CLINICAL STUDY DOCUMENT APPROVAL FORM

Study Name: Trevo Retriever Registry (China)

Document Type: Statistical Analysis Plan (CDM10001420) Document Date or Version: **AA**

We, the undersigned, have read and approve the document specified above:

1. Name: **Lixian Sun** Functional Role: BioStats Function Level: Functional Representative (FR)

Signature/Date: _____ 08/15/2018

2. Name: **Yi-Ping Sun** Functional Role: CA Safety Function Level: Functional Representative (FR)

Signature/Date: _____ 14 Aug 2018

3. Name: **Dong Yu** Functional Role: CPM Function Level: Manager (M)

Signature/Date: _____ 8/14/2018

4. Name: Functional Role: **Choose an item.** Function Level: **select**

Signature/Date: _____

5. Name: Functional Role: **Choose an item.** Function Level: **select**

Signature/Date: _____

DocuSign Envelope ID: 32508BE4-AF6D-4950-9F15-90A0F6B24B22

Trevo® Retriever Registry (China)

Statistical Analysis Plan (SAP)

Version AA

DocuSign Envelope ID: 32508BE4-AF6D-4950-9F15-90A0F6B24B22

Contents

STRYKER CONFIDENTIAL - THIS DOCUMENT CONTAINS CONFIDENTIAL AND PROPRIETARY INFORMATION THAT IS THE PROPERTY OF STRYKER CORPORATION. NEITHER THIS DOCUMENT NOR THE INFORMATION HEREIN MAY BE REPRODUCED, USED, OR DISCLOSED TO ANY THIRD PARTY WITHOUT THE PRIOR WRITTEN CONSENT OF STRYKER CORPORATION

DocuSign Envelope ID: 32508BE4-AF6D-4950-9F15-90A0F6B24B22

STRYKER CONFIDENTIAL - THIS DOCUMENT CONTAINS CONFIDENTIAL AND PROPRIETARY INFORMATION THAT IS THE PROPERTY OF STRYKER CORPORATION. NEITHER THIS DOCUMENT NOR THE INFORMATION HEREIN MAY BE REPRODUCED, USED, OR DISCLOSED TO ANY THIRD PARTY WITHOUT THE PRIOR WRITTEN CONSENT OF STRYKER CORPORATION

DocuSign Envelope ID: 32508BE4-AF6D-4950-9F15-90A0F6B24B22

1. Introduction

This document contains a detailed description of the Statistical Analysis Plan (SAP) for the data from the Trevo® Retriever Registry (China), coordinated with protocol of CDM 10001400.
This document provides specifications for the statistical analyses of the data to be analyzed for publications and presentations.

2. Study Design

This Trevo® Retriever Registry is a prospective, open-label, multi-center, international trial. The purpose of the Trevo® Registry is to assess the performance of the Trevo® retriever in real world practice to increase knowledge on the performance of the device, monitor safety outcomes, detect rare complications, and to obtain information for potential improvements for next generation devices.

2.1. Study Objectives

2.1.1. Primary Objective

To assess real world performance of the CFDA cleared Trevo® Retriever intended to restore blood flow in the neurovasculature by removing thrombus in subjects experiencing ischemic stroke.

2.1.2. Secondary Objectives

1) To identify optimal interventional techniques, including type of anesthesia, access, and method of clot retrieval, to result in successful outcomes.
2) To provide robust registry data that maybe used to support expanded indications in regulatory submissions and support reimbursement dossiers.
3) To gather significant amount of real-world safety data to allow further subset analyses.

2.2. Study Endpoints

2.2.1. Primary Endpoint

The primary endpoint is revascularization status at the end of the procedure using the modified TICI scale.

2.2.2. Secondary Endpoints

1) Day 90 mRS (good clinical outcomes defined as mRS of 0-2).
2) Day 90 mortality.
3) Neurological deterioration at 24 hours.

STRYKER CONFIDENTIAL - THIS DOCUMENT CONTAINS CONFIDENTIAL AND PROPRIETARY INFORMATION THAT IS THE PROPERTY OF STRYKER CORPORATION. NEITHER THIS DOCUMENT NOR THE INFORMATION HEREIN MAY BE REPRODUCED, USED, OR DISCLOSED TO ANY THIRD PARTY WITHOUT THE PRIOR WRITTEN CONSENT OF STRYKER CORPORATION

DocuSign Envelope ID: 32508BE4-AF6D-4950-9F15-90A0F6B24B22

4) Rates of device and procedure related Serious Adverse Events (SAE).

