Post-Marketing Study – Implantation of GORE® VIABAHN® for Treatment of patients with stenosis or occlusion at the venous anastomosis of synthetic arteriovenous (AV) access graft

Statistical Analysis Plan

4th ed.

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1. Introduction

1.1 Position of Statistical Analysis Plan

This plan shows the statistical analysis plan of "Post-Marketing Study – Implantation of GORE® VIABAHN® for Treatment of patients with stenosis or occlusion at the venous anastomosis of synthetic arteriovenous (AV) access graft (hereinafter referred to as the "Study").

1.2 Purpose of the Study

To confirm the efficacy and safety of GORE® VIABAHN® (hereinafter referred to as the "Device") implanted in patients for the treatment of stenosis or occlusion at the venous anastomosis of synthetic arteriovenous (AV) access graft in the actual usage after approval.

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2.2 Dictionary used

Dictionaries used for adverse events, complications and medical history are shown below.

Item	Name of Dictionary※	Note
Adverse event Complications Medical History	MedDRA/J	• SOC and PT are used for System Organ Class and Symptom Name, respectively • If SOC is shown, it is listed in order of the international agreement • If PT is shown, it is listed in order of PT code

※The version used is the version used for coding. In principle, it is the latest version.

3. Definition of Abbreviations and Terms

3.1 Abbreviations

Abbreviation	Full description
MedDRA/J	Medical Dictionary for Regulatory Activities/Japanese version
SOC	System Organ Class。System Organ Class in MedDRA/J
PT	Preferred Term。Basic term in MedDRA/J

3.2 Safety endpoint

3.2.1 Adverse Event/ Device deficiency

Term	Definition
Adverse Event	Any undesirable or unintended signs (including abnormal laboratory results), symptoms, or diseases occurring related to the use of a medical device. A patient's primary disease is not considered an adverse event unless it aggravates in severity or increase in frequency during the study.
Device deficiency	A condition that is not good in a broad scope, such as fracture, malfunction, regardless of whether it is caused by design, manufacture, distribution, or use. Device deficiencies include: (1) Specification problem (2) Defective product (3) Malfunction/fracture (4) Insufficient description in the insert, etc. (5) Adverse events caused by the device
Serious Adverse Event	Serious adverse events are defined as any of the following among adverse events. (1) Death (2) Disability (3) May lead to death (4) May lead to disability (5) Requires hospitalization or prolonged hospitalization for treatment in a hospital or a clinic (6) Serious cases similar to those listed in (1) though (5) (7) Congenital disease or abnormality in future generations

Term	Definition
Unanticipated Device Deficiency/Adverse Event	Device deficiency and Adverse Event not described in the insert are classified as “Unanticipated Device deficiency/Adverse Event”.

3.2.1.1 Judgement of Causal relationship of Adverse Events

Causal relationship	Criteria for Judgement
Not related to the Device/ Procedures	In cases of no causal relationship between the investigational device/ index procedure and an adverse event
Related to the Device	In cases of a causal relationship between the investigational device and an adverse event among the adverse events occurring after index procedure
Related to Procedures at the time of implantation of the investigational device	In cases of a causal relationship between index procedure and an adverse event
Unknown	In cases of an undeniable causal relationship between the investigational device and an adverse event

3.2.2 [redacted]

[redacted]

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[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
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3.2.3 [redacted]

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[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

3.3 Efficacy endpoints

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[redacted]	[redacted]	[redacted]

Definition for each efficacy endpoint is as follows.

Primary Patency of target lesion	Period from index procedure until observation of occlusion in a target lesion or period of retention of patency until reintervention of a target lesion.
Secondary Patency of target lesion	Period from index procedure until retention of patency in a target lesion (including period of patency after reintervention)
Primary patency of vascular access	Period from index procedure until observation of occlusion in vascular access or period of retention of patency until reintervention in vascular access circuit.
Secondary patency of vascular access	Period that patency is maintained from index procedure until discontinuation of use of vascular access circuit.

3.3.1 Events of Primary Patency of Target Lesions and Termination

Primary patency of a target lesion is defined as the period after index procedure until reaching one of the following conditions at the earliest.

