Statistical Analysis Plan (SAP)

A PROSPECTIVE, MULTI-CENTER, SINGLE ARM STUDY TO OBTAIN "REAL WORLD" CLINICAL DATA AND CHARACTERIZE THE ACUTE AND LONG-TERM PERFORMANCE OF THE MICRUSFRAME AND GALAXY COILS INCLUDING THE PULSERIDER ANEURYSM NECK RECONSTRUCTION DEVICE FOR THE ENDOVASCULAR TREATMENT OF INTRACRANIAL ANEURYSMS

STERLING REGISTRY

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A PROSPECTIVE, MULTI-CENTER, SINGLE ARM STUDY TO OBTAIN "REAL WORLD" CLINICAL DATA AND CHARACTERIZE THE ACUTE AND LONG-TERM PERFORMANCE OF THE MICRUSFRAME AND GALAXY COILS INCLUDING THE PULSERIDER ANEURYSM NECK RECONSTRUCTION DEVICEFOR THE ENDOVASCULAR TREATMENT OF INTRACRANIAL ANEURYSMS

Protocol Version: 4.0

The following individuals have reviewed this version of the Statistical Analysis Plan and are in agreement with the content:

Signature Page

Study Biostatistician:

PPD

_____ _____
(Print) (Sign) Date

Head of Biostatistics:

PPD

_____ _____
(Print) (Sign) Date

Clinical Study Lead:

PPD

_____ _____
D

Franchise Platform Head of Clinical Research:

PPD

_____ _____
D

Revision History

Revision Number	Revision Date (DD/MM/YYYY)	Reasons for Revision
Version 1	11/11/2020	First edition.
Version 2	31/07/2025	Updates include: 1. Section 7.5.2, Analyses of Secondary Packing Density Endpoints, removing the reporting of packing density assessment from local investigators 2. Section 7.7 Analyses of adverse events (AEs), detailing “intra-procedural” for symptomatic thromboembolic events 3. Section 7.9 Handling of Missing Data, modification of missing data imputation rule for length of stay 4. Section 7.10 Subgroup Analyses, updating language for type of coils subgroup 5. Section 7.11 Additional Analyses, for interval censoring of primary endpoint, specifying event to be Raymond-Roy Classification of III of 275+ days; removing scenario where Raymond-Roy Classification of III of 275+ days is missing; updating language for type of practice subgroup

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1 Study Design

This study is designed as a prospective, multi-center, single-arm evaluation of the MICRUSFRAME and GALAXY coils including the PulseRider Aneurysm Neck Reconstruction device in the treatment of ruptured or unruptured intracranial aneurysms. Approximately 850 subjects will be enrolled and treated with the MicrusFrame and/or Galaxy G3 coils at approximately 60 clinical sites across the US, EMEA (Europe, Middle East, Africa) and Japan.

The objective of this study is to obtain “real world” clinical data and characterize the acute and long-term performance of the MICRUSFRAME and GALAXY coils for the endovascular treatment of intracranial aneurysms. The secondary objective of this study is to evaluate “real world” outcomes with the use of the PulseRider Aneurysm Neck Reconstruction device for the endovascular treatment of intracranial aneurysms.

It will take each participant approximately 1 year to complete the follow-up visits post-procedure (180-Day follow-up and 1-Year follow-up).

2 Treatment Assignment

This registry is a single arm study and all enrolled patients will be implanted with MICRUSFRAME and GALAXY coils.

Adjunctive devices such as balloon, stents, PulseRider or flow diverters may be used in conjunction with the MICRUSFRAME and GALAXY coils as needed. Up to 200 cases with flow diverters and up to 200 cases with intrasaccular flow disruptors used in conjunction with study articles will be allowed.

3 Interval Windows

Study reports will be summarized by scheduled visit (as defined in Protocol Section 7). The study schedule is to be adhered to as closely as possible for all subjects. Measurements outside the interval windows will be treated as missing. In the case of repeated measurements taken at the same visit, the most recent non-missing measurement will be used unless specified otherwise.