3. Analysis Population

The Intent-to-treat principle will be followed to define the analysis population. All subjects who signed the informed consent and in whom Trevo® Retriever was deployed through the microcatheter are considered enrolled and will be included in all the analyses.

4. Sample Size and Power

There will be no sample size/or power estimation for this single-arm registry. Two hundred subjects will be enrolled at up to 15 centers in China.

5. Statistical Analysis

5.1. Primary Endpoint

Primary Endpoint is : Revascularization status at the end of the procedure.

The primary endpoint is measured using the modified TICI scale at the end of procedure. Success of primary endpoint was defined as a modified TICI score of 2b or better at the end of procedure.
Primary endpoint will be analyzed by percentages, frequencies and the 95% confidence interval of the percentage of success. The 95% confidence interval will be calculated using Clopper-Pearson exact method.

5.2. Secondary Endpoints

5.2.1. Analysis Methods

Secondary endpoints will be analyzed by percentages, and frequencies.

5.2.2. Secondary Endpoints Definition

1. Day 90 mRS (good clinical outcomes defined as mRS of 0-2).
2. Day 90 mortality.
   If the subjects had completed their 90-day visit, the subjects will be considered as alive at Day 90. If the subjects did not come for their Day 90 visit and died, the date of death will be used to compare with the upper window of their Day 90 (90 + 14 days post procedure). If the subjects died after the upper window of their Day 90, the subjects will be considered as alive at their Day 90. Otherwise, the subjects will be counted as death before Day 90.
3. Neurological deterioration at 24 hours which is defined as four or more points increase in the NIHSS score from the baseline to 24 hours post procedure.

STRYKER CONFIDENTIAL - THIS DOCUMENT CONTAINS CONFIDENTIAL AND PROPRIETARY INFORMATION THAT IS THE PROPERTY OF STRYKER CORPORATION. NEITHER THIS DOCUMENT NOR THE INFORMATION HEREIN MAY BE REPRODUCED, USED, OR DISCLOSED TO ANY THIRD PARTY WITHOUT THE PRIOR WRITTEN CONSENT OF STRYKER CORPORATION

DocuSign Envelope ID: 32508BE4-AF6D-4950-9F15-90A0F6B24B22

4. Rate of study device and procedure related serious adverse events (SAE) through Day 90.

5.3. Additional Safety Analyses

Adverse Events

- All SAEs through Day 90.

All SAEs through Day 90 will be summarized by number of events, number of subjects with events and the percentages of subjects with events by the type of SAEs and by their relatedness.

- All AEs during procedure.

All AEs during procedure will be summarized by number of events, number of subjects with events and the percentages of the subjects with events by the type of AEs and by their relatedness.

5.4. Descriptive Analyses

5.4.1. Demographics and Baseline Characteristics

Subjects' demographic characteristics will be summarized using descriptive statistic methods.

Continuous variables will be summarized by mean±SD, median, minimum and maximum.

Categorical variables will be summarized by percentages and frequencies.

5.4.2. Medical History

Subjects' medical history will be summarized by percentages and frequencies.

5.4.3. Modified Rankin Scale (mRS)

mRS will be summarized by frequencies and percentages and by visits. The difference of mRS from Day 90 to baseline, defined as mRS at Day 90 – mRS at baseline, will be categorized by decreased or no change (mRS from Day 90 - mRS from baseline<=0) or increased and will be analyzed by frequencies and percentages.

5.4.4. NIHSS

NIHSS will be summarized by mean ± SD, median, minimum and maximum and by visits.

5.4.5. Procedural Characteristics

The continuous variables will be summarized by mean ± SD, median, minimum and maximum. The categorical variables will be summarized by frequencies and percentages.

5.4.6. Device Malfunction

All the device malfunction will be summarized by number of device malfunctions, number of device with device malfunction, percentage of device with device malfunction, number of subjects with device malfunctions and percentages of subjects with device malfunctions.

STRYKER CONFIDENTIAL - THIS DOCUMENT CONTAINS CONFIDENTIAL AND PROPRIETARY INFORMATION THAT IS THE PROPERTY OF STRYKER CORPORATION. NEITHER THIS DOCUMENT NOR THE INFORMATION HEREIN MAY BE REPRODUCED, USED, OR DISCLOSED TO ANY THIRD PARTY WITHOUT THE PRIOR WRITTEN CONSENT OF STRYKER CORPORATION

DocuSign Envelope ID: 32508BE4-AF6D-4950-9F15-90A0F6B24B22

5.4.7. Time Intervals

Time intervals will include but not limited to time from stroke symptom onset to admission to hospital/emergency department, intravenous tissue plasminogen (IV tPA), angio suite, arterial puncture, first Trevo® deployed, last Trevo® deployed and the end of the procedure. Time of clot integration, is calculated from the Trevo® deployed to the Trevo® starting to pulled.

