Protocol Number: WQ11-2402

A Prospective, Multicenter, Superiority, Randomized Controlled Study to Evaluate the Safety and Efficacy of the Aortic Endovascular Patch System (WeFlow-EndoPatch™) for the Treatment of Distal Tears Following Aortic Repair

Trial Medical Device Name: Aortic Endovascular Patch System(WeFlow-EndoPatch™)

Model Specification: Refer to the protocol for specification details

Trial Medical Device Regulatory Classification:

Class III medical device requiring clinical trial approval Yes □ No ■

Presence or absence of similar products in China Yes □ No ■

Protocol Version Number and Date: V1.3/20260605

Lead Unit: First Medical Center of The Chinese PLA General Hospital

Coordinating Investigator: Professor Guo Wei

Sponsor: Hangzhou Endonom Medtech Co., Ltd.

Confidential

This document is confidential. The contents of this document may not be disclosed to other parties by any person or entity without express written permission from Hangzhou Endonom Medtech Co., Ltd. The above restriction excludes subjects or their legal representatives who signed an informed consent form as well as discussions with governing bodies, independent ethics committees (IECs) or staff involved in the trial.

Trial Protocol Summary

Name of the Trial	A prospective, multicenter, Superiority, randomized controlled study to evaluate the safety and efficacy of the aortic endovascular patch system (WeFlow-EndoPatch™) for the treatment of distal tears following aortic repair
Sponsor	Hangzhou Endonom Medtech Co., Ltd.
Trial Objective	The purpose of this clinical trial is to evaluate the safety and efficacy of the aortic endovascular patch system (WeFlow-EndoPatch ™) developed and manufactured by Hangzhou Endonom Medtech Co.; Ltd. for the treatment of distal tears following aortic repair. To provide clinical evidence for the formal application of this product in China.
Trial Equipment	Aortic endovascular patch system (WeFlow-EndoPatch™)
Sample Size	A total of 128 patients are planned to be enrolled in each of the test group and the control group, with an overall sample size of 256.
Sample Size Design	[redacted] A superiority trial design was adopted with $\alpha = 0.025$ (single tailed), $\beta = 0.20$ (power = 80%), equal allocation between the test and control groups, and a superiority margin of 0%. With a 20% dropout rate, it is planned to finally enroll at least 108 subjects in each of the test and control group, with a total sample size of 216 subjects in both groups. Additionally, each group will independently enroll 1 subject as part of a learning curve prior to initiating randomized enrollment, These learning curve cases will not be included in the statistical analysis of the 108 patients in the test group for the confirmatory trial.
Follow-Up Period	Each subject will require 60 months of follow-up post-procedure.
Patient Inclusion/ Exclusion Criteria	**Inclusion Criteria** 1. Patients aged 18 to 80 years old. 2. Patients with chronic aortic dissection who have previously undergone aortic repair, with the presence of a distal tear in the descending thoracic aorta that exhibits persistent retrograde flow. 3. The maximum diameter of the descending thoracic aorta is [redacted]cm. 4. The maximum diameter of the distal tear in the descending thoracic aorta is [redacted]mm. 5. Imaging assessment confirms the presence of a suitable arterial access

route for performing endovascular aortic therapy.

6. Patients are able to understand the purpose of the trial, participate in this study voluntarily, has signed the informed consent form personally or via their legal representative, and is willing to complete follow-up in accordance with the protocol requirements.

Exclusion Criteria

1. Rupture or impending rupture of aortic dissection.
2. Proximal type I endoleak following aortic repair.
3. Stent-induced new distal tear (SINE).
4. Rapid aortic diameter growth ≥10 mm/year.
5. Abdominal aortic dissecting aneurysm diameter ≥5 cm.
6. Distance from the tear margin to the celiac artery orifice [redacted]mm.
7. Only one tear present in the abdominal aorta or more distally.
8. Concurrent need for intervention on other vascular lesions (e.g., coronary, carotid, renal, superior mesenteric arteries, etc.) during the same procedure.
9. Acute systemic infection.
10. Uncontrollable hypertension (blood pressure remains elevated >12 hours despite the use of more than three different types of antihypertensive drugs at maximum recommended or tolerated doses).
11. History of myocardial infarction, transient ischemic attack (TIA), or cerebral infarction within the past 3 months.
12. New York Heart Association (NYHA) class IV heart failure or left ventricular ejection fraction (LVEF) <30%.
13. Hematological abnormalities defined as: leukopenia (WBC < 3×10^9 /L), anemia (Hb < 90 g/L), coagulation disorders, thrombocytopenia (platelet count < 50×10^9/L).
14. Renal insufficiency with serum creatinine >221 μ mol/L (or 2.5 mg/dL) and/or end-stage renal disease requiring dialysis, as determined by the investigator after comprehensive evaluation.
15. Severe hepatic dysfunction: alanine aminotransferase (ALT) or aspartate aminotransferase (AST) >5 times the upper limit of normal, or serum total bilirubin (STB) >2 times the upper limit of normal.
16. Allergy to contrast media, the vascular patch, or the delivery system materials.

	17. Pregnancy or lactation. 18. Concurrent participation in another drug or device clinical study. 19. Life expectancy less than 12 months (e.g., advanced malignancy). 20. Presence of a distal tear in the descending thoracic aorta that cannot be sealed, or any other condition that, in the investigator's judgment, makes the subject unsuitable for participation in this study.
Primary Endpoints	**The 12-month Clinical Success Rate.** Evaluation Time Point: 12 months post-procedure Evaluation Method: The 12-month clinical success rate is a composite endpoint, defined as achieving all of the following at 12 months post-procedure: [redacted] Favorable aortic remodeling of the descending thoracic aorta is defined as meeting at least one of the following three criteria:① The maximum diameter of the false lumen is reduced, and the increase in the maximum diameter of the total aorta is < 5 mm compared with baseline;② The maximum diameter of the true lumen is enlarged, and the increase in the maximum diameter of the total aorta is < 5 mm compared with baseline;③ The maximum diameter of the total aorta is reduced (i.e., smaller than the baseline value), with no specific requirement for changes in the diameters of the true and false lumina. Disease-related or device-related surgical intervention during follow-up primarily refers to open or endovascular procedures triggered by disease progression or device-related complications or adverse events，including: (1) disease progression (e.g., retrograde Stanford type A aortic dissection, severe endoleak, residual dissection expansion ≥5.5 cm or expansion rate ≥1.0 cm/year, new entry tear leading to significant false lumen expansion, vital organ ischemia, stent infection, etc.); (2) device-related complications (e.g., patch-induced tear enlargement, patch detachment, etc.). This does not include elective or planned surgeries, nor non-aortic procedures. Note: The need for surgical intervention is determined by the investigator. If the investigator determines that surgical intervention is necessary but the subject does not undergo the actual intervention for other reasons, it is still counted as a lesion- or

	device-related surgical intervention.
Secondary Efficacy Endpoints	**1）Immediate technical success rate in the Test Group** Evaluation Time: Intraoperative Evaluation Method: Immediate technical success is defined as successful delivery of the vascular patch to the intended position, accurate positioning and successful deployment, with the delivery sheath safely withdrawn outside the body, and no conversion to open surgery.。 **2）Success rate of tear closure in the Test Group** Evaluation Time: 30 days, 6 months, 12 months, and 24–60 months postoperatively Evaluation Method: After implantation of the vascular patch, successful closure is confirmed by CTA showing no blood flow entering the false lumen or retrograde true lumen across the vascular patch. [redacted] **3 ） Thrombosis status of the false lumen in the descending thoracic aortic segment** Evaluation Time: 30 days, 6 months, 12 months, and 24–60 months postoperatively Evaluation Method: Record the CTA results at each follow-up time point, observe and document the thrombosis status of the false lumen in the descending thoracic aortic segment (no thrombosis / partial thrombosis / complete thrombosis). **4 ） Changes in true lumen diameter / false lumen diameter / maximum diameter in the descending thoracic aortic segment** Evaluation Time: 30 days, 6 months, 12 months, and 24–60 months postoperatively Evaluation Method: Compare CTA results before the procedure and at each follow-up time point, observe and document the minimum true

	lumen diameter, maximum false lumen diameter, maximum aortic diameter, and their changes in the descending thoracic aortic segment. **5）Changes in true lumen volume / false lumen volume / total volume in the descending thoracic aortic segment** Evaluation Time: 30 days, 6 months, 12 months, and 24–60 months postoperatively Evaluation Method:Compare CTA results before the procedure and at each follow-up time point, observe and document the changes in true lumen volume, false lumen volume, and total aortic volume in the descending thoracic aortic segment. **6）Lesion- or device-related surgical intervention** Evaluation Time: 30 days, 6 months, 12 months, and 24–60 months postoperatively
Safety Evaluation	**1）Incidence of freedom from major adverse events within 30 days postoperatively.** Evaluation Time: Before discharge, and at 30 days post-procedure Definition: Major adverse events within 30 days post-procedure refer to the occurrence of any of the following within 30 days after the procedure: all-cause death, aortic rupture, myocardial infarction, renal failure, respiratory failure, ischemic stroke, intestinal necrosis, severe lower limb ischemia or necrosis, or paraplegia. Among these: Renal failure refers to renal failure leading to persistent dialysis, renal transplantation, or other fatal outcomes. Respiratory failure refers to respiratory failure leading to significantly prolonged intubation time, tracheostomy, deterioration of lung function, or other fatal outcomes. Intestinal necrosis refers to intestinal ischemia requiring bowel resection or leading to other fatal outcomes. Severe lower limb ischemia refers to new-onset severe claudication or rest pain in the lower limbs following the

	procedure. **2) Vascular Patch Detachment Rate of the Test Group** Evaluation Time: 30 days post-procedure, 6 months post-procedure, 12 months post-procedure, and 24–60 months post-procedure Evaluation Method: Following implantation of the vascular patch, CTA is used to assess the occurrence of vascular patch detachment. **3)All-Cause Mortality Rate, Aortic Dissection-Related Mortality Rate, Serious Adverse Event Rate, and Device-Related Adverse Event Rate** ① All-Cause Mortality Rate Evaluation Time: 30 days, 6 months, 12 months, and 24–60 months post-procedure Evaluation Method: All-cause death refers to death from any cause during the follow-up period. ② Aortic Dissection-Related Mortality Rate Evaluation Time: 30 days, 6 months, 12 months, and 24–60 months post-procedure Evaluation Method: Aortic dissection-related death refers to death caused by aortic dissection rupture or death related to surgery for the treatment of aortic dissection. ③ Serious Adverse Event Rate Evaluation Time: 30 days, 6 months, 12 months, and 24–60 months post-procedure Evaluation Method: A serious adverse event is defined as any adverse event occurring during the clinical trial that leads to death or serious deterioration in health status, including a life-threatening disease or injury, permanent impairment of body structure or body function, or an event

	requiring medical or surgical intervention to prevent permanent impairment of body structure or body function. ④ Device-Related Adverse Event Rate Evaluation Time: 30 days, 6 months, 12 months, and 24–60 months post-procedure Evaluation Method: A device-related adverse event refers to an adverse medical event associated with the use of the device that occurs during the clinical trial. However, normal post-procedural stress responses, such as fever or chest/back discomfort, should be distinguished. If the investigator determines these to be normal post-procedural stress responses, they need not be recorded as adverse events. Recorded device-related adverse events refer to those judged by the investigator as definitely or possibly related to the investigational device.
Trial Visitation Plan	➢ Visit 1: Screening period (Day -15 to 0) ➢ Visit 2: Day of Surgery (Day 0) ➢ Visit 3: Before discharge ➢ Visit 4: 30-day (±7 days) postoperative visit ➢ Visit 5: 6-month (±30 days) postoperative visit ➢ Visit 6: 12-month (±30 days) postoperative visit ➢ Visits 7,8,9,10: 24-month (±30 days), 36-month (±30 days), 48-month (±30 days), 60-month (±30 days) after surgery

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Full Trial Protocol Text

1. Sponsor Information

1.1. Sponsor Name

Hangzhou Endonom Medtech Co., Ltd.

1.2. Sponsor Address

Room 619, 6rd Floor, Building 2, No. 8 Jiangling Road, Binjiang District, Hangzhou City, Zhejiang Province

1.3. Sponsor Contact Information

Company Phone Number: 0571-81398035

2. List of Clinical Trial Sites and Investigators:

For details, see Annex 1 of the Protocol.

3. Statistical Analysis

Yao Chen, Peking University Clinical Research Institute

Address: No. 38 Xueyuan Road, Haidian District, Beijing

4. Clinical Trial Objectives and Content

4.1. Objectives

The purpose of this clinical trial is to evaluate the safety and efficacy of the WeFlow-EndoPatch™ aortic endovascular patch system developed and manufactured by Hangzhou Endonom Medtech Co.; Ltd. for the treatment of distal tears following aortic repair, and to provide clinical evidence for formal application of this product in China.

