Efficacy and Safety of a Intracranial Thrombectomy Stent in Patients With Acute Ischemic Stroke:

(A Prospective, Multicenter, Randomized Controlled, Non-inferiority Study)

Statistical Analysis Plan

Version: **0.3**
Version Date: **July 11, 2022**

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1. Study Overview

1.1. Study Objective

To validate that the intracranial thrombectomy stents manufactured by Sinomed Neurovita Technology Inc. (hereinafter referred to as "Sinomed Neurovita") for endovascular treatment of acute ischemic stroke demonstrate non-inferiority in immediate recanalization rates compared to the Solitaire FR system, and to conduct a clinical trial to verify the safety and efficacy of this product in compliance with the Good Clinical Practice for Medical Devices.

1.2. Scope of the Trial

The intracranial thrombectomy stent is intended for use within 24 hours of symptom onset to remove thrombi from large intracranial vessels in ischemic stroke patients, thereby restoring blood flow.

1.3. Study Design

This is a prospective, multicenter, randomized controlled, non-inferiority clinical trial. The investigational device is the Intracranial Thrombectomy Stent (Sino Neurovita), with the comparator device being the Solitaire FR (Covidien Medical Device International Trading (Shanghai) Co., Ltd., hereinafter referred to by its trade name Solitaire FR). The trial is planned to be conducted at more than 10 clinical trial sites, enrolling 220 subjects. Eligible subjects were randomized 1:1 to either the study group or control group. The study evaluated whether the immediate recanalization rate of the Sinomed Neurovita Intracranial Thrombectomy Stent was non-inferior to that of the Solitaire FR when used for endovascular treatment of acute ischemic stroke. A central reading laboratory independent of the trial conducted blinded assessments of target vessel recanalization. The study evaluated whether there were statistically significant differences between the Sinomed Neurovita Intracranial Thrombectomy Stent and the Solitaire FR in the following outcomes for acute ischemic stroke endovascular therapy: 90-day mRS 0-2 rate, time from femoral artery puncture to recanalization or

procedure end time for non-recanalized subjects, proportion of subjects with NIHSS improvement ≥4 points, and device procedural success rate. Evaluate whether there are statistically significant differences between the Sinomed Neurovita Intracranial Thrombectomy Stent and Solitaire FR in the following outcomes for endovascular treatment of acute ischemic stroke: incidence of symptomatic intracranial hemorrhage within 24 hours post-procedure, all-cause mortality within 90 days, incidence of serious adverse events (SAE), incidence of adverse events (AE), and incidence of device failure.

1.4. Trial Process

Visit time / Visit contents	Screening/Baseline period	Treatment period	Observation period	Follow-up period	
	Preoperatively -1 d ~ 0 d	Day of operation/0 d	Postoperatively 24 h ± 12 h	Postoperatively 7 d ± 2 d	Postoperatively 90 d ± 14 d
Signing of ICF	×				
Medical history	×				
Preoperative diagnosis	×				
Vital signs[1]	×		×	×	
NIHSS score[2]	×		×	×	
mRS score[3]	×				×
Laboratory test[1]	×		×		
Pregnancy test[5]	×				
Cerebral CT or MR[6,7]	×		×		
Cerebrovascular DSA[7]	×				
Verification of eligibility criteria		×			
Randomization		×			
Operations		×			
Antiplatelet and anticoagulant medication	×	×	×	×	×
Adverse event		×	×	×	×
Device defect		×			

Figure1 Study Flowchart

Note:

1) Vital signs include heart rate and blood pressure.
2) NIHSS score: assessing the degree of neurological impairment of the subject.
3) MRS score: assessing the degree of disability of the subject.
4) Laboratory tests (The laboratory test results at 24 h preoperatively are accepted during the screening period, and one laboratory test within 9d postoperatively is sufficient):
5) Blood routine: Red blood cell, hemoglobin, white blood cell count, and platelet count
6) Blood chemistry: Urea nitrogen (urea), serum creatinine, blood glucose
7) Coagulation: Prothrombin time, activated partial thromboplastin time and INR
8) Only for women of childbearing potential who are planning to become pregnant, blood or urine pregnancy test

result is acceptable.

9) Cerebral CT or MR is performed when the onset time is ≤ 6h; cerebral CT or MR is performed when the onset time is 6 (exclusive)-24h (inclusive) to determine whether ASPECTS score ≥ 6 is met; (if immediate CT perfusion imaging or MR perfusion imaging is feasible, CTP or MRP is recommended to assist in the assessment of the infarct core to determine whether ASPECTS score ≥ 6 is met).
10) CT or MRI images and DSA images during thrombectomy are burned on a CD in DICOM format and evaluated by a central interpretation room.
11) Randomization: An electronic randomization system is logged into for randomization.

* If any of the micro-guidewire and microcatheter does not pass through the thrombus segment of the target vessel during the operation, or if the thrombectomy device is not used for thrombectomy, this subject is statistically processed as having a blank randomization number.

1.5. Sample Size

The primary endpoint of this trial is the success rate of recanalization. It adopts a prospective, multicenter, randomized controlled design, with a non-inferiority test.

Based on existing clinical evidence and expert consensus, the pre-specified non-inferiority margin was set at 12.5%, assuming both groups achieved an 89% recanalization rate within 24 hours. With a one-sided significance level α of 0.025 and a power (1-β) of 80%, the calculated sample size per group is 99 subjects. Considering a maximum possible 10% dropout rate, the sample size per group is increased to 110 subjects, totaling 220 subjects. Based on statistical principles,

The corresponding sample size formula is:

$$n_T = n_C = \frac{\left(Z_{1-\alpha/2} + Z_{1-\beta}\right)^2 [P_C(1-P_C) + P_T(1-P_T)]}{(|D| - \Delta)^2}$$

In the formula, nT and nC are the respective sample size of the test group and control group; Z1-a/2 and Z1-β are the percentiles in standard normal distribution; P_T is the expected success rate of recanalization in the test group, Pc is the expected success rate of recanalization in the control group; |D| is the absolute value of the difference between groups in the expected recanalization, $|D|=|P_T-P_C|$; Δ is the non-inferiority margin (taking the negative value).