5.5. Subgroup Analyses

Sub-group analyses (such as ICAD, IV Lytic use) for the Registry will be performed as needed.

5.6. Ad hoc Analyses

Ad hoc analyses will be generated as needed.

6. Analyses Schedule

6.1. Interim Analyses

Interim analysis may be performed as needed.

6.2. Final Report

Final report will be generated when all the 200 enrolled subjects complete their Day 90 visit or terminated before their Day 90.

7. Analysis Software

All statistical analyses will be generated using SAS® 9.4 or higher.

STRYKER CONFIDENTIAL - THIS DOCUMENT CONTAINS CONFIDENTIAL AND PROPRIETARY INFORMATION THAT IS THE PROPERTY OF STRYKER CORPORATION. NEITHER THIS DOCUMENT NOR THE INFORMATION HEREIN MAY BE REPRODUCED, USED, OR DISCLOSED TO ANY THIRD PARTY WITHOUT THE PRIOR WRITTEN CONSENT OF STRYKER CORPORATION

DocuSign Envelope ID: 32508BE4-AF6D-4950-9F15-90A0F6B24B22

8. Analysis Table Template

The following tables are provided as samples and are subject to change as needed.

Table 1 Subjects Disposition

	Number of Subjects Enrolled (N=xxx*)	Subjects Eligible at 24 Hours (-6/+24) post procedure (N=xxx*)	Subjects Eligible at Discharge/Day 5-7 (whichever comes first) (N=xxx*)	Subjects Eligible at Day 30 (N=xxx*)	Subjects Eligible at Day 90 (N=xxx*)
Visit Completed	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Visit Not Completed	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Reason for not completing the visit					
Missed Visit	NA	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Early Termination	NA	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
*List Reason for Early Termination***	NA	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

*: N = Number of subjects expected at this visit

**: The percentage is calculated based on the number of early terminations.

STRYKER CONFIDENTIAL - THIS DOCUMENT CONTAINS CONFIDENTIAL AND PROPRIETARY INFORMATION THAT IS THE PROPERTY OF STRYKER CORPORATION. NEITHER THIS DOCUMENT NOR THE INFORMATION HEREIN MAY BE REPRODUCED, USED, OR DISCLOSED TO ANY THIRD PARTY WITHOUT THE PRIOR WRITTEN CONSENT OF STRYKER CORPORATION

DocuSign Envelope ID: 32508BE4-AF6D-4950-9F15-90A0F6B24B22

Table 3: Baseline Demographics and Clinical Characteristics

	Number of Subjects (N=xxx)
Age	
Mean ± SD (N)	xx.x ± xx.x (xxx)
Median (Q1, Q3)	xx.x (xx.x, xx.x)
Range (min, max)	xx.x (xx.x, xx.x)
Gender	
Male	xx.x% (xx/xxx)
Female	xx.x% (xx/xxx)
Body Mass Index	
Mean ± SD (N)	xx.x ± xx.x (xxx)
Median (Q1, Q3)	xx.x (xx.x, xx.x)
Range (min, max)	xx.x (xx.x, xx.x)
Medical History	
Hypertension (HTN)	xx.x% (xx/xxx)
Heart Failure (CHF)	xx.x% (xx/xxx)
Coronary Artery Disease (CAD)	xx.x% (xx/xxx)
Extracranial Carotid Artery Disease	xx.x% (xx/xxx)
Left	xx.x% (xx/xxx)
Right	xx.x% (xx/xxx)
Bilateral	xx.x% (xx/xxx)
Atrial Fibrillation (A-fib)	xx.x% (xx/xxx)
Peripheral Vascular Disease (PVD)	xx.x% (xx/xxx)
Diabetes Mellitus	xx.x% (xx/xxx)
Other	xx.x% (xx/xxx)
Dyslipidemia	xx.x% (xx/xxx)
Current Smoker (within last year)	xx.x% (xx/xxx)
Past Smoker (>1 year ago)	xx.x% (xx/xxx)
Previous Transient Ischemic Attack (TIA)	xx.x% (xx/xxx)
Previous Ischemic Stroke	xx.x% (xx/xxx)
Previous Ischemic Stroke in the same erritory	xx.x% (xx/xxx)
Previous Intra-cerebral Hemorrhage	xx.x% (xx/xxx)
Previous History of known ICAD (intracranial atherosclerotic disease)	xx.x% (xx/xxx)
History of Alcohol Abuse	xx.x% (xx/xxx)
Other	xx.x% (xx/xxx)

