedom arm 10. Section 6.11 removed the third paragraph	Te-Hsin Lung Principal Statistician
3.0	1. Section 6.1 removed the sentence "Pivotal date is defined to be the date that a subject transitions from DAPT to SAPT." 2. Section 6.7 Changed subgroup "SAPT type after pivotal date" to "SAPT type after one month" 3. Section 6.8 replaced "pivotal date" with "one month"	Te-Hsin Lung Principal Statistician

Version	Summary of Changes	Author(s)/Title
4.0	1. Section 2 added the words "and publications" to the first sentence. 2. Section 3.2 changed the word "all" to "appropriate" in the first sentence. Spelled out the word "definite" and "probable". 3. Section 6.1 capitalized the word "treated" 4. Section 6.5 clarified the time points for secondary endpoint assessment. All secondary endpoints except acute success will be assessed at 1, 2 and 6 months, 1 year, and 2 years for AT set; also at 6 months, 1 year and 2 years for AT one-month clear set. 5. Section 6.5.1 removed AT one-month clear set from the secondary analysis for the secondary endpoints because it is the analysis cohort for the primary analysis for the secondary endpoints. Removed ITT set from the secondary analysis because it is not needed for the clinical study report. 6. Section 6.6 changed "vs" to "vs." 7. Section 6.6 was removed and the content was moved to section 6.7 because the landmark analysis is for publication only. 8. Section 6.6 updated the definition of analysis cohort for this subgroup to "This only applies to one-month clear population and who actually transitioned to SAPT from DAPT." for clarification purpose. 9. Section 6.6 updated the wording for subgroup analysis on US vs. Japan to "US vs. Japan (p-value from comparing US subjects to Japan subjects will be calculated)" 10. Section 6.7 added a sentence "This section describes the planned analyses for publication purposes only" to clarify the intention of the outlined analyses in this section. 11. Section 6.7 added landmark analyses for publications.	Te-Hsin Lung Principal Statistician

2. Introduction

This Statistical Analysis Plan has been designed to document, before data are analyzed, the rationale for the study design and the planned analyses that will be included in study reports and publications. This statistical analysis plan is developed based on the Onyx ONE Clear Study Clinical Investigational Plan (CIP).

The purpose of this study is to evaluate the clinical safety and effectiveness of the Resolute Onyx stent in subjects deemed at high risk for bleeding and/or medically unsuitable for more than one-month dual antiplatelet therapy (DAPT) treatment receiving reduced duration (one month) of DAPT following stent implantation. The primary endpoint is the composite rate of cardiac death and myocardial infarction at one year for a one-month clear population [timeframe: one month to one year].

The Onyx ONE Clear Study is a prospective, multi-center, single arm study for a commercially approved product. A total of 700 subjects will be enrolled in the United States and 100 subjects may additionally be enrolled in Japan. Subjects will be enrolled in up to 70 centers over an approximate 10-month period or until study enrollment is completed.

A study report will be prepared for submission to FDA at the time when 700 US subjects have completed their 1-year follow up, for the purpose of seeking market approval. After all enrolled subjects have completed all protocol-specified follow-up, a final clinical report will be prepared and submitted.

Any deviations from the Statistical Analysis Plan will be described and justified in the Final Report, as appropriate.

3. Study Objectives

The primary objective of the study is to evaluate the clinical safety of the Resolute Onyx stent as compared to the Performance Goal (PG), with use of one-month DAPT in subjects deemed at high risk for bleeding and/or medically unsuitable for more than one-month DAPT treatment.

The secondary objective of the study is to evaluate the clinical effectiveness of the Resolute Onyx stent, with use of one-month DAPT in subjects deemed at high risk for bleeding and/or medically unsuitable for more than one-month DAPT treatment.

The following endpoints will be used to evaluate the study objectives.

3.1. Primary Endpoint

The primary endpoint is a composite rate of cardiac death and myocardial infarction at one year for a one-month clear population [timeframe: one month to one year]. The definition for one-month clear population is defined in section 6.1.