This trial will be conducted simultaneously across multiple clinical trial sites. Considering feasibility and enrollment progress, the enrollment quotas for each participating site will be adjusted based on actual circumstances to ensure balanced enrollment across centers. The final enrollment size

for any single site should not exceed 50% of the total number of cases.

2. Evaluation Endpoint

2.1. Efficacy Endpoints

2.1.1. Primary efficacy endpoint

Success rate of immediate recanalization.

Vascular recanalization success: Target vessel recanalization with mTICI grade 2b or 3.

Success rate of immediate recanalization = Number of subjects in this group with immediate recanalization success / Number of subjects in this group undergoing intracranial thrombectomy with stenting × 100%.

Vascular recanalization success is assessed independently by both the treating clinician and a central reading laboratory. In case of disagreement, the blinded assessment by the central reading laboratory prevails.

2.1.2. Secondary efficacy endpoints

1. 90-day Postoperative mRS 0-2 Score Ratio: mRS 0-2 Score Ratio = Number of subjects with mRS 0-2 score at 90 days postoperatively / Number of subjects undergoing thrombectomy via intracranial thrombectomy device × 100%.
2. Time to recanalization: Time to recanalization = End time - Femoral artery puncture time (If recanalization is successful, the end time is the time of successful recanalization; if no recanalization occurs, the end time is recorded as the time of procedure completion). Here, recanalization refers to successful target vessel recanalization with mTICI grade 2b or 3 following thrombectomy using the investigational device.
3. Postoperative NIHSS score improvement >4 points: Improvement in NIHSS score at 24 ± 12 hours postoperatively, 7 ± 2 days postoperatively/prior to discharge compared to baseline. Percentage of subjects with >4-point NIHSS improvement = Number of subjects in this group

with >4-point postoperative NIHSS improvement / Number of subjects in this group treated with thrombectomy via thrombotic stents × 100%.

4. Success rate of device operation: Defined as successful delivery of the device to the target lesion site, followed by accurate deployment and retrieval. Success rate of device operation = Number of devices successfully delivered, deployed, and retrieved in this group / Total number of devices used in this group × 100%.

2.2. Safety Endpoints

1. Incidence of symptomatic intracranial hemorrhage within 24 hours postoperatively: Symptomatic intracranial hemorrhage refers to intracranial hemorrhage (cerebral parenchymal hematoma, subarachnoid hemorrhage, subdural hematoma, ventricular hemorrhage) accompanied by neurological deterioration (NIHSS score increase ≥4 points compared to preoperative). Incidence of symptomatic intracranial hemorrhage within 24 hours = Number of subjects in this group with symptomatic intracranial hemorrhage confirmed by CT or MR within 24 hours / Number of subjects in this group undergoing intracranial thrombectomy with a thrombectomy stent × 100%. CT or MR findings were evaluated by the central reading center.
2. All-cause mortality within 90 days postoperatively: All-cause mortality rate = Number of deaths in this group / Total number of subjects in this group undergoing intracranial thrombectomy with a thrombectomy stent × 100%.
3. Incidence of SAEs, incidence of AEs.
4. Device defects rate.

3. Analysis Set

Full Analysis Set (FAS): A population defined according to the intention-to-treat principle, comprising all subjects who participated in randomization and received the study product. For patients in whom the primary efficacy endpoint was not observed, missing data will be carried forward using

the Worst Observation Carry Forward (WOCF) strategy.

Protocol-Compliant Set (PPS): Refers to the subgroup of the treated population that completed the trial, excluding those with major protocol deviations (e.g., subjects violating inclusion or exclusion criteria).

Safety Set (SS): Refers to the population of all subjects who used the study device and had at least one safety assessment.

Efficacy analyses will be conducted on the basis of the full analysis set and the per-protocol set. Additionally, all baseline demographic analyses will be performed on the full analysis set, while safety evaluations will be conducted on the safety set.

4. Missing Data Imputation

For patients in the FAS who did not have an observed primary efficacy endpoint, worst-case imputation was applied, defined as failure to achieve immediate reperfusion in the target vessel. No imputation was performed for secondary endpoints or efficacy data in the PPS. Missing safety data were not imputed.

5. Statistical Analysis Methods

5.1. General Principles

Statistical analyses were performed using SAS version 9.4 statistical software.

Descriptive Statistics: Count data were described using frequency and proportion; continuous data were described using mean, standard deviation, maximum, minimum, median, and 25th and 75th percentiles.

Statistical Inference: For comparisons between two groups, quantitative indicators were analyzed using paired t-tests or Wilcoxon signed-rank tests based on data distribution. Categorical indicators were analyzed using chi-square tests or exact probability methods (if chi-square tests were not applicable). Ordinal data were analyzed using Wilcoxon signed-rank tests or the Cumulative

Hypothesis Test (CMH).

Unless otherwise specified, all statistical tests were two-tailed. A P-value < 0.05 (two-tailed) was considered statistically significant.

5.2. Subject Distribution

Summarize enrollment and completion numbers by center, listing dropout cases. Provide comparisons of dataset sizes across groups, case distribution by center, overall dropout rates, and detailed reasons for non-completion.

5.3. Demographic and Baseline Characteristics Analysis

Describe patient demographics (age, gender, etc.), relevant medical history, and treatment history. Compare characteristics such as age and gender between groups to assess comparability. Demographic analysis is based on the FAS analysis set.

5.4. Efficacy Analysis

5.4.1. Primary Efficacy

Primary efficacy evaluation is based on the Full Analysis Set (FAS) and the Per-Protocol Set (PPS).

This trial employs a prospective, multicenter, randomized controlled design with a non-inferiority comparison. It demonstrates that the investigational device meets clinical application requirements by comparing it with an approved comparator. The primary endpoint evaluates intraoperative vascular recanalization success rate, with the corresponding statistical hypothesis test defined as:

$$H_0 : p_T - p_C \leq -\Delta$$
$$H_1 : p_T - p_C > -\Delta$$

In the formula, P_T represents the expected recanalization success rate in the test group, P_C denotes the expected recanalization success rate in the control group, and -Δ indicates the non-inferiority margin of -12.5%.