STRYKER CONFIDENTIAL - THIS DOCUMENT CONTAINS CONFIDENTIAL AND PROPRIETARY INFORMATION THAT IS THE PROPERTY OF STRYKER CORPORATION. NEITHER THIS DOCUMENT NOR THE INFORMATION HEREIN MAY BE REPRODUCED, USED, OR DISCLOSED TO ANY THIRD PARTY WITHOUT THE PRIOR WRITTEN CONSENT OF STRYKER CORPORATION

DocuSign Envelope ID: 32508BE4-AF6D-4950-9F15-90A0F6B24B22

Table 4: Baseline Lab

	Number of Subjects (N=xxx)
Platelets (10^9/L)	
Mean ± SD (N)	xx.x ± xx.x (xxx)
Median (Q1, Q3)	xx.x (xx.x, xx.x)
Range (min, max)	xx.x (xx.x, xx.x)
PT (sec)	
Mean ± SD (N)	xx.x ± xx.x (xxx)
Median (Q1, Q3)	xx.x (xx.x, xx.x)
Range (min, max)	xx.x (xx.x, xx.x)
PTT (sec)	
Mean ± SD (N)	xx.x ± xx.x (xxx)
Median (Q1, Q3)	xx.x (xx.x, xx.x)
Range (min, max)	xx.x (xx.x, xx.x)
INR (RATIO)	
Mean ± SD (N)	xx.x ± xx.x (xxx)
Median (Q1, Q3)	xx.x (xx.x, xx.x)
Range (min, max)	xx.x (xx.x, xx.x)
Blood Glucose (mmol/L)	
Mean ± SD (N)	xx.x ± xx.x (xxx)
Median (Q1, Q3)	xx.x (xx.x, xx.x)
Range (min, max)	xx.x (xx.x, xx.x)

STRYKER CONFIDENTIAL - THIS DOCUMENT CONTAINS CONFIDENTIAL AND PROPRIETARY INFORMATION THAT IS THE PROPERTY OF STRYKER CORPORATION. NEITHER THIS DOCUMENT NOR THE INFORMATION HEREIN MAY BE REPRODUCED, USED, OR DISCLOSED TO ANY THIRD PARTY WITHOUT THE PRIOR WRITTEN CONSENT OF STRYKER CORPORATION

DocuSign Envelope ID: 32508BE4-AF6D-4950-9F15-90A0F6B24B22

Table 5: Procedural Characteristics

	Number of Subjects (N=xxx)
IA Medication Administered at Site of Thrombus	xx.x% (xx/xxx)
Drug Type	
Lytic Used	xx.x% (xx/xxx*)
Anti-vasospasm	xx.x% (xx/xxx*)
Other	xx.x% (xx/xxx*)
Clot Location	
CA - cervical	xx.x% (xx/xxx)
CA - petrous	xx.x% (xx/xxx)
ICA - cavernous	xx.x% (xx/xxx)
ICA - supraclinoid	xx.x% (xx/xxx)
ICAT bif	xx.x% (xx/xxx)
A1	xx.x% (xx/xxx)
A2	xx.x% (xx/xxx)
MCA-M1	xx.x% (xx/xxx)
MCA-M2	xx.x% (xx/xxx)
MCA-M3	xx.x% (xx/xxx)
Vert	xx.x% (xx/xxx)
P1	xx.x% (xx/xxx)
P2	xx.x% (xx/xxx)
Target Vessel - Laterality	
Right	xx.x% (xx/xxx)
Left	xx.x% (xx/xxx)
Target Vessel Pass Basilar	
Proximal	xx.x% (xx/xxx)
Mid	xx.x% (xx/xxx)
Distal tip	xx.x% (xx/xxx)
Baseline Imaging	
CTP/CTA	xx.x% (xx/xxx)
MRI/MRA	xx.x% (xx/xxx)
Non-Contrast CT Only	xx.x% (xx/xxx)
Embolization to New Territory Observed	xx.x% (xx/xxx)
Distal Embolization Observed	xx.x% (xx/xxx)
Number Passes of Trevo® Retriever(s)	
Mean ± SD (N)	xx.x ± xx.x (xxx)