Event	EDC item	Date of Event
Occlusion of VIABAHN	Answer to “Did the device implanted in a treated lesion maintain patency? ([redacted]）” is “Loss of patency ([redacted]	Date of follow-up ([redacted])

Event	EDC item	Date of Event
	Enter “Occlusion of VIABAHN” in “Adverse Event [redacted]”	Date of onset [redacted]
Conduct reintervention	“Purpose of reintervention [redacted]” is “Patency of the initial implanted device [redacted]”	Date of reintervention [redacted]
Discontinuation of study	Answer to “Did conduct follow-up [redacted]” is “Discontinuation [redacted]” and “Reason for discontinuation [redacted]” is “Other (discontinuation of use of the device, etc. [redacted]”	Date determined to be discontinued [redacted]
	Answer to “Did complete the study? [redacted] ” is “Discontinuation [redacted]” and “Reason for discontinuation [redacted]” is “Other (discontinuation of use of the device, etc. [redacted]”	Date determined to be discontinued [redacted]

In addition, termination is defined as the latest of the following dates.

Termination	EDC Item	Termination date
Completion of study	Answer to “Did complete the study? [redacted]) ” is “Completed [redacted]” and to “Did the device implanted in a treated lesion maintain patency? [redacted] ” is “Patency [redacted] ”	Date of completion [redacted]
Study ongoing	Date of procedure [redacted]	Date of procedure [redacted]
	Answer to “Did the device implanted in a treated lesion maintain patency? [redacted]” is “Patency [redacted]	Date of follow-up [redacted]

3.3.2 Events of Secondary patency of target lesions and termination

Secondary patency of a target lesion is defined as the period after index procedure until reaching one of the following conditions at the earliest. In the event "VIABAHN occlusion", if the follow-up date for "Loss of Patency ([redacted]" as the answer to the question "Did the device implanted in a treated lesion maintain patency? ([redacted])" and onset date [redacted] or outcome date ([redacted]) of "recovered ([redacted])" or "relived ([redacted])" adverse event "Occlusion of VIABAHN" as the answer to "Outcome ([redacted])" are the same, the event is not treated as an event.

Event	EDC Item	Event date
Occlusion of VIABAHN	After answering "Loss of Patency [redacted])" to "Did the device implanted in a treated lesion maintain patency? ([redacted])", answer to the question "Did the device implanted in a treated lesion maintain patency? ([redacted])" is not "Patency ([redacted])" as well as "Recovered ([redacted]" or "Relived ([redacted])" adverse event "Occlusion of VIABAHN" is not entered in "Outcome ([redacted])".	Follow-up date of "Loss of Patency [redacted]" ([redacted])
	"Occlusion of VIABAHN" is entered in "Adverse event ([redacted]" and "Outcome ([redacted]" of adverse event "Occlusion of VIABAHN" is either "Unrecovered ([redacted] "Death [redacted]" or "Unknown ([redacted]", and the answer to the subsequent question "Did the device implanted in a treated lesion maintain	Onset date [redacted])

Event	EDC Item	Event date
	patency? [redacted])" is not "Patency ([redacted] [redacted]" as well as "Recovered ([redacted]" or "Relived ([redacted]" adverse event "Occlusion of VIABAHN" is not entered in "Outcome ([redacted]".	
Discontinuation of study	Answer to "Did conduct follow-up ([redacted])" is "Discontinuation ([redacted])" and "Reason for discontinuation ([redacted]" is "Other (discontinuation of use of the device, etc. ([redacted]"	Date determined to be discontinued ([redacted])
	Answer to "Did complete the study? ([redacted] " is "Discontinuation [redacted]" and "Reason for discontinuation ([redacted])" is "Other (discontinuation of use of the device, etc. ([redacted])"	Date determined to be discontinued ([redacted]

In addition, termination is defined as the latest of the following dates.