The target vessel recanalization rates between the test and control groups will be compared, and the 95% confidence interval (CI) for the rate difference between the two groups will be calculated. If the lower limit of the 95% CI for the rate difference is greater than -12.5%, the test group will be considered non-inferior to the control group. The intergroup comparison will employ a CMH chi-square analysis adjusted for center effects.

5.4.2. Secondary Endpoints

Secondary efficacy assessments were based on the full analysis set (FAS) and the per-protocol set (PPS).

The 90-day postoperative mRS 0-2 rate, the proportion of subjects with NIHSS improvement >4 points, and the device procedural success rate were analyzed as categorical data; recanalization time was analyzed as a quantitative endpoint.

5.5. **Safety Analysis**

The incidence of symptomatic intracranial hemorrhage within 24 hours postoperatively (data from the central reading center) and all-cause mortality within 90 days postoperatively were analyzed as categorical data.

Adverse events were described by the number of cases and incidence rate, with detailed descriptions of the specific manifestations, severity, and relationship to the study product for all adverse events that occurred.

The number and proportion of cases with normal findings before treatment and abnormal findings after treatment were described separately .

Device defects were described using incidence rates.

6. Statistical Analysis Results

6.1. Subject Distribution

Table1 Case distribution across centers

Center ID	Research Center	Group	Enrollment	Dropout Count	Dropout Rate (%)	Number of Exclusions	Exclusion Rate (%)	Completed
01		Experimental group						
		Control Group						
		Total						
02		Experimental Group						
		Control Group						
		Total						
03		Experimental Group						
		Control Group						
		Total						
……		Experimental Group						
		Control Group						
		Total						
	Total	Experimental Group						
		Control Group						
		Total						

Note 1: Number of completers = Number enrolled - Number of dropouts.

Note 2: Exclusion refers to subjects who completed the trial but were not included in the PPS set.

Table2 Population Distribution by Center

		FAS			PPS			SS		
Research Hospital	Center	Experimental group	Control group	Total	Experimental group	Control Group	Total	Experimental group	Control Group	Total
01										
02										
03										
……										
Total										

Table3 Enrolled Cases and Safety/Efficacy Analysis Dataset

Item	Indicator	Experimental Group	Control Group	Total
Reasons for Early Withdrawal	Randomly Assigned			
	Completed Trial			
	Adverse events			
	Unsatisfactory treatment response			
	Subject withdrawal of informed consent			
	Protocol violation			
	Other			
	Subject or family member requests withdrawal from the study			
	Loss to follow-up			
	Death			
	Total			
FAS				
PPS				
SS				

6.2. **Demographic and Baseline Characteristics (FAS)**

6.2.1. Demographic Information

Table4 Population Demographic Information

Project	Indicator	Experimental Group	Control Group	Total
Gender	Male n(%)			
	Female n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Age (years)	N(Missing)			
	Mean (SD)			
	Median			
	Q1, Q3			
	Min, Max			
	Statistic			
	P-value			
Height (cm)	N(Missing)			
	Mean(SD)			
	Median			

Project	Indicator	Experimental Group	Control Group	Total
	Q1, Q3			
	Min, Max			
	Statistic			
	P-value			
Weight (kg)	N(Missing)			
	Mean(SD)			
	Median			
	Q1, Q3			
	Min,Max			
	Statistic			
	P-value			

Note: Age = (Date of informed consent signature - Date of birth) / 365.25, rounded down.

6.2.2. Personal and Medical History

Table5 Clinical Diagnosis

Item	Indicator	Experimental Group	Control Group	Total
Acute Ischemic Stroke	Yes n(%)			
	No n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Onset time	0–6 hours n(%)			
	6–24h n(%)			
	>24h n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Other comorbidities or admission diagnoses	None n(%)			
	Yes n(%)			
	Total (Missing)			
	Statistic			
	P-value			

Table6 Past Medical History

Item	Indicator	Experimental Group	Control Group	Total
Hypertension	Yes n(%)			
	No n(%)			
	Unknown n(%)			
	Total (Missing)			

Item	Indicator	Experimental Group	Control Group	Total
	Statistic			
	P-value			
Diabetes	Yes n(%)			
	No n(%)			
	Unknown n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Hyperlipidemia	Yes n(%)			
	No n(%)			
	Unknown n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Atrial fibrillation	Yes n(%)			
	No n(%)			
	Unknown n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Coronary heart disease	Yes n(%)			
	No n(%)			
	Unknown n(%)			
	Total (Missing)			
	Statistic			
	P-value			
	Yes n(%)			
Hyperhomocysteinemia	No n(%)			
	Unknown n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Heart failure	Yes n(%)			
	No n(%)			
	Unknown n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Recent smoking	Yes n(%)			
(within 6 months)	No n(%)			
	Unknown n(%)			

Item	Indicator	Experimental Group	Control Group	Total
	Total (Missing)			
	Statistic			
	P-value			
Previous smoking (6 months prior)	Yes n(%)			
	No n(%)			
	Unknown n(%)			
	Total (Missing)			
	Statistic			
	P-value			
History of Alcohol Consumption	Yes n(%)			
	No n(%)			
	Unknown n(%)			
	Total (Missing)			
	Statistic			
	P-value			
History of combined peripheral arterial stenosis (≥50%) or occlusion	Yes n(%)			
	No n(%)			
	Unknown n(%)			
	Total (Missing)			
	Statistical measure			
	P-value			
History of stroke	Yes n(%)			
	No n(%)			
	Unknown n(%)			
	Total (Missing)			
	Statistical measure			
	P-value			
Previous Stroke Type	Ischemic n(%)			
	Hemorrhagic n(%)			
	Mixed n(%)			
	Total (Missing)			
	Statistical Measure			
	P-value			
Liver failure	Yes n(%)			
	No n(%)			
	Unknown n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Renal failure	Yes n(%)			
	No n(%)			

Item	Indicator	Experimental Group	Control Group	Total
	Unknown n(%)			
	Total (Missing)			
	Statistic			
	P-value			