4.2. Content

This study is a prospective, multicenter, superiority, randomized controlled clinical trial conducted at qualified clinical research institutions. An internet-based registration system will be used to register enrolled subjects. After signing informed consent, subjects who meet all inclusion criteria and none of the exclusion criteria will be enrolled. Each center will enroll 1 learning- curve subject, and after completion, 1:1 randomization will be initiated. The test group will receive the aortic endovascular patch system developed and manufactured by Hangzhou Endonom Medtech Co., Ltd. for endovascular treatment, while the control group

will receive only conservative medical management for chronic thoracic aortic dissection as recommended by the Chinese Expert Consensus on Diagnosis and Treatment of Stanford Type B Aortic Dissection (2022 Edition) (mainly blood pressure control and regular imaging follow-up).

This project is expected to start in May 2024 and complete enrollment by August 2026. All subjects will undergo clinical follow-up post-operatively until discharge, and at 30 days, 6 months, 12 months, 24 months, 36 months, 48 months, and 60 months, with CTA imaging follow-up at 30 days, 6 months, 12 months, 24 months, 36 months, 48 months, and 60 months.

The primary endpoint of this trial is the 12-month clinical success rate. Safety is further assessed by the 30-day freedom from major adverse events, test group vascular patch detachment rate, all-cause mortality, aortic dissection-related mortality, serious adverse event rate, and device-related adverse event rate. Efficacy is further assessed by immediate technical success rate in the test group, test group tear closure success rate, false lumen thrombosis status in the descending thoracic aorta, changes in true lumen diameter/false lumen diameter/maximum diameter, changes in true lumen volume/false lumen volume/total volume, and re-intervention rate. After completing the 12-month primary endpoint assessment, the sponsor will issue a clinical trial report and submit it to NMPA. Subsequent annual follow-up will continue until the 5th year to observe long-term efficacy.

5. Background Information Pertaining to the Clinical Trial

Aortic Dissection (AD) is a severe cardiovascular emergency with acute onset, rapid progression, and extremely high mortality. AD results from various causes leading to intimal tear, blood flow entering the media, and separation of the aortic wall layers, dividing the lumen into true and false lumens[1]. After the formation of aortic dissection, high-pressure blood flow continuously enters the false lumen through the primary entry tear, causing further dissection and the formation of one or multiple secondary tears distally; these distal tears are considered outlets of the false lumen[2]. In addition to medical therapy, open surgery or endovascular repair is commonly used to treat the proximal primary tear.

However, an increasing number of researchers have pointed out that “only sealing the

proximal tear while leaving distal tears untreated" has certain drawbacks: blood can re-enter the false lumen through distal tears, leading to progressive distal aortic dilation in 20 - 40% of cases[3], and increased pressure in the proximal false lumen may also increase the risk of retrograde dissection[4]. Wojciechowski et al. noted that the presence of distal tears with high flow velocity is an unfavorable factor for false lumen thrombosis and aortic remodeling[5], and persistent false lumen patency is associated with late aortic events[6]. In clinical practice, most TBAD patients have more than one tear. A 15 - year retrospective study with 333 subjects reported that during follow - up after aortic repair, 97.00% had more than 2 tears, 51.35% had residual tears in the descending thoracic aorta, and 78.98% had tears involving abdominal branch arteries[7]. Kölbel et al.[8] showed that treating distal tears reduces retrograde perfusion into the false lumen, promotes false lumen thrombosis, and reduces mortality. The 10 - year survival rate for complete closure of all false lumen tears in the descending aorta was 90%, significantly higher than 60% for incomplete closure.

The Chinese Expert Consensus on Diagnosis and Treatment of Stanford Type B Aortic Dissection (2022 Edition)[9] states that for acute or subacute TBAD patients, after sealing the proximal primary tear, whether and how to treat distal tears in one stage remains inconclusive. The indications and methods for second - stage distal tear treatment are still under investigation and lack evidence. The consensus recommends re - intervention for chronic TBAD patients with retrograde dissection (RTAD), severe endoleak, residual dissection expansion $\geq$ 5.5 cm or expansion rate $\geq$ 1.0 cm/year or 0.5 cm/6 months, new tear causing significant false lumen enlargement, or vital organ ischemia. For patients without such indications, the main treatment is blood pressure control and regular imaging follow - up. However, some experts believe that preoperative aortic diameter and false lumen patency are closely related to prognosis; a preoperative descending thoracic aortic maximum diameter [redacted] mm is a risk factor for negative remodeling. Aortic dissection progression is dynamic, and some patients with high - risk aortic features, if distal tears are left untreated, have an increasing risk of distal aortic dilation and long - term mortality. Thus, they advocate that eliminating all tears should be the core requirement of TEVAR for acute Stanford B dissection, aiming for a "radical" cure[10]. The management of

aortic dissection tears should follow the principle from proximal to distal; tears in the descending thoracic aorta should be addressed as completely as possible during the first surgery, and tears in the supra-renal abdominal aorta should not be blindly treated before infra-renal tears[2].

Therefore, various second-stage distal tear treatment strategies have emerged, including true lumen approaches such as extending covered stent grafts to cover the entire descending aorta to seal all distal tears (with risk of spinal cord ischemia), multi-layer bare stent techniques (which do not directly seal tears and may allow late expansion), and off-label use of congenital heart defect occluders (not specifically designed for dissection tears, with risks of migration, inaccurate positioning, and endoleak). False lumen embolization with coils, Onyx, fibrin glue, filters, etc., are also off-label uses without dedicated devices[11]. Hence, exploring a simple, minimally invasive, safe, easy-to-master, and cost-effective method to seal distal tears after classic TEVAR, ultimately achieving "radical" repair of the entire dissection, is a research direction for both domestic and international scholars.

In fact, the concept of using congenital heart defect occluders for aortic dissection tears is feasible. Because these devices are small, unlike covered stents that cover a large segment of the vessel, they can precisely target "dot-shaped" tears, offering greater flexibility. As early as 2008, Tang et al.[12] reported a case of using a double-disc congenital heart defect occluder to seal a distal tear in type B dissection, with false lumen thrombosis at 1-year follow-up. Since then, many successful cases have been reported[13-17]. Using occluders to seal distal tears after covering the proximal tear with a stent graft significantly promotes false lumen thrombosis, prevents aneurysmal dilation, and reduces mortality. However, occluders are not morphologically optimized for aortic walls, and complications such as migration, inaccurate positioning, and endoleak have been reported[18-19]. Therefore, Hangzhou Endonom Medtech Co., Ltd. developed a novel aortic endovascular patch system to address these issues. The system consists of a vascular patch, a delivery cable, and a steerable delivery sheath. The patch is pre-loaded on the cable; the sheath delivers the patch to the target lesion, and the cable releases the patch so that the tear is located at the waist of the patch, and the double discs are

locked. The self-expanding discs appose the vessel wall and seal the tear. The implanted patch blocks blood flow through the tear into the false lumen, reducing false lumen pressure and preventing further expansion and rupture.

The product has completed animal and simulated human experiments, in which delivery, positioning, and deployment met clinical requirements. Post-procedure angiography in animal experiments showed good patch morphology and satisfactory sealing without endoleak; 6-month follow-up angiography showed no structural damage or migration; histopathology showed mild inflammatory reaction and good biocompatibility. Furthermore, full performance testing of the product showed stable performance and quality compliance. Therefore, the product is ready for clinical trials to evaluate the safety and efficacy of the WeFlow-EndoPatch ™ system for treating distal tears after aortic repair.

6. Product Basic Information

6.1. Product Structural Composition, Working Principles and Mechanism of Action

The aortic endovascular patch system consists of a vascular patch system and a steerable delivery sheath.

The vascular patch system comprises the vascular patch and a delivery cable, with the patch pre-loaded on the cable, as shown in Figure 1.

The vascular patch is made of a nitinol alloy mesh and an expanded polytetrafluoroethylene (ePTFE) flow-blocking membrane sewn together, as shown in Figure 2. The delivery cable consists of an outer cable assembly, an inner cable assembly, a handle assembly, and a loader, as shown in Figure 3.

The steerable delivery sheath consists of a delivery sheath and a dilator. The effective length of the delivery sheath is coated with a hydrophilic coating (polyvinylpyrrolidone), as shown in Figures 4 and 5.

The vascular patch is a self-expanding double-disc structure with two discs connected by a waist. It can be compressed and loaded into a small sheath. Through a percutaneous endovascular approach, the steerable delivery sheath delivers the patch to the target lesion, and the delivery cable releases the patch so that the tear is positioned at the waist, and the discs are

locked. The self - expanding discs appose the vessel wall and seal the target lesion. The implanted patch blocks blood flow through the tear into the false lumen, reducing false lumen pressure and preventing further expansion and rupture.

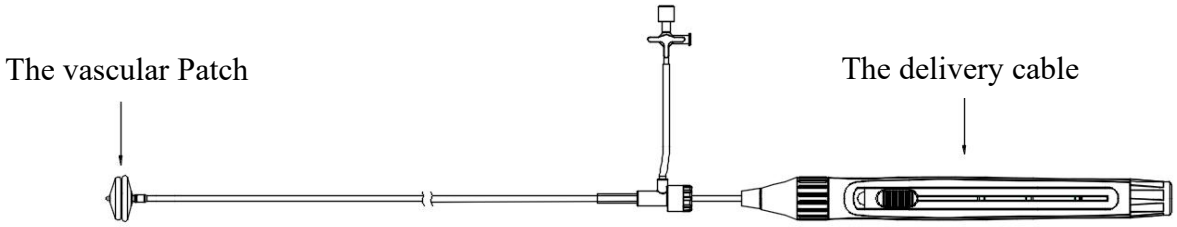


Figure 1. Diagram of the Vascular Patch System

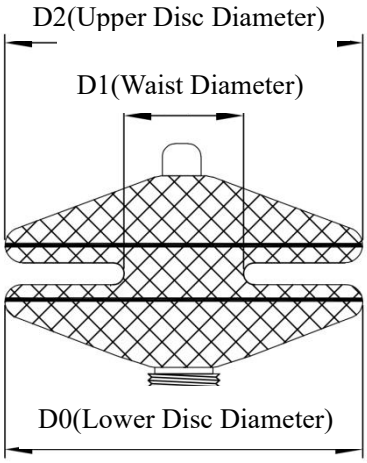


Figure 2.Diagram of the Vascular Patch

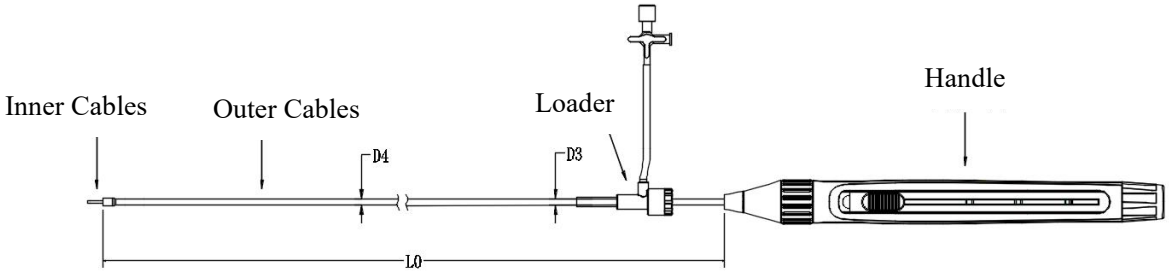


Figure 3. Diagram of the Delivery Cable

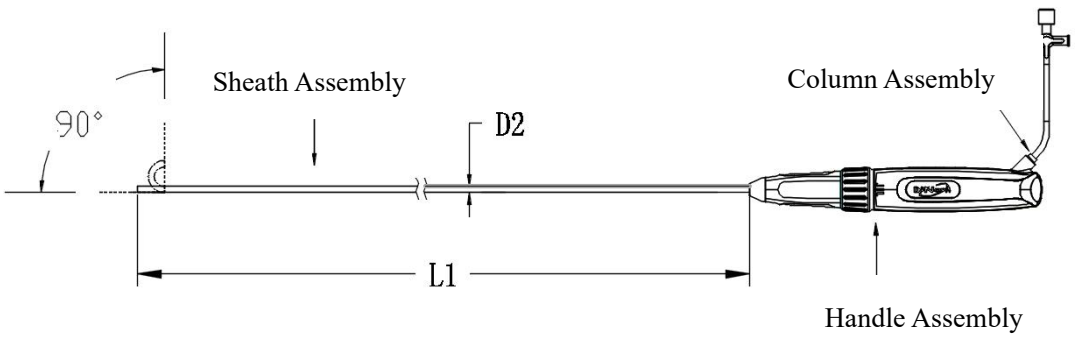


Figure 4. Diagram of the Delivery Sheath

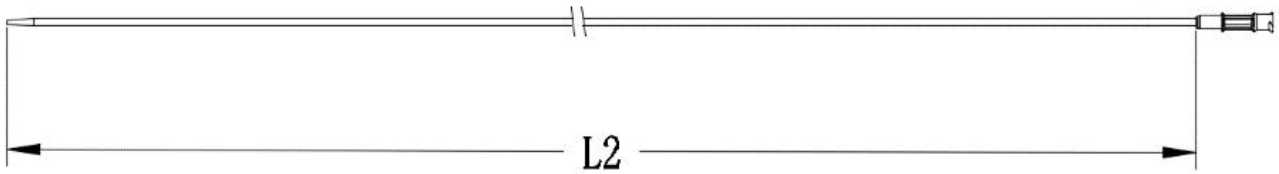


Figure 5. Diagram of the Dilator

6.2. Product Specifications

The vascular patch system model specification consists of a model code and a specification code, as shown in Figure 6. The steerable delivery sheath model specification consists of a model code and a specification code, as shown in Figure 7.