Termination	EDC Item	Termination date
Completion of study	Answer to "Did complete the study? [redacted]) " is "Completed ([redacted])" and to "Did the device implanted in a treated lesion maintain patency? ([redacted]) " is "Patency [redacted] "	Date of completion [redacted])
Study ongoing	Date of procedure[redacted])	Date of procedure [redacted])

Termination	EDC Item	Termination date
	“Occlusion of VIABAHN” is entered in “Adverse event ([redacted])” and answer to “Outcome [redacted])” of Adverse event “Occlusion of VIABAHN” is “Recovered ([redacted])” or “Relived ([redacted])”	Outcome date ([redacted])
	Answer to “Did the device implanted in a treated lesion maintain patency? [redacted]) ” is “Patency ([redacted]	Date of follow-up ([redacted])

3.3.3 Events of primary patency of vascular access circuit and termination

Primary patency of vascular access circuit is defined as the period after index procedure until reaching one of the following conditions at the earliest. (If "Date of vascular access discontinuation" is entered, it is judged within the period up to the date of the discontinuation)

Evet	EDC Item	Date of Event
VIABAHN [redacted] Occlusion of VIABAHN	Answer to "Did the device implanted in a treated lesion maintain patency? [redacted]) " is "Loss of patency ([redacted] "	Date of follow-up ([redacted])
	[redacted] "Occlusion of VIABAHN" is entered in "Adverse Event [redacted] "	[redacted] Date of onset [redacted])
Occlusion of vascular access	Answer to "Vascular access maintain patency? ([redacted] " is Loss of patency ([redacted]	Date of follow-up ([redacted])
	Enter "Occlusion of vascular access (Other than treated lesion)" in "Adverse Event [redacted])"	Date of onset ([redacted])
Conduct reintervention	"Purpose of reintervention [redacted])" is "Patency of the initial implanted device ([redacted] " or "Patency of vascular access circuit (excluding a site of initial implantation of the device) ([redacted])"	Date of reintervention [redacted])
Discontinuation of study	Answer to "Did conduct follow-up [redacted])" is "Discontinuation ([redacted] " and "Reason for discontinuation ([redacted])" is "Other (discontinuation of use of the device, etc. ([redacted])"	Date determined to be discontinued ([redacted])
	Answer to "Did complete the study? ([redacted]) " is "Discontinuation ([redacted])" and "Reason for	Date determined to be discontinued ([redacted])

Evet	EDC Item	Date of Event
	discontinuation ( )" is "Other (discontinuation of use of the device, etc.)"	
Discontinuation of vascular access	Answer to "Is vascular access used at the time of treatment continuously used? " is "No ( )"	Date of discontinuation of vascular access used at the time of treatment)

In addition, termination is defined as the latest of the following dates.

Termination	EDC Item	Termination date
Completion of study	Answer to "Did complete the study? (" is "Completed (", to "Did vascular access maintain patency? " is "Patency (", and to "Did the device implanted in the treated lesion maintain patency?) " is "Patency (".	Date of completion)
Study ongoing	Date of procedure)	Date of procedure ( )
	The answer to "Did vascular access maintain patency? (" is "Maintain patency ", and	Date of follow-up ( )

Termination	EDC Item	Termination date
	to “Did the device implanted in the treated lesion maintain patency? [redacted]）” is “Maintain patency [redacted]	

3.3.4 Events of Secondary patency of vascular access circuit and termination

Secondary patency of a target lesion is defined as the period after index procedure until reaching one of the following conditions at the earliest (If "Date of vascular access discontinuation" is entered, it is judged within the period up to the date of the discontinuation). In the event "VIABAHN occlusion" and "vascular access occlusion", if the follow-up dates ([redacted]) for "Loss of Patency ([redacted] as the answer to the question "Did the device implanted in a treated lesion maintain patency? ([redacted]" and "Did vascular access maintain patency (FU.FUVASOPYN)" and onset date ([redacted]) or outcome date ([redacted] of "Recovered [redacted]" or "Relived [redacted]" adverse event "Occlusion of VIABAHN" and "Occlusion of vascular access (Other than treated lesion)"as the answer to "Outcome ([redacted])"are the same, the event is not handled as an event.

Event	EDC Item	Event date
Occlusion of VIABAHN	After answering "Loss of Patency ([redacted] to "Did the device implanted in the treated lesion maintain patency? ([redacted])" , answer to the question "Did the device implanted in the treated lesion maintain patency? ([redacted])" is not "Patency ([redacted] as well as "Recovered ([redacted]" or "Relived ([redacted]" adverse event "Occlusion of VIABAHN" is not entered in "Outcome ([redacted])".	Follow-up date of "Loss of Patency ([redacted]
	"Occlusion of VIABAHN" is entered in "Adverse event ([redacted])" and "Outcome ([redacted])" of adverse event "Occlusion of VIABAHN" is either "Unrecovered ([redacted] "Death ([redacted] or "Unknown ([redacted] and the answer to the subsequent question "Did the device implanted in a treated lesion	Onset date [redacted]