3.2. Secondary Endpoints

The following secondary endpoints will be assessed at appropriate follow-up time points (1, 2, 6 months, 1 and 2 years) except acute success:

1. Acute success (device, lesion, procedure)
    - Device success is defined as the attainment of <30% residual stenosis by QCA (or <20% by visual assessment) and TIMI flow 3 after the procedure, using the assigned device only.
    - Lesion success is defined as the attainment of <30% residual stenosis by QCA (or < 20% by visual assessment) and TIMI flow 3 after the procedure, using any percutaneous method.
    - Procedure success is defined as attainment of <30% residual stenosis by QCA (or <20% by visual assessment) and TIMI flow 3 after the procedure, using any percutaneous method without the occurrence of MACE during the hospital stay.
2. All deaths including cardiac death
3. Major adverse cardiac event (MACE)
    - Defined as death, myocardial infarction, or clinically driven repeat target lesion revascularization by percutaneous or surgical methods

4. Composite of cardiac death and myocardial infarction
5. Target vessel failure (TVF)
    - Defined as cardiac death, target vessel myocardial infarction or clinically-driven target vessel revascularization
        - Target vessel failure will be reported when ANY of the following events occur:
            - Recurrent MI occurs in territory not clearly attributed to a vessel other than the target vessel
            - Cardiac death not clearly due to a non-target vessel endpoint
            - Target vessel revascularization is determined
6. Target lesion failure (TLF)
    - Defined as cardiac death, target vessel myocardial infarction (Q wave and non-Q wave), or clinically driven target lesion revascularization (TLR) by percutaneous or surgical methods.
7. All revascularizations (TLR, TVR and non-TVR)
8. Stent thrombosis (definite/probable)
9. Stroke
10. Bleeding per BARC criteria
    - BARC 3 to 5
    - BARC 2 to 5
    - All BARC

4. Investigation Plan

A total of 700 subjects will be enrolled in the United States, and 100 subjects may additionally be enrolled in Japan. Subjects will be enrolled in up to 70 centers over an approximate 10-month period or until study enrollment is completed. A maximum of 140 subjects (approximately 20% of the primary analysis population) may be enrolled at one study center. While all sites are expected to contribute to enrollment, there is no set minimum requirement for the number of subjects enrolled at each study center; however, it is expected that a minimum of five (5) subjects will be enrolled per study center.

Subjects may receive treatment of one or more lesions. Planned staged procedures within 30 days of the index procedure are allowed. Subjects who are enrolled with an attempted implant procedure will be considered part of the intent-to-Treat (ITT) population. ITT subjects implanted with Resolute Onyx stent will be followed through two years. Clinic visit health status assessments will be documented at the 1-month time point. Subject contact health status assessments will be documented at 2 months, 6 months, 1 year, and 2 years. The study will be conducted to allow data collection and analysis for 2 years from treatment of the final subject or until the study has been formally terminated. The total study duration is estimated to be 34 months from first enrolled subject through final follow-up.

5. Sample Size and Power Considerations

5.1. Sample Size for Primary Objective

Based on historical short DAPT studies with high-bleeding risk patient populations (LEADERS FREE, ZEUS, and SENIOR)[1,2,3,4,5] the weighted average of cardiac death and myocardial infarction at one year was 9.6%. As disproportionally higher rates of STEMI, unstable angina, and multi-vessel disease were identified in the ZEUS study population which could have led to a higher rate of cardiac death, the ZEUS rate was revised. Similarly, the SENIOR rate contribution was derived from the published rates based on subjects with planned one-month DAPT use.

Approximately 3% of CD/MI events occurred in LEADERS FREE study at 30 days. To account for a "one-month clear" population, the weighted CD/MI rate at 12 months will be discounted by 3%, resulting in an average rate of 6.6%. In addition, to account for the 3% population that will also be removed from the denominator of the rates, the expected CD/MI rate between 30 days and one year is more accurately represented as 6.8%.