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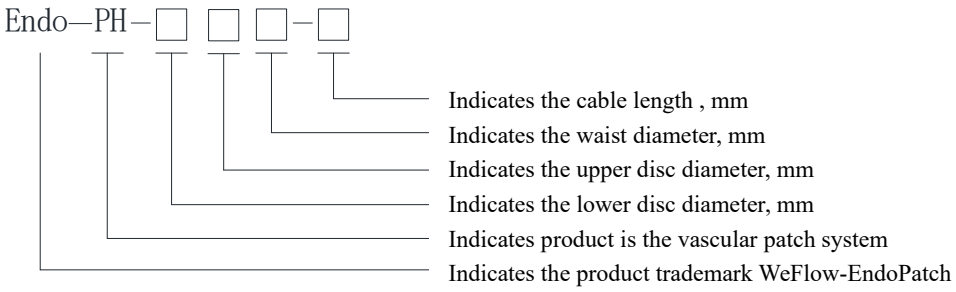


Figure 6 Model and Specification Designation for the Vascular Patch System

Example: Endo-PH-161608-1150 indicates lower disc diameter 16 mm, upper disc diameter 16 mm, waist diameter 8 mm, cable effective length 1150 mm.

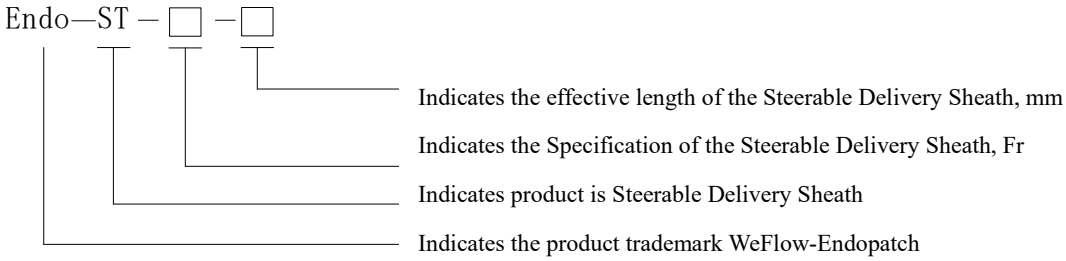


Figure 7：Model and Specification Designation for the Steerable Delivery Sheath

Example: Endo-ST-09-0750 indicates the product is Steerable Delivery Sheath, the sheath size is 9F, the effective length is750 mm.

The specification series table for the vascular patch system is shown in Table 1; the specification series table for the delivery cable is shown in Table 2; and the specification series table for the steerable delivery sheath is shown in Table 3.

Table 1 Specification Series of Vascular Patch System (Unit: mm)

Specification Series	Lower Disc Diameter D0	Upper Disc Diameter D2	Waist Diameter D1	Cable Effective Length L0	Recommended Minimum Sheath Size（Fr）
06	6	[redacted]	[redacted]	900 1150 1400	8F
08	8	[redacted]	[redacted]		8F
10	10	[redacted]	[redacted]		8F
12	12	[redacted]	[redacted]		9F
14	14	[redacted]	[redacted]		9F
16	16	[redacted]	[redacted]		9F
18	18	[redacted]	[redacted]		9F
20	20	[redacted]	[redacted]		10F
22	22	[redacted]	[redacted]		10F
24	24	[redacted]	[redacted]		10F
26	26	[redacted]	[redacted]		10F
28	28	[redacted]	[redacted]		10F
30	30	[redacted]	[redacted]		10F
32	32	[redacted]	[redacted]		10F
34	34	[redacted]	[redacted]		10F
36	36	[redacted]	[redacted]		10F
38	38	[redacted]	[redacted]		10F
40	40	[redacted]	[redacted]		10F

Table 2 Specification Series of Delivery Cable (mm)

Specification Series	Cable Effective Length L0	Outer Cable Outer Diameter D4
0900	900	2.0
1150	1150	2.0
1400	1400	2.0

Table 3 Specification Series of Steerable Delivery Sheath (mm)

Specification Series	Model	Sheath Inner Diameter D2	Sheath Effective Length L1	Dilator Effective Length L2	Corresponding Cable Effective Length L0
8F	Endo-ST-08-0500	2.85	500	700	900
	Endo-ST-08-0750		750	950	1150
	Endo-ST-08-1000		1000	1200	1400
9F	Endo-ST-09-0500	3.05	500	700	900
	Endo-ST-09-0750		750	950	1150
	Endo-ST-09-1000		1000	1200	1400
10F	Endo-ST-10-0500	3.40	500	700	900
	Endo-ST-10-0750		750	950	1150
	Endo-ST-10-1000		1000	1200	1400

7. Product Indications, Contraindications and Precautions

7.1. Indications

The aortic endovascular patch system is indicated for interventional closure of aortic dissection tears.

7.2. Contraindications

The aortic endovascular patch system is contraindicated in, but not limited to, the following conditions:

- Acute systemic infection;

- Allergy to contrast media;
- Allergy to the vascular patch, delivery cable, or delivery sheath;
- Vascular morphology unsuitable for endovascular repair;
- Ruptured aortic dissecting aneurysm.

8. Trial Design

8.1. Trial Methodology and Rationale

This trial is designed as a prospective, multicenter, randomized controlled clinical study.

1）Multicenter: The trial will be conducted at multiple qualified clinical centers across China to facilitate enrollment, healthy competition, and faster target completion. Moreover, because subject data are collected from different regions and centers by different investigators, the conclusions will be broadly representative.

2）Randomized controlled: Randomization is a fundamental principle for clinical trials including parallel control, paired design, and crossover design. It means that each subject has an equal chance (e.g., 1:1 allocation) or another predefined probability (e.g., n:1) of being assigned to either the test or control group, uninfluenced by subjective preferences of investigators and/or subjects. Randomization ensures comparability between groups in all known and unknown baseline variables that may affect outcomes. The rationale for choosing a randomized controlled design and the control group is as follows:

The Chinese Expert Consensus on Diagnosis and Treatment of Stanford Type B Aortic Dissection (2022 Edition) states that in clinical practice, most TBAD patients have more than one tear. For acute or subacute TBAD, after sealing the proximal primary tear, distal secondary tears are usually not treated in the same stage. Whether to treat distal tears in one stage and how remains inconclusive.

With technological advances and accumulated case experience, more researchers have proposed that leaving distal tears untreated allows blood to re-enter the false lumen through distal tears, leading to progressive distal aortic dilation in 25-40% of patients. Treating distal tears at an appropriate time can reduce retrograde perfusion and promote false lumen thrombosis, thereby reducing long-term mortality.

However, the consensus further notes that the indications and methods for second-stage distal tear treatment are still exploratory and lack evidence. The consensus recommends re-intervention for chronic TBAD patients with retrograde dissection, severe endoleak, expansion≥5.5 cm or rate ≥1.0 cm/year or 0.5 cm/6 months, new tear causing significant false lumen expansion, or vital organ ischemia. For patients without such indications, conservative medical management (blood pressure control and regular imaging follow-up) is recommended. However, some experts believe that preoperative aortic diameter and false lumen patency are closely related to prognosis; a descending thoracic aortic maximum diameter [redacted] mm is a risk factor for negative remodeling. Aortic dissection progression is dynamic, and some patients with high-risk features have increasing risk of distal aortic dilation and long-term mortality if distal tears are left untreated. Therefore, treating distal tears at an appropriate time is becoming increasingly important.

Thus, to achieve a "radical" cure, various second-stage strategies have emerged, including true lumen approaches (extending covered stents to cover the entire descending aorta, risking spinal cord ischemia), multilayer bare stents (not directly sealing tears, allowing late expansion), off-label congenital heart defect occluders (not designed for dissection tears, lacking consideration of tear morphology), and false lumen embolization with coils, Onyx, fibrin glue, filters, Candy-Plug, etc. All these are off-label uses without dedicated devices.

This trial is designed for patients with chronic aortic dissection who have undergone prior aortic repair, with persistent retrograde distal tears in the descending thoracic aorta, and a descending thoracic aortic maximum diameter between [redacted] cm. It adopts a randomized controlled design against the consensus-recommended conservative management to evaluate the safety and efficacy of the WeFlow-EndoPatch™ system, providing clinical evidence for formal application in China. The treatment goal for the test group is to seal all eligible distal tears in the descending thoracic aorta.

This study uses a central randomization system, and subjects will be assigned 1:1 to test or control groups.

3）Open-label: Because the test and control treatments are obviously different, blinding of subjects, investigators, and evaluators is not feasible. Therefore, an open-label design is adopted, with allocation concealment to minimize bias until randomization.

4）Primary endpoint and target value design: Although this product is not a covered stent, its indication is aortic dissection, and the applicable regulatory guidance is the Guideline for Clinical Trials of Aortic Stent-Graft Systems (No. 8 of 2019). The guidance recommends 30-day major adverse events and 12-month dissection treatment success as primary safety and efficacy endpoints. Because this is a randomized controlled study, the primary endpoint must adequately reflect the risk-benefit of both groups. Short-term safety events may not compare the clinical risks of patch implantation versus tear neglect; thus, we defined a composite endpoint—12-month clinical success rate

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5）Learning curve: To accommodate the learning curve for the patch system, each center may designate the first treated subject meeting all entry criteria as a learning-curve case. Each center will have 1 learning-curve subject. During the learning curve, the operator learns and masters device usage. Learning-curve subjects will undergo all study procedures and are not included in the statistical analysis of the 108 test-group subjects.

8.2. Subject Selection

8.2.1. Selection Criteria (All of the following conditions must be met prior to enrollment)

1）Age 18-80 years, either sex.

2）Patients with chronic aortic dissection who have previously undergone aortic repair, with the presence of a distal tear in the descending thoracic aorta that exhibits persistent retrograde flow.

3）The maximum diameter of the descending thoracic aorta is between cm.

4） The maximum diameter of the distal tear in the descending thoracic aorta ranges from [redacted]mm.

5) Imaging assessment confirms the presence of a suitable arterial access route for performing endovascular aortic therapy.

6） Patients are able to understand the purpose of the trial, participate in this study voluntarily, have signed the informed consent form personally or via their legal representative, and are willing to complete follow-up in accordance with the protocol requirements.

8.2.2. Exclusion Criteria (Enrollment will not be allowed if any of the following criteria are met)

1) Rupture or impending rupture of aortic dissection.
2) Proximal type I endoleak following aortic repair.
3) Stent-induced new distal tear (SINE).
4) Rapid aortic diameter growth≥10 mm/year.
5) Abdominal aortic dissecting aneurysm diameter≥5 cm.
6) Distance from the tear margin to the celiac artery orifice [redacted]mm.
7) Only one tear present in the abdominal aorta or more distally.
8) Concurrent need for intervention on other vascular lesions (e.g., coronary, carotid, renal, superior mesenteric arteries, etc.) during the same procedure.
9) Acute systemic infection.
10) Uncontrollable hypertension (blood pressure remains elevated >12 hours despite the use of more than three different types of antihypertensive drugs at maximum recommended or tolerated doses).
11) History of myocardial infarction, transient ischemic attack (TIA), or cerebral infarction within the past 3 months.
12) New York Heart Association (NYHA) class IV heart failure or left ventricular ejection fraction (LVEF) <30%.
13) Hematological abnormalities defined as: leukopenia (WBC $<3\times10^9$/L), anemia (Hb <90 g/L), coagulation disorders, thrombocytopenia (platelet count $<50\times10^9$/L).

14) Renal insufficiency with serum creatinine >221 μmol/L (or 2.5 mg/dL) and/or end-stage renal disease requiring dialysis, as determined by the investigator after comprehensive evaluation.
15) Severe hepatic dysfunction: alanine aminotransferase (ALT) or aspartate aminotransferase (AST) >5 times the upper limit of normal, or serum total bilirubin (STB) >2 times the upper limit of normal.
16) Allergy to contrast media, the vascular patch, or the delivery system materials.
17) Pregnancy or lactation.
18) Concurrent participation in another drug or device clinical study.
19) Life expectancy less than 12 months (e.g., advanced malignancy).
20) Presence of a distal tear in the descending thoracic aorta that cannot be sealed, or any other condition that, in the investigator's judgment, makes the subject unsuitable for participation in this study.

8.2.3. Dropout Criteria

All subjects who completed an informed consent form and were screened for entry into the clinical trial and who later withdrew, regardless of when and for what reason (excluding those who met the primary endpoint), will be counted as dropouts.