Table7 Clinical Score

Item	Indicator	Experimental Group	Control Group	Total
mRS score <2 before onset	Yes n(%)			
	No n(%)			
	Total (Missing)			
	Statistic (CMH)			
	P-value			
NIHSS score ≥ 6 before enrollment	Yes n(%)			
	No n(%)			
	Total (Missing)			
	Statistic (CMH)			
	P-value			

Table8 Thrombolytic Therapy Information After Admission and Before Thrombectomy

Item	Indicator	Experimental Group	Control Group	Total
Whether intravenous thrombolysis was administered after onset of symptoms and prior to mechanical thrombectomy	No n(%)			
	Yes n(%)			
	Total (Missing)			
	Statistical measure			
	P-value			

6.2.3. Screening Period Check

Table9 Screening Period Vital Signs

Item	Indicator	Experimental Group	Control Group	Total
Systolic Blood Pressure (mmHg)	N(Missing)			
	Mean (SD)			
	Median			
	Q1, Q3			
	Min, Max			
	Statistic			
	P-value			
Diastolic Blood	N(Missing)			

Item	Indicator	Experimental Group	Control Group	Total
Pressure (mmHg)	Mean(SD)			
	Median			
	Q1, Q3			
	Min, Max			
	Statistic			
	P-value			
Heart Rate (beats per minute)	N(Missing)			
	Mean(SD)			
	Median			
	Q1, Q3			
	Min, Max			
	Statistic			
	P-value			

Table10 Screening Period Pregnancy Checkup (Applicable to Women of Childbearing Age)

Item	Indicator	Experimental Group	Control Group	Total
Serum HCG	Normal n(%)			
	Abnormal but Clinically Insignificant n(%)			
	Abnormal and Clinically Significant n(%)			
	Not tested n(%)			
	Not applicable n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Urinary pregnancy test	Normal n(%)			
	Abnormal but Clinically Insignificant n(%)			
	Abnormal measurement with clinical significance n(%)			
	Not Performed n(%)			
	Not applicable n(%)			
	Total (Missing)			
	Statistic			
	P-value			

Table11 Screening period imaging examination - Subjects with time from stroke onset to femoral artery puncture ≤6 hours (inclusive)

Item	Indicator	Experimental Group	Control Group	Total
Cranial CT or MRI	Yes n(%)			

Item	Indicator	Experimental Group	Control Group	Total
examination	No n(%)			
	Total (Missing)			
	Statistical measure			
	P-value			
Evaluation Information	None n(%)			
	Present n(%)			
	Total (Missing)			
	Statistic			
	P-value			

Table12 Screening period imaging examination - Participants with onset to femoral artery puncture exceeding 6 hours but not exceeding 24 hours (inclusive)

Item	Indicator	Experimental Group	Control Group	Total
Cranial CT or MRI examination	Yes n(%)			
	No n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Evaluation Information	None n(%)			
	Present n(%)			
	Total (Missing)			
	Statistic			
	P-value			
ASPECTS Score - Anterior Circulation Occlusion	N(Missing)			
	Mean (SD)			
	Median			
	Q1, Q3			
	Min,Max			
	Statistic			
	P-value			
ASPECTS Score - Anterior Circulation Occlusion - Qualitative	＜6 points n(%)			
	≥6 points n(%)			
	Total (Missing)			
	Statistic			
	P-value			
ASPECTS Score - Post-Circulation Occlusion	N(Missing)			
	Mean (SD)			
	Median			
	Q1, Q3			

Item	Indicator	Experimental Group	Control Group	Total
	Min,Max			
	Statistic			
	P-value			
ASPECTS Score - Post-Circulation Occlusion - Qualitative	＜6 points n(%)			
	≥6 points n(%)			
	Total (Missing)			
	Statistic			
	P-value			
ASPECTS Score - Anterior Circulation Occlusion (CTP or MRP-assisted assessment)	N(Missing)			
	Mean (SD)			
	Median			
	Q1, Q3			
	Min,Max			
	Statistic			
	P-value			
ASPECTS score - anterior circulation occlusion (based on CTP or MRP-assisted assessment) - qualitative	＜6 points n(%)			
	≥6 points n(%)			
	Total (Missing)			
	Statistic			
	P-value			
ASPECTS Score - Post-occlusion (CTP or MRP-assisted assessment)	N(Missing)			
	Mean(SD)			
	Median			
	Q1, Q3			
	Min,Max			
	Statistic			
	P-value			
ASPECTS score - posterior circulation occlusion (CTP or MRP-assisted assessment) - qualitative	＜6 points n(%)			
	≥6 points n(%)			
	Total (Missing)			
	Statistic			
	P-value			

Table13 Screening Period Angiography Data

Item	Indicator	Experimental Group	Control Group	Total
Normal Vessel Diameter Proximal to Target Lesion (mm)	N(Missing)			
	Mean(SD)			
	Median			
	Q1, Q3			

Item	Indicator	Experimental Group	Control Group	Total
	Min,Max			
	Statistic			
	P-value			
Pre-thrombectomy mTICI classification of the primary responsible vessel	Grade 0 n(%)			
	Grade 1 n(%)			
	Grade 2a n(%)			
	Grade 2b n(%)			
	Grade 3 n(%)			
	Total (Missing)			
	Statistic (CMH)			
	P-value			
Location of Primary Culprit Vessel Before Thrombectomy - ICA	Yes n(%)			
	No n(%)			
	Total (Missing)			
	Statistic (CMH)			
	P-value			
Location of the primary responsible vessel before thrombectomy - MCA	Yes n(%)			
	No n(%)			
	Total (Missing)			
	Statistic (CMH)			
	P-value			
Location of the primary responsible vessel prior to thrombectomy - V4	Yes n(%)			
	No n(%)			
	Total (Missing)			
	Statistic (CMH)			
	P-value			
Location of the primary culprit vessel before thrombectomy - BA	Yes n(%)			
	No n(%)			
	Total (Missing)			
	Statistic (CMH)			
	P-value			