Event	EDC Item	Event date
	maintain patency? ([redacted])" is not "Patency ([redacted] as well as "Recovered ([redacted])" or "Relived ([redacted]" adverse event "Occlusion of VIABAHN" is not entered in "Outcome ([redacted])".	
Occlusion of vascular access	After answering "Loss of Patency ([redacted] to "Did vascular access maintain patency? [redacted]" , the answer to the question "Did vascular access maintain patency? ([redacted] " is not "Patency ([redacted] as well as "Recovered [redacted]" or "Relived [redacted])" adverse event "Occlusion of vascular access (Other than treated lesion) " is not entered in "Outcome ([redacted])".	Follow-up date of "Loss of Patency [redacted]
	Enter "Occlusion of vascular access (Other than treated lesion) " in "Adverse event ([redacted])" , "Outcome ([redacted])" of "Occlusion of vascular access (Other than treated lesion) " is either "Unrecovered ([redacted] "Death ([redacted] or "Unknown ([redacted] and the answer to the subsequent question "Did vascular access maintain patency? ([redacted]" is not "Patency ([redacted] as well as "Recovered ([redacted]	Onset date ([redacted])

Event	EDC Item	Event date
	or "Relived ( )" adverse event "Occlusion of vascular access (Other than treated lesion)" is not entered in "Outcome (.	
Discontinuation of study	Answer to "Did conduct follow-up " is "Discontinuation " and "Reason for discontinuation " is "Other (discontinuation of use of the device, etc. "	Date determined to be discontinued
	Answer to "Did complete the study?) " is "Discontinuation)" and "Reason for discontinuation " is "Other (discontinuation of use of the device, etc.	Date determined to be discontinued)
Discontinuation of vascular access	Answer to "Is vascular access used at the time of treatment continuously used?)" is "No (	Date of discontinuation of vascular access used at the time of treatment)

In addition, termination is defined as the latest of the following dates.

Termination	EDC Item	Termination date
Completion of study	Answer to "Did complete the study? ( ) " is "Completed and to "Did vascular access maintain patency? is "Patency (" , to "Did the device implanted in the treated lesion maintain patency? (" is "Patency	Date of completion ( )
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Termination	EDC Item	Termination date
	Enter “Occlusion of VIABAHN” or “Occlusion of vascular access (Other than treated lesion)” in “Adverse event [redacted])” , and “Recovered ([redacted]”or “Relived ([redacted])” in “Outcome ([redacted] of each adverse event.	Outcome date [redacted]
	Answer to “Did vascular access maintain patency? [redacted] is “Patency [redacted] ” and to “Did the device implanted in the treated lesion maintain patency? ([redacted])” is “Patency [redacted]	Date of completion （FU.FUYDAT）

3.3.5 Technical Success

The residual stenosis rate after initial treatment is defined as less than 30%.

The residual stenosis rate is calculated using the following formula.

$$\text{Residual stenosis rate (\%)} = \frac{\text{Standard diameter} - \text{Diameter of stenosis part}}{\text{Standard diameter}} \times 100$$

The definitions of diameter of stenosis part and standard diameter are as follows.

Diameter of stenosis part: Diameter of the narrowest part after deployment of the device

Standard diameter: Diameter of the part without stenosis in the area near the stenosis

3.3.6 Clinical Success

It is defined as resumption of one or more normal dialyses after initial treatment with this device.

3.4 [redacted]

[redacted]

[redacted]

3.4.1 BMI

It is calculated using the following formula.

$BMI[kg/m^2] = Weight\ [kg] \div (Hight\ [cm]/100)^2$

3.4.2 [redacted]

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3.4.3 [redacted]

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3.4.4 [redacted]

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[redacted]
[redacted]

3.4.5 [redacted]

[redacted]

4. Cases and Data Handling

4.1 Case Handling

The analysis population is defined as follows.