The performance goal (9.7%) incorporated a clinically acceptable margin of 2.9% to the expected rate.

In defining a "one-month clear" population, an attrition rate of 20% will be applied to account subjects who interrupted or discontinued DAPT (greater than 3 cumulative days) within the first one month of procedure, who were excluded due to events that would prohibit them from discontinuing DAPT beyond one month, who failed to transition from DAPT to single antiplatelet therapy (SAPT) one month after procedure, and who were lost to follow-up. Peri-procedural MIs will not exclude the patient from being considered as "one month clear". For the secondary endpoints like TLF, all available biomarkers (including peri-procedural) will be forwarded to the CEC to be used towards the adjudication of events.

Assuming a one-sided alpha level of 0.025 and a true event rate of 6.8%, an effective sample size of 1360 subjects will yield a greater than 97% power to reject the null hypothesis. Assuming a 20% attrition rate, a total sample size of 1700 subjects will be needed.

The outcomes from 700 US subjects enrolled in this study will be combined with those of 1000 subjects from the Resolute Onyx arm of the Onyx ONE Study to form the total sample size of 1700. In addition, subjects enrolled in Japan in this study who have completed their one-year follow-up at the time when the 700 US subjects have completed their one-year follow up will also be included in the primary analysis.

6. Statistical Methods

6.1. Analysis Populations

Per the CIP, subjects will be considered enrolled into the trial after the following criteria have been met:

1. The signed and dated informed consent has been obtained
2. The patient and target vessel(s)/lesion(s) have met all of the inclusion and none of the exclusion criteria

3. The study stent is introduced into the guide catheter

Intent-to-Treat (**ITT**): All enrolled subjects. Time zero begins at the date of the index procedure.

As Treated (**AT**): All ITT subjects who received the Resolute ONYX stent only. Time zero begins at the date of the index procedure.

One-month Clear: All subjects who meet all of the following criteria:

- [redacted]

[redacted]

Event-free is defined as that a subject must not have myocardial infarction (MI) (excluding peri-procedural MIs), repeat coronary revascularization, stroke, stent thrombosis (ARC definite/probable), and death. [redacted]

As Treated and Intent-to-Treat for one-month clear are:

- As Treated Set for One-month Clear: All AT subjects who are in the one-month clear population. This is the primary cohort for the primary endpoint analysis.
- Intent-to-Treat Set for One-month Clear: All ITT subjects who are in the one-month clear population.

6.2. Description of Baseline Variables

All clinically relevant baseline variables will be tabulated and reported. Categorical variables will be reported using counts and percentages, and continuous variables will be reported by giving the number of known values, the means, medians, standard deviations, interquartile ranges, minimum and maximum values. Baseline demographic and clinical variables will be summarized for the AT, AT one-month clear set.

6.3. Kaplan-Meier Analyses

For safety related endpoints, a Kaplan-Meier analysis of event rates at 1 month, 2 months, 6 months, 1 year, and 2 years will also be provided.

6.4. Primary Objective

The primary endpoint is a composite of cardiac death and myocardial infarction (MI) at one year for a one-month clear population [timeframe: one month to one year].

6.4.1. Hypothesis

The primary endpoint of the study will be compared to a pre-specified PG of 9.7%. The study hypotheses are:

H_0: $\pi \geq 9.7\%$

H_A: $\pi < 9.7\%$

where π denotes the binary rate of cardiac death and myocardial infarction at one year in a one-month clear population [timeframe: one month to one year]. This one-sided test will be carried out at the 0.025 significance level using the binomial exact test.

6.4.2. Primary Endpoint Definition

The primary endpoint is the binary rate of the composite event rate of cardiac death, and myocardial infarction at one-year post-procedure in a one-month clear population. The numerator will be the number of one-month clear subjects who have cardiac death or myocardial infarction, on or before one-year post-procedure (365 days). The denominator will be the number of one-month clear subjects who either have CEC events on or before one year, or have latest date of all follow-up visits, assessments, or events on or after the lower window of one year follow up.