STRYKER CONFIDENTIAL - THIS DOCUMENT CONTAINS CONFIDENTIAL AND PROPRIETARY INFORMATION THAT IS THE PROPERTY OF STRYKER CORPORATION. NEITHER THIS DOCUMENT NOR THE INFORMATION HEREIN MAY BE REPRODUCED, USED, OR DISCLOSED TO ANY THIRD PARTY WITHOUT THE PRIOR WRITTEN CONSENT OF STRYKER CORPORATION

DocuSign Envelope ID: 32508BE4-AF6D-4950-9F15-90A0F6B24B22

Median (Q1-Q3)	xx.x (xx.x, xx.x)
Range (Min-Max)	xx.x (xx.x, xx.x)
1 pass	xx.x% (xx/xxx)
2 passes	xx.x% (xx/xxx)
>=3 passes	xx.x% (xx/xxx)
Number Passes of All Thrombectomy Device(s)	
Mean ± SD	xx.x ± xx.x (xxx)
Median (Q1-Q3)	xx.x (xx.x, xx.x)
Range (Min-Max)	xx.x (xx.x, xx.x)
*: Denominator is the number of subjects who used IA medicine	

STRYKER CONFIDENTIAL - THIS DOCUMENT CONTAINS CONFIDENTIAL AND PROPRIETARY INFORMATION THAT IS THE PROPERTY OF STRYKER CORPORATION. NEITHER THIS DOCUMENT NOR THE INFORMATION HEREIN MAY BE REPRODUCED, USED, OR DISCLOSED TO ANY THIRD PARTY WITHOUT THE PRIOR WRITTEN CONSENT OF STRYKER CORPORATION

DocuSign Envelope ID: 32508BE4-AF6D-4950-9F15-90A0F6B24B22

Table 6: Time Intervals

Time Intervals*	Number of Subjects (N=xx)
Stroke symptom onset to first hospital	
Mean ± SD (N)	xx.x ± xx.x (xxx)
Median (Q1, Q3)	xx.x (xx.x, xx.x)
Range (min, max)	xx.x (xx.x, xx.x)
Stroke symptom onset to second hospital	
Mean ± SD (N)	xx.x ± xx.x (xxx)
Median (Q1, Q3)	xx.x (xx.x, xx.x)
Range (min, max)	xx.x (xx.x, xx.x)
Stroke symptom onset to primary hospital	
Mean ± SD (N)	xx.x ± xx.x (xxx)
Median (Q1, Q3)	xx.x (xx.x, xx.x)
Range (min, max)	xx.x (xx.x, xx.x)
Stroke symptom onset to IV Lytic	
Mean ± SD (N)	xx.x ± xx.x (xxx)
Median (Q1, Q3)	xx.x (xx.x, xx.x)
Range (min, max)	xx.x (xx.x, xx.x)
Stroke symptom onset to angiography suite	
Mean ± SD (N)	xx.x ± xx.x (xxx)
Median (Q1, Q3)	xx.x (xx.x, xx.x)
Range (min, max)	xx.x (xx.x, xx.x)
Stroke symptom onset to arterial puncture	
Mean ± SD (N)	xx.x ± xx.x (xxx)
Median (Q1, Q3)	xx.x (xx.x, xx.x)
Range (min, max)	xx.x (xx.x, xx.x)
Stroke symptom onset to first Trevo® deployed	
Mean ± SD (N)	xx.x ± xx.x (xxx)
Median (Q1, Q3)	xx.x (xx.x, xx.x)
Range (min, max)	xx.x (xx.x, xx.x)
Stroke symptom onset to last Trevo® deployed	
Mean ± SD (N)	xx.x ± xx.x (xxx)
Median (Q1, Q3)	xx.x (xx.x, xx.x)
Range (min, max)	xx.x (xx.x, xx.x)
Stroke symptom onset to the end of procedure	
Mean ± SD (N)	xx.x ± xx.x (xxx)
Median (Q1, Q3)	xx.x (xx.x, xx.x)

STRYKER CONFIDENTIAL - THIS DOCUMENT CONTAINS CONFIDENTIAL AND PROPRIETARY INFORMATION THAT IS THE PROPERTY OF STRYKER CORPORATION. NEITHER THIS DOCUMENT NOR THE INFORMATION HEREIN MAY BE REPRODUCED, USED, OR DISCLOSED TO ANY THIRD PARTY WITHOUT THE PRIOR WRITTEN CONSENT OF STRYKER CORPORATION

DocuSign Envelope ID: 32508BE4-AF6D-4950-9F15-90A0F6B24B22

Range (min, max)	xx.x (xx.x, xx.x)
Stroke symptom onset to reperfusion	
Mean ± SD (N)	xx.x ± xx.x (xxx)
Median (Q1, Q3)	xx.x (xx.x, xx.x)
Range (min, max)	xx.x (xx.x, xx.x)
Time of clot integration	
Mean ± SD (N)	xx.x ± xx.x (xxx)
Median (Q1, Q3)	xx.x (xx.x, xx.x)
Range (min, max)	xx.x (xx.x, xx.x)
*: Time intervals may be reported but not limited to those listed in the table. It will subject to change as needed.	

