Protocol Number: WQ202502

A Prospective, Multicenter, Randomized Controlled Study to Evaluate the Safety and Efficacy of the WeFlow-EndoSeal™ Aorta Vascular Plug System Combined with TEVAR for the Treatment of Stanford Type B Aortic Dissection

Trial Medical Device Name: WeFlow-EndoSeal™ Aorta Vascular Plug System

Model Specification: Refer to the protocol for specification details

Trial Medical Device Regulatory Classification:

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

Protocol Version Number and Date: V1.0/20250930

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

Coordinating Investigator: Professor Guo Wei

Sponsor: Hangzhou Endonom Medtech Co., Ltd.

Confidential

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Trial Protocol Summary

Name of the Trial	A prospective, multicenter, randomized controlled study to evaluate the safety and efficacy of the WeFlow-EndoSeal™ Aorta Vascular Plug System combined with TEVAR for the treatment of stanford type B aortic dissection
Sponsor	Hangzhou Endonom Medtech Co., Ltd.
Trial Objective	The purpose of this clinical trial is to evaluate the safety and efficacy of the WeFlow-EndoSeal™ Aorta Vascular Plug System developed and manufactured by Hangzhou Endonom Medtech Co.; Ltd. combined with TEVAR for the treatment of stanford type B aortic dissection
Trial Equipment	WeFlow-EndoSeal™ Aorta Vascular Plug System
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 Calculation	[redacted] [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 128 subjects in each of the test group and the control group, with a total sample size of 256 subjects in both groups.
Follow-Up Period	After surgery, each subject will require 60 months of follow-up.
Patient Inclusion/ Exclusion Criteria	**Inclusion Criteria** 1. Patients aged 18 to 80 years old. 2. Patients are diagnosed with subacute or chronic Stanford Type B aortic dissection and are scheduled to undergo TEVAR. 3. Upon imaging evaluation, the maximum diameter of the false lumen landing zone where the vascular plug is intended to be deployed shall be ≤[redacted] mm. 4. Patients have suitable access conditions evaluated by imaging, allowing the steerable catheter delivery systems to enter the false lumen via the iliac artery, infrarenal aorta, or at the level of the renal artery tear. 5. 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** **General Exclusion Criteria** 1. Presence of persistent malperfusion of visceral arterial branches caused by dissection. 2. [redacted] 3. Infectious aortic disease, Takayasu's arteritis, Marfan syndrome (or other connective tissue diseases). 4. Acute systemic infection. 5. History of myocardial infarction, TIA, or stroke within the past 3 months. 6. NYHA Class IV cardiac dysfunction (see Appendix 1 of the protocol) or LVEF < 30%. 7. Hematologic abnormalities, defined as: leukopenia (WBC < 3×10^9/L), anemia (Hb < 90 g/L); coagulopathy, thrombocytopenia (PLT count < 50×10^9/L). 8. Renal insufficiency with serum creatinine > 221 μmol/L (or 2.5 mg/dL) and/or end-stage renal disease requiring renal dialysis, as determined by the investigator after comprehensive assessment. 9. Severe hepatic insufficiency: alanine aminotransferase (ALT) or aspartate aminotransferase (AST) > 5× upper limit of normal; serum total bilirubin (STB) > 2× upper limit of normal. 10. Hypersensitivity to contrast media, materials of the Aorta Vascular Plug, or the delivery system. 11. Female subjects who are pregnant or breastfeeding. 12. Concurrent participation in another clinical trial of drugs or devices. 13. Patients with a life expectancy of less than 12 months (e.g., advanced malignant tumor). 14. Any other medical conditions or abnormalities that, in the investigator's opinion, render the subject ineligible for this study.

	Intraoperative Angiography Exclusion Criteria After completion of the stent-graft procedure (including implantation of stents for the proximal and/or distal tears as necessary), DSA angiography revealed: 1. Presence of other vascular lesions (e.g., coronary, renal, mesenteric arteries, etc.) requiring intervention, resulting in an impact on the postoperative medical regimen. 2. Proximal Type I endoleak or Type III endoleak. 3. Presence of a tear in the descending aorta above the upper margin of the celiac trunk ostium.
Primary Efficacy Endpoints	**Primary Efficacy Endpoint: The 12-month Clinical Success Rate.** Time Point: 12 months postoperatively [redacted] Secondary surgical intervention refers to open or endovascular reinterventions in subjects caused by procedure- and device-related complications or adverse events, such as aortic rupture, migration of the Aorta Vascular Plug, infection, etc. Secondary surgical intervention does not include scheduled elective procedures and non-aortic surgeries.
Secondary	**Secondary Efficacy Endpoints：**

Efficacy Endpoints	**1）Immediate Technical Success Rate in the Test Group** Time of Evaluation: Intraoperative Evaluation Method: Immediate technical success is defined as successful delivery of the Aorta Vascular Plug 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）Thrombosis Status of the False Lumen in the Descending Thoracic Aorta** Time of Evaluation: 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). **3）Change in the Maximum Diameter of the Descending Thoracic Aorta** Time of Evaluation: 30 days, 6 months, 12 months, and 24–60 months postoperatively Evaluation Method: Compare the CTA results obtained preoperatively and at 30 days, 6 months, 12 months, and 24–60 months postoperatively to assess the change in the maximum diameter of the descending thoracic aorta.。 **4）Change in Volume in the Descending Thoracic Aorta** Time of Evaluation: 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 change in true lumen, false lumen and total volume above the