Due to Covid-19, the 1-year clinic visit may be performed remotely and the 1-year angiogram may be conducted up to an extended window as allowed by the protocol. However, the following study visits and windows are still anticipated for subjects unaffected by Covid-19.

- 180-day follow-up (-3 to +3 months) is considered as 90 – 270 days post procedure.
- 1-ye r follow-up (-3 to +6 months) s cons dered s 2 5 – 545 d ys post procedure.

In particular, study window will be calculated in terms of ‘study days’ as follows (refer to section 7.1 for the definition of study days, where it is defined differently for subjects with and without a pre-planned staged procedure due to aneurysm rupture status prior to the initial study procedure.)

4 Levels of Significance

There are no formal hypotheses tests in this study. Confidence intervals will use a 95% confidence level unless otherwise specified.

5 Analysis Sets

The analysis sets to be used are defined as follows:

- Safety analysis set: it consists of all enrolled subjects in whom coil treatment is attempted as defined by advancement of a coil outside of the distal end of the microcatheter inside the subject.

  A subject is considered enrolled in this study after the subject is consented and the treating physician confirms the subject continues to meet all eligibility criteria on the day of the study procedure.

- Per-Protocol (PP) analysis set: it consists of subjects in the safety analysis set who satisfy all of the following criteria:
  - have met the eligibility criteria per the final version of the protocol;
  - have been treated with at least 75% GALAXY/MICRUSFRAME coils by length (including total cumulative coils from both part 1 and part 2 of staged procedures should there be any);
  - have completed 1-year digital subtraction angiography (DSA)/magnetic resonance angiography (MRA).

6 Sample Size Justification

Up to 850 subjects will be enrolled into the study at up to 60 clinical sites from the US, EMEA and Japan. Due to heterogeneity in aneurysm characteristics and treatment (e.g., rupture status, aneurysm location, aneurysm neck-size, adjunctive treatment, etc.), multiple subgroup analyses are planned. A sample size of 850 subjects was selected to ensure there are a sufficient number of subjects to allow for subgroup analyses and to emulate “real world” clinical data to characterize the acute and long-term performance of the MICRUSFRAME and GALAXY coils including the PulseRider Aneurysm Neck Reconstruction device for the endovascular treatment of intracranial aneurysms.

With an enrolled sample size of 850 and an attrition rate of no more than 20%, the maximum margin of error for the primary endpoint is anticipated to be 3.8% when the primary endpoint rate is at 50%.

$$Maximum\ Margin\ \approx 2 \times SE = 2\sqrt{\frac{p(1-p)}{680}} = 2\sqrt{\frac{0.5 \times 0.5}{680}} = 3.8\%$$

where SE denotes the 2-sided 95% confidence margin of error, and p denotes the proportion of subjects who exhibit adequate occlusion.

7 Analyses to be Conducted

7.1 General Conventions

The number of observations with data, the number of observations with missing data, mean, standard deviation, median, first quartile (Q1), third quartile (Q3), minimum and maximum will be provided for continuous data; and the number and percentage will be provided for categorical data. Percentages will be based on the number of subjects with non-missing data, unless specified otherwise.

- Baseline

  Unless specified otherwise, baseline is defined as the last non-missing measurement prior to the start of the first study procedure.

- Rupture status

  Subjects are classified by their aneurysm rupture status prior to the index procedure, regardless of the change in their rupture status during procedure.

- Study day

  Study day will be calculated as the difference between the assessment date and the date of the most recent study procedure as follows,

  - Subjects without a pre-planned staged procedure

    Study day = assessment date – date of part 1 procedure

  where the day of part 1 procedure is considered as Day 0.

  - Subjects with a pre-planned staged procedure

    Study day = assessment date – date of part 2 staged procedure

  where part 2 of the staged procedure is considered as Day 0.

- End of study

  Due to Covid-19, the 1-year imaging can be delayed up till 30 months (913 days) post-procedure. Estimates at the end of study beyond 913 days will be excluded from analysis, unless instructed otherwise.

- Retreatment

  At the discretion of the investigators, a subject may be retreated (e.g. with coils, stent, etc.) at any time. All subjects who are retreated will remain in the study and will continue to receive all follow-up assessments in the study.