In addition, the KM event rates at 1 month, 2 months, 6 months, 1 year, and 2 years, as well as the KM plot will be provided.

6.4.3. Data Collection and Analysis Methods

Cardiac death and myocardial infarction events will be adjudicated by the CEC and the data on the CEC adjudication form will be used in the analysis.

The primary endpoint rates in the AT set for one-month clear population will be reported, as well as the two-sided 95% confidence interval. If the upper limit of the two-sided 95% confidence interval is smaller than 9.7%, the primary objective will be considered as a success.

The one-sided binomial exact test will be carried out to assess statistical significance at the 0.025 alpha level.

6.4.4. Determination of Patients/Data for Analysis

The primary analysis will be performed in the AT set for one-month clear population.

6.4.5. Missing Data Analysis

Every effort will be undertaken to minimize missing data. One-month clear AT subjects with primary endpoint events, or with CEC events on or before one year, or with any follow-up visits, assessments, or events on or after the lower window of one year follow up will be considered to have complete data for the purposes of this analysis. If outcome data are missing, to assess the potential impact of missing data, a sensitivity analysis will be conducted which will include a complete case (including only subjects whose status is known at one year), a best-case (assume missing Resolute Onyx subjects are event free at one year), a worst-case (assume missing Resolute Onyx subjects have event at one year), and a tipping point analysis if the conclusion is changed in the worst-case analysis.

6.5. Secondary Endpoints

The following secondary endpoints will be assessed:

1. Acute success (device, lesion, procedure)
2. All deaths including cardiac death
3. Major adverse cardiac event (MACE)
    - Defined as death, myocardial infarction, or clinically driven repeat target lesion revascularization by percutaneous or surgical methods
4. Composite of cardiac death and myocardial infarction
5. Target vessel failure (TVF)
    - Defined as cardiac death, target vessel myocardial infarction or clinically-driven target vessel revascularization
        - Target vessel failure will be reported when ANY of the following events occur:
            - Recurrent MI occurs in territory not clearly attributed to a vessel other than the target vessel
            - Cardiac death not clearly due to a non-target vessel endpoint
            - Target vessel revascularization is determined
6. Target lesion failure (TLF)
    - Defined as cardiac death, target vessel myocardial infarction (Q wave and non-Q wave), or clinically driven target lesion revascularization (TLR) by percutaneous or surgical methods
7. All revascularizations (TLR, TVR and non-TVR)

8. Stent thrombosis (def/prob)
9. Stroke
10. Bleeding per BARC criteria
    - BARC 3 to 5
    - BARC 2 to 5
    - All BARC

All secondary endpoints except acute success will be assessed at 1, 2 and 6 months, 1 year, and 2 years for AT set; also at 6 months, 1 year and 2 years for AT one-month clear set.

6.5.1. Data Collection and Analysis Methods

The data on the CEC adjudication form will be used in the analysis. For secondary endpoints, event rates/success rates, and 95% two-sided confidence interval will be provided. The time-sensitive nature of any response variable will be displayed by using a Kaplan-Meier plot.

The primary analysis for secondary endpoints at follow-up time points (2, 6 months, 1 and 2 years) will be performed for AT one-month clear population, except that the acute success. The secondary analysis for secondary endpoints (except acute success) at all follow-up time points (1, 2, 6 months, 1 and 2 years) will be performed based on the AT set.

6.6. Analysis of Subgroups

Subgroup analyses of the primary and secondary endpoints (AT set, AT set for one-month clear population) include the following patient characteristics.