1) Subjects who withdraw themselves from the experiment for various reasons;
2) The ethics committee considers discontinuation of the study necessary for ethical and moral reasons due to one or more adverse events, especially serious adverse events;
3) The investigators consider it medically necessary for the subject to withdraw for the study;
4) There is a serious deviation from the trial protocol;
5) Subjects who are lost to follow up due to changes in work or living conditions or an accident, but for patients who are lost to follow up due to accidents such as traffic accidents, death, fractures, etc., a follow-up should be conducted promptly to determine whether or not there exists causal relationship with the trial device;
6) The subject's informed consent process was inadequate or absent;
7) Subjects who are required to stop the trial for other reasons.

Notes: When a subject drops out due to a subject-related reason, the investigators should use all available avenues to contact the subject in order to inquire after the reason; if the subject drops out due to an adverse event, and the follow-up ultimately determines that there is a causal relationship with the trial device, the event must be recorded in the eCRF and the sponsor should be notified accordingly. All original data and source documents, i.e., retention files, which are also required for an intention-to-treat analysis (ITT Analysis), should be retained for all subjects who are enrolled and have entered the trial, regardless of whether they drop out.

8.2.4. Standards and Procedures for Stopping the Trial

Trial discontinuation refers to a situation in which the clinical study is not completed according to the protocol and all related clinical studies are stopped midway through the trial. Under all of the following conditions, with the exception of 5), will trigger mutual discussion between the sponsor and the investigator to determine whether or not to terminate the trial.

1) In the event that a serious safety concern arises during the course of the clinical trial the trial should be promptly terminated;
2) The trial should be discontinued when significant errors in the protocol are identified during the course of clinical studies, or when serious deviations in the implementation of the protocol make it difficult to evaluate the efficacy of the product;
3) The trial should be discontinued if the product is found to show sub-par efficacy or even complete inefficacy and is determined to be of no clinical value during the course of clinical research.
4) The sponsor requests discontinuation of the trial;
5) The State Food and Drug Administration (SFDA) orders the trial to be discontinued for any reason.

Early discontinuation of the trial must be agreed upon in writing by the principal investigator and the sponsor, and all trial data should be retained for reference purposes.For subjects already treated with the device, the sponsor must fulfill its responsibilities to subjects as per the informed consent.

8.2.5. Enrollment Timetable

A subject may be enrolled upon obtaining confirmation that a signed informed consent form has been obtained, that the subject meets all entry criteria, and that the subject does not

meet any exclusion criteria.

8.2.6. Expected Overall Duration of the Clinical Trial and Underlying Reasoning

This clinical trial is planned to be conducted at multiple qualified centers simultaneously across China. Based on patient numbers at each center, the complexity of inclusion/exclusion criteria, and the difficulty of informed consent, we anticipate an enrollment period of 20 months. Each subject will be followed for 60 months. The first subject is expected to enroll in April 2026, the last subject in December 2027, and the last subject will complete follow-up around December 2032.

8.2.7. Expected Duration of Participation for Each Subject

For each subject, it is expected to take 60 to 62 months from the time of screening to performance of the procedure and the end of postoperative follow-up.

8.2.8. Number of Subjects Required for the Clinical Trial

A total sample size of 216 subjects (108 test, 108 control) is planned, plus 1 learning-curve subject per center (not included in statistical analysis).

8.3. Assessment Methods

8.3.1. Primary Endpoints

The 12-month Clinical Success Rate.

Time Point: 12 months postoperatively

Definition:The 12- month clinical success rate is a composite endpoint, defined as [redacted]

8.3.2. Secondary Endpoints

1）Immediate Technical Success Rate in the Test Group

Evaluation Time: Intraoperative

Evaluation Method: Immediate technical success is defined as successful delivery of the vascular patch to the intended position, accurate positioning and successful deployment, with the delivery sheath safely withdrawn outside the body, and no conversion to open surgery.

2）Success rate of tear closure in the test group

Evaluation Time: 30 days, 6 months, 12 months, and 24-60 months postoperatively.

Evaluation Method: After implantation of the vascular patch, successful closure is confirmed by CTA showing no blood flow entering the false lumen or retrograde true lumen across the vascular patch. [redacted]

3）Thrombosis Status of the False Lumen in the Descending Thoracic Aorta

Evaluation Time: 30 days, 6 months, 12 months, and 24–60 months postoperatively

Evaluation Method: Compare CTA results obtained preoperatively and at 30 days, 6 months, 12 months, and 24–60 months postoperatively to assess the thrombosis status of the false lumen in the descending thoracic aorta (no thrombosis/partial thrombosis/complete thrombosis).

4）Changes in true lumen diameter / false lumen diameter / maximum diameter in the descending thoracic aortic segment

Evaluation Time: 30 days, 6 months, 12 months, and 24–60 months postoperatively

Evaluation Method: Compare CTA results before the procedure and at each follow-up time point, observe and document the minimum true lumen diameter, maximum false lumen diameter, maximum aortic diameter, and their changes in the descending thoracic aortic segment..

5) Changes in true lumen volume / false lumen volume / total volume in the descending thoracic aortic segment

Evaluation Time: 30 days, 6 months, 12 months, and 24–60 months postoperatively

Evaluation Method: Compare CTA results before the procedure and at each follow-up time point, observe and document the changes in true lumen volume, false lumen volume, and total aortic volume in the descending thoracic aortic segment.

6）Disease- or device-related surgical intervention

Evaluation Time: 30 days, 6 months, 12 months, and 24–60 months postoperatively

8.3.3. Safety Endpoints

1) Incidence of freedom from major adverse events(MAE) within 30 days postoperatively.

Evaluation Time:Before discharge and 30 days postoperatively

Major adverse events within 30 days post-procedure refer to the occurrence of any of the following within 30 days after the procedure: all-cause death, aortic rupture, myocardial infarction, renal failure, respiratory failure, ischemic stroke, intestinal necrosis, severe lower limb ischemia or necrosis, or paraplegia. Among these: Renal failure refers to renal failure leading to persistent dialysis, renal transplantation, or other fatal outcomes. Respiratory failure refers to respiratory failure leading to significantly prolonged intubation time, tracheostomy, deterioration of lung function, or other fatal outcomes. Intestinal necrosis refers to intestinal ischemia requiring bowel resection or leading to other fatal outcomes. Severe lower limb ischemia refers to new-onset severe claudication or rest pain in the lower limbs following the procedure.

2) Vascular patch detachment rate of the Test group

Evaluation Time: 6 months, 12 months, and 24–60 months postoperatively

Evaluation Method: Following implantation of the vascular patch, CTA is used to assess the occurrence of vascular patch detachment.

3) All-cause mortality rate, aortic dissection-related mortality rate, serious adverse events rate, and device-related adverse events rate

① All-cause mortality rate

Evaluation Time: 30 days, 6 months, 12 months, and 24–60 months postoperatively.

Evaluation Method: All-cause death refers to death from any cause during the follow-up period.

② Aortic dissection-related mortality rate

Evaluation Time: 30 days, 6 months, 12 months, and 24–60 months postoperatively

Evaluation Method: Aortic dissection-related death refers to death caused by aortic dissection rupture or related to the procedure for treating aortic dissection.

③ Serious adverse events rate

Evaluation Time: 30 days, 6 months, 12 months, and 24–60 months postoperatively

Evaluation Method: A serious adverse event refers to any event occurring during the clinical trial that results in death or severe deterioration in health status, including fatal disease or injury, permanent impairment of body structure or function, or requiring medical or surgical intervention to prevent permanent impairment of body structure or function.

④ Device-related adverse events rate

Evaluation Time: 30 days, 6 months, 12 months, and 24–60 months postoperatively

Evaluation Method: A device-related adverse event refers to any adverse medical event occurring during the clinical trial that is associated with the use of the device. Normal postoperative stress reactions (e.g., fever, chest or back discomfort) judged by the investigator as normal postoperative responses shall be excluded and not recorded as adverse events. Device-related adverse events are those judged by the investigator as definitely related or possibly related to the investigational device.

8.3.4. Imaging Examinations

Imaging studies will include echocardiography and angiography, and CT imaging should be standardized in terms of measurement methods used, such as the angle of measurement, data to be collected, reporting modalities, etc. CT scans must be used to provide information on vascular anatomy and potential lesions. The evaluation of the examination data, a qualified third-party core laboratory should be selected to evaluate imaging data.

8.4. Trial Procedure

(1) Sign informed consent.

(2) Screen subjects according to inclusion and exclusion criteria.

(3) Enroll subjects: Each center's first subject is a learning-curve case; after completion, each center initiates 1:1 randomization.

(4) According to randomization results:

Test group: The investigator chooses appropriate device specifications and performs implantation; sponsor provides devices free of charge.

Control group: The investigator determines whether to continue or adjust the previous medication regimen based on subject condition.

(5) Post-operative follow-up: The investigator conducts clinical follow-up before discharge, at 30 days, 6 months, 12 months, 24 months, 36 months, 48 months, and 60 months; CTA follow-up is performed at 30 days, 6 months, 12 months, 24 months, 36 months, 48 months, and 60 months (sponsor covers CTA costs).

(6) Data analysis and summary: The sponsor collects all data and commissions a third party for evaluation, management, statistical analysis, and summary.

8.4.1. Trial Procedure Chart

Trial Procedure	**Screening**	**Surgery**	**Follow-up**					
Visit	V1	V2	V3	V4	V5	V6	V7-10	Unscheduled
Days	-15~0d	0	Before discharge	30d±7d	6m±30d	12m±30d	24-60m annually ±30d	
Sign informed consent	X							
Inclusion/Exclusion criteria	X							
Medical history/Demographics	X							
Pregnancy test	X							
Physical examination	X	X	X	X	X	X	X	
Blood panel	X		X					
Urine panel	X		X					
Coagulation function	X		X					
Liver/kidney function	X		X					
12-lead ECG	X		X					
Echocardiography	X							
Aortic CTA	X			X	X	X	X	
DSA		X						
Surgical records		X						

Medication records*	X	X	X	X	X	X	X	X
Adverse event records		X	X	X	X	X	X	X

Notes:

- Pregnancy Test: Women of childbearing age as well as women who are suspected of being pregnant during the trial will be subject to this test.
- Physical Examination: Heart rate, respiration, blood pressure and body temperature.
- Blood Panel: RBC, WBC, platelet count and hemoglobin.
- Urine Panel: pH,WBC, RBC and proteins.
- Liver and Kidney Function: Creatinine (Cr), alanine aminotransferase (ALT), aspartate aminotransferase (AST), total bilirubin (TBIL) and direct bilirubin (DBIL).
- Coagulation Function Testing: Activated partial thromboplastin time (APTT), prothrombin time (PT), internationalized standard ratio (INR), fibrinogen (FIB), thromboplastin time (TT) and D-dimer.
- Past medication and history are collected for the 3 months before informed consent.
- Screening CTA measurements must be reviewed and confirmed by the lead unit; after verifying other inclusion/exclusion criteria, the subject is randomized.
- Test group receives patch implantation.
- Visit 3 (before discharge): a visit on any day from post- op to discharge; collect last pre-discharge lab results.
- CTA data are collected pre-operatively and at 30d±7d, 6m±30d, 12m±30d, and 24,36,48,60m ±30d. If CTA is not feasible due to subject condition, CT plain scan may be substituted at investigator’s discretion.
- Medication records include drugs related to device evaluation (anticoagulants, antiplatelets, antihypertensives, sedatives/analgesics), and medications for underlying diseases, comorbidities, or AEs.
- Adverse events are recorded from Visit 2 onward.
- Medication Record: Medications relevant to the assessment of the investigational product (including anticoagulants, antiplatelet agents, antihypertensive drugs, etc.); medications for

underlying diseases, comorbidities, or adverse events; and medications related to medical history.

- If feasible, lab data within 15 days before enrollment (before ICF), and CTA, ultrasound, ECG within 30 days before enrollment may be used as baseline without repeating.

8.4.2. Subject Visitation Plan

Visit 1: Screening Period (Day -15 to 0)

For ethical reasons, interventional examinations performed before signed informed consent may be used as trial data; imaging within 1 month and lab results within 15 days may be used without repeating.