  No pre-planned staged procedures on unruptured target aneurysms will be allowed in the study. Pre-planned staged procedures are not considered as retreatment for subjects with ruptured aneurysms.

- SAS version

  All statistical analyses will be performed using SAS®, Version 9.4 or later, unless otherwise noted.

7.2 Disposition of Study Subjects

The number and percentage of subjects in each analysis set will be provided, together with a summary of subjects who completed or discontinued the study with associated reasons.

Enrollment by site will be summarized for consented subjects and each analysis set. Study eligibility by inclusion and exclusion criteria will be summarized for consented subjects as well.

7.3 Demographics and Baseline Characteristics

All demographic profiles and baseline characteristics, procedural, and immediate post-operative data will be summarized descriptively for each analysis set as applicable, including but not limited to:

- Demographics
- Medical history, smoking status
- Neurosurgical history
- Platelet reactivity testing
- Baseline scores for mRS
- Baseline Hunt & Hess scale (for ruptured aneurysms only)
- Target aneurysms and vessel characteristics

7.4 Procedural Characteristics

All procedural and aneurysm characteristics will be summarized descriptively for each analysis set as applicable, including but not limited to:

- Procedure characteristics
- Total number of coils placed, number of GALAXY coils, GALAXY G3 Mini coils placed, percentage of GALAXY/MICRUSFRAME coils used

  Coils used during the part 1 and part 2 procedures will be summarized together.
- Adjunctive devices used (e.g., stents, flow diverters, balloons, PulseRider, etc.)

7.5 Primary and Secondary Endpoint Analyses

For the analyses of retreatment and device-related SAEs, Kaplan-Meier analysis (using product limit estimates) will be applied. Kaplan-Meier event rate and its associated two-sided 95% CI using log-log transformation will be reported, the estimate of standard error will be computed using Greenwood's formula. The event date and the censoring date will be calculated with respect to the date of the most recent study procedure, in terms of study days (refer to section 7.1 on the algorithm for subjects with or without part 2 procedure).

7.5.1 Analysis of Primary Endpoint

- Adequate occlusion rate at 1 year without retreatment

Adequate occlusion rate is defined as the proportion of subjects who achieved a modified Raymond-Roy I or II classification of the aneurysm at 1 year without retreatment. Raymond-Roy classification will be assessed by the independent core lab, and retreatment will be reported by the local investigators. The primary endpoint will be analyzed using PP analysis set.

The number and percentage of subjects who reached adequate occlusion at 1-year without retreatment will be summarized at following two timepoints by cohorts of subjects who received and who didn't receive flow diverter and/or intrasaccular assisted coiling. Two-sided exact 95% CIs for the adequate occlusion rate will be conducted around the percentage.

- 1 year estimate: by regular 1-year window as defined by protocol, i.e., imaging assessments completed from 9-month up till 18 months post-procedure (i.e., days 275-545); subjects without 1-year imaging assessments between days 275-545 will be excluded from the calculation of the rate of adequate occlusion unless they undergo retreatment by day 545. Subjects who are retreated prior to 1-year imaging within 545 days will also be counted as failures.
- End of Study estimate: by extended 1-year window as allowed by protocol to account for delays due to Covid-19, i.e., imaging assessments completed from 9-month up till the last imaging date in the study, i.e., days 275 till end of study. All subjects with imaging assessments between day 275 until exit from study will be included in the calculation of the rate of adequate occlusion. Subjects who achieve adequate occlusion based on an image obtained after 275 days will be counted as failures if this image is obtained after retreatment.

All subject data, those who achieved this primary endpoint and those who failed to achieve this endpoint will be listed.

7.5.2 Analyses of Secondary Packing Density Endpoints

The main analyses for packing density will be performed on the PP analysis set using the assessments from the independent core lab. No imputation is planned for missing data (refer to section 7.8).

- Packing density (%)

  Packing density is defined as the ratio of the volume of coils to the volume of the coiled part of the aneurysm achieved during the procedure. This will be calculated via AngioSuite based on the aneurysm volume and the coils used to the treat the target aneurysm.

