GORE® VIABAHN® Endoprosthesis Post-Marketing Surveillance Study

-Treatment of patients with symptomatic peripheral arterial disease in superficial femoral arteries-

Protocol Number: JPS 16-03

Statistical Analysis Plan Date: February 1, 2019

NCT Number: NCT04706273

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Medical Products Division

Statistical Analysis Plan

Study Acronym/Protocol #: JPS 16-03 / Protocol #1

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1.0 Introduction

This Statistical Analysis Plan (SAP) describes the statistical analyses planned to address the objectives of JPS 16-03. This SAP summarizes the analyses that will be performed to determine the safety and effectiveness of the GORE® VIABAHN® Endoprosthesis (VIABAHN®) when used for the treatment of patients with symptomatic peripheral arterial disease in superficial femoral arteries (SFA). This SAP outlines tables, figures, and listings that are included in reports for the JPS 16-03 Post-Marketing Surveillance.

2.0 Study Design Overview

2.1 Objectives

The objectives of JPS 16-03 is to document the efficacy and safety of the VIABAHN® for the treatment of patients with symptomatic peripheral arterial disease in the SFA.

2.2 Design Summary

This is a Japanese regulatory post-marketing surveillance to investigate the safety and effectiveness of VIABAHN®. The surveillance will continuously enroll all patients treated for symptomatic peripheral arterial disease with VIABAHN® at the participating institutions, until 250 patients with lesions longer than 15 cm have been enrolled. Patients who have the treatment of traumatic or iatrogenic vessel injury in thoracic abdominal, or pelvic arteries (except the aorta, coronary, brachiocephalic, aortic, vertebral and pulmonary arteries) with VIABAHN® will be excluded. Patients treated with VIABAHN® before conclusion of a contract will be enrolled in this surveillance retrospectively.

2.3 Data Analysis

Efficacy

Primary assisted patency at 12 and 24 months after implant will be estimated by Kaplan-Meier analysis.

Freedom from Target Lesion Revascularization (TLR) at 1, 12, and 24 months after implant will be estimated by Kaplan-Meier analysis.

Safety

Occurrence of device or procedure related serious adverse events or deficiencies. The number of events and subjects for which a reported serious adverse event occurred will be calculated at procedure and 1, 12, 24, 36, 48, and 60 months after implant.

Stent fracture rates will be estimated at 12, 24, 36, 48 and 60 months calculated using Kaplan-Meier analysis. When an occurrence of fracture is suspected at the site, the image will be sent to Core lab for assessment.

2.4 Statistical Hypotheses and Sample Size

[redacted]

3.0 Study Data Collection

3.1 Study Data Collection Intervals

Subjects will be asked to return for follow-up visits at 1, 12, 24, 36, 48, and 60 months. Evaluations and information to be collected at each visit is shown in Table 1.

Table 1: Examination schedule

Diagnostic Test	Procedure	1 Month	12 Months	24 Months	36 Months	48 Months	60 Months
Patient background and pre-operative patient information	X						
Date of discharge		X					
Device usage information	X						
Presence / absence of concurrent treatments and their detail if there was any	X						
Information on antiplatelet, anticoagulant drug administration	X	X	X	X			
Rutherford classification	X	X	X	X	X	X	X
ABI (or TBI)	X	X	X	X	X	X	X
CDUS			X	X	X	X	X
Plain X-ray			X	X	X	X	X
Adverse events and/or deficiencies and details	X	X	X	X	X	X	X

3.2 Study Interval Windows

The visit windows and corresponding analysis windows are shown in Table 2.

Table 2: Assessment period

Follow-up visit	Visit Window (days)	Analysis Window (days)	Kaplan-Meier Window (days)
Procedure	0	0	0
1 month	23 - 44	1 - 37	1 - 30
12 months	275 - 455	38 - 395	31 - 365
24 months	640 - 820	396 - 760	366 - 730
36 months	1005 - 1185	761 - 1277	731 - 1095
48 months	1370 - 1550	1278 - 1642	1096 - 1460
60 months	1735 - 1855	1643 - 1855	1461 - 1825

3.3 Core lab

When a site suspects the occurrence of a stent fracture, the x-ray image will be sent to the Core lab for assessment.