- Acute Coronary Syndrome (ACS) vs. no ACS
  Acute coronary syndrome is NSTEMI or STEMI, or unstable angina at baseline
- Diabetes vs. no diabetes
- Age (≤75 vs. >75 years)
- Sex (female vs. male)
- Multi-vessel vs. Single vessel treatment
- Multi-lesion vs. Single lesion treatment
- Overlapping stent vs. none
- Off-label (Complex) vs. on-label (Simple)
  For the purposes of stratification, subjects are considered “complex” if they have total occlusion or are off-label because of any of these conditions: bifurcation, saphenous vein graft (SVG), target lesion in-stent restenosis (ISR), Acute MI (≤ 72 hrs), left ventricular ejection fraction (LVEF) < 30%, unprotected left main (LM), more than two vessels stented, renal insufficiency or failure (creatinine ≥ 140 µmol/L), lesion length

> 35 mm, more than one lesion per vessel, or pre-procedure thrombus. "Simple" subjects are all the subjects excluding "complex" subjects. "Simple" subjects are also on-label subjects except those have total occlusion.

- US vs. Japan (p-value from comparing US subjects to Japan subjects will be calculated)
- With staged procedure vs. without staged procedure
- OAC vs no OAC planned to continue after PCI
- Renal failure (creatinine clearance < 40 ml/min) vs. no renal failure
- Minimum sent diameter ≤ 2.5 mm vs. > 2.5 mm
- With vs without anemia or hospital admission for bleeding < 12 months
- With vs without planned major surgery during the next 12 months
- Total stent length ≤ 30 mm vs. > 30 mm
- Femoral vs. non-femoral final vascular access site
- Enrolled by age criteria only vs. not enrolled by age criteria only
- Bifurcation vs. none
- Subjects switched from DAPT to SAPT between 27 days and 35 days post procedure, to be referred to as a "medication adherent subgroup"
- Number of HBR criteria
- SAPT type after one month: aspirin vs. P2Y12 inhibitor. This only applies to one-month clear population and who actually transitioned to SAPT from DAPT.

6.7. Analysis for Publications for Extension of Onyx One Global RCT Study

This section describes the planned analyses for publication purpose only. Baseline demographic and clinical data from the pooled Resolute Onyx subjects will be compared to the data from the BioFreedom arm of Onyx One study for ITT, AT, and AT one-month clear sets. The cumulative analysis (from one month to 365 days post procedure) will be performed for the AT one-month clear population and the landmark analysis will be performed for ITT and AT sets on all clinical endpoints and for all subgroups defined in Section 6.6 except the US vs Japan subgroup, Medication Adherent subgroup, and SAPT type after one-month subgroup. The analysis populations for the cumulative and landmark analyses are specified in Tables 1 to 2.

Landmark analyses at 30 days for all clinical endpoints will be performed for the AT and ITT set, and will be compared to the corresponding populations in the BioFreedom arm of Onyx One Global RCT study. The Kaplan Meier method will be used to calculate event rates for events that occur between 31- and 365-days post index procedure. Subjects who died or withdrew before 30 days will be excluded from this analysis. Subjects who experienced non-terminal events (e.g., MI) before 30 days will be included from this analysis. The cumulative incidence function in the presence of a competing risk will be estimated, and comparisons between Onyx and BioFreedom arms will be made using Gray's test.

Table 1. Analysis Populations for Pooled Cumulative Analysis

Cumulative Analysis	Planned Analysis	Analysis Population for Cumulative Analysis
All clinical endpoints, from one month to one year	Principal effective and safety table	AT one month clear

Subgroup analysis from one month to one year	Principal effective and safety table	AT one month clear

Table 2. Analysis Populations for Pooled Landmark Analysis

Landmark Analysis	Planned Analysis	Analysis Population for Landmark Analysis
All clinical endpoints, from 30 days to one year	Principal effective and safety table	ITT/AT
Subgroup analysis from 30 days to one year	Principal effective and safety table	ITT/AT

6.8. Heterogeneity/Poolability

6.8.1. Geography Poolability Analysis

Poolability analysis for the primary endpoint will be performed to evaluate potential difference between studies/regions (US vs. OUS). This analysis will be performed on the AT set for one-month clear population, from the Onyx ONE CLEAR Study and from the Resolute Onyx arm of the Onyx ONE Global RCT Study.