  For subjects without a pre-planned staged procedure, the packing density reported at the end of index procedure will be used; however, for subjects with a pre-planned staged procedure, the packing density reported at the end of part 2 of the staged procedure will be used.

  Summary statistics of packing density will be provided for subjects with non-missing data.

7.5.3 Analyses of Secondary Effectiveness Endpoints

Analyses for the secondary effectiveness endpoints will be performed using PP analysis set.

- Complete occlusion at 1 year

  Complete occlusion rate is defined as the proportion of subjects who achieved a modified Raymond-Roy I classification at 1 year, as assessed by the independent core lab.

  The number and percentage of subjects with complete occlusion will be summarized at following two timepoints. Two-sided exact 95% CIs for complete occlusion rate will be conducted around the percentage.

  - 1 year estimate: by regular 1-year window as defined by protocol, i.e., imaging assessments completed from days 275-545; subjects without 1-year imaging assessments between days 275-545 will be excluded from analysis.
  - End of Study estimate: by extended 1-year window as allowed by protocol, i.e., days 275 till end of study. All subjects with imaging assessments between day 275 until exit from study will be included in the calculation of the rate of complete occlusion.

- Recanalization rate at 1 year

  Recanalization rate is defined as the proportion of subjects with worsening in aneurysm occlusion grading (modified Raymond-Roy Classification Scale) for the target aneurysms as assessed by the independent core lab.

  The number and percentage of subjects with recanalization will be summarized at following two timepoints. Two-sided exact 95% CIs for recanalization rate will be conducted around the percentage.

  - 1 year estimate: by regular 1-year window as defined by protocol, i.e., imaging assessments completed from days 275-545; subjects without 1-year imaging assessments between days 275-545 will be excluded from analysis.
  - End of Study estimate: by extended 1-year window as allowed by protocol, i.e., days 275 till end of study. All subjects with imaging assessments between day 275 until exit from study will be included in the calculation of the rate of recanalization.

- mRS 0-2 score at 1 year

  The number and percentage of subjects with mRS 0-2 at 1 year follow-up will be summarized for subjects with unruptured aneurysms.

  Subjects with missing mRS scores due to death will be analyzed with an mRS score of 6 for the subsequent visits, subjects with missing mRS scores due to reasons other than all-cause mortality will be excluded from the analysis.

- Retreatment rate up to 1 year

Kaplan-Meier analysis will be performed to calculate the rate of retreatment. Retreatment is considered as the event; where the event date is the date of retreatment.

Subjects without events will be censored at the date of last contact. The Kaplan-Meier event (failure) rates at 365, 545 days and at the end of the study will be reported with associated 95% CIs.

7.5.4 Analyses of Secondary Safety Endpoint

Kaplan-Meier analyses will be performed to calculate device-related serious adverse event (SAE) rate using safety analysis set.

Device-related SAEs are considered as events; where the event date is the date of first event of any device related SAEs. Subjects without events will be censored at the date of last contact in the study (e.g., date of completion or discontinuation). Kaplan-Meier event (failure) rates at 365, 545 days and at the end of the study will be reported with associated 95% CIs.

In addition, device-related SAEs will be summarized by body system organ class and preferred term using the latest version of Medical Dictionary for Regulatory Activities (MedDRA). Related events are defined as those AEs that are reported to have causal, probable or possible relationship.

7.6 Analyses of Additional Endpoints

The following health economic endpoints will be summarized for PP analysis set.

- Length of stay for study procedure hospitalization

Length of stay in hospitalizations due to study procedure will be summarized at the subject level per the following formula.

Length of stay (days) = date of discharge – date of admission + 1.

Length of stay will be summarized for subjects who were discharged alive following study procedure. For staged procedures, the length of stay for subjects who received part 2 procedure will be averaged with the length of stay from part 1 procedure, before the overall summarization at the subject level. Deaths before discharge following study procedure will be summarized separately.

Discharge locations (e.g., home, nursing home etc.) will be summarized for subjects who were discharged alive following study procedure, separately for those discharged following part 1 and part 2 procedures.