	celiac trunk in the descending thoracic aorta. **5）Rate of Secondary Surgical Intervention** Time of Evaluation: 30 days, 6 months, 12 months, and 24–60 months postoperatively Secondary surgical intervention refers to open or endovascular reinterventions performed on subjects due to procedure-related and device-related complications or adverse events, including but not limited to aortic rupture, migration of the Aorta Vascular Plug, infection, etc. Secondary surgical intervention does not include scheduled elective procedures or non-aortic surgeries.
Primary Safety Endpoints	**Primary Safety Endpoint: Incidence of freedom from major adverse events within 30 days postoperatively.** Time of Evaluation: Within 30 days postoperatively Definition: Freedom from all-cause death, aortic rupture, myocardial infarction, renal failure, respiratory failure, ischemic stroke, intestinal necrosis, severe lower extremity ischemia or necrosis, and paraplegia within 30 days postoperatively. Among them: renal failure refers to failure resulting in permanent dialysis, renal transplantation, or other fatal outcomes. respiratory failure refers to failure resulting in significantly prolonged intubation, tracheotomy, deteriorated pulmonary function, or other fatal outcomes. Intestinal necrosis refers to intestinal ischemia requiring intestinal resection or resulting in other fatal outcomes. severe lower extremity ischemia refers to new-onset severe claudication or rest pain postoperatively.
Secondary Safety Endpoints	**1) Migration of the Aorta Vascular Plug** Time of Evaluation: 6 months, 12 months, and 24–60 months

	postoperatively Device migration is defined as displacement of the Aorta Vascular Plug by more than 10 mm at 6 months, 12 months, and 24–60 months postoperatively compared with that at 30 days postoperatively. **2) All-cause mortality, aortic dissection-related mortality, incidence of serious adverse events, and incidence of device-related adverse events.** ① All-cause mortality Time of Evaluation: 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 Time of Evaluation: 30 days, 6 months, 12 months, and 24–60 months postoperatively Evaluation Method: Aortic dissection-related death refers to death resulting from aortic dissection rupture or related to the procedure for treating aortic dissection. ③ Incidence of serious adverse events Time of Evaluation: 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 Incidence of device-related adverse events Time of Evaluation: 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.
Trial Visitation Plan	➢ Visit 1: Screening period (Day -15 to 0) ➢ Visit 2: Day of Surgery (Intraoperatively, after completion of stent-graft deployment) (Day 0) ➢ Visit 3: Randomization and treatment ➢ Visit 4: Before discharge ➢ Visit 5: 30-day (±7 days) postoperative visit ➢ Visit 6: 6-month (±30 days) postoperative visit ➢ Visit 7: 12-month (±30 days) postoperative visit ➢ Visits 8, 9, 10 and 11: 24 months (±30 days) after surgery, 36 months (±30 days) after surgery, 48 months (±30 days) after surgery, 60 months (±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

Xiaoyan Yan, 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-EndoSeal™ Aorta Vascular Plug System developed and manufactured by Hangzhou Endonom Medtech Co.; Ltd. combined with TEVAR for the treatment of stanford type B aortic dissection.

4.2. Content

This study is a prospective, multi-center, randomized controlled clinical trial, which will be conducted in qualified clinical research institutions. A central randomization system will be adopted in this study, and subjects will be randomly assigned to the test group and the control group at a ratio of 1:1. The test group will be treated with the WeFlow-EndoSeal™ Aorta Vascular Plug System developed and produced by Hangzhou Endonom Medtech Co., Ltd. combined with TEVAR for patients with Stanford Type B aortic dissection, while the control group will receive conventional TEVAR treatment in accordance with guidelines and

expert consensus. An internet-based registration system will be used to register the enrolled subjects. A stratified block randomization method will be used, with study center as the stratification factor. ① Randomization procedure: The investigator logs into the central randomization system, enters the basic information of eligible subjects who have successfully passed screening and meet the randomization criteria, and performs online randomization. ② Timing of randomization: Randomization will be performed at Visit 3 (intraoperatively). Specifically, randomization will be conducted after completion of stent-graft implantation and confirmation by intraoperative angiography that the subject meets all pre- and intraoperative inclusion and exclusion criteria. The random allocation result will be generated and locked immediately by the system; neither the investigator nor the sponsor can predict the group assignment in advance, thereby effectively controlling selection bias. This project is expected to start in March 2026 and complete 256 clinical implantations by March 2027. Clinical follow-up will be conducted from postoperative period to discharge, and at 30 days, 6 months, 12 months, 24 months, 36 months, 48 months, and 60 months postoperatively, among which CTA imaging follow-up will be performed at 30 days, 6 months, 12 months, 24 months, 36 months, 48 months, and 60 months postoperatively. The primary efficacy endpoint of this trial is the 12-month clinical success rate, [redacted]

Meanwhile, the secondary efficacy endpoints: immediate technical success rate, thrombosis status of the false lumen in the descending thoracic aorta, change in the maximum diameter of the descending thoracic aorta, change in volume in the descending thoracic aorta, and rate of secondary surgical intervention will be combined to reflect the efficacy of the device. The primary safety endpoint is the incidence of freedom from major adverse events within 30 days postoperatively, which refers to the absence of all-cause death, aortic rupture, myocardial

infarction, renal failure, respiratory failure, ischemic stroke, intestinal necrosis, severe lower extremity ischemia or necrosis, and paraplegia within 30 days postoperatively. Meanwhile, the secondary safety endpoints: migration of the Aorta Vascular Plug, all-cause mortality, aortic dissection-related mortality, incidence of serious adverse events, and incidence of device-related adverse events will be combined to reflect the safety of the device. After completing the assessment of the primary endpoint at 12 months, the sponsor will issue a clinical trial report and submit it to NMPA. Subsequent follow-up will be conducted once a year until the 5th year to observe long-term efficacy.

The trial will be conducted at a qualified clinical research institution, with investigators using a modular embedded aortic arch stent graft system developed and manufactured by Hangzhou Endonom Medtech Co., Ltd. The trial corresponds to a prospective, multicenter, single-arm objective performance criteria clinical study. A web-based registration system will be used to register enrolled subjects. This trial is expected to start in December 2020 with 80 clinical implants performed by December 2022 and with clinical follow-up performed at discharge as well as 30 days, 6 months, 12 months, 24 months, 36 months, 48 months, and 60 months after surgery. CTA imaging follow-up was conducted for 30 days, 6 months and 12 months after surgery.