Subjects will be fully informed and sign ICF; baseline data and exams are collected; after results, screening is performed per criteria; eligible subjects are randomized and scheduled for surgery; failures exit the trial. Items collected:

- Demographic information, including age, gender, height, weight
- Physical examination data, including heart rate, respiration, blood pressure and body temperature
- Family history and previous medical history, including surgical history, concomitant diseases, concomitant medications and medical treatments
- Routine laboratory testing:
    - Blood panel: RBC, WBC, platelet count and hemoglobin
    - Urine panel: pH,WBC, RBC and proteins
    - Liver and kidney function: Creatinine, alanine aminotransferase (ALT), aspartate aminotransferase (AST), total bilirubin (TBIL) and direct bilirubin (DBIL)
    - Coagulation function: Activated partial thromboplastin time (APTT), prothrombin time (PT), internationalized standard ratio (INR), fibrinogen (FIB), thromboplastin time (TT) and D-dimer
- Pregnancy test (for female patients of childbearing age)
- 12-Lead ECG
- CTA angiography

- Echocardiography examination
- Concomitant medications

Visit 2: Intraoperative

Intraoperative visit; record surgical process. The following data will be collected:

- Physical exam
- DSA imaging data
- Surgery-related records (device model, arterial access, Interventional operation time (from sheath insertion to removal), deployment, immediate success, etc.)
- Concomitant medications
- Adverse events
- Device defects

Visit 3: Before discharge

- Physical examination
- Blood panel: RBC, WBC, platelet count and hemoglobin
- Urine panel: pH,WBC, RBC and proteins
- Liver and kidney function: Creatinine, alanine aminotransferase (ALT), aspartate aminotransferase (AST), total bilirubin (TBIL) and direct bilirubin (DBIL)
- Coagulation function: Activated partial thromboplastin time (APTT), prothrombin time (PT), internationalized standard ratio (INR), fibrinogen (FIB), thromboplastin time (TT) and D-dimer
- 12-Lead ECG
- Concomitant medications
- Adverse events
- Device defects

Visit 4: (30 ± 7 days after surgery)

This visit will be a post-discharge follow-up visit with the following information collected from the subject:

- Physical exam

- CTA angiography
- Concomitant medications
- Adverse events
- Device defects

Visit 5: (6 months ± 30 days after surgery)

This visit will be a post-discharge follow-up visit with the following information collected from the subject:

- Physical exam
- CTA angiography
- Concomitant medications
- Adverse events
- Device defects

Visit 6: (12 months ± 30 days after surgery)

This visit will be a post-discharge follow-up visit with the following information collected from the subject:

- Physical exam
- CTA angiography
- Concomitant medications
- Adverse events
- Device defects.

Visits 7,8,9,10: (24 months to 60 months ± 30 days after surgery)

This visit will be a post-discharge follow-up visit with the following information collected from the subject:

- Physical exam
- CTA angiography
- Concomitant medications
- Adverse events
- Device defects.

8.5 Treatment Description

1.Patch Implantation

1) Femoral artery puncture. Bilateral common femoral arteries are punctured, sheaths inserted, aortography performed, pre-closure sutures placed bilaterally, and systemic heparinization established.

2) False lumen confirmation: Through the left sheath, a pigtail catheter with a guidewire is placed in one lumen (true or false) for angiography to confirm position. Through the right sheath, a curve catheter is used to select the appropriate tear and enter the other lumen, confirmed by angiography.

3) Guidewire exchange and insertion of steerable delivery sheath: Withdraw the guidewire placed in the tear, exchange for a stiff guidewire, remove the curve catheter leaving the stiff guidewire in the other lumen. Advance the steerable delivery sheath over the stiff guidewire across the tear to the intended deployment position, then withdraw the stiff guidewire and dilator. (See Figure 8.)

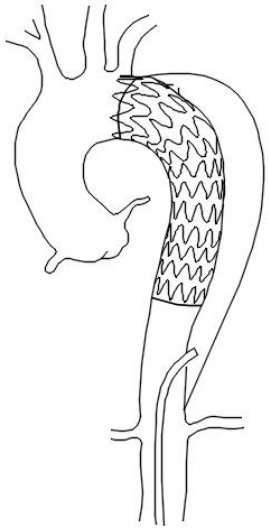


Figure 8 Illustration of Steerable Delivery Sheath Positioning

4) Insertion of patch: Load the patch/cable into the sheath hub and slowly advance to the distal end of the sheath to the predetermined position. (See Figure 9.).

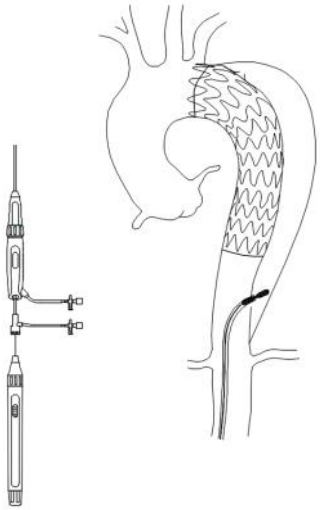


Figure 9 Illustration of Vascular Patch Insertion

5) Deploy the upper disc: Retract the slider on the cable handle to release the upper disc in one lumen; gently retract the cable and sheath to appose the upper disc against the intimal flap; confirm position. (See Figure 10.)

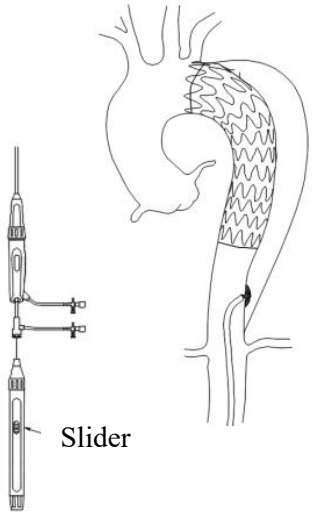


Figure 10 Illustration of the upper disc Deployment

6) Deploy the lower disc: Fix the cable and retract the sheath to release the lower disc in the other lumen; retract the slider to appose the lower disc against the intimal flap. (See Figure 11.)

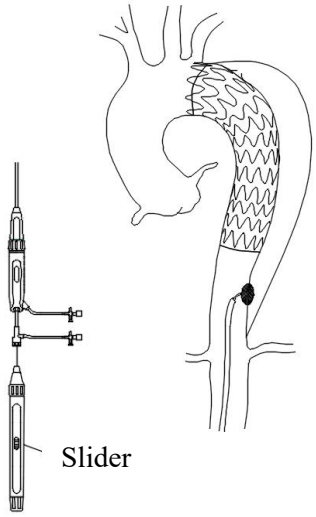


Figure 11 Illustration of the lower disc Deployment

7) Lock the patch: Adjust the sheath to be perpendicular to the patch, retract the slider again to lock both discs onto the intimal flap. (See Figure 12.)

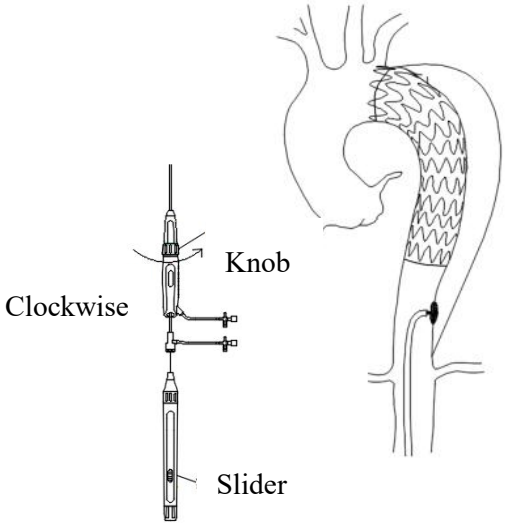


Figure 12 Illustration of Vascular Patch Locking

Note: If the deployment position is unsatisfactory, before detachment, the patch can be fully retrieved and redeployed at any time. Retrievals should not exceed 5 times. If still unsatisfactory, replace the device.

8) Detach the cable: Rotate the knob counterclockwise to unscrew the inner cable, then clockwise to unscrew the outer cable; adjust sheath curvature and withdraw the delivery system. (See Figure 13.)

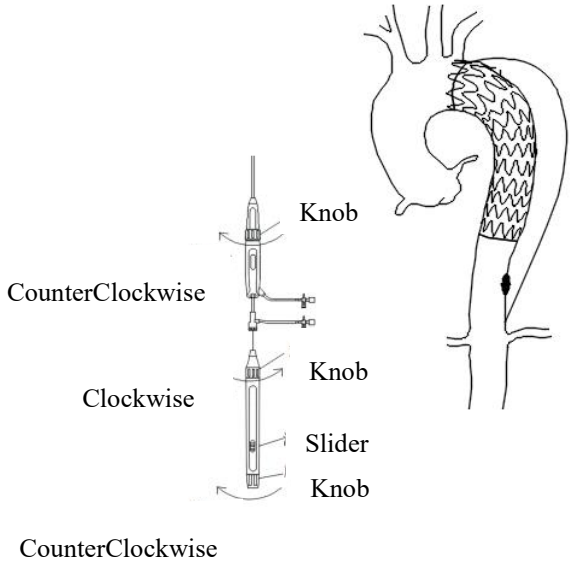


Figure 13 Illustration of Vascular Patch Implantation

① Perform angiography to evaluate sealing, endoleak, migration, and successful closure.

② Remove catheters and wires, and close the access site.

2. Regarding medical therapy during follow-up

The 2022 Chinese expert consensus recommends initial medical therapy to control blood pressure; target systolic BP 100-130 mmHg. The 2014 ESC guidelines recommend target BP <130/80 mmHg. In this study, medical therapy follows routine clinical practice, with target BP <130/80 mmHg. The investigator may adjust target up to 140 mmHg systolic based on comorbidities, baseline BP, and age.

3.For control group subjects who develop disease progression requiring intervention during follow-up (i.e., reaching the study-defined endpoint), the investigator may decide to provide standard clinical treatment (open or endovascular) according to expert consensus.

8.6 Device Usage Specification

After obtaining approval from the Ethics Committee, the Sponsor shall be responsible for providing the investigational medical devices to the clinical trial institutions and investigators, and determining the transportation conditions, storage conditions, storage duration, shelf life, etc.

The investigational medical devices shall be qualified in quality, with easy identification, proper coding, and affixed with the special label “For Clinical Trial Use Only”. They shall be properly packaged and stored in accordance with the requirements of the clinical trial protocol.

The Sponsor shall be responsible for the safety of the investigational medical devices during the clinical trial. When the Sponsor becomes aware of any issues that may affect the safety of subjects or that may alter the Ethics Committee's approval for the continuation of the trial, it shall immediately notify all clinical trial institutions and investigators and take appropriate measures.

8.7 Bias Control Measures

1) The clinical study shall be conducted in accordance with the study protocol, relevant national regulations for medical device clinical trials, GCP (Good Clinical Practice) principles, and the company's Standard Operating Procedures (SOP).
2) This clinical trial is a randomized controlled clinical study conducted simultaneously at multiple centers across the country. Subjects will be enrolled in accordance with the inclusion and exclusion criteria specified in the protocol, and the enrolled study population will be randomly assigned to either the test group or the control group to minimize bias.
3) Subjects will be registered using sequential enrollment at each center. A strict follow-up mechanism will be established, and adequate communication with subjects will be maintained to ensure the quality of follow-up for enrolled cases, and to minimize missing data and subject dropout to the greatest extent possible.
4) The sponsor shall provide training on the study protocol and operating specifications of the investigational device to investigators participating in this study, to ensure that investigators fully understand the study procedures and instructions for use of the investigational device.
5) The company shall appoint qualified Clinical Research Associates (CRAs) to conduct regular visits and monitoring at study centers, perform quality control and complete monitoring records, and communicate issues identified during monitoring with investigators in a timely manner.
6) Proper data storage and sorting shall be implemented. When data discrepancies are identified, data analysts shall verify and confirm the data via data query forms to avoid recording errors.

9. Statistical Considerations

9.1. Sample Size Calculation

9.1.1. Total Sample Size

This trial uses a prospective, multicenter, randomized controlled, superiority design with the 12-month clinical success rate as the primary endpoint.

[redacted] Using a superiority design with α=0.025 (one-sided), β=0.2 (power 80%), equal allocation, superiority margin 0%, and a 20% dropout rate, the required sample is 108 per group, total 216. Additionally, each center has 1 learning-curve subject (not in statistical analysis).

When subjects are randomized 1:1 to the test group and the control group, and the primary endpoint is an event rate with homogeneous variance and not close to 0% or 100%, the sample size estimation formula is:

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

Where P_T and P_C are the expected event rates in the test group and control group, respectively; $|D|$ is the absolute value of the expected difference between the two groups, i.e., $|D| = |P_T - P_C|$； Δ is the superiority margin.

9.1.2. Number of Clinical Trial Subjects per Disease and Basis for the Determination

This study does not address issues of multimorbidity, so only the total number of clinical trial subjects is subject to requirements.

9.1.3. Minimum and Maximum Number of Subjects per Clinical Trial Institution and Corresponding Reasoning

This trial will be conducted simultaneously at multiple qualified clinical trial institutions in China. In principle, the number of enrolled subjects will be distributed as evenly as possible across each center to ensure sufficient center representativeness. However, considering feasibility and enrollment progress, adjustments to the number of enrollments will be made based on actual conditions to maintain a relatively balanced enrollment size per center. The final enrollment size of any given single center shall not exceed 50% of the total number of subjects.

9.1.4. Clinical Trial Significance Level and Power

For each hypothesis, Set to $\alpha = 0.025$ (one-sided), $1-\beta = 0.80$.

9.1.5. Expected Dropout Rate

The dropout rate for this trial is expected to be no higher than 20%.