If the resulting test (chi-square test, unless >20% of the expected cell frequencies are less than 5, when Fisher's exact test will be used) is significant at the 0.15 level, further exploratory analysis will be attempted to identify covariates that may explain differences. Otherwise, the data will be considered to be poolable across studies/regions.

Primary Endpoint by Region

This analysis will be performed in the AT set for one-month clear population. If the resulting test (chi-square test, unless >20% of the expected cell frequencies are less than 5, when Fisher's exact test will be used) is significant at the 0.15 level, further exploratory analysis will be conducted.

6.8.2. Site Poolability Analysis

If the geographic regions are considered to be poolable, then the site poolability analysis for the primary endpoint will be performed on all sites, regardless of geography; the studies/regions will not be taken into account.

Should, however, the studies/regions not be considered to be poolable, then for the studies/regions, a separate site poolability analysis for the primary endpoint will take place.

Sites should contribute at least 5 subjects to the AT set for one-month clear population. If this is not the case, the site is considered a "small site"; small sites will be excluded from the site poolability analyses.

Primary Endpoint by Site

This analysis will be performed in the AT set for one-month clear population. If the resulting test (chi-square test, unless >20% of the expected cell frequencies are less than 5, when Fisher's exact test will be used) is significant at the 0.15 level, further exploratory analysis will be conducted.

6.9. Interim Analysis

No formal interim analysis is planned for this study.

6.10. Additional Analysis

In addition to the analyses described above, other study data such as site report AEs and protocol deviations may be summarized for the AT set and AT one-month-clear population.

There may be additionally 100 subjects enrolled in Japan in this study. Once all enrolled subjects (US and Japan) have had the chance to complete one year follow up, an additional report (including subjects from Onyx ONE Clear Study as well as the Onyx arm of Onyx ONE Global RCT Study) may be prepared as requested by PMDA.

7. Validation Requirements

Statistical programming for the primary endpoint and secondary endpoints, require Level 1 (independent) validation. Other analyses require Level 1 (independent) or Level 2 (Peer review) validation.

8. References

1. Urban P, Meredith IT, Abizaid A, et al. Polymer-free drug-coated coronary stents in patients at high bleeding risk. NEJM Oct 14, 2015.
2. Urban P, Abizaid A, et al. LEADERS FREE Biolimus-coated vs. Bare-metal Coronary Stents in High Bleeding Risk Patients. TCT2015.
3. Ariotti S, Adamo M, Costa F, et al. Is Bare-Metal Stent Implantation Still Justifiable in High Bleeding Risk Patients Undergoing Percutaneous Coronary Intervention?: A Pre-Specified Analysis From the ZEUS Trial. JACC Cardiovasc Interv 2016;9:426-36.
4. Valgimigli M, et al. J Am Coll Cardiol. 2015;65:805–15.
5. Varenne O, Cook S, Sideris G, et al. Drug-eluting stents in elderly patients with coronary artery disease (SENIOR): a randomised single-blind trial. The Lancet 2017.

9. Appendices

Appendix I: Incomplete Date of AE Onset

The following table is guiding on how to input missing dates for AE onset.

Valid Portion	Missing Portion	Imputed Value for missing Portion
Month, Year	Day	Set Day = first day of that month and year, then set the day = later of (New onset date, procedure date).
Year	Day, Month	Set date = later of (January 1st of that year, procedure date).
None	Day, Month, Year	Date of Procedure

Appendix II: Follow-up Visit Windows

The following table defines the study visit windows.

Follow-up interval	Window
30 days	30 ± 5 days
2 months	60 ± 10 days
6 months	6 calendar months ± 14 days
1 year	1-year anniversary ± 30 days
2 years	2-year anniversary ± 30 days