Analysis population	Definition
Enrolled patients	All patients enrolled
Patients with completed study form	Patients with at least one item entered in the study form

Analysis population	Definition
Patents for each period (at the time of treatment, at 1-month – 24-month)	Patients with at least one item entered in the study form for each period
Patients with the fixed study form for each period	Patients with completion of DM review as specified in the data management plan of study form for each period.
Patients with the unfixed study form for each period	Patients with at least one item entered in the study form for each period, but DM review not completed.
[redacted]	[redacted]
[redacted]	

4.2 Handling of missing values

4.2.1 Data Complements

For missing data, data complements are not performed.

4.2.2 Missing continuous quantity

In cases of missing data in aggregate calculation of continuous quantities, they are excluded from the aggregate calculation.

4.2.3 Nominal scale, Ordinal scale

- If there is an entry of unknown, handle it as “Unknown”
- If an analysis is performed with unfixed data, the data that have not been collected are treated as “Not described”.
- In cases of an item that allows multiple answers, if all the items are not selected, it is classified as “Not described”.
- Included in the denominator of percentage unless otherwise noted.
- “Unknown” and “Not described” are excluded from the test.

4.2.4 Date Variables

If year is known but month and date are unknown, “01” is applied to each month and date for the aggregate calculation. If year is unknown or date is unrecognizable, handle it as unknown.

However, if the onset date of an adverse event or a device deficiency is before the date of initial procedure as a result of above complements, the same date as the date of the initial procedure is to be complemented.

4.3 Handling of Safety Data

4.3.1 Handling of Adverse Event/ Device Deficiency

4.3.1.1 Number of Onset Patients

If multiple adverse events (device deficiencies for the aggregate calculation of device deficiencies) occur in the same patient, they are counted together as one case.

4.3.1.2 Aggregation method for the same patient and the same adverse event

4.3.1.2.1 Aggregate calculation of the number of patients

If the same adverse event (device deficiencies for the aggregate calculation of device deficiencies) occurs in the same patient, aggregate it together. In the case of periodic aggregate calculation, aggregate the data for each period.

4.3.1.2.2 Aggregate calculation of cases

Aggregate all events without grouping them together. In cases of periodic aggregate calculation, aggregate by time of onset date.

4.4 Handling of data over time

4.4.1 Calculation of the number of days

In this statistical analysis plan, the calculation of the number of days is unified by the following calculation method.

Strat n day = Subject date – Date of Procedure

Therefore, Start day is Start 0 day, the day after the start is Start 1 day, and the day before the start is Start -1 day.

4.4.2 Adoption Range of Time Period

The data for each evaluation period is adopted from the adoption range specified in the table below.

4.4.2.1 Adoption Range for Adverse Event/Device Deficiency

Follow-up window	Classification of Adoption Range
Day of Procedure	Day 0
1 month	Day 1≦ ≦ Day 37
3 months	Day 38 ≦ ≦Day 121

6 months	Day 122≦ ≦Day 212
12 months	Day 213≦ ≦Day 395
24 months	Day 396≦ ≦Day 760
Over 24 months	Day 761≦

4.4.2.2 Adoption Range of the number of patients for the study of adverse events/device deficiency

For the period other than “the date of procedure”, calculate the latest date – date of procedure, and the number of target patients is defined as those meeting the following criteria: Latest date is that among the “Latest follow-up date”, “Latest onset date of adverse event”, “Latest onset date of device deficiency”, and “Latest date of implementing reintervention”.

Follow-up window	Classification of Adoption Range
Day of Procedure	Patients with procedure performed
1 month	1≦
3 months	38≦
6 months	122≦
12 months	213≦
24 months	396≦
Over 24 months	761≦

4.4.2.3 [redacted]Adoption Range of Reintervention

Period	Stipulated date	Classification of Adoption Range for reintervention
1 month	30 days	Day 0≦ ≦Day 30
3 months	91 days	Day 0≦ ≦Day 91
6 months	183 days	Day 0≦ ≦Day 183
12 months	365 days	Day 0≦ ≦Day 365
24 months	730 days	Day 0≦ ≦Day 730

4.4.2.4 [redacted] Adoption Range of Kaplan-Meier Estimate

Period	Classification of Adoption Range
0 day	Day 0
1 month	Day 1≦ ≦Day 30
3 months	Day 31≦ ≦Day 91
6 months	Day 92≦ ≦Day 183

12 months	Day 184≦ ≦Day 365
24 months	Day 366≦ ≦Day 730

4.4.3 Day of Procedure

The date of the procedure is the date indicated in the “Procedural Information at the time of Treatment” section of the study form.