STRYKER CONFIDENTIAL - THIS DOCUMENT CONTAINS CONFIDENTIAL AND PROPRIETARY INFORMATION THAT IS THE PROPERTY OF STRYKER CORPORATION. NEITHER THIS DOCUMENT NOR THE INFORMATION HEREIN MAY BE REPRODUCED, USED, OR DISCLOSED TO ANY THIRD PARTY WITHOUT THE PRIOR WRITTEN CONSENT OF STRYKER CORPORATION

DocuSign Envelope ID: 32508BE4-AF6D-4950-9F15-90A0F6B24B22

Table 7: Modified Rankin Scale (mRS)

Modified Rankin Scale (mRS)	% (n/N)
Pre-Stroke (N=xxx)	
0	xx.x% (xx/xxx)
1	xx.x% (xx/xxx)
2	xx.x% (xx/xxx)
Discharge/Day 5-7 (whichever comes first) (N=xxx)	
0	xx.x% (xx/xxx)
1	xx.x% (xx/xxx)
2	xx.x% (xx/xxx)
3	xx.x% (xx/xxx)
4	xx.x% (xx/xxx)
5	xx.x% (xx/xxx)
6	xx.x% (xx/xxx)
0-2 combined	xx.x% (xx/xxx)
Day 30	
0	xx.x% (xx/xxx)
1	xx.x% (xx/xxx)
2	xx.x% (xx/xxx)
3	xx.x% (xx/xxx)
4	xx.x% (xx/xxx)
5	xx.x% (xx/xxx)
6	xx.x% (xx/xxx)
0-2 Combined	xx.x% (xx/xxx)
Day 90	
0	xx.x% (xx/xxx)
1	xx.x% (xx/xxx)
2	xx.x% (xx/xxx)
3	xx.x% (xx/xxx)
4	xx.x% (xx/xxx)
5	xx.x% (xx/xxx)
6	xx.x% (xx/xxx)
0-2 Combined	xx.x% (xx/xxx)

STRYKER CONFIDENTIAL - THIS DOCUMENT CONTAINS CONFIDENTIAL AND PROPRIETARY INFORMATION THAT IS THE PROPERTY OF STRYKER CORPORATION. NEITHER THIS DOCUMENT NOR THE INFORMATION HEREIN MAY BE REPRODUCED, USED, OR DISCLOSED TO ANY THIRD PARTY WITHOUT THE PRIOR WRITTEN CONSENT OF STRYKER CORPORATION

DocuSign Envelope ID: 32508BE4-AF6D-4950-9F15-90A0F6B24B22

Table 8: Summary of NIH Stroke Scale (NIHSS)

NIH Stroke Scale (NIHSS)	Number of Subjects (N=xxx)
Pre-procedure	
Mean ± SD (N)	xx.x ± xx.x (xxx)
Median (Q1, Q3)	xx.x (xx.x, xx.x)
Range (min, max)	xx.x (xx.x, xx.x)
24(-6/+24) post procedure	
Mean ± SD (N)	xx.x ± xx.x (xxx)
Median (Q1, Q3)	xx.x (xx.x, xx.x)
Range (min, max)	xx.x (xx.x, xx.x)
Discharge/Day 5-7 (whichever comes first)	
Mean ± SD (N)	xx.x ± xx.x (xxx)
Median (Q1, Q3)	xx.x (xx.x, xx.x)
Range (min, max)	xx.x (xx.x, xx.x)

STRYKER CONFIDENTIAL - THIS DOCUMENT CONTAINS CONFIDENTIAL AND PROPRIETARY INFORMATION THAT IS THE PROPERTY OF STRYKER CORPORATION. NEITHER THIS DOCUMENT NOR THE INFORMATION HEREIN MAY BE REPRODUCED, USED, OR DISCLOSED TO ANY THIRD PARTY WITHOUT THE PRIOR WRITTEN CONSENT OF STRYKER CORPORATION

