7 June 2016 [redacted]

GORE® VIABAHN® Endoprosthesis Post-Marketing Surveillance Study -Treatment of patients with symptomatic peripheral arterial disease in superficial femoral arteries-

Protocol Number: JPS 16-03

Protocol Date: June 7, 2016

NCT Number: NCT04706273

W. L. Gore & Associates, Inc.
Medical Products Division

7 June 2016 [redacted]

Execution Plan for Post-Marketing Surveillance Study

GORE® VIABAHN® Endoprosthesis Post-Marketing Surveillance Study -Treatment of patients with symptomatic peripheral arterial disease in superficial femoral arteries-

1. Study Device

Category	Instrument and Apparatus(07)Visceral Function Substitute Device
Generic Name	Stent graft with heparin for blood vessel
Commercial Name	GORE® VIABAHN® Endoprosthesis

2. Purpose of surveillance study

To confirm device efficacy and safety in the clinical setting after the launch of the GORE® VIABAHN® Endoprosthesis (hereafter "VB device") for the treatment of symptomatic peripheral arterial disease in the superficial femoral arteries.

3. Planned number of subjects and its rationale

Planned number of subjects: A minimum of 250 cases (Enrollment will be continued until 250 patients with lesion length greater than or equal to 15 cm will be enrolled)

Rationale:
[redacted]

4. Patients to be subjected to this surveillance study

Patients with symptomatic peripheral arterial disease in superficial femoral artery lesions 10cm or more in length with reference vessel diameters ranging from 4.0 to 7.5mm (hereafter, "study target patient") and also other patients had treatments with VB device during the enrollment period in addition to the study target patient. The patients who have the treatment of traumatic or iatrogenic vessel injury in thoracic, abdominal, and pelvic arteries (except the aorta, coronary, brachiocephalic, carotid, vertebral and pulmonary arteries) with VB device are not included into this study.

5. Planned number of institutions by department

The planned number of institutions: About 60 institutions which conclude a contract that adheres to GPSP ordinances after the study initiation, or use the GORE® VIABAHN® Endoprosthesis before conclusion of a contract that adheres to GPSP ordinances and NHG knows that information. This institutions includes the study sites for VJH-11-01 study.

The number of institutions of VHJ-11-01 Pre-Market Study: 15 sites 3 departments (Vascular surgery department: 6 sites, Cardiovascular internal medicine department: 6 sites, Radiology department: 3 sites)

6. Method of Surveillance Study

1) To make a written agreement between the participating institutions, NHG, and NHG's outsourcing contractor on the surveillance study.
2) This survey will continuously enroll all patients treated for symptomatic peripheral arterial disease with this device in each of the participating institutions, except the patients who have the treatment of traumatic or iatrogenic vessel injury in thoracic, abdominal, and pelvic arteries (except the aorta, coronary, brachiocephalic, carotid, vertebral and pulmonary arteries) with VB device. The patients who have a treatment with VB device before conclusion of a contract will be enrolled to this study retrospectively.
3) The surveillance of the PAD patients who have a treatment with VB device is conducted in accordance with this protocol.
4) The surveillance of the patients who had a treatment with VB device for the disease except PAD is also

conducted in accordance with the contents stipulated in Attachment 1 of this protocol.
5) After one month from the procedure and on annually afterwards, the study doctor needs to submit the case report form with inputting the data to Electric Data Capture system that NHG indicates.
6) After one month from the procedure and on annually afterwards, representatives of NHG or the outsourcing contractor are to collect case report forms for the post-marketing surveillance study on which necessary items are filled out.
7) If any deficiencies of VIABAHN are recognized, the physicians responsible for the case or representatives of the outsourcing contractor will immediately report them to representatives of NHG and the GVP section of NHG will handle them appropriately.
8) From the approval date, an annual report will be made, reviewed, and approved by the Post-Marketing Surveillance Study team and the GVP section of NHG, and then submitted to PMDA.