4.4.4 Age

Age is calculated as follows, using the full age at the date of the procedure, starting from the date of birth on the study form.

① Calculate the difference between the date and the date of birth

② If the date is before the date of birth, subtract 1 from the difference to obtain the full age.
If the date is the same as or later than the date of birth, the difference is taken as the full age.

4.4.5 History of Smoking [year]

Calculated as follows.

1) Currently smoking = (Day of Procedure – Since when smoking (For information up to year/month, use yyyy-mm-01 with 01 complemented to the day)/ 365.25
2) Past smoking
Number of years stated in “Smoking History”

4.4.6 Hemodialysis treatment history [year]

Calculated as follows.

Hemodialysis treatment history [year]= (Day of Procedure – Starting date of Hemodialysis/ 365.25

4.4.7 Number of years currently in use of vascular access

Calculated as follows.

Number of years currently in use of vascular access = (Day of Procedure – Day of creation of vascular access used currently)

4.4.8 Number of days until reintervention

Calculated as follows.

Number of days until reintervention = Date of (First) reintervention - Day of Procedure

※ “Number of days until reintervention for the first treated lesion” is for the first reintervention for which the answer to “Purpose of reintervention” is the “Patency of the initial implanted device”.

※ "Number of days until reintervention for vascular access circuit (Other than first treated lesion) is for the first reintervention for which the answer to "Purpose of reintervention" is the "Patency of vascular access circuit (excluding a site of initial implantation of the device)".

5. Items related to Statistical Processing

5.1 Significance Level, Confidence Coefficient

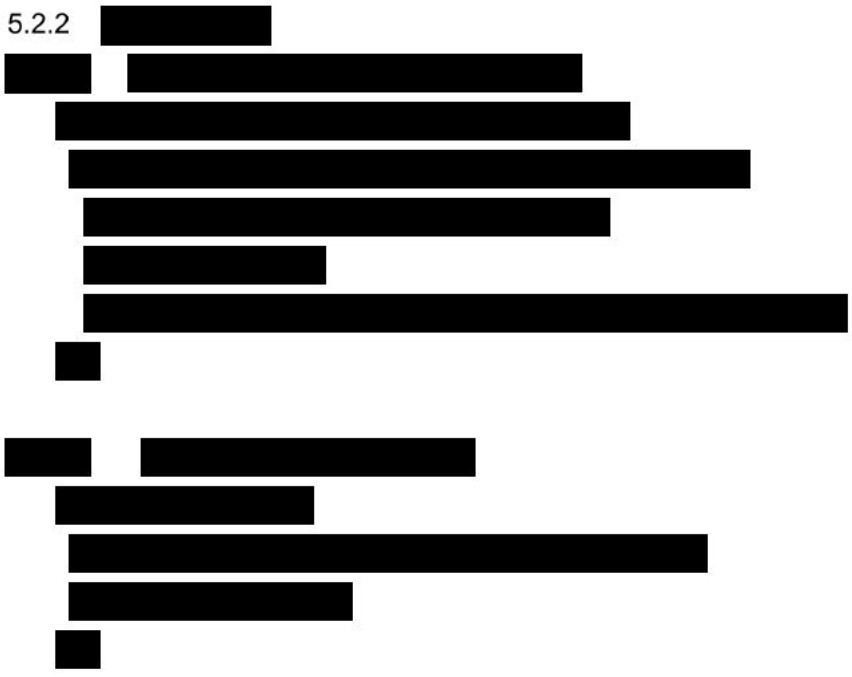
The significant level of the test is 5% two-sided, unless otherwise specified. When interval estimation is performed, it is two-sided unless otherwise specified, and the confidence coefficient is 95%.

5.2 Details of Statistical method

5.2.1 Summary Statistics

In this statistical analysis plan, summary statistics mean the number of patients, mean, standard deviation, minimum, median and maximum values.

5.2.2 [redacted]



5.3 Displayed Digit of Calculated value

5.3.1 Displayed Digit of Summary Statistics, etc.

Mean, Standard deviation, Median, 95% confidence interval

Round off the last 2 digits of displayed digits and display up to single digit.

Minimum value and Maximum value

Round off the last 1 digit of displayed digits, and display up to the displayed digit.