The primary endpoints of the trial are incidence of all-cause mortality and severe stroke within 12 months after surgery. The incidence of Type I or Type III endoleaks, incidence of aortic arch coated stent migration, postoperative branch vessel patency rate, and incidence of aortic aneurysm converted to open-heart surgery or secondary intervention will be used as indicators of device efficacy. The incidence of all-cause mortality, aortic aneurysm-related mortality, incidence of severe adverse events and incidence of device-related adverse events will be used as indicators of device safety. The sponsor will issue a clinical trial report for submission to the NMPA after completion of a 12-month primary endpoint assessment. Subsequent annual follow-ups will be conducted up to Year 5 to observe long-term treatment efficacy.

5. Background Information Pertaining to the Clinical Trial

Aortic Dissection (AD) is a severe acute cardiovascular critical illness with acute onset,

rapid progression and extremely high mortality. It has been reported in the literature that the incidence of AD in China is approximately 2.8 per 100,000 people[1]. According to the location of the entry tear and the extent of dissection involvement, aortic dissection is clinically classified into Stanford Type A and Stanford Type B. For Stanford Type A dissection, without early intervention, the mortality rate increases by 1% per hour within 24 hours after onset, and the mortality rate reaches up to 50% within one week. At present, ascending aortic replacement combined with stent graft implantation (Sun's procedure) is the standard surgical method for Type A dissection. For acute complicated Type B dissection, Thoracic Endovascular Aortic Repair (TEVAR) has become the preferred surgical method for Type B dissection due to its advantages of minimal invasiveness, simple surgical operation, short operation time, low blood loss, low perioperative mortality and complication rate.

The core goal of TEVAR technology is to eliminate the proximal entry tear of the aorta from the lumen using a stent graft and related auxiliary instruments, thereby inducing false lumen thrombosis and aortic remodeling. However, many scholars have found that the results of aortic remodeling after classic TEVAR that only closes the proximal entry tear and leaves the distal entry tears untreated are not satisfactory. Only about 40% of patients can achieve complete false lumen thrombosis by covering only the proximal entry tear after TEVAR[2–4]. The presence of residual distal entry tears will gradually form new dissecting aneurysms, increase the occurrence of long-term aortic events, and inhibit aortic remodeling[5]. More than one-third of patients who only receive TEVAR treatment have false lumen progression, with a mortality rate of 36% after three years[6–7]. The relationship between incomplete false lumen thrombosis and long-term mortality has been reported in many literatures.

Chinese Expert Consensus on the Diagnosis and Treatment of Stanford Type B Aortic Dissection (2022 Edition) [8] points out that for patients with large retrograde flow in the false lumen above the celiac trunk artery, primary repair can be performed, but attention should be paid to the high risk of spinal cord ischemia. In fact, most TBAD patients adopt a follow-up strategy and a "watch-and-wait" mode after surgery. This strategy means that they are exposed to extremely high long-term risks. Once a dissecting aneurysm forms, the secondary surgery is

difficult, high-risk and costly. Therefore, exploring an active primary intervention strategy for patients with high-risk anatomical types is an urgent and unmet clinical need.

Some existing endovascular treatment methods for distal dissecting aneurysms still have certain drawbacks: for example, using a stent graft to cover the descending aorta to close the distal entry tear of aortic dissection, but this method has the risk of spinal cord ischemia; the multi-layer bare stent technology induces false lumen thrombosis through flow diversion, but this technology does not directly isolate the entry tear, and there is a risk of continued false lumen expansion in the later stage.

In response to the above problems, the method of false lumen obliteration has been gradually applied to patients with distal false lumen expansion. By filling devices such as coils or occluders into the false lumen, the blood flow in the false lumen is blocked, and false lumen thrombosis is promoted. There are many specific instruments available for false lumen embolization, but none of them are specially designed for false lumen obliteration. Loubert et al.[9] reported in 2003 that filters, detachable balloons and occluders were used to block the blood flow in the false lumen, and both patients achieved complete false lumen thrombosis during follow-up. The results of a study involving 27 patients with chronic Type B dissection showed[10] that after false lumen embolization with coils (vascular occluders were used as auxiliary for patients with large false lumens), 81.5% of the patients achieved false lumen thrombosis. On the other hand, Zhang et al.[11] performed coil embolization on 7 patients with persistent false lumen in the thoracic aorta segment after TEVAR. Two patients died of dissection-related causes after discharge. Only 1 patient achieved complete false lumen thrombosis in the thoracic aorta segment 1 year after surgery, 4 patients had no improvement in the false lumen, and 1 patient had thoracic aorta widening: it is considered that the effect of coil embolization is limited, especially in patients with thoracic aortic aneurysmal dilatation. When the distal false lumen is significantly dilated, a large number of coils are needed, and the cost of obliterating the false lumen is often too high. In addition, how to avoid ectopic embolization of coils and other devices during the obliteration process is also a difficulty. In addition, iliac artery occluders can also be used for false lumen embolization, but their maximum diameter is only 24mm, which may not fill the entire false

lumen, and their circular shape cannot fully match the mostly crescent-shaped false lumen[12]. Some researchers have also explored the use of organic materials such as biologic glue and ethylene-vinyl alcohol copolymer for embolization to achieve complete or partial false lumen thrombosis[13–14]. Kölbel et al.[15] sutured the middle part of a 42mm thoracic aortic stent graft and reduced its diameter to form a self-made large vascular occluder, which was used for false lumen embolization in patients with thoracic aortic dissecting aneurysm. After implantation, a vascular occluder needs to be implanted in the middle of the stent to completely block the blood flow in the false lumen; the first patient of this method was a chronic Type B dissection patient with a false lumen diameter of 36mm, and complete false lumen thrombosis was achieved 3 months after surgery: this method is also called "Candy-plug" because the stent is shaped like a candy. Since then, many related cases have been reported with good results[16–17]. The results of a retrospective study involving 18 patients with chronic Type B dissection showed[18] that after Candy-plug treatment, the complete aortic remodeling rate was 70% and the dissecting aneurysm stability rate was 30% during 14.7 months of follow-up. The second-generation Candy-plug is produced by Cook Company in the United States, whose middle diameter is consistent with both ends. After deployment, it can automatically occlude the middle part of the stent without additional implantation of a vascular occluder; the maximum diameter is 46mm and the length is 71mm, with a wider scope of application. However, it has not been marketed yet, and there are only small-sample studies[19]. In general, reports on Candy-plugs are relatively limited, and its effect needs to be further confirmed.