9.2. Analysis Sets

The trial's statistical analysis will be conducted on the basis of the following analyzed populations, which need to be clearly defined before the statistical analysis begins, and in this trial they include:

1. Full Analysis Set (FAS): Refers to the subject set that is as close as possible to intention-to-treat (ITT) principles, which is derived from all randomized subjects with minimal and reasonable censoring, and contains all subjects who have been subject to randomization and have previously used an investigational device. The FAS will be used for the evaluation of primary and secondary indicators.

2. Per Protocol Set (PPS): All patients showing good compliance with the trial protocol, good adherence, completion of the treatment specified in the trial protocol and no deficiencies in key efficacy indicators. The PPS will be used for the evaluation of primary and secondary indicators.

3. Safety Set (SS): All subjects who used an investigational device following randomization and underwent a safety evaluation. The SS will be is used for an analysis of safety indices.

9.3. Elimination Criteria

Prior to the statistical analysis of data, the principal investigator, sponsor, and statistical analysis institution shall assess whether an individual subject meets any of the following conditions. The principal investigator shall comprehensively determine whether to eliminate the subject from the analysis sets based on factors including the subject’s completion of the trial, reasons for trial, and shall issue a relevant written explanation for the elimination. A subject shall be considered for elimination if any of the following criteria is met:

1) The subject was enrolled in violation of the inclusion/exclusion criteria and should not have been admitted to the trial.
2) During the trial, the investigator determined that the subject had other factors precluding

continued trial participation, and the subject's trial participation was formally terminated.

3) Major protocol deviations occurred during the implementation of the clinical trial protocol, including subjects whose treatment regimen were modified during the trial.
4) The subject failed to comply with the trial plan with poor compliance, which has impaired the efficacy or safety evaluation. Examples include: never used the investigational medical device, failure to collect data required for efficacy and safety evaluation in accordance with the trial protocol, and absence of any observation data.

9.4. Statistical Design, Methodology and Analytical Procedures

9.4.1. Statistical Design

This clinical trial adopts a prospective, multi-center, superiority, randomized controlled trial design to evaluate the efficacy and safety of the investigational device.

9.4.2. Statistical Methodology and Analysis

a) General Principles

For quantitative variables, mean, standard deviation, median, minimum, maximum, lower quartile (Q1), and upper quartile (Q3) will be calculated. For categorical variables, the number and percentage of subjects in each category will be presented.

Comparison of general characteristics between the two groups will be analyzed using appropriate methods according to the type of variables. Between-group comparisons of quantitative data will be performed using the independent samples t-test (for homogeneous variance and normal distribution) or the Wilcoxon rank-sum test, depending on the data distribution. Categorical data will be analyzed using the chi-square test or Fisher's exact test (if the chi-square test is not applicable). Ordinal data will be analyzed using the Wilcoxon rank-sum test or the CMH test.

b) Completion Status and Demographic Analysis

The number of enrollments and completions for each center will be summarized and a list of fallout cases as well as a detailed list of reasons for non-completion will be created. Patients' demographic characteristics (age, sex, etc.), relevant medical history treatment, etc. will be described. A demographic analysis will be performed based on an FAS analysis set.

c) Primary Endpoints

Primary Endpoints: 12-month clinical success rate. The primary endpoint will be analyzed using a superiority test, with the test hypotheses as follows:

H0: $P_T-P_C \leq \Delta$

H1: $P_T-P_C > \Delta$

α=0.025 (single tail)

The 12-month clinical success rates will be calculated separately for the test group and the control group, as well as the 95% confidence interval (CI) for the difference in success rates between the two groups. If the lower limit of the 95% CI for the difference is greater than the superiority margin Δ%, the test group will be considered superior to the control group. Between-group comparisons will be performed using the CMH chi-square test adjusted for center effect. If necessary to adjust for the influence of center and other factors, a logistic regression model may be used for between-group comparisons.

d) Other Endpoints

Secondary efficacy endpoints: Secondary efficacy endpoints will be analyzed in accordance with general statistical principles based on endpoint characteristics.

Immediate technical success rate in the test group will be summarized descriptively as a categorical variable.

Comparisons between the two groups for complete thrombosis of the false lumen in the thoracic descending aorta, and lesion- or device-related intervention rate will be performed using the chi-square test or Fisher's exact test (if the chi-square test is not applicable).Comparisons between the two groups for changes in the maximum diameter of the thoracic descending aorta and changes in false lumen volume of the thoracic descending aorta will be performed using the independent samples t-test (for homogeneous variance and normal distribution) or the Wilcoxon rank-sum test.

Safety endpoints include: freedom from major adverse events within 30 days, displacement rate of the vascular occlusion device in the test group, all-cause mortality, aortic dissection-related mortality, incidence of serious adverse events, and incidence of device-related adverse events. All safety endpoints will be summarized descriptively as categorical variables. The number and incidence of adverse events (AEs), serious adverse events (SAEs), and device-related adverse events will be presented. All adverse events in subjects will be listed, including event name, start and end time, severity, relationship to the investigational medical device, and outcome.

Laboratory test values and changes from baseline will be summarized descriptively by treatment group and/or time point.

Clinical interpretations of laboratory test results (normal, abnormal without clinical significance, abnormal with clinical significance, not done) at each post-baseline assessment will be presented as counts in cross-tabulations.

In addition to the above statistical methods, detailed and additional exploratory analyses may be performed and will be confirmed in the study report and Statistical Analysis Plan (SAP).

9.5. Statistical methods for all data, including the handling of missing, unused or erroneous data (including premature discontinuation and withdrawal) and inconsistent data.

A Statistical Analysis Plan (SAP) shall be developed prior to study initiation. After database lock, statistical analysis shall be performed in accordance with the SAP, and a statistical analysis report shall be generated based on the results.

（1）Handling of missing data: Missing data shall be handled according to the analysis set in which they are included. Missing data for the primary endpoint in the Full Analysis Set (FAS) shall be classified by reason as follows:

Missing data clearly due to unsatisfactory efficacy: loss to follow-up or missing primary efficacy data resulting from adverse events, death, etc., related (or possibly related) to the investigational device or aortic dissection.

Missing data not attributable to unsatisfactory efficacy: loss to follow-up, failure to complete assessments, or other reasons such as force majeure (e.g., epidemic restrictions) resulting from adverse events, death, etc., unrelated to the investigational device or aortic dissection.

For the first category of missing data, worst-case imputation shall be used in both the FAS and Per Protocol Set (PPS), treated as “12-month postoperative failure”. For the second category of missing data, three imputation methods shall be applied separately, followed by sensitivity analysis:

1)Best-case imputation: all treated as “12-month postoperative success”; 2)Worst-case imputation: all treated as “12-month postoperative failure”; 3)Tipping-point analysis: the imputation proportions of success and failure in the two groups shall be varied iteratively to comprehensively demonstrate whether the study meets the statistical hypothesis under different scenarios and to

identify the tipping point at which the conclusion changes.

No statistical imputation shall be used for missing data of other endpoints.

（2）Handling of inconsistent data: During data management, logical checks shall be performed on the database. Inconsistent data shall be queried via data query forms sent to investigators. Inconsistent data shall be resolved based on written responses from investigators. The database shall not be locked until all inconsistent data has been resolved.

（3）Handling of erroneous data: During data management, quality control should be conducted on the database. Erroneous data shall be identified and queried via data queries (Query). Errors shall be corrected based on investigators' responses, and queries shall be closed only after confirmation from investigators. The database shall not be locked until all erroneous data has been corrected.

10. Monitoring Plan

In accordance with the requirements of the Medical Device Clinical Trial Quality Management Regulations, the sponsor will select inspectors who meet relevant requirements to perform inspection duties at all participating institutions. The number of supervisors and the frequency of supervision will be confirmed with the supervisor in accordance with the specific visit requirements and test procedures. Specific responsibilities shall include:

1) Confirm prior to the trial that clinical trial institutions are sufficiently equipped, including staffing and training, laboratories are fully equipped and in good working condition, there are enough subjects to participate in the trial and researchers are familiar with the trial requirements;
2) Monitor clinical trial institutions and researchers before, during, and after the trial to determine whether or not they are compliant with relevant regulations, the Medical Device Clinical Trial Quality Management Regulations and the clinical trial protocol;
3) Confirm that each subject signs an informed consent form prior to participating in the clinical trial, and understands the state of subject enrollment and trial progress; ascertain and record instances of failure to follow-up, perform testing or perform examinations by the investigators as well as whether or not such errors were subject to correction; and ensure that patients who have yet to complete the trial procedure and who are affected by revisions to

the informed consent form re-sign the form;

4) Confirm that all case report forms are correctly filled out and consistent with the original data; all errors or omissions have been corrected or noted, and signed and dated by the investigator; and the disease type, total number of cases and the gender, age, and treatment efficacy pertaining to each case are confirmed and recorded;
5) Confirm that subject withdrawal from the clinical trial or failure to comply with the requirements specified in the informed consent form are recorded, and discusses the situation with an investigator;
6) Confirm that all adverse events, complications and device defects are recorded, and serious adverse events and device defects that may cause serious adverse events are reported and recorded by the appropriate deadlines;
7) Monitor the provision, use, maintenance, transportation, receipt, storage, distribution, processing, and recycling of trial medical devices;
8) Supervise regular maintenance and calibration of related equipment during the clinical trial;
9) Ensure that all clinical trial related documents received by investigators are current;
10) The monitor should issue a written report to the sponsor after each monitoring session; the report shall include the name of the monitor, the date of the monitoring session, the time of the monitoring session, the location of the monitoring session, the content of the monitoring session, the names of any related investigators, the completion status of the project, existing problems, a conclusion, and corrections, etc. to any errors or omissions.

11. Data Management

11.1. Data Management System

The data collection/management system used for this trial corresponds to an electronic data capture (EDC) system. An EDC system that has been systematically validated and has trace management and user rights management has been selected.

11.2. eCRF Design

The data manager will design the eCRF according to the needs of the protocol and each eCRF will contain all the data points specified in the protocol, excluding external data. eCRFs will be

directly exported from the corresponding EDC system (in PDF format).

11.3. Data Management Plan

The data manager will draft a DMP based on the finalized protocol, project requirements, etc. It will furthermore be determined after discussion by all parties involved in the clinical trial.

11.4. Data Verification Plan

The data manager will draft a data verification plan based on the clinical trial protocol and eCRFs. It will furthermore be determined after discussion by all parties involved in the clinical trial.

11.5. Electronic Database Construction and Testing

A database builder will construct the database, including configuring logical verification rules, system function settings, etc.; a data administrator will manage rights according to each user's job role(s). Database testing will include entry, export, logical verification, eCRF interface, and system functionality testing.

11.6. Database Training and Formal Launch

Prior to the official launch of the trial database, the data manager will train relevant personnel. The training will include: System operation skill training and/or project requirement training. The specific nature of the training will depend on each participant's responsibilities and previous experience. Database launch: Once the database passes testing and all other preparatory work is completed and following confirmation by the sponsor, the database will be officially launched.

11.7. Data Verification

Data verification includes source data verification (SDV) conducted by monitors through comparing electronic Case Report Forms (eCRF) with source documents, logical review by the medical team in accordance with the Medical Review Plan, and verification by the data management team in accordance with the verification rules specified in the Data Review Plan. In case of any queries, the personnel responsible for queries may directly issue manual queries in the database. If data violates the system verification rules configured by the data management team in the database, the system will generate automated queries. After the data entry personnel confirm the source data and clarify the queries, the personnel responsible for queries shall confirm the data status and clarification description and may close the query only after confirmation of correctness. This process

may be repeated until no data queries remain. The generation and resolution of all queries, as well as all data updates and modifications, will be automatically saved in the system audit trail for reference.

11.8. Medical Coding

Medical terminology included in clinical trial data must be standardized prior to carrying out statistical analysis. Medical codes need to be created systematically or manually, based on a medical code dictionary that is in common use in the field of clinical trials. Data that do not meet the requirements of the selected medical coding dictionary or for which there exist unresolved questions need to be confirmed with a clinical investigator in the form of a data query. Medical coding content may include: Past medical history, concomitant medications and adverse events. The specific requirements for coding are defined in the Data Management Plan.

11.9. External Data Management

When external data exists for the clinical trial, the data manager must develop an external data management plan and plan out the entire process for managing external data during the clinical trial in advance.

11.10. Data Backup

The system will be automatically backed up daily on a data management cloud server.

11.11. Data Review

Data generated during the course of a clinical trial may violate the clinical trial protocol, requiring a clinical data review at the general trial level. Problems identified in the data review can be addressed by taking appropriate measures, such as revising the clinical trial protocol and censoring subject data.

11.12. Locking of Data

At the end of the study, once the database lock list has been reviewed, the principal investigator, sponsor, statisticians, data managers, supervisors, and other relevant personnel will jointly authorize locking of the database. When data errors are discovered after the database is locked, the potential impact of these data errors on the safety and efficacy analyses will be assessed jointly by the principal investigator, sponsor, statisticians, data managers, and related personnel. If there is a significant impact on the above, the stakeholders will co-sign to unlock the database after which data

corrections can be made; if there is no significant impact, the errors in question will be documented in corresponding statistical analysis and clinical summary reports.

