Post-Marketing Surveillance Study Protocol

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(1) Purpose of Surveillance Study

To confirm the effectiveness and safety of the Conformable GORE® TAG® Thoracic Endoprosthesis (hereinafter referred to as “Device”) in post-marketing utilization for the new indications of acute complicated Stanford Type B aortic dissection and traumatic thoracic aortic transection.

(2) Number of subjects to be surveyed and Rationale for setting the number

Number of subjects to be surveyed: 43 subjects with acute complicated Stanford Type B aortic dissection.

Rationale for Setting:

[redacted]

(3) Target Patients for Surveillance Study

Among patients with acute complicated Stanford Type B aortic dissection of descending thoracic aorta who meet all of the following anatomic requirements, those who have not responded to medical therapy.

- Have adequate iliac and femoral artery access route
- Aortic inner diameter at the leading end of the proximal landing zone is within the rage of 16-42mm.
- ≥20mm landing zone is on proximal side of primary entry tear and there is no dissection at the leading end of the landing zone.

(4) Number of sites by department to be surveyed

The number of sites by department and the total number of sites where this survey is possibly conducted are as follows. During the survey period, the number of sites may increase or decrease depending on the enrollment status.

Department	**Number of Sites**	**Site**
Vascular surgery	1	•The Jikei University Hospital
Cardiovascular surgery	6	•Osaka University Hospital •Morinomiya Hospital •The Sakakibara Heart Institute of Okayama •Iwaki Shiritsu Sogoiwakikyoritsu Clinics •Sendai Kousei Hospital •National Cerebral and Cardiovascular Center
Radiology	1	•Nagasaki University Hospital
Total	8	

(5) Method of Surveillance Study

1） 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.

2） 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.

3） 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.

4） An annual report of the survey is prepared every year after the start of the survey, and submitted to the Pharmaceuticals and Medical Devices Agency after internal evaluation and approval by post-marketing surveillance department and safety management department.

(6) Scheduled Period of Surveillance Study

Enrollment period: Enrollment continues until 43 subjects with complicated acute Stanford Type B aortic dissection treated with the Device has been enrolled. The enrollment period is expected to be [redacted].

Observation period: 5 years after the implantation of the Device

Rationale for Setting:

[redacted]

[redacted]

(7) Items to be surveyed, etc.

1） Items to be surveyed

① Information on Subject and Procedure

- Background of patient, preoperative patient information, etc.
- Information on the use of the Device
- Use and place of ballooning
- Additional procedure at the time of treatment and detailed information
- Hospitalization period

② Safety endpoints

- Death
- Serious adverse events (including stroke, respiratory failure, cardiac infarction, renal failure, paraplegia/paraparesis, and bowel ischemia)

③ Effectiveness endpoints

- Primary Entry Tear Exclusion
- Aortic rupture
- Primary Events related to the devices
- Incidence rate of secondary interventional treatment (including additional implantation of the Device and conversion to surgical operation), description of the procedure, and reasons for intervention
- Change in true and false lumen diameters

2） Priority Survey Items, Rationale for Setting and Specific Survey Methods

Priority Survey item: All-cause mortality for 30 days

Rationale for Setting: [redacted]

(8) Items and Methods for Analysis

1） All-cause Mortality Rate

Of the number of valid subjects in each evaluation period, the percentage of subjects with reported deaths is shown and is used as a characteristic evaluation.

2） Serious Adverse Events

Of the number of valid subjects in each evaluation, the percentage of subjects with reported adverse events including stroke, respiratory failure, cardiac infarction, renal failure, paraplegia/paraparesis, and bowel ischemia is shown and is used as a characteristic evaluation. Causal relationships※1 are investigated for each event.

Causal relationships※1

For each report of an adverse event, the physician in charge evaluates the primary relationship to the Device or procedure as follows.