Hangzhou Endonom Medtech Co., Ltd. has developed a new type of Aorta Vascular Plug System to address the problems faced by the above technologies. The system includes a Aorta Vascular Plug, a delivery cable and a steerable delivery sheath. The clinical trial product has passed the registration inspection, and the test results of its chemical and physical properties are all qualified. The product has also completed animal experiments and simulated human experiments. The operation and use such as the introduction of the delivery sheath, the positioning and deployment of the Aorta Vascular Plug in the experiments all meet the clinical requirements. Postoperative angiography in animal experiments showed that the occlusion device

had a good shape and satisfactory vascular occlusion results; angiography at 6-month follow-up showed no damage to the structure of the occlusion device, no migration or other adverse phenomena; pathological section results showed that the inflammatory reaction of the occlusion device material was mild and the biocompatibility was good. In addition, the safety performance of the test product was tested, and the results showed that the performance of the product was stable, and the quality met the requirements. Therefore, the test product has the conditions to carry out clinical trials. Now, an application for clinical trials is submitted to verify the safety and efficacy of the WeFlow-EndoSeal™ Aorta Vascular Plug System combined with TEVAR in the treatment of Stanford Type B dissection.

6. Product Structural Composition, Working Principles, Mechanism of Action and Scope of Testing

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

The WeFlow-EndoSeal™ Aorta Vascular Plug System consists of a vascular occlusion plug, a delivery cable, and a steerable delivery sheath, each individually packaged. Their cooperative relationship during use is shown in Figure 1:

According to cross-sectional morphology, the Aorta Vascular Plug is classified into three types: Crescent, Convex Crescent, and Full Moon, as shown in Figure 2a, Figure 2b, and Figure 2c, respectively.

The delivery cable is composed of a cable, a handle, and a loader.

The steerable delivery sheath is composed of a delivery sheath and a dilator.

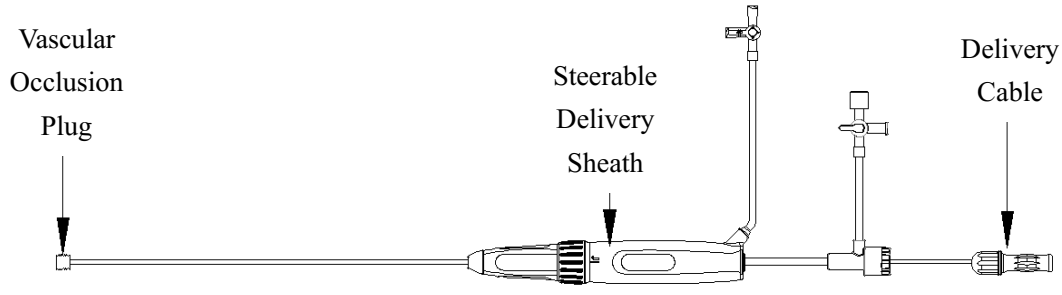


Figure 1. Diagram of the Aorta Vascular Plug System

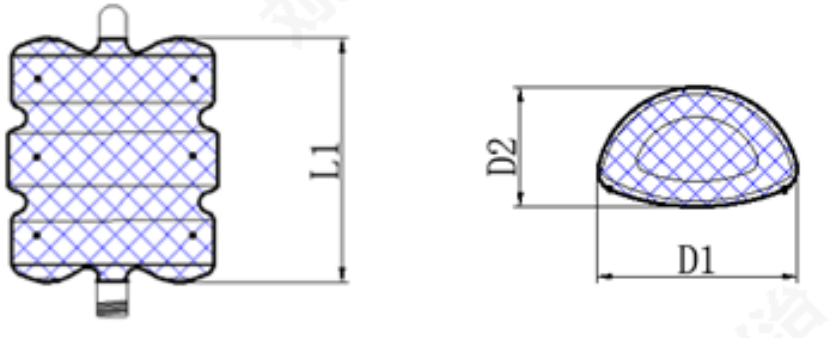


Figure 2a. Diagram of the Aorta Vascular Plug (Crescent Type)

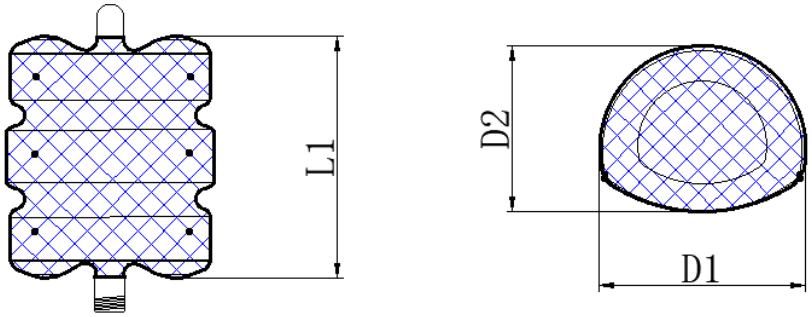


Figure 2b. Diagram of the Aorta Vascular Plug (Convex Crescent Type)