5.3.2 Displayed Digit for Percentage and the Confidence interval

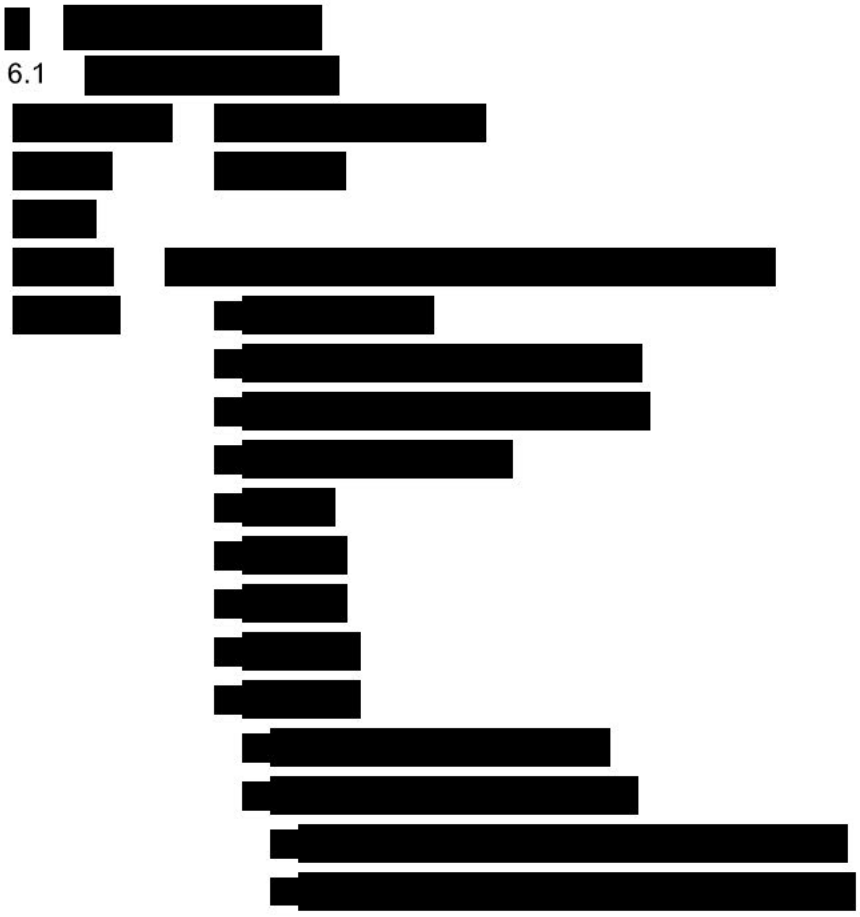
Round off to the third decimal place and displayed to the second decimal place.

5.3.3 Displayed digit of p value

Round off to the fourth decimal place and displayed up to the third decimal place. In addition, if the value is less than 0.001, $p < 0.001$ is shown.

[redacted]

6.1 [redacted]



6.2 [redacted]

6.3 [redacted]

6.4 [redacted]

6.5 [redacted]

6.6 [redacted]

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[redacted] [redacted]

7.1 [redacted]

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7.2 [redacted]

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7.3 [redacted]

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7.4 [redacted]

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7.5 [redacted]

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7.6 [redacted]

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7.7 [redacted]

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7.8 [redacted]

[redacted]

[redacted]

8.1 Incidence rates of adverse events related to the device and the procedure at the time of treatment and up to 30 days post-treatment

Title of Table： 8.1 Incidence rates of adverse events related to the device and the procedure at the time of treatment and up to 30 days post-treatment

Analysis object： Patients with completed study form

Contents of Analysis：

- For adverse events observed up to 30 days after the procedure, the following analysis is performed for each onset date of events: the date of procedure and from 1 to 30 days after the procedure.
- Calculate the overall number of sites, target patients, patients with adverse events, number of cases with adverse events, and incidence of adverse events
- Calculate the number of patients with adverse events, incidence of adverse events, and the number of cases with adverse events for each SOC/PT by the time of occurrence
- The denominator of incidence rate is the number of patients for the study.
- If a patient has multiple occurrences of the same SOC/PT at the same time, it is counted as one case in the case-counting. The number of cases is not summarized, but all are counted.
- If a patient has multiple occurrences of the same SOC/PT at different time points, count one case at each time . The number of cases is not summarized, but counted at each time point.
- The denominator of incidence rate is the number of patients for the study. Refer to “4.4.2.2 Adoption Range of number of patients for study of adverse events/ device deficiency” for the calculation method for the number of patients for the study.
- [redacted]