6.3. **Protocol Deviation (SS)**

Table14 Protocol Deviation

Item	Indicator	Experimental Group	Control Group	Total
Protocol Deviations Occurred	None n(%)			
	Yes n(%)			
	Total (Missing)			

Item	Indicator	Experimental Group	Control Group	Total
	Statistic			
	P-value			

6.4. **Anticoagulant and Antiplatelet Medication Use (SS)**

Table15 Anticoagulant use during screening period

Item	Indicator	Experimental Group	Control Group	Total
Warfarin	Yes n(%)			
	No n(%)			
	Unknown n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Low molecular weight heparin	Yes n(%)			
	No n(%)			
	Unknown n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Unfractionated heparin	Yes n(%)			
	No n(%)			
	Unknown n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Urokinase	Yes n(%)			
	No n(%)			
	Unknown n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Other anticoagulants	Yes n(%)			
	No n(%)			
	Unknown n(%)			
	Total (Missing)			
	Statistic			
	P-value			

Table16 Antiplatelet Drugs During Screening Period

Item	Indicator	Experimental Group	Control Group	Total
Aspirin	Yes n(%)			
	No n(%)			
	Unknown n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Clopidogrel	Yes n(%)			
	No n(%)			
	Unknown n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Cilostazol	Yes n(%)			
	No n(%)			
	Unknown n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Other Antiplatelet Agents	Yes n(%)			
	No n(%)			
	Unknown n(%)			
	Total (Missing)			
	Statistical measure			
	P-value			

Table17 Anticoagulants on the day of surgery

Item	Indicator	Experimental Group	Control Group	Total
Warfarin	Yes n(%)			
	No n(%)			
	Unknown n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Low molecular weight heparin	Yes n(%)			
	No n(%)			
	Unknown n(%)			
	Total (Missing)			
	Statistic			
	P-value			

Item	Indicator	Experimental Group	Control Group	Total
Unfractionated heparin	Yes n(%)			
	No n(%)			
	Unknown n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Urokinase	Yes n(%)			
	No n(%)			
	Unknown n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Other anticoagulants	Yes n(%)			
	No n(%)			
	Unknown n(%)			
	Total (Missing)			
	Statistic			
	P-value			

Table18 Antiplatelet Medication on the Day of Surgery

Item	Indicator	Experimental Group	Control Group	Total
Aspirin	Yes n(%)			
	No n(%)			
	Unknown n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Clopidogrel	Yes n(%)			
	No n(%)			
	Unknown n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Cilostazol	Yes n(%)			
	No n(%)			
	Unknown n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Other Antiplatelet	Yes n(%)			

Item	Indicator	Experimental Group	Control Group	Total
Agents	No n(%)			
	Unknown n(%)			
	Total (Missing)			
	Statistical measure			
	P-value			

Table19 Postoperative Anticoagulants

Item	Indicator	Experimental Group	Control Group	Total
Warfarin	Yes n(%)			
	No n(%)			
	Unknown n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Low molecular weight heparin	Yes n(%)			
	No n(%)			
	Unknown n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Unfractionated heparin	Yes n(%)			
	No n(%)			
	Unknown n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Urokinase	Yes n(%)			
	No n(%)			
	Unknown n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Other anticoagulants	Yes n(%)			
	No n(%)			
	Unknown n(%)			
	Total (Missing)			
	Statistic			
	P-value			

Table20 Postoperative Antiplatelet Therapy

Item	Indicator	Experimental Group	Control Group	Total
Aspirin	Yes n(%)			
	No n(%)			
	Unknown n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Clopidogrel	Yes n(%)			
	No n(%)			
	Unknown n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Cilostazol	Yes n(%)			
	No n(%)			
	Unknown n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Other Antiplatelet Agents	Yes n(%)			
	No n(%)			
	Unknown n(%)			
	Total (Missing)			
	Statistical measure			
	P-value			

6.5. **Surgical Record (FAS)**

Table21 Target Vessel Surgery Information

Item	Indicator	Experimental Group	Control Group	Total
Number of Target Vessels*	1 n(%)			
	2 n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Number of devices used	1 n(%)			
	2 n (%)			
	Total (Missing)			
	Statistic			
	P-value			

Item	Indicator	Experimental Group	Control Group	Total
Number of Thrombectomy Procedures	N(Missing)			
	Mean (SD)			
	Median			
	Q1, Q3			
	Min,Max			
	Statistic			
	P-value			
Number of Thrombectomy Procedures - Qualitative	1 time n(%)			
	2 times n(%)			
	≥3 times n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Distal Embolism	Yes n(%)			
	No n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Whether underlying stenosis was detected after recanalization	Yes n(%)			
	No n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Use of Recute or Other Auxiliary Therapy	Yes n(%)			
	No n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Stent implantation for recute treatment	Yes n(%)			
	No n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Use of Balloon Dilatation for Recute Treatment	Yes n(%)			
	No n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Other Recute Treatments Used	Yes n(%)			
	No n(%)			
	Total (Missing)			

Item	Indicator	Experimental Group	Control Group	Total
	Statistic			
	P-value			

Note: Except for analyses where the number of target vessels is the subject unit, all other analyses in this table use target vessel units.

Table22 Thrombectomy Device Usage Information (Device Units)

Item	Indicator	Experimental Group	Control Group	Total
Stent Diameter (mm)	N(Missing)			
	Mean(SD)			
	Median			
	Q1, Q3			
	Min,Max			
	Statistic			
	P-value			
Stent Length (mm)	N(Missing)			
	Mean(SD)			
	Median			
	Q1, Q3			
	Min,Max			
	Statistic			
	P-value			
Device Specifications (Diameter × Length) (mm × mm)	3×20 n(%)			
	3×30 n(%)			
	3×40 n(%)			
	4×15 n(%)			
	4×20 n(%)			
	4×30 n(%)			
	4×40 n(%)			
	6×20 n(%)			
	6×30 n(%)			
	6×40 n(%)			
	Total (Missing)			
	Statistic			
	P-value			

6.6. **Efficacy Endpoints**

6.6.1. Primary Efficacy Endpoints- core laboratory

Table23 Immediate Postoperative Revascularization Rate

Item	Indicator	FAS Experimental Group	FAS Control Group	PPS Experimental Group	PPS Control Group
Immediate Postoperative Revascularization Rate	Recanalization n(%)				
	Non-recanalization n(%)				
	Total (Missing)				
	Statistic				
	P-value				
Immediate postoperative mTICI classification	Grade 0 n(%)				
	Grade 1 n(%)				
	Grade 2a n(%)				
	Grade 2b n(%)				
	Grade 3 n(%)				
	Total (Missing)				
	Statistic (CMH)				
	P-value				

Note 1: Target vessel recanalization, mTICI grade 2b or 3. The same applies below.