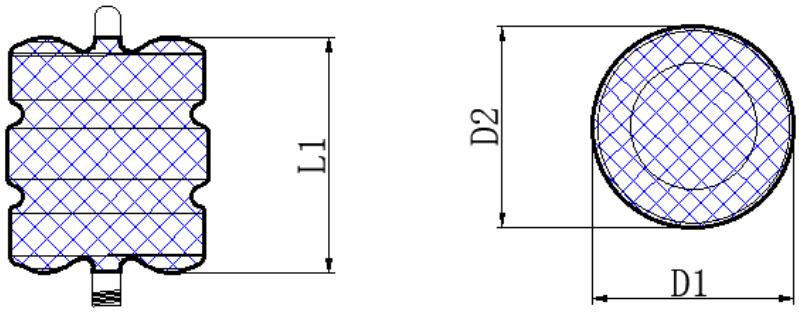


Figure 2c. Diagram of the Aorta Vascular Plug (Full Moon Type)

6.2. Product Specifications

Specifications of the Aorta Vascular Plug are classified according to the cross-sectional type, cross-sectional dimensions, and main body length of the nitinol mesh. The cross-sectional types include three categories: Crescent, Convex Crescent, and Full Moon. Cross-sectional dimensions consist of the major diameter D1 (primary dimension) and minor diameter D2 (secondary dimension), and the main body length is defined as the distance L1 between the two end surfaces. For devices with the same cross-sectional type, Aorta Vascular Plugs with the same major diameter are regarded

as belonging to the same specification series, as listed in Table 1.

The model and specification of the Aorta Vascular Plug System consist of a model code and a specification code. The model is composed of letters, indicating the trademark code and product category; the specification is composed of numbers, indicating the specific product dimensions.

The model and specification designation of the Aorta Vascular Plug is shown in Figure 3a, 3b, and 3c, respectively. Herein, Endo-SL is the abbreviation of the trade name WeFlow-EndoSeal™. Cross-section type X stands for Crescent, T for Convex Crescent, and M for Full Moon.

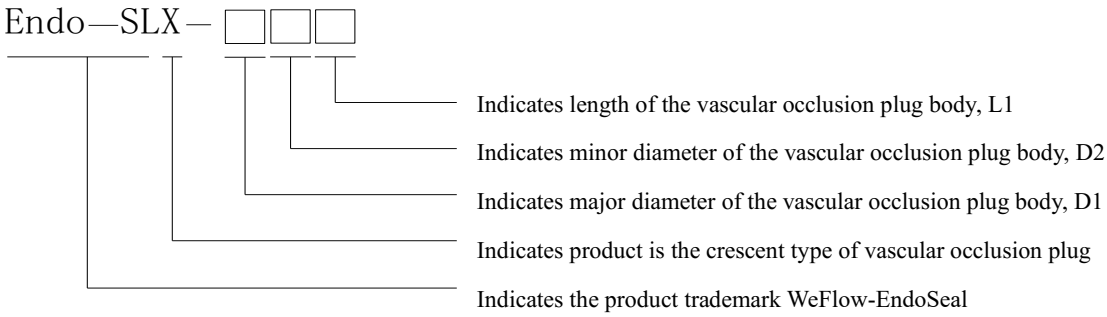


Figure 3a The model and specification designation of the Aorta Vascular Plug (Crescent Type)

Example: Endo-SLX-261528 designates a Crescent type Aorta Vascular Plug with a device specification of 26 mm, major diameter (primary dimension) 26 mm, minor diameter (secondary dimension) 15 mm, and length 28 mm.

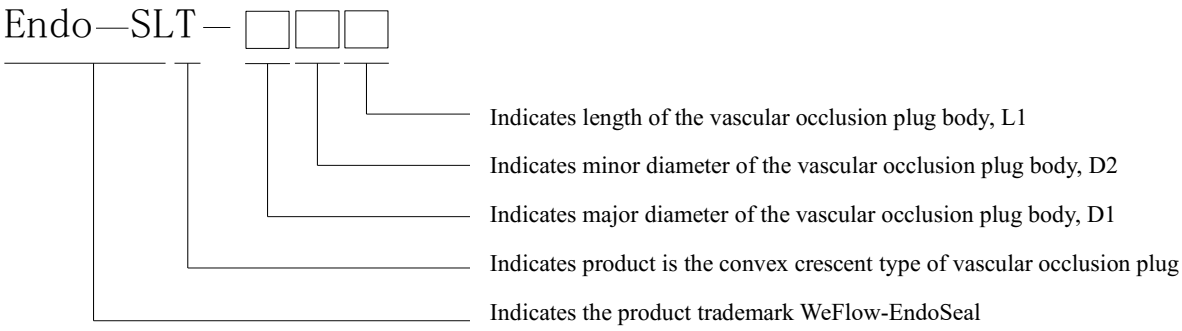


Figure 3b The model and specification designation of the Aorta Vascular Plug (Convex Crescent Type)

Example: Endo-SLT-262028 designates a Convex Crescent type Aorta Vascular Plug with a specification of 26 mm, major diameter (primary dimension) 26 mm, minor diameter (secondary dimension) 20 mm, and total length 28 mm.

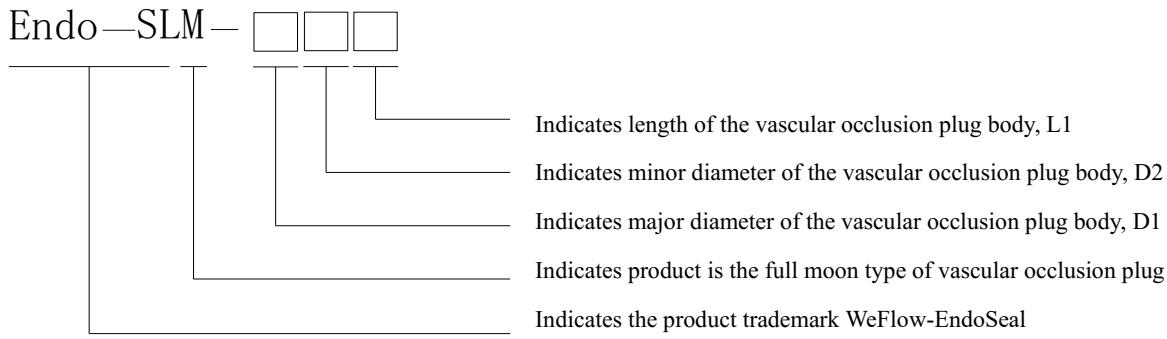


Figure 3c The model and specification designation of the Aorta Vascular Plug (Full Moon Type)

Example: Endo-SLM-262628 designates a Full Moon-type Aorta Vascular Plug with a specification of 26 mm, major diameter (primary dimension) 26 mm, minor diameter (secondary dimension) 26 mm, and length 28 mm.