8.2 [redacted]

[redacted]

[redacted]

Contents of Analysis :

- The following analysis is performed for each category of “4.4.2.1 Adoption Range for Adverse Event / Device Deficiency”
- Calculate the overall number of sites, target patients, patients with adverse events, number of cases with adverse events, and incidence of adverse events
- Calculate the number of patients with adverse events, incidence of adverse events, and the number of cases with adverse events for each SOC/PT by the time of occurrence
- If a patient has multiple occurrences of the same SOC/PT at the same time, it is counted as one case in the case-counting. The number of cases is not summarized, but all are counted.
- If a patient has multiple occurrences of the same SOC/PT at different time points, count one case at each time . The number of cases is not summarized, but counted at each time point.
- The denominator of incidence rate is the number of patients for the study. Refer to “4.4.2.2 Adoption Range of number of cases for study of adverse events/ device deficiency” for the calculation method for the number of patients for the study.
- The same analysis is performed for patients with On-Label use
- Analysis of the device and procedure-related adverse events and serious adverse events is conducted in a similar layout. Analysis is also conducted for adverse events, and adverse events and serious adverse events related to the device and the procedure similarly in the categories of under 65 years old/ 65 years old and older and under 75 years old/75 years old and older.

8.3 List of occurrences of device deficiency and infectious disease in post-marketing study, etc. (Appendix Form 3-3)

Title of Table：	8.3 List of occurrences of device deficiency and infectious disease in post-marketing study, etc. (Appendix Form 3-3)
Analysis object：	Patients with completed study form
Contents of Analysis：	・ The following analysis is performed for each category of “4.4.2.1 Adoption Range for Adverse Event / Device Deficiency” ・ Calculate the overall numbers of sites, target patients, patients with device deficiency, and cases of device deficiency, as well as incidence of device deficiency ・ Calculate the numbers of patients, incidence for each adverse device effect (or an infectious disease if it occurred) by the time of occurrence ・ If a patient has multiple occurrences of the same device deficiency at the same time, it is counted as one case in the case-counting. ・ If a patient has multiple occurrences of the same device deficiency at different time points, count one case at each time . ・ If both known and unknown cases exist in the same event, they are counted as separate events, and the unknown event is presented first ・ An unknown event is indicated by prefixing the event name with “*” ・ The denominator of incidence rate is the number of patients for the study. Refer to “4.4.2.2 Adoption Range of number of patients for study of adverse events/ device deficiency” for the calculation method for the number of patients for the study.

8.4 [redacted]

9. [redacted]

9.1 [redacted]

[redacted] [redacted]

[redacted]

[redacted] [redacted]

[redacted]

[redacted] [redacted]

[redacted] [redacted] all

[redacted]

[redacted]

9.2 [redacted]

[redacted] 9.6 [redacted]

[redacted]

[redacted]

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[redacted]

[redacted]

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[redacted]

[redacted]

[redacted]

[redacted]

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9.3 [redacted]

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9.4 List of Cases

Title of Table： 9.4 List of Cases

Analysis object： Enrolled patients

Contents of Analysis：

- Show the list of study items for each patient. The time period is specified in the study form as follows.
  - 1 month
  - 3 months
  - 6 months
  - 12 months
  - 24 months
- Refer to the output plan for the study items and the details.

9.5 List of Mortality Cases

Title of Table： 9.5 List of Mortality cases

[redacted]

Analysis object：	Enrolled patients
Contents of Analysis：	・ Show the cause of death, days to death, causal relationship, course of occurrence, details of treatment for each patient who “Died” as the outcome of an adverse event. In addition, the following items on the study form are shown. ・ Cause of death: Name of adverse event ・ Causal relationship: Causal relationship judgement ・ Course of occurrence: Course of occurrence of adverse event ・ Treatment: Treatment for adverse event The day to death is defined as the number of days from the date of the procedure to the date of outcome of the adverse event (Date of outcome of the adverse event – Date of procedure).

10. References

Nothing in particular