4.0 Statistical Analyses

4.1 Analysis Populations

The following populations will be used in the analysis of the endpoints:

1. All Subjects – All subjects receiving a VIABAHN® device with symptomatic peripheral arterial disease.

[redacted]

Data analyses will be implemented by using following populations:

- Efficacy: All Subjects [redacted]
- Safety: All Subjects [redacted]

If there are subjects who receive a VIABAHN® device with symptomatic peripheral arterial disease outside the SFA or other diseases than symptomatic peripheral arterial disease, target disease, target vessel and severe adverse event will be summarized in annual reports and a final report.

4.2 Timing of Analyses

Annual reports will be created on the anniversary of the approval date. A final analysis will be performed after all enrolled subjects complete the 60-month follow-up or have been withdrawn from the surveillance.

4.3 Data analysis

Primary assisted patency

Primary assisted patency is defined as hemodynamic evidence of flow through a device that had not required target lesion revascularization to restore flow after total occlusion. This will be estimated at 12 and 24 months by Kaplan-Meier analysis.

[redacted]

Freedom from Target Lesion Revascularization

Target Lesion Revascularization (TLR) is defined as repeat intervention performed at initial VIABAHN® implantation site of the study limb to maintain or re-establish patency. This will be estimated at 1, 12, and 24 months after implant by Kaplan-Meier analysis.

[redacted]

Occurrence of device or procedure related serious adverse events

The number of subjects for which a reported serious adverse event occurred will be calculated at procedure and 1, 12, 24, 36, 48, and 60 months after implant.

If deficiencies occurred, the detail will be reported in annual reports and a final report.

Serious adverse events (SAE), regardless of their causal relationship, are the events that fall under these categories:

1) Death
2) A case in which the event is suspected to cause a life-threatening condition.
3) A case that requires hospitalization in a hospital or a clinic or an extension of a hospital stay.
4) Disability
5) A case in which the event could have resulted in disability.
6) A case that is serious according to the cases in the above 1 to 5.
7) A congenital disease or abnormality from which a later generation of a patient will suffer.

An SAE is classified by the physician who is responsible for the subject.

Hospitalization without the onset of a new adverse event or aggravation of a pre-procedure complication, such as the reasons for hospitalization listed below, will not be handled as a serious adverse event.

- Hospitalization due to treatment that had previously been scheduled before the procedure to implant VIABAHN® (i.e., hospitalization due to surgery for a pre-procedure complication that can be conducted after improvement of the target lesion).
- Administrative hospitalization (e.g. hospitalization for a regular medical checkup, examination, or training).
- Hospitalization at a rehabilitation facility.

[redacted]

Stent fracture

Stent fracture rates will be estimated at 12, 24, 36, 48 and 60 months by Kaplan-Meier analysis. When an occurrence of fracture is suspected at the site, the image will be sent to Core lab for assessment.

[redacted]

5.0 Analysis Specifications

5.1 SAS Analysis Dataset Specifications

[redacted]

[redacted]

5.2 Statistical Output Specifications

[redacted]

5.3 Verification Level for Statistical Output

[redacted]

- All Analysis Datasets – Level I
- All Tables – Level I
- All Listings – Level II

6.0 Data Sets, Tables, Figures, and Listings

At a minimum, the follow set of Tables and Figures will be produced for the reports defined in section 4.2. Unless specified, the Tables and Figures will be analyzed using [redacted] All Subjects [redacted] Listings will be produced for the final report.

6.1 Analysis Tables

[redacted]

[redacted]

[redacted]

6.2 Analysis Listings

[redacted]

6.3 Analysis Figures

[redacted]

7.0 References

[redacted]