DocuSign Envelope ID: 32508BE4-AF6D-4950-9F15-90A0F6B24B22

Table 9: Recanalization Results

Modified TICI	%(n/N)
Subjects in Pre-procedure (N=xxx)	
0	xx.x% (xx/xxx)
1	xx.x% (xx/xxx)
2a	xx.x% (xx/xxx)
2b	xx.x% (xx/xxx)
3	xx.x% (xx/xxx)
2b+	xx.x% (xx/xxx)
Subjects at the end of each pass* (N=xxx)	
0	xx.x% (xx/xxx)
1	xx.x% (xx/xxx)
2a	xx.x% (xx/xxx)
2b	xx.x% (xx/xxx)
3	xx.x% (xx/xxx)
2b+	xx.x% (xx/xxx)
Subjects at the end of procedure (N=xxx)	
0	xx.x% (xx/xxx)
1	xx.x% (xx/xxx)
2a	xx.x% (xx/xxx)
2b	xx.x% (xx/xxx)
3	xx.x% (xx/xxx)
2b+	xx.x% (xx/xxx)
*: mTICI from all passes (up-to 6) need to be reported.	

Table 10: Primary endpoint

mTICI 2b+ at the end of procedure	% of subjects with mTICI2b+	95%CI
Yes	xx.x% (xx/xxx)	(xx.x%, xx.x%)

STRYKER CONFIDENTIAL - THIS DOCUMENT CONTAINS CONFIDENTIAL AND PROPRIETARY INFORMATION THAT IS THE PROPERTY OF STRYKER CORPORATION. NEITHER THIS DOCUMENT NOR THE INFORMATION HEREIN MAY BE REPRODUCED, USED, OR DISCLOSED TO ANY THIRD PARTY WITHOUT THE PRIOR WRITTEN CONSENT OF STRYKER CORPORATION

DocuSign Envelope ID: 32508BE4-AF6D-4950-9F15-90A0F6B24B22

Table 11: Secondary endpoints

Secondary Endpoints	% of Subjects with Clinical Outcomes (n/N)*
mRS** of 0-2 at Day 90	xx.x% (xx/xxx)
Mortality rate at Day 90	xx.x% (xx/xxx)
Neurological deterioration at 24(-6/+24) hours	xx.x% (xx/xxx)
Study Device and procedure related SAE	xx.x% (xx/xxx)
*:95% CI will be generated as needed for ad hoc analysis **: LOCF is used for Day 90 mRS.	

STRYKER CONFIDENTIAL - THIS DOCUMENT CONTAINS CONFIDENTIAL AND PROPRIETARY INFORMATION THAT IS THE PROPERTY OF STRYKER CORPORATION. NEITHER THIS DOCUMENT NOR THE INFORMATION HEREIN MAY BE REPRODUCED, USED, OR DISCLOSED TO ANY THIRD PARTY WITHOUT THE PRIOR WRITTEN CONSENT OF STRYKER CORPORATION

DocuSign Envelope ID: 32508BE4-AF6D-4950-9F15-90A0F6B24B22

Table 12: All SAEs

	# of events	Percentages of subjects with events* (Total subjects=xxx)
All SAEs		
Details of all SAEs	xx	xx.x% (xx/xxx)
…	xx	
…	xx	xx.x% (xx/xxx)
…	xx	xx.x% (xx/xxx)
Study device and procedure related SAEs		
Total	xx	xx.x% (xx/xxx)
Details of study device and procedure related SAEs	xx	xx.x% (xx/xxx)
…	xx	xx.x% (xx/xxx)
…	xx	xx.x% (xx/xxx)
…	xx	xx.x% (xx/xxx)
Study device related SAEs only		
Total	xx	xx.x% (xx/xxx)
Details of study device related SAEs	xx	xx.x% (xx/xxx)
…	xx	xx.x% (xx/xxx)
…	xx	xx.x% (xx/xxx)
…	xx	xx.x% (xx/xxx)
Procedure but not study device related SAEs		
Total	xx	xx.x% (xx/xxx)
Details of procedure but not study device related SAEs	xx	xx.x% (xx/xxx)
…	xx	xx.x% (xx/xxx)
…	xx	xx.x% (xx/xxx)
…	xx	xx.x% (xx/xxx)
Study device or procedure related SAEs		
Total	xx	xx.x% (xx/xxx)
Details of study device or procedure related SAEs	xx	xx.x% (xx/xxx)
…	xx	xx.x% (xx/xxx)
…	xx	xx.x% (xx/xxx)
Not study device and not procedure related SAEs		
Total	xx	xx.x% (xx/xxx)
Details of not study device and not procedure related SAEs	xx	xx.x% (xx/xxx)
…	xx	xx.x% (xx/xxx)
…	xx	xx.x% (xx/xxx)
*: Some subjects may experience multiple events		