The specification series table of the Aorta Vascular Plug and corresponding relevant dimensions are as follows:

Table 1 Specification Series of Aorta Vascular Plug (Unit: mm)

Specification Series	Major Diameter D1	Crescent Type	Convex Crescent Type	Full Moon Type	Length L1	Recommended Inner Diameter of Steerable Delivery Sheath & Delivery Cable (F)
		Minor Diameter D2	Minor Diameter D2	Minor Diameter D2		
06	6	[redacted]	[redacted]	[redacted]	[redacted]	6F/8F/10F/12F
08	8	[redacted]	[redacted]	[redacted]	[redacted]	
10	10	[redacted]	[redacted]	[redacted]	[redacted]	
12	12	[redacted]	[redacted]	[redacted]	[redacted]	
14	14	[redacted]	[redacted]	[redacted]	[redacted]	8F/10F/12F
16	16	[redacted]	[redacted]	[redacted]	[redacted]	
18	18	[redacted]	[redacted]	[redacted]	[redacted]	
20	20	[redacted]	[redacted]	[redacted]	[redacted]	
22	22	[redacted]	[redacted]	[redacted]	[redacted]	
24	24	[redacted]	[redacted]	[redacted]	[redacted]	
26	26	[redacted]	[redacted]	[redacted]	[redacted]	
28	28	[redacted]	[redacted]	[redacted]	[redacted]	10F/12F
30	30	[redacted]	[redacted]	[redacted]	[redacted]	
32	32	[redacted]	[redacted]	[redacted]	[redacted]	
34	34	[redacted]	[redacted]	[redacted]	[redacted]	
36	36	[redacted]	[redacted]	[redacted]	[redacted]	
38	38	[redacted]	[redacted]	[redacted]	[redacted]	
40	40	[redacted]	[redacted]	[redacted]	[redacted]	12F
42	42	[redacted]	[redacted]	[redacted]	[redacted]	

44	44	[redacted]	[redacted]	[redacted]	[redacted]	
46	46	[redacted]	[redacted]	[redacted]	[redacted]	

7. Product Indications, Contraindications and Precautions

7.1. Indications

The WeFlow-EndoSeal™ Vascular Occlusion System is used in combination with TEVAR for the treatment of patients with Stanford Type B aortic dissection.

7.2. Contraindications

The Vascular Occlusion System is contraindicated in (but not limited to) the following conditions:

- Patients with acute systemic infection;
- Patients with hypersensitivity to contrast media;
- Patients with hypersensitivity to the Aorta Vascular Plug, delivery cable, or delivery sheath;
- Patients whose vascular morphology is not suitable for false lumen occlusion.

8. Trial Design

8.1. Trial Methodology and Rationale

This study is designed as a prospective, multi-center, randomized controlled clinical trial.

1）Multi-center design: The trial will be conducted at multiple qualified clinical centers across China to accelerate patient enrollment, promote healthy competition, and achieve enrollment targets more efficiently. Since subject data are collected from different regions, centers, and investigators, the conclusions will have broad representativeness.

2）Randomized controlled design: 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 between test and control groups) or another predefined probability (e.g., n:1 allocation) of being assigned to either the test group or the control group, without influence from the subjective preferences of investigators and/or subjects. Randomization ensures comparability between the test and control groups in all known and unknown baseline variables that may affect the trial outcome.

The rationale for adopting a randomized controlled design and selecting the control group is as follows:

Currently, for Stanford Type B aortic dissection, TEVAR alone is the standard treatment recommended by domestic and international guidelines. Random assigning patients to either the standard treatment group or the “standard treatment + investigational device” group is ethically acceptable and consistent with international practice. For the treatment of distal thoracoabdominal aortic dissection aneurysms, guidelines have mentioned false lumen obliteration techniques, but the optimal intervention strategy remains undetermined.

False lumen occlusion/obliteration has been reported as an important endovascular approach to achieve long-term aortic remodeling. This technique has a long clinical history with various available devices, including coils, Onyx, fibrin sealant, filters, and various types of congenital heart defect occludes. Unfortunately, all these are used off-label. Among them, the Candy-plug technique is widely used abroad; however, it is a customized product not approved for marketing and not available in China.

3）Determination of Indications

With reference to domestic and international guidelines: Subjects diagnosed with Stanford Type B dissection and scheduled for TEVAR; the maximum diameter of the aorta false lumen landing zone where the vascular plug is intended to be deployed shall be ≤ [redacted] mm.

4）Primary Endpoints

Primary Efficacy Endpoint: Clinical success rate at 12 months postoperatively, [redacted].

Primary Safety Endpoint: Freedom from major adverse events at 30 days postoperatively, defined as the absence of all-cause death, aortic rupture, myocardial infarction, renal failure, respiratory failure, ischemic stroke, intestinal necrosis, severe lower extremity ischemia or necrosis, and paraplegia within 30 days postoperatively.

8.2. Subject Selection

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

1. Patients aged 18 to 80 years old.

2. Patients are diagnosed with subacute or chronic Stanford Type B aortic dissection and are scheduled to undergo TEVAR.

3. Upon imaging evaluation, The the maximum diameter of the false lumen landing zone where the vascular plug is intended to be deployed shall be in the descending thoracic aorta is ⩽ [redacted] mm..

4. Patients have suitable access conditions evaluated by imaging, allowing the steerable catheter delivery systems to enter the false lumen via the iliac artery, infrarenal aorta, or at the level of the renal artery tear.

5. 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.