Note 2: The 95% confidence interval for the single-group success rate was calculated using the Clopper-Pearson method.

Note 3: For subjects with missing immediate postoperative recanalization rates in FAS, worst-case imputation was applied, treating them as having failed to achieve immediate recanalization. The same applies below.

Note 4: Analysis of immediate postoperative recanalization and mTICI classification based on external data: XX.

Table24 Hypothesis Testing for Immediate Postoperative Recanalization Rate

Population	Indicator	Treatment Group n(%)	Control Group n(%)	Difference in Rates Between Groups	Difference in Rates Between Groups Two-sided 95% CI	Statistic	P-value	Non-inferiority margin
FAS	Immediate postoperative revascularization rate							-12.5%
PPS	Immediate postoperative revascularization rate							-12.5%

Note 1: Rate difference = experimental group - control group. Non-inferiority margin set at -10%. The 95%

confidence interval for the rate difference was calculated using the exact probability method.

Note 2: The lower limit of the 95% confidence interval for the difference in patency success rates between groups exceeded -12.5%, confirming non-inferiority.

Table25 Immediate Postoperative Vascular Recanalization Rates by Center

			FAS		PPS	
Center ID	Item	Indicator	Experimental Group	Control Group	Experimental Group	Control Group
01	Immediate Postoperative Vascular Recanalization Rate	Recanalizationn(%)				
		Non-recanalizationn(%)				
		Total (Missing)				
02	Immediate Postoperative Vascular Recanalization Rate	Recanalizationn(%)				
		Non-recanalizationn(%)				
		Total (Missing)				
03	Immediate Postoperative Vascular Recanalization Rate	Recanalizationn(%)				
		No recanalizationn(%)				
		Total (Missing)				
……	Immediate Postoperative Vascular Recanalization Rate	Recanalizationn(%)				
		No recanalizationn(%)				
		Total (Missing)				

6.6.2. Primary Efficacy Endpoint - EDC

Table26 Immediate Postoperative Revascularization Rate

		FAS		PPS	
Item	Indicator	Experimental Group	Control Group	Experimental Group	Control Group
Immediate Postoperative Revascularization Rate	Recanalizationn(%)				

Item	Indicator	FAS Experimental Group	FAS Control Group	PPS Experimental Group	PPS Control Group
	Non-recanalization n(%)				
	Total (Missing)				
	Statistic				
	P-value				
Immediate postoperative mTICI classification	Grade 0 n(%)				
	Grade 1 n(%)				
	Grade 2a n(%)				
	Grade 2b n(%)				
	Grade 3 n(%)				
	Total (Missing)				
	Statistic (CMH)				
	P-value				

Note 1: Target vessel recanalization, mTICI grade 2b or 3. Same applies below.

Note 2: The 95% confidence interval for the single-group success rate was calculated using the Clopper-Pearson method.

Note 3: For missing immediate post-procedural recanalization rates in the FAS, worst-case imputation was applied, treating missing values as non-achievement of immediate recanalization. The same applies below.

Table27 Hypothesis Test for Immediate Postoperative Vascular Recanalization Rate

Population	Indicator	Experimental Group n(%)	Control Group n(%)	Difference in Rates Between Groups	Difference in Rates Between Groups Two-sided 95% CI	Statistic	P-value	Non-inferiority margin
FAS	Immediate postoperative revascularization rate							-12.5%
PPS	Immediate postoperative revascularization rate							-12.5%

Note 1: Rate difference = experimental group - control group. Non-inferiority margin set at -10%. The 95% confidence interval for the rate difference was calculated using the exact probability method.

Note 2: The lower limit of the 95% confidence interval for the difference in patency success rates between groups exceeded -12.5%, confirming non-inferiority.

Table28 Immediate Postoperative Vascular Recanalization Rates by Center

			FAS		PPS	
Center ID	Item	Indicator	Experimental Group	Control Group	Experimental Group	Control Group
01	Immediate Postoperative Vascular Recanalization Rate	Recanalizationn(%)				
		Non-recanalization n(%)				
		Total (Missing)				
02	Immediate Postoperative Vascular Recanalization Rate	Recanalizationn(%)				
		No recanalization n(%)				
		Total (Missing)				
03	Immediate Postoperative Vascular Recanalization Rate	Recanalizationn(%)				
		No recanalization n(%)				
		Total (Missing)				
……	Immediate Postoperative Vascular Recanalization Rate	Recanalizationn(%)				
		No recanalization n(%)				
		Total (Missing)				

6.6.3. Secondary efficacy endpoint

Table29 mRS 0-2 at 90 days post-surgery

		FAS		PPS	
Item	Indicator	Experimental Group	Control Group	Experimental Group	Control Group
mRS 0-2 at 90 days post-surgery	Yes n(%)				
	No n(%)				
	Total (Missing)				
	Statistic (CMH)				
	P-value				
90-day postoperative mRS	Grade 0 n(%)				
	Grade 1 n(%)				
	Grade 2 n(%)				
	Grade 3 n(%)				

Item	Indicator	FAS Experimental Group	FAS Control Group	PPS Experimental Group	PPS Control Group
	Grade 4 n(%)				
	Level 5 n(%)				
	Level 6 n(%)				
	Total (Missing)				
	Statistic				
	P-value				

Table30 Recanalization Time

Item	Indicator	FAS Experimental Group	FAS Control Group	PPS Experimental Group	PPS Control Group
Recanalization Time (min)	N(Missing)				
	Mean(SD)				
	Median				
	Q1, Q3				
	Min, Max				
	Statistic				
	P-value				

Note: Time to reperfusion = End time - Femoral artery puncture time (If reperfusion is successful, the end time is the time of successful reperfusion; if reperfusion fails, the end time is recorded as the time of surgical completion).