- Number of re-hospitalizations related to the target aneurysm
  - Maximum length of stay for re-hospitalization

Hospitalizations not due to study procedure (neither part 1 nor part 2 procedures) are considered as re-hospitalizations. Re-hospitalizations will be evaluated for subjects who were discharged alive from study procedure. Deaths related to the target aneurysm will be counted towards re-hospitalization. Subjects who were re-

hospitalized but withdrew from the study before discharge will be excluded. Refer to section 7.9 in case of missing dates on discharge.

The number of re-hospitalizations, the number and percentage of subjects with re-hospitalizations and the maximum length of re-hospitalizations will be summarized, where the maximum length of stay is taken to be the maximum number of stay across all re-hospitalizations at the subject level.

The rate of re-hospitalization per patient year of follow up will also be reported per the following formula:

Event rate per patient year =

$$\frac{\text{Number of re-hospitalizations}}{\text{Total length of follow-up in years for all subjects in the population}}$$

where the length of follow-up (years) = (date of study completion/early discontinuation – date of index procedure + 1)/365, and the number of re-hospitalizations includes deaths related to target aneurysm post procedure.

7.7 Analyses of adverse events (AEs)

Analyses for AEs will be performed using safety analysis set. The number of events, the number and percentage of subjects with at least one AE will be summarized overall and by following categories.

- All AEs
- Symptomatic intra-procedural thromboembolic events
- Intra-procedural aneurysm ruptures
- AEs by causality
- Serious AEs
- AEs by severity
- AEs by outcome
- Unanticipated events

7.8 Plans for Interim Analyses

Interim analyses will be conducted approximately after every 200 subjects are treated and their imaging data are evaluated. Only descriptive statistics will be reported.

7.9 Handling of Missing Data

In case of missing or incomplete hospital discharge date that makes the calculation of length of stay cannot be performed due to reasons such as death before discharge, then length of stay will be imputed via following methods:

- If only the day is missing, while the month and year of discharge are available, then it will be imputed to be day 30 of that month; otherwise

- By randomly drawing from the upper 90th percentile of the distribution of lengths of stay, from all other hospitalizations with non-missing values of discharge date.

No other missing data imputation is planned in the study.

7.10 Subgroup Analyses

Subgroup analyses will be performed for the primary and secondary endpoints, using the PP and safety analysis sets across various subgroups using the same approach as in Section 7.5. Descriptive statistics and associated 95% CI will be provided for each subgroup when there is a minimum of 30 subjects in all subgroup levels, unless instructed otherwise.

Subgroup analyses to be performed including but not limited to the following, additional subgroups may be explored as needed.

- Rupture status prior to study procedure (ruptured vs. unruptured)
- Aneurysm location (anterior circulation vs. posterior circulation)
- Aneurysm location relative to artery (bifurcation vs. sidewall)
- Aneurysm neck size (wide-neck vs. narrow-neck)

  A wide-neck aneurysm is defined as the neck size ≥ 4 mm or a dome to neck ratio is < 2; narrow-neck otherwise.
- Aneurysm size (small, medium vs. large)

  An aneurysm is considered as small if the maximum diameter < 5 mm; medium if ≥ 5 - <13mm; and large otherwise.
- Use of coils in combination with other devices (coils alone, coils + stents, coils + PulseRider, coils + flow diverters, coils + intrasaccular flow disruptor)

  This analysis will be performed regardless the number of subjects at each subgroup level.
- By geography (EMEA, US and Japan)
- Years of experience by the procedure operator at the beginning of the study (0-2, >2 - 5, >5 – 10 vs. >10)
- Type of coils (100% GALAXY/MICRUSFRAME coils vs.< 100% GALAXY/MICRUSFRAME coils)

7.11 Additional Analyses

- mRS scores, frequency of mRS scores by categories of 0, 1, 2, …, 6 will be summarized at all timepoints (baseline, discharge, 6 months and 1 year follow-ups) using the PP analysis set. A shift table summarizing the mRS scores at baseline and 1-year follow-up will be presented as well.
- A shift table of Raymond-Roy classifications (based on independent core lab) from index procedure to 6-month and 1-year follow-up visits will be summarized for subjects with non-missing assessments using the PP analysis set. The subject rate will be

calculated based on binary proportions using the non-missing assessments. Raymond-Roy classifications at 1-year follow up will be reported at two timepoints: 1-year estimate by regular window of 275-545 days and by extended window from 275 days until the end of study.