STRYKER CONFIDENTIAL - THIS DOCUMENT CONTAINS CONFIDENTIAL AND PROPRIETARY INFORMATION THAT IS THE PROPERTY OF STRYKER CORPORATION. NEITHER THIS DOCUMENT NOR THE INFORMATION HEREIN MAY BE REPRODUCED, USED, OR DISCLOSED TO ANY THIRD PARTY WITHOUT THE PRIOR WRITTEN CONSENT OF STRYKER CORPORATION

DocuSign Envelope ID: 32508BE4-AF6D-4950-9F15-90A0F6B24B22

Table 13: All AEs during procedure

	# of events	Percentages of subjects with events* (N=xxx)
Total AEs	xx	xx.x% (xx/xxx)
Details of AEs during procedure	xx	xx.x% (xx/xxx)
…	xx	xx.x% (xx/xxx)
…	xx	xx.x% (xx/xxx)
…	xx	xx.x% (xx/xxx)
Study device and procedure related AEs		
Total	xx	xx.x% (xx/xxx)
Details of study device and procedure related SAE	xx	xx.x% (xx/xxx)
…	xx	xx.x% (xx/xxx)
…	xx	xx.x% (xx/xxx)
…	xx	xx.x% (xx/xxx)
Study device related AEs		
Total	xx	xx.x% (xx/xxx)
Details of study device related AEs	xx	xx.x% (xx/xxx)
…	xx	xx.x% (xx/xxx)
…	xx	xx.x% (xx/xxx)
…	xx	xx.x% (xx/xxx)
Procedure but not study device related AEs		
Total	xx	xx.x% (xx/xxx)
Details of procedure but not study device related AEs	xx	xx.x% (xx/xxx)
…	xx	xx.x% (xx/xxx)
…	xx	xx.x% (xx/xxx)
…	xx	xx.x% (xx/xxx)
Study device or procedure related AEs		
Total	xx	xx.x% (xx/xxx)
Details study device or procedure related AEs	xx	xx.x% (xx/xxx)
…	xx	xx.x% (xx/xxx)
…	xx	xx.x% (xx/xxx)
Not study device and not procedure related AEs		
Total	xx	xx.x% (xx/xxx)
Details of not study device and not procedure related SAEs	xx	xx.x% (xx/xxx)
…	xx	xx.x% (xx/xxx)
…	xx	xx.x% (xx/xxx)

*: Some subjects may experience multiple events

STRYKER CONFIDENTIAL - THIS DOCUMENT CONTAINS CONFIDENTIAL AND PROPRIETARY INFORMATION THAT IS THE PROPERTY OF STRYKER CORPORATION. NEITHER THIS DOCUMENT NOR THE INFORMATION HEREIN MAY BE REPRODUCED, USED, OR DISCLOSED TO ANY THIRD PARTY WITHOUT THE PRIOR WRITTEN CONSENT OF STRYKER CORPORATION

DocuSign Envelope ID: 32508BE4-AF6D-4950-9F15-90A0F6B24B22

Table 14: Device Malfunction

	# of events	Percentages of study devices with events* (Total device=xxx)	Percentages of subjects with events** (Total subjects=xxx)
Total	xx	xx.x% (xx/xxx)	xx.x% (xx/xxx)
Details of device malfunction	xx	xx.x% (xx/xxx)	xx.x% (xx/xxx)
…	xx	xx.x% (xx/xxx)	xx.x% (xx/xxx)
…	xx	xx.x% (xx/xxx)	xx.x% (xx/xxx)
…	xx	xx.x% (xx/xxx)	xx.x% (xx/xxx)

*: One device may have multiple malfunctions
**: One subject may have multiple devices with malfunctions

STRYKER CONFIDENTIAL - THIS DOCUMENT CONTAINS CONFIDENTIAL AND PROPRIETARY INFORMATION THAT IS THE PROPERTY OF STRYKER CORPORATION. NEITHER THIS DOCUMENT NOR THE INFORMATION HEREIN MAY BE REPRODUCED, USED, OR DISCLOSED TO ANY THIRD PARTY WITHOUT THE PRIOR WRITTEN CONSENT OF STRYKER CORPORATION