Table31 Postoperative NIHSS Score Improvement

Item	Indicator	FAS Experimental Group	FAS Control Group	PPS Experimental Group	PPS Control Group
Preoperative NIHSS Score	N(Missing)				
	Mean(SD)				
	Median				
	Q1, Q3				
	Min,Max				
	Statistic				
	P-value				
NIHSS score at 24±12 hours postoperatively	N(Missing)				
	Mean(SD)				
	Median				
	Q1, Q3				
	Min,Max				
	Statistic				
	P-value				

Item	Indicator	FAS Experimental Group	FAS Control Group	PPS Experimental Group	PPS Control Group
NIHSS score reduction >4 points (postoperative 24±12 h vs. preoperative)	Yes n(%)				
	No n(%)				
	Total (Missing)				
	Statistic				
	P-value				
NIHSS score at 7±2 days post-op/prior to discharge	N(Missing)				
	Mean (SD)				
	Median				
	Q1, Q3				
	Min,Max				
	Statistic				
	P-value				
Proportion of subjects with NIHSS score reduction >4 points (7 ± 2 days post-op/prior to discharge)	Yes n(%)				
	No n(%)				
	Total (Missing)				
	Statistic				
	P-value				

Table32 Device Operation Success Rate (per device unit)

Item	Indicator	FAS	PPS
Whether Device Operation Was Successful	Yes n(%)		
	No n(%)		
	Total (Missing)		

6.7. **Safety endpoint (SS)**

6.7.1. Symptomatic intracranial hemorrhage within 24 hours postoperatively

Table33 Symptomatic intracranial hemorrhage within 24 hours postoperatively

Item	Indicator	Experimental Group	Control Group	Total
Symptomatic intracranial hemorrhage within 24 hours postoperatively	No n(%)			
	Yes n(%)			
	Total (Missing)			
	Statistical measure			
	P-value			

Note: Symptomatic intracranial hemorrhage within 24 hours postoperatively refers to intracranial hemorrhage detected on cranial CT or MR imaging during the 24-hour postoperative follow-up, accompanied by an increase in NIHSS score of ≥4 points compared to the preoperative score.

6.7.2. All-cause mortality within 90 days postoperatively

Table34 Study All-cause mortality within 90 days

Item	Indicator	Experimental Group	Control Group	Total
All-cause mortality within 90 days post-surgery	No n(%)			
	Yes n(%)			
	Total (Missing)			
	Statistic			
	P-value			

6.7.3. Adverse Events

Table35 Summary of Adverse Events

	Experimental Group (n=)			Control Group (n=)			Total (n=)			
Item	Number of Occurrence	Number of Subjects	Incidence Rate (%)	Number of Occurrence	Number of Cases	Incidence Rate (%)	Number of cases	Number of Cases	Incidence Rate (%)	P value
Adverse Event										
Mild adverse events										
Moderate adverse events										
Severe adverse events										
Adverse events related to the investigational device										
Adverse events leading to subject withdrawal from the trial										
Adverse events resulting in death										

Note: Definition of trial device-related adverse events: Adverse events classified as "definitely related," "probably related," "possibly related," or "unclassifiable" to the trial device.

Table36 Summary of Serious Adverse Events

	Treatment Group (n=)			Control group (n=)			Total (n=)			
Item	Number of Occurrence	Number of Subjects	Incidence Rate (%)	Number of Occurrence	Number of Cases	Incidence Rate (%)	Number of cases	Number of Cases	Incidence Rate (%)	P value
Serious Adverse Events										
Serious adverse events related to the investigational device										
Serious adverse events resulting in death										

Note: Definition of serious adverse events related to the investigational device: Serious adverse events determined to be "definitely related," "probably related," "possibly related," or "unclassifiable" to the investigational device.

Table37 Event Coding

	Experimental Group (n=)			Control Group (n=)			Total (n=)			
Item	Number of Occurrence	Number of Subjects	Incidence Rate (%)	Number of Occurrence	Number of Cases	Incidence Rate (%)	Number of cases	Number of Cases	Incidence Rate (%)	P value
Adverse Event										
SOC1										
PT1										
PT2										
……										
SOC2										
……										

Table38 Serious Adverse Event Codes

	Experimental Group (n=)			Control Group (n=)			Total (n=)			
Item	Number of Occurrence	Number of Subjects	Incidence Rate (%)	Number of Occurrence	Number of Cases	Incidence Rate (%)	Number of cases	Number of Cases	Incidence Rate (%)	P value
Serious Adverse Events										
SOC1										
PT1										
PT2										

	Experimental Group (n=)			Control Group (n=)			Total (n=)			
Item	Number of Occurrence	Incidence Subjects	Rate (%)	Number Occurrence	Incidence of Cases	Rate (%)	Number of cases	Number of Cases	Incidence Rate (%)	P value
……										
SOC2										
……										

6.7.4. Cross-tabulation of Laboratory Findings Before and After Treatment

Table39 Blood Count Red Blood Cells

		24±12 hours postoperatively or 7±2 days postoperatively				
Group	Screening period (-1 to 0 days)	Normal	Abnormal but not clinically significant	Abnormal but clinically significant	Not Tested	Missing	Total
Experimental group	Normal						
	Abnormal but not clinically significant						
	Abnormal but clinically significant						
	Not detected						
	Missing						
	Total						
Control group	Normal						
	Abnormal but not clinically significant						
	Abnormal but clinically significant						
	Not tested						
	Missing						
	Total						

Table40 Complete blood count Hemoglobin

		24±12 hours post-op or 7±2 days post-op				
Group	Screening Period (-1 to 0 days)	Normal	Abnormal but not clinically significant	Abnormal but clinically significant	Not Tested	Missing	Total
Experimental group	Normal						
	Abnormal but not clinically significant						

