Statistical Analysis Plan

Post-Marketing Surveillance Study on the Conformable GORE® TAG® Thoracic Endoprosthesis

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1.0 Introduction

This Statistical Analysis Plan (SAP) describes the statistical analyses planned to address the objectives of this Post-Marketing Surveillance Study. This SAP summarizes the analyses that will be performed to determine the safety and efficacy of the Conformable GORE® TAG® Thoracic Endoprosthesis (CTAG Device) when used for the treatment of acute complicated Stanford Type B dissection or traumatic thoracic aortic transection. This SAP outlines tables, figures, and listings that are included in reports for the study.

2.0 Study Design Overview

2.1 Purpose

The purpose of the surveillance study is to confirm the safety and efficacy in a clinical setting after the launch of the CTAG Device for the indications of acute complicated Stanford Type B dissection and traumatic thoracic aortic transection.

2.2 Method of Surveillance Study

The request for cooperation in this surveillance study should be notified to the sites in advance, and the sites should contact our company as soon as the eligible subjects are identified. A written contract for the survey shall be concluded between the sites for the survey, the company, and the company's subcontractor.

In case device failure is recognized, physician in charge or person in charge at our company's subcontractor will immediately contact the person in charge of the survey at our company, and in-house safety management department will take necessary action.

The sites complete and submit the results of surveillance study questionnaire within 1 month and 1 year after implantation of the Device, and annually thereafter until the completion of the fifth year of the survey.

2.3 Data Analysis

All analyses will be performed separately for the dissection and trauma cohorts, unless specified otherwise.

2.3.1 Safety Data

<u>All-Cause Mortality (Dissection and Trauma)</u>

All-cause mortality through 30 days post-treatment will be evaluated. For the dissection cohort, this result will be compared descriptively with the performance goal of 0.25 from the TAG 08-01 study. Additionally, Kaplan-Meier plots of all-cause mortality will be generated.

<u>Serious Adverse Events (Dissection and Trauma)</u>

The proportion of subjects reporting serious adverse events (including stroke, respiratory failure, myocardial Infarction, renal failure, paralysis/paraparesis and bowel ischemia) among the eligible subjects in each follow-up period shall be provided.

2.3.2 Efficacy Data

Primary Entry Tear Exclusion (Dissection)

The proportion of subjects reporting exclusion of the primary entry tear shall be evaluated among the eligible dissection subjects in each follow-up period. The result in the one month study window will be compared descriptively with the primary efficacy endpoint result from the TAG 08-01 study.

Aortic Rupture (Dissection and Trauma)

The proportion of subjects reporting aortic rupture among the eligible subjects in each follow-up period shall be provided.

Major Device Events (Dissection and Trauma)

The proportion of subjects reporting major device events among the eligible subjects in each follow-up period shall be provided. Major device events include endoleak, access and deployment failure, lumen obstruction (including device compression and thrombus), device integrity events, extrusion/erosion, device migration, intercomponent migration and wire fracture with severity from major A to major D selected.

Secondary Interventions (Dissection and Trauma)

The proportion of subjects reporting secondary interventions among the eligible subjects in each follow-up period shall be provided with the treatment and reason of the intervention.

True and False Lumen Diameter Changes (Dissection)

Changes in true lumen and false lumen measurements in both the treated segment and distal to the treated segment among the eligible dissection subjects in each follow-up period shall be provided. Changes of ≥5 mm will be considered an increase, changes of ≤-5 mm will be considered a decrease, and changes between -5 mm and 5 mm will be considered stable.

Lesion Diameter Changes (Trauma)

Changes in lesion diameter among the eligible trauma subjects in each follow-up period shall be provided. Changes of ≥5 mm will be considered an increase, changes of ≤-5 mm will be considered a decrease, and changes between -5 mm and 5 mm will be considered stable.

2.4 Statistical Hypotheses

No formal hypothesis tests will be performed.

2.5 Sample Size Determination

[redacted] The sample size of 43 subjects [redacted] Subjects in the trauma cohort will be enrolled from sites already participating in the dissection cohort, and there is no sample size requirement for the trauma cohort.

3.0 Study Data Collection

3.1 Follow-up Visits

Unless specified otherwise, follow-up visits will be summarized in the Analysis Windows outlined in Table 1.

Table 1: Follow-up Visit Windows

Follow-up Visit	Ideal Window (days)	Analysis Window (days)
Procedure	0	0
Discharge	Before hospital discharge	N/A
Post-Procedure	1-14	1-14
1 month	23-44	15-59
6 month	150-210	60-242
12 month	275-455	243-546
24 month	640-820	547-911
36 month	1005-1185	912-1275
48 month	1370-1550	1276-1640
60 month	1735-1915	1641-2006

4.0 Statistical Analyses

4.1 Analysis Populations

All enrolled subjects will be included in reported data. Results will be reported separately for the dissection and trauma cohorts, unless specified otherwise.

4.2 Timing of Analyses

Analysis of the study results will be ongoing throughout enrollment. Serial analyses of long-term results will occur during the follow-up period. No adjustment to overall alpha level will be made for this surveillance study.

4.3 Specified Analyses

Statistical analyses will include summary statistics, including frequency counts for categorical variables, and measures of dispersion for continuous variables. [redacted] No inferential analyses will be performed.

[redacted]

[redacted]

4.4 Site Poolability

Site data will be pooled based on clinical comparability, i.e., the study sites followed a common protocol, and the data collection and handling procedures were similar at all study sites.

4.5 Adverse Events

Adverse Events (AEs) will be recorded on the appropriate Case Report Form (CRF). The Investigator at each Site is ultimately responsible for reporting all AEs. The most appropriate AE code will be chosen from the AE list and will also have an accompanying description. Each AE will be assessed by the Investigator to determine if it is: serious/non-serious, major/minor, and related to the device/TEVAR procedure/concomitant procedure as described in the CRF.

5.0 Analysis Specifications

[redacted]

5.3 Verification Level for Statistical Output

All necessary analysis datasets as well as tables referenced herein will be verified at Level I. All listings and figures referenced herein will be verified at Level II. [redacted]

6.0 Data Sets, Tables, Figures, and Listings

At a minimum, the following set of Tables, Figures and Listings will be produced.

[redacted]