7. Planned surveillance period

Total surveillance period: Six years and ten months
Sales preparation period: About five month
Enrollment period: About five months (until the 250 cases treated with 15cm of lesion lengths will be enrolled)
Follow-up period: For five years from procedure
CRF collection period, Analysis period and Data Fixation period: twelve months

8. Items to be investigated

8.1 Items to be investigated

The following items are investigated in each time window

8.1.1 On the procedure day

- Patient background, pre-operative patient information, etc
- Device usage information
- Presence / absence of concurrent treatments and their detail if there was any
- Rutherford classification
- ABI
- Information on antiplatelet drug administration
- Adverse events and/or device deficiencies and their details (Thrombosis, TLR (Revascularization for restenosis or occlusion of the treatment lesion) , Stent graft occlusion, Stent graft stricture etc)

8.1.2 At 1 month Follow-up visits

- Date of discharge
- Rutherford classification
- ABI (or TBI) (Presence / absence of patent of the treatment site)
- Information on antiplatelet drug administration
- Adverse events and/or deficiencies and details (Thrombosis, TLR, Stent graft occlusion, Stent graft stricture etc)

8.1.3 At 12, 24months Follow-up visits

- Rutherford classification
- ABI (or TBI) (Presence / absence of patent of the treatment site)
- CDUS (Presence / absence of patent of the treatment site)
- Plain X-ray (Presence / absence of Stent fracture)
- Information on antiplatelet drug administration
- Adverse events and/or deficiencies and details (Thrombosis, TLR, Stent graft occlusion and Stent graft stricture etc)

8.1.4 At 36, 48 and 60months Follow-up visit

- Rutherford classification
- ABI (or TBI) (Presence / absence of patent of the treatment site)

- CDUS (Presence / absence of patent of the treatment site)
- Plain X-ray (Presence / absence of Stent fracture)
- Adverse events and/or deficiencies and details (Thrombosis, TLR, Stent graft occlusion and Stent graft stricture etc)

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

8.2 Focused survey items and concrete survey methods of the items
Focused survey item: Stent Fracture
Rationale: [redacted]

9. Items and methods of analysis

Following endpoints for efficacy and safety and focused survey items will be aggregated

9.1 Efficacy:

9.1.1 Primary assisted patency at 12 and 24 months

Primary assisted patency defined as hemodynamic evidence of flow through a device that had not required a TLR to restore flow after total occlusion. This will be calculated using Kaplan-Meier analysis and will be estimated at 12 and 24month.

9.1.2 Freedom from TLR at 1, 12 and 24months

Freedom from TLR will be calculated using Kaplan-Meier analysis and will be estimated at 1, 12 and 24months.

9.2 Safety:

9.2.1 Occurrence of device- or procedure-related serious adverse events and deficiencies

Among the valid subjects at procedure, 1, 12, 24, 36, 48 and 60months, the proportion of the subjects for whom the occurrence of serious adverse events were reported.

Serious Adverse events / SAE, regardless of their causal relationship with the device are the events fall under the below categories among the adverse events/ device deficiencies caused by the device. A SAE is classified by the physician who is responsible for the case.

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.

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 by VIABAHN(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

9.2.2 Stent fracture

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

9.3 Assessment period

Assessment windows are as below;

Table 2: Assessment period

Follow-up visit	Ideal allowance of follow-up window	Analysis window
Procedure	0	0
1 month	23~44	15~59
12 months	275~455	243~546
24 months	640~820	547~911
36 months	1005~1185	912~1275
48 months	1370~1550	1276~1640
60 months	1735~1855	1641~2006

10. Organization for Operation of Post-Marketing Surveillance Study

The same as that written in Master Plan of Post-Marketing Surveillance Study

11. Name, address, and scope of service of outsourcing contractor when outsourcing a part of the surveillance study

[redacted]

12. Others

There is no other information to describe.