		24±12 hours post-op or 7±2 days post-op				
Group	Screening Period (-1 to 0 days)	Normal	Abnormal but not clinically significant	Abnormal but clinically significant	Not Tested	Missing Total
Control group	Normal					
	Abnormal but not clinically significant					
	Abnormal but clinically significant					
	Not tested					
	Missing					
	Total					

Table41 Complete Blood Count White Blood Cell Count

		24±12 hours post-op or 7±2 days post-op				
Group	Screening Period (-1 to 0 days)	Normal	Abnormal but not clinically significant	Abnormal but clinically significant	Not detected	Missing Total
Experimental group	Normal					
	Abnormal but not clinically significant					
	Abnormal but clinically significant					
	Not detected					
	Missing					
	Total					
Control group	Normal					
	Abnormal but not clinically significant					
	Abnormal but clinically significant					
	Not tested					
	Missing					
	Total					

Table42 Complete blood count Platelet count

		24±12 hours post-op or 7±2 days post-op				
Group	Screening Period (-1 to 0 days)	Normal	Abnormal but not clinically significant	Abnormal but clinically significant	Not Tested	Missing Total
Experimental group	Normal					
	Abnormal but not clinically significant					
	Abnormal but clinically significant					
	Not detected					
	Missing					
	Total					
Control group	Normal					
	Abnormal but not clinically significant					
	Abnormal but clinically significant					
	Not tested					
	Missing					
	Total					

Table43 Blood Biochemistry Urea Nitrogen

		24±12 hours post-op or 7±2 days post-op				
Group	Screening Period (-1 to 0 days)	Normal	Abnormal but not clinically significant	Abnormal but clinically significant	Not Tested	Missing Total
Experimental group	Normal					
	Abnormal but not clinically significant					
	Abnormal but clinically significant					
	Not detected					
	Missing					
	Total					
Control group	Normal					
	Abnormal but not clinically significant					
	Abnormal but clinically significant					
	Not tested					
	Missing					

		24±12 hours post-op or 7±2 days post-op				
Group	Screening Period (-1 to 0 days)	Normal	Abnormal but not clinically significant	Abnormal but clinically significant	Not Tested	Missing Total
	Total					

Table44 Blood Biochemistry Urea

		24±12 hours post-op or 7±2 days post-op				
Group	Screening Period (-1 to 0 days)	Normal	Abnormal but not clinically significant	Abnormal but clinically significant	Not Tested	Missing Total
Experimental group	Normal					
	Abnormal but not clinically significant					
	Abnormal but clinically significant					
	Not detected					
	Missing					
	Total					
Control group	Normal					
	Abnormal but not clinically significant					
	Abnormal but clinically significant					
	Not tested					
	Missing					
	Total					

Table45 Blood Biochemistry Blood Creatinine

		24±12 hours post-op or 7±2 days post-op				
Group	Screening Period (-1 to 0 days)	Normal	Abnormal but not clinically significant	Abnormal but clinically significant	Not Tested	Missing Total
Experimental group	Normal					
	Abnormal but not clinically significant					
	Abnormal but clinically significant					
	Not detected					
	Missing					
	Total					

		24±12 hours post-op or 7±2 days post-op				
Group	Screening Period (-1 to 0 days)	Normal	Abnormal but not clinically significant	Abnormal but clinically significant	Not Tested	Missing Total
Control group	Normal					
	Abnormal but not clinically significant					
	Abnormal but clinically significant					
	No findings					
	Absent					
	Total					

Table46 Blood Biochemistry Random Blood Glucose

		24±12 hours post-op or 7±2 days post-op				
Group	Screening period (-1 to 0 days)	Normal	Abnormal but not clinically significant	Abnormal but clinically significant	Not Tested	Missing Total
Experimental group	Normal					
	Abnormal but not clinically significant					
	Abnormal but clinically significant					
	Not detected					
	Missing					
	Total					
Control group	Normal					
	Abnormal but not clinically significant					
	Abnormal but clinically significant					
	Not tested					
	Missing					
	Total					

Table47 Coagulation Function Prothrombin Time

		24±12 hours postoperatively or 7±2 days postoperatively				
Group	Screening Period (-1 to 0 days)	Normal	Abnormal but not clinically significant	Abnormal but clinically significant	Not Tested	Missing Total
	Normal					

		24±12 hours postoperatively or 7±2 days postoperatively				
Group	Screening Period (-1 to 0 days)	Normal	Abnormal but not clinically significant	Abnormal but clinically significant	Not Tested	Missing Total
Experimental group	Abnormal but not clinically significant					
	Abnormal but clinically significant					
	Not detected					
	Missing					
	Total					
Control group	Normal					
	Abnormal but not clinically significant					
	Abnormal but clinically significant					
	Not tested					
	Missing					
	Total					

Table48 Coagulation Function Partial Thromboelastography Time

		24±12 hours postoperatively or 7±2 days postoperatively				
Group	Screening period (-1 to 0 days)	Normal	Abnormal but not clinically significant	Abnormal but clinically significant	Not Tested	Missing Total
	Normal					
Experimental group	Abnormal but not clinically significant					
	Abnormal but clinically significant					
	Not detected					
	Missing					
	Total					
Control group	Normal					
	Abnormal but not clinically significant					
	Abnormal but clinically significant					
	Not tested					
	Missing					
	Total					

Table49 International Normalized Ratio (INR)

		24±12 hours post-op or 7±2 days post-op				
Group	Screening Period (-1 to 0 days)	Normal	Abnormal but not clinically significant	Abnormal but clinically significant	Not Tested	Missing Total
Experimental group	Normal					
	Abnormal but not clinically significant					
	Abnormal but clinically significant					
	Not detected					
	Missing					
	Total					
Control group	Normal					
	Abnormal but not clinically significant					
	Abnormal but clinically significant					
	Not tested					
	Missing					
	Total					

6.7.5. Device defect

Table50 Device defect

Item	Indicator	Experimental Group	Control Group	Total
Device Defects	No n(%)			
	Yes n(%)			
	Total (Missing)			
	Statistic			
	P-value			

7. List

See the appendix for the detailed checklist.