11.13. Data Management Reports

The data manager will summarize the process by which data management work was performed as well as operational specifications and management quality and thereby draft a data management report.

12. Feasibility Analysis

12.1. Probability of Success Analysis

The investigational device will be manufactured in accordance with the requirements of the medical device quality management system. The trial device was analyzed and evaluated for physical, chemical and biological properties as well as associated risks, and the results of the analysis demonstrated the feasibility and safety of the product; furthermore, all risks were identified as within acceptable limits, with potential clinical benefits outweighing the risks of use and the device was determined to be more beneficial to subjects' health, with the potential to improve their quality of life.

This trial device was tested on animals and complete experimental data were obtained during the animal testing process, with no adverse events reported in animal test results, demonstrating that the product is safe and effective (refer to the Animal Studies Report).

12.2. Probability of Failure Analysis

- Subjects experienced serious adverse events and an excessive level of dropouts;
- Information provided on the label does not effectively provide guidance to the operator;
- Too many subjects were lost to follow-up;

However, the above factors remain under control, and assuming training can improve the level and proficiency of operation, the investigators have also developed a complete test protocol accounting for the specific nature of the trial.

In addition, the clinical institutions undertaking the trial are well endowed with equipment and technical resources, and the clinical trial leadership has excellent clinical experience, so the likelihood of trial failure is low.

13. Clinical Trial Ethical Issues and Informed Consent

13.1. Ethical Considerations

This clinical trial is conducted in compliance with the Declaration of Helsinki and applicable national regulations. The investigator is responsible for submitting the clinical trial protocol, informed consent form, and informational materials provided to subjects to the Ethics Committee, in order to obtain an independent approval document for the conduct of the clinical trial. Approval from the Ethics Committee must be obtained before initiation of the clinical trial. Written approval from the Ethics Committee shall be issued to the investigator, who shall then provide a copy of the approval document to the study sponsor. The Ethics Committee's approval document shall be accompanied by a list of all committee members involved in the review and approval, together with their respective roles.

During the clinical study, any issues related to the safety of the clinical study, such as amendments to the clinical trial protocol or the informed consent form, and serious adverse events occurring during the study also must be promptly reported to the Ethics Committee. The completion or early termination of the clinical study must also be reported to the Ethics Committee.

13.2. Trial Protocol Approval

Prior to the clinical study, the investigator shall submit the clinical study protocol, informed consent form and other relevant documents to the Medical Ethics Committee of the hospital where the institution of the clinical study responsible is located. The clinical study may only commence after obtaining approval from the Ethics Committee. Any amendments to the study protocol shall be implemented only after approval by the Ethics Committee. Serious adverse events during the clinical study shall be reported in a timely manner in accordance with GCP requirements.

13.3. Informed Consent Process

It is the responsibility of the investigators to explain the purpose, methods, benefits, and potential risks of the clinical trial to each subject and to obtain an informed consent form signed by each subject of the clinical trial. Informed consent must be obtained from the subject prior to the commencement of any operational procedures associated with the clinical trial. For those subjects who, for any reason, are unable to sign an informed consent form themselves, their guardian or witness must sign the informed consent form. By signing an informed consent form, the subject shall

authorize the clinical study monitor/auditor/health investigation organization to verify raw data that has been obtained from the clinical study to determine the reliability of the clinical study data.

14. Provisions for Reporting Adverse Events and Device Defects

15. Clinical Trial Quality Control

In order to ensure the accuracy and completeness of the data in each eCRF, the implementing institution or a designated supervisor must monitor the research center on a regular basis. During each monitoring visit, the data submitted by the center needs to be compared with corresponding raw data. Investigators' compliance with appropriate regulations and research guidelines will also be assessed.

Researchers must ensure that medical documentation is kept properly and remains intact. Research documents should be subject to inspection by the implementing organization and/or regulatory authorities. Supervisors need to confirm that the rights and welfare of subjects are protected, that the research adheres to GCP guidelines, and that the trial protocol is followed.

15.1. Adverse Events

Definition of Adverse Event

An adverse medical event that occurs during the conduct of a clinical trial of a medical device, regardless of whether it is related to the investigational medical device.

Any pre-existing disease documented in medical history during the screening period shall not be considered an adverse event unless there is a change in its nature, severity, frequency, or required intervention.

Severity Assessment of Adverse Events

Mild: Symptoms are slight and do not interfere with normal daily activities, generally, no treatment is required, and symptoms are resolved spontaneously.

Moderate: Symptoms are sufficient to cause discomfort and interfere with normal daily activities; treatment may be required.

Severe: Symptoms result in significant discomfort; may lead to subject withdrawal from the trial; may result in discontinuation of treatment with the investigational device; specific treatment is required.

Causality Assessment between Adverse Event and Investigational Medical Device

The investigator shall assess the causality between the adverse event and the investigational medical device according to the following criteria:

Related to the investigational medical device: (1) There is a reasonable temporal relationship. (2) The event is a known risk of the device or can be explained by its mechanism of action. (3) The injury improves or resolves after cessation of device use. (4) The injury recurs upon rechallenge with the device. (5) The event cannot be explained by other confounding factors. If all five criteria are met, the relationship is assessed as "Definite"; if at least two criteria are met, it is assessed as "Possible".

Not related to the investigational medical device: (1) There is no reasonable temporal relationship. (2) The event type cannot be caused by the investigational medical device. (3) The event can be explained by concomitant devices/medications, disease progression, or other therapeutic interventions. (4) Definitely Not Related: All 3 criteria are satisfied. (5) Probably Not Related: At least 1 criterion is satisfied.

Potential Adverse Events

Allergy, infection, dissection rupture, arteriovenous thrombosis, arterial injury, arterial perforation, pseudoaneurysm, bleeding/hematoma, pulmonary syndrome, heart failure/myocardial infarction, stroke, conversion to open surgery, death, edema, fever, renal insufficiency/failure, wound syndrome, air embolism, device complications including incorrect deployment position, migration of the vascular occlusion device, etc.

Reporting of Adverse Events

The investigator shall document all adverse events occurring during the clinical trial of the medical device.

When an adverse event occurs, the investigator shall provide adequate and timely treatment and management for the subject. If the subject develops concurrent illnesses requiring treatment, the investigator shall inform the subject promptly.

15.2. Severe Adverse Events

Definition of Serious Adverse Event:

A Serious Adverse Event refers to any untoward medical occurrence during a clinical trial of a

medical device that results in death or severe deterioration of health status, including fatal disease or injury, permanent impairment of body structure or function, requirement for hospitalization or prolongation of hospitalization, medical intervention required to prevent permanent impairment of body structure or function, fetal distress, fetal death, congenital anomaly or congenital defect.

Planned hospitalization due to a pre-existing disease or surgery specified in the clinical trial protocol that does not cause severe deterioration of health status shall not be regarded as a Serious Adverse Event.

Serious Adverse Event Reporting:

If a serious adverse event occurs during a medical device clinical trial, the investigator shall immediately take appropriate therapeutic measures for the subject. Meanwhile, the investigator shall report the serious adverse event to the sponsor, the administrative department of the medical device clinical trial institution, and the ethics committee within 24 hours after becoming aware of the event. The investigator shall follow up the serious adverse event and submit follow-up reports in accordance with the clinical trial protocol. If it is found that the risk of the medical device clinical trial outweighs the potential benefit, requiring suspension or termination of the clinical trial, the principal investigator shall report to the sponsor, the administrative department of the medical device clinical trial institution, and the ethics committee, notify the subject in a timely manner, and ensure that the subject receives appropriate treatment and follow-up.

The sponsor shall report within 7 days after becoming aware of a death or life-threatening serious adverse event related to the investigational medical device, and within 15 days after becoming aware of a non-fatal, non-life-threatening serious adverse event related to the investigational medical device or other serious safety risk information. The report shall be submitted to other investigational sites, ethics committees, and principal investigators involved in the clinical trial, to the drug regulatory authority of the province, autonomous region, or municipality directly under the Central Government where the sponsor is located, and to the drug regulatory authority and health administration department of the province, autonomous region, or municipality directly under the Central Government where the investigational site is located. The sponsor shall take risk control measures accordingly. If information emerges that may affect subject safety, conduct of the medical

device clinical trial, or change the approval opinion of the ethics committee, the sponsor shall promptly revise the clinical trial protocol, informed consent form, other information provided to subjects, and other relevant documents, and submit them to the ethics committee for review. In the event of widespread serious adverse events related to the investigational medical device or other major safety issues, the sponsor shall suspend or terminate the medical device clinical trial, and report to all investigational site management departments, ethics committees, and principal investigators, to the drug regulatory authority of the province, autonomous region, or municipality directly under the Central Government where the sponsor is located, and to the drug regulatory authorities and health administration departments of all provinces, autonomous regions, or municipalities directly under the Central Government where the investigational sites are located.

15.3. Device Defects

Definition of Device Deficiency

Device defects refer to unreasonable risks that may endanger human health and life during normal use of the medical device and may include label errors, quality problems, and other malfunctions.

Reporting of Device Deficiency

The investigator shall document any device deficiency identified during the clinical trial of the medical device.

16. Provisions Pertaining to Clinical Trial Protocol Deviations and Clinical Trial Protocol Revisions

1) Protocol Deviations

A protocol deviation refers to a case of non-compliance with protocol requirements, which in turn makes data unavailable or inaccessible.

Protocol deviations include, but are not limited to:

- An operation was not performed within the permitted follow-up window
- Required data was not obtained
- Follow-up procedures were conducted at an unapproved center

2) Protocol Violations

A protocol violation refers to a case of non-compliance with protocol requirements and/or regulatory guidelines. Protocol violations may affect the scientific validity of the study and/or the rights and safety of subjects.

Protocol violations include, but are not limited to:

- Failure to obtain informed consent
- Violations of the inclusion/exclusion criteria
- Violations of protocol requirements which affect the main objectives of the study design

In some cases, compliance issues may arise during the informed consent process. Investigators should try to obtain guidance from the ethics committee of the research center to ensure that subjects receive the appropriate information required to make a decision as to whether or not to participate in the trial. The investigators are obligated to take any measures that the EC deems necessary, including subject withdrawal. In the analysis of the study data, deviations from the consent process of subjects who were deemed by the EC to be available for continued participation in the study would be considered a protocol violation.

3) Provisions Governing Revision of the Clinical Trial Protocol

A clinical trial protocol for medical device testing should as a primary matter of principle provide the maximum protection possible of the rights, safety and health of subjects and should be jointly designed and formulated by the medical institution responsible for the clinical research as well as the sponsor, and implemented only after approval by an ethics committee; if there is any modification of the clinical trial protocol, informed consent, or case report form during the course of the trial, said modification must be approved by the ethics committee before continuing the clinical trial.

17. Direct Access to Source Data and Files

All clinical findings, observations, and other activities carried out throughout clinical study must be documented and maintained in the medical records of each enrolled subject, either in the original records or in a copy that is consistent with the original. For data recorded on an eCRF, the corresponding medical records (source documents) must also show the same source data.

The medical records (source documents) must contain, but are not limited to contain, the following information:

- Date of informed consent
- The fact that the subject is participating in a clinical trial
- Demographic characteristics
- Dated discharge reports
- Medical history / surgical history records and previous medications
- Size and characteristics of blood vessels and lesions
- Description of device use (all materials used, intraoperative medications, dates, times, etc.)
- All adverse events (AEs, SAEs, ADEs and SADEs): Diagnosis and symptoms, start and end dates, severity, measures taken and outcome
- Concomitant medication
- Clinical trial outcome or withdrawal date

The following additional documents are considered source documents and must be filed with corresponding medical records / subject records:

- Serious adverse event reports

Clinical trial institutions should retain all clinical trial data for a period of 10 years after the end of the clinical trial. The sponsor should save clinical trial data until the medical device is no longer in use.

18. Financing and Insurance

The research funding required for this trial is being provided by Hangzhou Endonom Medtech Co., Ltd.; refers to the clinical study protocol for specific costs and details.

To ensure the rights and safety of subjects, the sponsor will purchase clinical trial insurance for subjects participating in this study, referring to the Insurance Policy for details and terms.

19. Content to be Covered in the Clinical Trial Report

After the completion of the clinical trial, the medical institution undertaking the clinical trial shall issue a clinical trial report in accordance with the requirements of the medical device clinical trial protocol and corresponding prescribed format. The clinical trial report shall include the name

and specifications of the trial device, a summary of the clinical protocol, a list of participating centers, a statistical analysis of the population, a record of adverse events occurring during the clinical trial and measures taken in response, an analysis of clinical trial results, product indications, contraindications and precautions, clinical trial conclusions and the opinions of the investigators and clinical trial management department of the clinical trial institution.

20. Confidentiality

All subjects' personal information shall be regarded as private, and only the sponsor (Hangzhou Endonom Medtech Co., Ltd.), ethics committee members, and relevant personnel belonging to the State/Local Food and Drug Administration shall have access to said information, in addition to relevant investigators. The investigators and sponsor shall be required to keep subjects' personal information confidential.