- Protocol deviations: the number of deviations, the number and percentage of subjects with at least one protocol deviation will be summarized.
- Concomitant medications: all medication data will be listed using the latest version of World Health Organization (WHO) Drug Dictionary.
- Device deficiency, frequency of device deficiency will be summarized based on the data collected from CRF.
- Retreatment: timing of retreatment (e.g. post-procedure up to 6 months), frequency of retreatments, retreatment reason, retreatment devices used, will be summarized overall and by aneurysm rupture status prior to the study procedures.
- Interval censoring for the primary endpoint

  To investigate the potential impact of Covid-19 on the extended window of the 1-year imaging, interval censoring analysis will be performed if more than 30% of subjects in the PP analysis set have non-missing 6 month imaging. All subjects with non-missing imaging assessments at 6-month in the PP analysis set will be included into the analysis. Lack of adequate occlusion (i.e., Raymond-Roy classification of III) beyond 275 days or retreatment (if prior to final imaging) is considered as events, the censoring algorithm is detailed as follows.

Retreat-ment	**Raymond-Roy Classification of III of 275+ days**	**Interval**	
		Date for left boundary	**Date for right boundary**
Yes	-	Date of retreatment	Date of retreatment
No	No	Date of last imaging (e.g., 1-year imaging)	Infinity (censored)
No	Yes	Later date of 1) Day 275, or 2) Previous imaging (e.g., 6-month imaging)	Date of last imaging (e.g., 1-year imaging)

The survival probabilities will be estimated using EMICM method under SAS proc iclifetest. The associated standard error will be estimated using multiple imputation

with 1000 iterations. Two-sided 95% confidence interval for the survival estimates will be presented using log-log transformation.

The survival rate (i.e., adequate occlusion without retreatment) at day 545 (upper bound of the regular window of 1-year imaging) and the last imaging date in the study will be reported. If the timepoint of interest is not directly available from interval censoring due to Turnbull intervals (undefined intervals without constant survival estimates), then estimates from the next interval will be reported. If the survival rate for the last imaging date is undefined, then survival rates from the immediately previous interval will be reported.

- Additional subgroup analyses

  1) Unruptured aneurysms: To investigate geographical differences in adequate occlusion at 1-year in wide-neck unruptured aneurysms, the subgroup analyses to be performed include but are not limited to:

     - Pairwise geographic difference (EMEA vs. US, US vs. Japan and EMEA vs. Japan).
     - Use of adjunctive devices (balloons, stents, PulseRider, flow diverter, intrasaccular flow disruptor).

  2) Ruptured aneurysms: To investigate the AE rates and aneurysm re-rupture rates, retreatment rates at 1-year within the cohort of patients with ruptured aneurysms using the safety analysis set, the subgroup analyses to be performed include but are not limited to:

     - Number of procedures (single procedure vs. pre-planned staged procedures).
     - Type of practice (academic practices vs. other practices).
     - Geographic differences in practice (EMEA vs. US, US vs. Japan and EMEA vs. Japan).

     Subjects who received single procedure are defined as those who received the index procedure only during the study, without retreatment or pre-planned staged procedure, also excluding those pre-planned staged procedures which end up without part 2 of the procedure.

7.12 Changes from Planned Analyses

- Updates on the definition of PP analysis set

  The protocol definition of PP analysis set requires subjects to complete the 1-year (-3/+6 months) DSA/MRA. However, this requirement is not updated to account for the extended angiogram window as agreed in the protocol section 7.6.1 regarding Covid 19: the 1-year angiogram may be conducted outside the protocol specified window up to a maximum of 18 months after the 1 year timepoint.

  Hence, the 1-year angiogram requirement in the PP analysis set is updated to include subjects with 1-year DSA/MRA, not only those in the regular window of (9 – 18 months

post procedure), but also those beyond 18 months post procedure. All other conditions in the PP analysis set remain the same.

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