- Not related to the Device or procedure -In case the cause or primary cause of an adverse event is due to a cause not related to the Device or procedure

- Related to the Device - The cause or primary cause of an adverse event is due to a function or characteristic of the Device
- Related to TEVAR - In case the cause or primary cause of an adverse event is due to TEVAR procedure (not due to the Device)
- Related to concomitant procedure - In case the cause or primary cause of an adverse event is due to concomitant procedure (not related to the Device or TEVAR)
- Unknown relation -Causal relationship with an adverse event cannot be determined

3） Primary Entry Tear Exclusion

Of subjects confirmed to have primary entry tear in each evaluation period, the percentage of those with primary entry tear is calculated. Confirm that primary entry tear exclusion is not significantly lower than that in TAG 08-01 study.

4） Aortic Rupture

Of the number of valid subjects in each evaluation period, the percentage of subjects with aortic rupture is shown and is used as a characteristic evaluation.

5） Primary events related to the Device

Of the number of valid subjects in each evaluation period, the percentage of subjects with a primary events related to the device※2 is shown and is used as a characteristic evaluation.

Primary events related to the device※2

Events reported as endoleak, access and deployment failure, luminal obstruction (including device compression and thrombus), stent graft structural failure, extrusion/erosion, stent graft migration, migration between components, and wire fracture, as well as selected as primary in severity.

- Incidence rate of secondary interventional treatment (including additional implantation of the Device and conversion to surgical operation), description of the procedure, and reasons for intervention

Of the number of valid subjects in each evaluation period, the percentage of subjects with secondary interventional treatment and the details of the procedure/the reason for the intervention are shown and is used as a characteristic evaluation.

6） Change in true and false lumen diameters

Of the number of valid subjects in each evaluation period, subjects with the change in true and false lumen diameters of the treated site and the distal side of the treated site are shown and are used as a characteristic evaluation.

8） Evaluation period
Each evaluation period is as follow

Follow-up visit	Desirable period for visit (Number of days)	Evaluation period (Number of days)
Time of Operation	0	0
Time of Discharge	Before Discharge	None Specified
After Operation	1～14	1～14
1 Month	23～44	15～59
6 Months	150～210	60～242
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	1735～1915	1641～2006

(9) Organization Structure for Survey
The same as Basic Plan for Post-Marketing Surveillance.

(10) In case a part of the work related to the survey is subcontracted, the name and address of the subcontractor and the scope of the work

Name and address of the contractor: [redacted]

Scope of the outsourced work: Collection of Survey forms, Data Management

(11) Other necessary items
In case of subjects with traumatic thoracic aortic transections enrolled during this surveillance study period for acute complicated Stanford type B aortic dissection, the results are traced as follows.

Item	Contents
Number of subjects to be surveyed and rationale for settings	Number of subjects to be surveyed: No setting Rationale for setting: Due to the difficulty in estimating the number of subjects
Target Patients for Surveillance Study	Patients with traumatic thoracic aortic transections meeting all of the following requirements for descending thoracic aortic lesions. ・ Have adequate iliac/femoral artery access routes ・ Inner diameter of proximal and distal aortic necks is within the range of 16-42mm ・ ≥20mm aortic neck length without aneurysm on proximal and distal sides of the lesion
Number of sites by department to be surveyed	The same as the survey sites for acute complicated Stanford Type B aortic dissection
Method of Surveillance Study	Patients are enrolled and surveyed if the device is used in patients with traumatic descending thoracic aortic transections at sits that contracted for this survey after obtaining a patient with

	complicated acute Stanford Type B aortic dissection.
Scheduled Period of Surveillance Study	Enrollment period: Until the enrollment of 43 subjects with acute complicated Stanford Type B aortic dissection Observation Period: 5 years after implantation of the device
Items, etc. for Surveillance Study	The same as acute complicated Stanford Type B aortic dissection
Analytical Items and Method	All-cause mortality rate, serious adverse events, primary events related to the Devices, secondary interventional treatment and change in lesion diameter are analyzed by the same method as for acute complicated Stanford Type B aortic dissection.