21. Stipulations Governing the Publication of Trial Results

The sponsor and investigators should agree upon a final version of the trial report.

Hangzhou Endonom Medtech Co., Ltd. shall have the right to include the clinical trial report in any registration documents or registration declarations as well as in any information materials compiled for use by medical professionals.

Prior to publication of the entire multicenter clinical trial results, information from each center cannot be published separately, and all research papers must be reviewed by Hangzhou Endonom Medtech Co., Ltd.

All information pertaining to the trial device (e.g., patent applications, previously undisclosed manufacturing processes provided to the researcher by the sponsor, basic scientific data, etc.) is considered confidential and is the exclusive property of the sponsor. Investigators may not use the above information for other purposes without the express written permission of the sponsor.

22. Allocation of Responsibilities

22.1 Responsibilities of the Sponsor

(1) The sponsor shall be responsible for the authenticity and compliance of the medical device clinical trial. Where the sponsor is an overseas institution, it shall appoint a Chinese enterprise legal person as its legal agent in accordance with relevant laws and regulations to assist the sponsor in fulfilling its obligations.

(2) The sponsor’s quality management system shall cover the entire process of the medical

device clinical trial, including selection of clinical trial institutions and principal investigators, design of the clinical trial protocol, conduct of the clinical trial, documentation, reporting of results, and archiving of records. The sponsor's quality management measures shall be appropriate to the risks of the clinical trial.

(3) Before initiating a medical device clinical trial, the sponsor shall: (i) Ensure that the product design is finalized, and that pre-clinical studies of the investigational medical device have been completed, including performance verification and validation, product inspection reports based on the product technical requirements, risk-benefit analysis, etc., and that the results support the clinical trial; (ii) Select registered medical device clinical trial institutions, specialties, and principal investigators according to the characteristics of the investigational medical device; (iii) Be responsible for developing and providing the investigator's brochure, clinical trial protocol, informed consent form, case report form, standard operating procedures, and other relevant documents to the medical device clinical trial institutions and principal investigators.

(4) The sponsor shall sign a contract with the medical device clinical trial institutions and principal investigators to clarify the rights and obligations of all parties in the clinical trial.

(5) After the medical device clinical trial has been approved by the ethics committee and the contract with the clinical trial institution has been signed, the sponsor shall register the clinical trial with the drug regulatory authority of the province, autonomous region, or municipality directly under the Central Government where the sponsor is located.

(6) The medical device clinical trial institution may start informed consent and screening of the first subject only after completion of clinical trial registration.

(7) Before initiation of the medical device clinical trial, the sponsor shall organize training related to the clinical trial, including the working principle, intended use, product performance, operation method, installation requirements, technical specifications of the investigational medical device, as well as the clinical trial protocol, standard operating procedures, and other relevant documents.

(8) The sponsor shall provide the investigational medical device free of charge in compliance with the Good Clinical Practice for Medical Devices (2022).

(9) The sponsor shall pay for expenses related to the medical device clinical trial for subjects. In the event of injury or death related to the medical device clinical trial, the sponsor shall bear the corresponding medical expenses, compensation, or indemnity, excluding injuries caused by negligence of the investigator and the clinical trial institution, or progression of the subject's underlying disease.

(10) The sponsor shall be responsible for the assessment and reporting of safety information during the medical device clinical trial.

(11) The sponsor shall assume responsibility for monitoring the medical device clinical trial, establish standard operating procedures for monitoring, and appoint monitors who meet the requirements of the Good Clinical Practice for Medical Devices (2022) to perform monitoring duties.

(12) To ensure the quality of the clinical trial, the sponsor may appoint auditors independent of the clinical trial, with appropriate training and experience, to conduct audits of the conduct of the clinical trial and assess compliance with the protocol, this regulation, and relevant laws and regulations.

(13) The sponsor shall ensure that the medical device clinical trial is conducted in accordance with the protocol. If the sponsor finds that the clinical trial institution or investigator fails to comply with the protocol, this regulation, or relevant laws and regulations, it shall promptly point out and correct the non-compliance. In case of serious or persistent non-compliance, the sponsor shall terminate the participation of such institution and investigator in the clinical trial and submit a written report to the drug regulatory authority of the province, autonomous region, or municipality directly under the Central Government where the clinical trial institution is located.

(14) The sponsor shall submit a written report to all principal investigators, the administrative department of the medical device clinical trial institutions, and the ethics committees within 10 working days after suspension, termination, or completion of the clinical trial.The sponsor shall report to the drug regulatory authority of the province, autonomous region, or municipality directly under the Central Government where the sponsor is located within 10 working days after termination or completion of the clinical trial.

22.2 Responsibilities of the Ethics Committee

(1) The Ethics Committee shall be responsible for protecting the legitimate rights, interests and safety of subjects, and safeguarding their dignity.

(2) The Ethics Committee shall comply with the ethical principles of the Declaration of Helsinki (World Medical Association) and relevant laws and regulations. The composition, operation and filing management of the Ethics Committee shall meet the requirements of the health administration department.

(3) All members of the Ethics Committee shall receive training in ethical knowledge, these Regulations and relevant laws and regulations, be familiar with the ethical principles and relevant laws and regulations for medical clinical trials and abide by the working procedures of the Ethics Committee.

(4) The Ethics Committee shall review the ethical acceptability and scientific validity of the medical device clinical trial.

(5) The Ethics Committee shall conduct follow-up oversight of the medical device clinical trial. If it finds that the rights, interests and safety of subjects cannot be guaranteed, it may require in writing the suspension or termination of the clinical trial at any time.

(6) The Ethics Committee shall review safety information such as serious adverse events occurring at the trial site reported by investigators, and safety information such as investigational device-related serious adverse events reported by the sponsor. The Ethics Committee may require amendments to the clinical trial protocol, informed consent form and other information provided to subjects, or suspend or terminate the clinical trial.

(7) The Ethics Committee shall review the potential impact of deviations from the clinical trial protocol on the rights, interests and safety of subjects, or on the scientific validity and integrity of the medical device clinical trial.

(8) During the medical device clinical trial, amendments to documents such as the clinical trial protocol and informed consent form, as well as resumption of a suspended clinical trial, may be implemented only after written approval has been obtained again from the Ethics Committee.

(9) The Ethics Committee shall retain all records of ethical review, including written review records, member information, submitted documents, meeting minutes and relevant correspondence

records.

22.3 Responsibilities of the Clinical Trial Institution

(1) The medical device clinical trial institution shall meet the filing requirements and establish a clinical trial management organizational structure and management system. The medical device clinical trial institution shall have a corresponding clinical trial management department responsible for the administration of medical device clinical trials.

(2) The management department of the medical device clinical trial institution shall be responsible for completing, managing and updating the filing information of the medical device clinical trial institution in the filing and management information system, including clinical trial specialties, principal investigators and other relevant information. It shall be responsible for submitting the annual work summary report of medical device clinical trials conducted in the previous year online via the filing system. Before the ethics committee reviews the medical device clinical trial, it shall organize the qualification assessment of the principal investigator of the clinical trial and complete the filing.

(3) The medical device clinical trial institution shall establish a quality management system covering the entire process of medical device clinical trial implementation, including training and assessment, conduct of clinical trials, management of medical devices, management of biological samples, handling of adverse events and device deficiencies, reporting of safety information, documentation, quality control and other systems, to ensure that the principal investigator fulfills his/her relevant clinical trial responsibilities, that subjects receive appropriate medical care, and that the data generated from the trial are authentic.

(4) Before undertaking a medical device clinical trial, the medical device clinical trial institution shall evaluate the relevant resources according to the characteristics of the investigational medical device to ensure that it has the appropriate qualifications, personnel, facilities and conditions.

(5) The medical device clinical trial institution and investigators shall cooperate with monitoring and audits organized by the sponsor, as well as inspections conducted by drug regulatory authorities and health administration departments.

(6) The medical device clinical trial institution shall properly keep clinical trial records and

essential documents in accordance with relevant laws and regulations and the contract signed with the sponsor.

22.4 Responsibilities of Investigators

(1) The Principal Investigator responsible for the medical device clinical trial shall possess the qualifications and conditions required by Good Clinical Practice for Medical Devices (2022).

(2) The Principal Investigator shall ensure that the medical device clinical trial is conducted in compliance with the latest version of the clinical trial protocol approved by the Ethics Committee and shall conduct the trial within the agreed time limit in accordance with this regulation and relevant laws and regulations.

(3) The Principal Investigator may, as required by the medical device clinical trial, delegate qualified investigators who have received clinical trial-related training to conduct the following: subject recruitment, informed consent, screening and follow-up; management and use of the investigational medical device and control medical device (if applicable); management and use of biological samples (if applicable); handling of adverse events and device deficiencies; documentation of clinical trial data and completion of case report forms.

(4) Investigators participating in the medical device clinical trial shall possess the qualifications and conditions required by Good Clinical Practice for Medical Devices (2022).

(5) Investigators shall comply with the ethical principles of the Declaration of Helsinki (World Medical Association) and relevant ethical requirements and meet the informed consent requirements specified in the Good Clinical Practice for Medical Devices (2022).

(6) Investigators shall be responsible for the management of the investigational medical device and control medical device (if applicable) provided by the sponsor. They shall ensure that such devices are used only for subjects enrolled in the clinical trial, stored and kept as required during the trial, and disposed of after completion or termination of the trial in accordance with relevant laws and regulations and the contract with the sponsor.

(7) Investigators shall ensure that the collection, processing, storage, transportation, destruction, etc. of biological samples in the medical device clinical trial comply with the clinical trial protocol and relevant laws and regulations.

(8) In the event of an adverse event during the medical device clinical trial, investigators shall provide adequate and timely treatment and management for the subject. If the subject develops concurrent diseases requiring treatment, investigators shall inform the subject promptly. Investigators shall document all adverse events and identified device deficiencies occurring during the medical device clinical trial.

(9) Investigators shall report safety information in the medical device clinical trial in a timely manner. The Principal Investigator shall promptly handle received safety information:(i) Upon receiving information related to the investigational medical device regarding serious adverse events and other safety information from the sponsor, the Principal Investigator shall acknowledge and review such information promptly, consider whether adjustments are needed for subject treatment, and communicate with subjects as early as necessary;(ii) Upon receiving notification from the sponsor or Ethics Committee to suspend or terminate the medical device clinical trial, the Principal Investigator shall notify subjects promptly and ensure that subjects receive appropriate treatment and follow-up.

(10) The Principal Investigator shall report the progress of the medical device clinical trial to the Ethics Committee on schedule, and promptly report events affecting the rights, interests and safety of subjects or deviations from the clinical trial protocol.

(11) If the sponsor seriously or persistently violates this regulation and relevant laws and regulations, or requests alteration of trial data or conclusions, the medical device clinical trial institution and investigators shall submit a written report to the drug regulatory authority of the province, autonomous region, or municipality directly under the Central Government where the sponsor is located.

Note: For other specific responsibilities of each party, please refer to the Clinical Trial Agreement and other relevant documents.

Investigator Declaration

I hereby agree to:

1) Conduct the clinical trial in strict accordance with the Helsinki Declaration, current Chinese regulations, and the trial protocol.
2) Accurately record all required data in the Case Report Form (CRF) and complete all clinical trial reports on time.
3) Allow the trial medical device to only be used in the clinical trial, and document completely and accurately the receipt and usage of the trial medical device during the clinical trial and keep corresponding records.
4) Allow any monitors or inspectors authorized by the sponsor, as well as all regulatory authorities to conduct monitoring and investigation of the clinical trial.
5) Strictly implement the terms of the clinical trial contract/agreement signed by the involved parties.

I have read the entire clinical trial protocol, including the above statement, and I agree with all the above.

Principal Investigator

Signature

(Year) (Month) (Day)

Medical Device Clinical Trial Institution

Signed (Stamped)

(Year) (Month) (Day)

Sponsor

Signed (Stamped)

(Year) (Month) (Day)

Annex 1.

NYHA Functional Classification

Class	Description
I	No limitation of physical activity; ordinary activity does not cause fatigue, palpitation, or dyspnea.
II	Slight limitation; comfortable at rest; ordinary activity causes fatigue, palpitation, or dyspnea.
III	Marked limitation; comfortable at rest; less than ordinary activity causes symptoms.
IV	Unable to engage in any physical activity; symptoms at rest; worsened by activity.

Abbreviations

AD	Aortic dissection
AE	Adverse Event
CRF	Case Report Form
CTA	Computed Tomography Angiography
DMP	Data Management Plan
EC	Ethics Committee
eCRF	Electronic Case Report Form
EDC	Electronic Data Capture
FAS	Full Analysis Set
ITT	Intention-to-treat
LVEF	Left Ventricular Ejection Fraction
MAE	Major Adverse Event
NYHA	New York Heart Association
PI	Principal Investigator
PPS	Per Protocol Set
SAE	Serious Adverse Event
SS	Safety Set
TBAD	Type B aortic dissection
TIA	Transient Ischemic Attack
TEVAR	Thoracic Endovascular Aortic Repair

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