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

General Exclusion Criteria

1) Presence of persistent malperfusion of visceral arterial branches caused by dissection.
2) [redacted].
3) Infectious aortic disease, Takayasu's arteritis, Marfan syndrome (or other connective tissue diseases).
4) Acute systemic infection.
5) History of myocardial infarction, TIA, or stroke within the past 3 months.
6) NYHA Class IV cardiac dysfunction (see Appendix 1 of the protocol) or LVEF < 30%.
7) Hematologic abnormalities, defined as: leukopenia (WBC < 3×10^9/L), anemia (Hb < 90 g/L); coagulopathy, thrombocytopenia (PLT count < 50×10^9/L).

8) Renal insufficiency with serum creatinine > 221 μmol/L (or 2.5 mg/dL) and/or end-stage renal disease requiring renal dialysis, as determined by the investigator after comprehensive assessment.
9) Severe hepatic insufficiency: alanine aminotransferase (ALT) or aspartate aminotransferase (AST) > 5× upper limit of normal; serum total bilirubin (STB) > 2× upper limit of normal.
10) Hypersensitivity to contrast media, materials of the Aorta Vascular Plug, or the delivery system.
11) Female subjects who are pregnant or breastfeeding.
12) Concurrent participation in another clinical trial of drugs or devices.
13) Patients with a life expectancy of less than 12 months (e.g., advanced malignant tumor).
14) Any other medical conditions or abnormalities that, in the investigator's opinion, render the subject ineligible for this study.

Intraoperative Angiography Exclusion Criteria

After completion of the stent-graft procedure (including implantation of stents for the proximal and/or distal tears as necessary), DSA angiography revealed:

1) Presence of other vascular lesions (e.g., coronary, renal, mesenteric arteries, etc.) requiring intervention, resulting in an impact on the postoperative medical regimen.
2) Proximal Type I endoleak or Type III endoleak.
3) Presence of a tear in the descending aorta above the upper margin of the celiac trunk ostium.

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.

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 simultaneously at multiple qualified research centers in China. Based on the number of potential subjects at each center, the complexity of the enrollment and exclusion criteria in the clinical protocol, and the difficulty in obtaining informed consent, the anticipated enrollment period is 12 months. Each subject will be followed up for 60 months. The enrollment of the first subject is expected in March 2026, the last subject is expected to be enrolled in March 2027, and the follow-up of the last subject is scheduled to be completed in approximately March 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

The test group and control group will be enrolled at a 1:1 ratio, with 128 subjects planned for each group and a total sample size of 256 subjects..

8.3. Assessment Methods

8.3.1. Primary Efficacy Endpoints

The 12-month Clinical Success Rate.

Time Point: 12 months postoperatively

[redacted]

[redacted]

Secondary surgical intervention refers to open or endovascular reinterventions in subjects caused by procedure- and device-related complications or adverse events, such as aortic rupture, migration of the Aorta Vascular Plug, infection, etc. Secondary surgical intervention does not include scheduled elective procedures and non-aortic surgeries.

8.3.2. Secondary Efficacy Endpoints

1）Immediate Technical Success Rate in the Test Group

Time of Evaluation: Intraoperative

Evaluation Method: Immediate technical success is defined as successful delivery of the Aorta Vascular Plug 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）Thrombosis Status of the False Lumen in the Descending Thoracic Aorta

Time of Evaluation: 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).

3）Change in the Maximum Diameter of the Descending Thoracic Aorta

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

Evaluation Method: Compare the CTA results obtained preoperatively and at 30 days, 6 months, 12 months, and 24﹣60 months postoperatively to assess the change in the maximum

diameter of the descending thoracic aorta.。

4）Change in Volume in the Descending Thoracic Aorta

Time of Evaluation: 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 change in true lumen, false lumen and total volume above the celiac trunk in the descending thoracic aorta.

5）Rate of Secondary Surgical Intervention

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

Secondary surgical intervention refers to open or endovascular reinterventions performed on subjects due to procedure-related and device-related complications or adverse events, including but not limited to aortic rupture, migration of the Aorta Vascular Plug, infection, etc. Secondary surgical intervention does not include scheduled elective procedures or non-aortic surgeries.

8.3.3. Primary Safety Endpoints

Incidence of freedom from major adverse events within 30 days postoperatively.

Time of Evaluation: Within 30 days postoperatively

Definition: Freedom from all-cause death, aortic rupture, myocardial infarction, renal failure, respiratory failure, ischemic stroke, intestinal necrosis, severe lower extremity ischemia or necrosis, and paraplegia within 30 days postoperatively.

Among them: renal failure refers to failure resulting in permanent dialysis, renal transplantation, or other fatal outcomes. respiratory failure refers to failure resulting in significantly prolonged intubation, tracheotomy, deteriorated pulmonary function, or other fatal outcomes. Intestinal necrosis refers to intestinal ischemia requiring intestinal resection or resulting in other fatal outcomes. severe lower extremity ischemia refers to new-onset severe claudication or rest pain postoperatively.

8.3.4. Secondary Safety Endpoints

1) Migration of the Aorta Vascular Plug

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

Device migration is defined as displacement of the Aorta Vascular Plug by more than 10 mm at 6 months, 12 months, and 24–60 months postoperatively compared with that at 30 days postoperatively.

2) All-cause mortality, aortic dissection-related mortality, incidence of serious adverse events, and incidence of device-related adverse events.

① All-cause mortality

Time of Evaluation: 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

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

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

③ Incidence of serious adverse events

Time of Evaluation: 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 Incidence of device-related adverse events

Time of Evaluation: 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.

8.3.5. 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

8.4.1. Trial Procedure Chart

Trial Procedure	Screening Period		Randomization and Treatment	Follow-Up					
	Preoperatively	Intraoperatively (stent-graft implantation)							
Visit	V1	V2	V3	V4	V5	V6	V7	V8-11	Unscheduled Visit
Days	-15~0 d	0	0	Discharge	30 ± 7 days after surgery	6 months ± 30 days after surgery	12 months ± 30 days after surgery	24-60 months±30 d days after surgery	
Signing of Informed Consent Form	X								
Inclusion/Exclusion Criteria	X	X							
Medical History/ Demographic data	X								
Pregnancy Test	X								
Physical Examination	X			X					
Blood Panel	X			X					

Urine Panel	X			X					
Coagulation Function	X			X					
Liver and Kidney Function	X			X					
12-Lead ECG	X			X					
Echocardiography	X								
CTA	X				X	X	X	X	
Chest X-ray		X	X*						
Surgical Records		X	X*						
Medication Records	X	X	X*	X	X	X	X	X	X
Adverse Event Records	X	X	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: Erythrocytes, leukocytes, platelet count and hemoglobin.
- Urine Panel: pH, leukocytes, erythrocytes 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
- Data pertaining to past medication and past medical history for the three months preceding the date on which informed consent is obtained will be collected
- Before discharge (Visit 4): Refers to a visit from the postoperative to a day before discharge, and the results of the last laboratory examination before discharge are collected;

- CTA data obtained prior to surgery and at 30 ± 7 days after surgery, 6 months ± 30 days after surgery and 12,24,36,48,60 months ± 30 days after surgery will be collected;
- Medication records created prior to surgery, during surgery, prior to discharge and at 30 ± 7 days after surgery, 6 months ± 30 days after surgery and 12,24,36,48,60 months ± 30 days after surgery as well as adverse event records created after informed consent is obtained, during surgery, prior to discharge and at 30 ± 7 days after surgery, 6 months ± 30 days after surgery and 12,24,36,48,60 months ± 30 days after surgery will be collected;
- Where feasible, laboratory test data obtained 15 days prior to subject enrollment (prior to signing of informed consent) as well as CTA and ultrasound, 12-lead ECG data, and chest radiographs obtained 30 days prior to enrollment (prior to signing of informed consent) may be used as baseline assessment data without any need for re-examination;
- 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.
- *Relevant examinations and data collection shall be performed only in patients randomized to the test group.

8.4.2. Trial Conduct

1) Signing of informed consent;
2) Patient screening: Patients will be screened according to the inclusion criteria and exclusion criteria;
3) Patient enrollment;
4) Selection of trial products: Investigators determine the product specifications required by each subject, and the sponsor provides the corresponding product free of charge;
5) Performance of surgery: Surgery will be completed by the investigator;
6) Postoperative follow-up: Investigators are required to perform clinical follow-ups after surgery and prior to discharge, and on Day 30 and Months 6, 12, 24, 36, 48, and 60 following surgery, with CTA follow-up required on Day 30 and Months 6 and 12

following surgery, at the sponsor's expense;

7) Data analysis summary: The sponsor will collect all relevant data and information and commission a third party to evaluate and manage as well as statistically and analytically summarize the data.

8.4.3. Subject Visitation Plan

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

In light of ethical considerations, laboratory test data obtained within 15 days prior to subject enrollment (before signing informed consent), and CTA, ultrasound, and 12-lead ECG data obtained within 30 days prior to subject enrollment (before signing informed consent) may be used as baseline assessment data without the need for re-examination of patients.

At this visit, subjects must be fully informed before signing the informed consent form. Baseline data and baseline examinations will be collected; after the results are available, screening will be performed in accordance with the inclusion and exclusion criteria. Eligible subjects will be registered for enrollment. The specific items to be collected are as follows:

- 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: Erythrocytes, leukocytes, platelet count and hemoglobin
    - Urine panel: pH, leukocytes, erythrocytes 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
- Adverse events

2) Visit 2: Screening Phase (Intraoperative)

This visit is an intraoperative visit. Following stent-graft implantation, further screening of the patient will be performed using DSA imaging. The specific items to be collected are as follows:

- DSA imaging data
- Surgery-related records (selection of stent type, arterial access, deployment, Interventional operation time (the time the sheath enters the body to the time the sheath is pulled out of the body), immediate success, etc.)
- Concomitant medications
- Adverse events
- Device defects

3) Visit 3: Intraoperative

This is an intraoperative visit. Randomization will be performed for the patient, and Aorta Vascular Plug implantation will be conducted for patients randomized to the test group. The following data will be collected:

- DSA imaging data
- Surgery-related records (selection of stent type, arterial access, deployment, Interventional operation time (the time the sheath enters the body to the time the sheath is pulled out of the body), immediate success, etc.)
- Concomitant medications
- Adverse events
- Device defects

4) Visit 4: Before discharge

- Physical examination
- Blood panel: Erythrocytes, leukocytes, platelet count and hemoglobin
- Urine panel: pH, leukocytes, erythrocytes 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

5) Visit 5: (30 ± 7 days after surgery)

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

- CTA angiography
- Concomitant medications
- Adverse events
- Device defects
- If a subject is unwilling to return to the hospital for a CTA examination, information such as adverse events and concomitant medications may be collected via telephone follow-up.

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

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

- CTA angiography
- Concomitant medications
- Adverse events

- Device defects
- If a subject is unwilling to return to the hospital for a CTA examination, information such as adverse events and concomitant medications may be collected via telephone follow-up.

7) Visit 7: (12 months ± 30 days after surgery)

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

- CTA angiography
- Concomitant medications
- Adverse events
- Device defects
- If a subject is unwilling to return to the hospital for a CTA examination, information such as adverse events and concomitant medications may be collected via telephone follow-up.

8) Visits 8, 9, 10 and 11: (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:

- CTA angiography
- Concomitant medications
- Adverse events
- Device defects
- If a subject is unwilling to return to the hospital for a CTA examination, information such as adverse events and concomitant medications may be collected via telephone follow-up.

8.4.4. Treatment Description

Procedure for Aorta Vascular Plug Implantation

1) Femoral artery puncture. Puncture both common femoral arteries and insert vascular sheaths; perform aortography. Predeploy suture closure devices bilaterally and establish

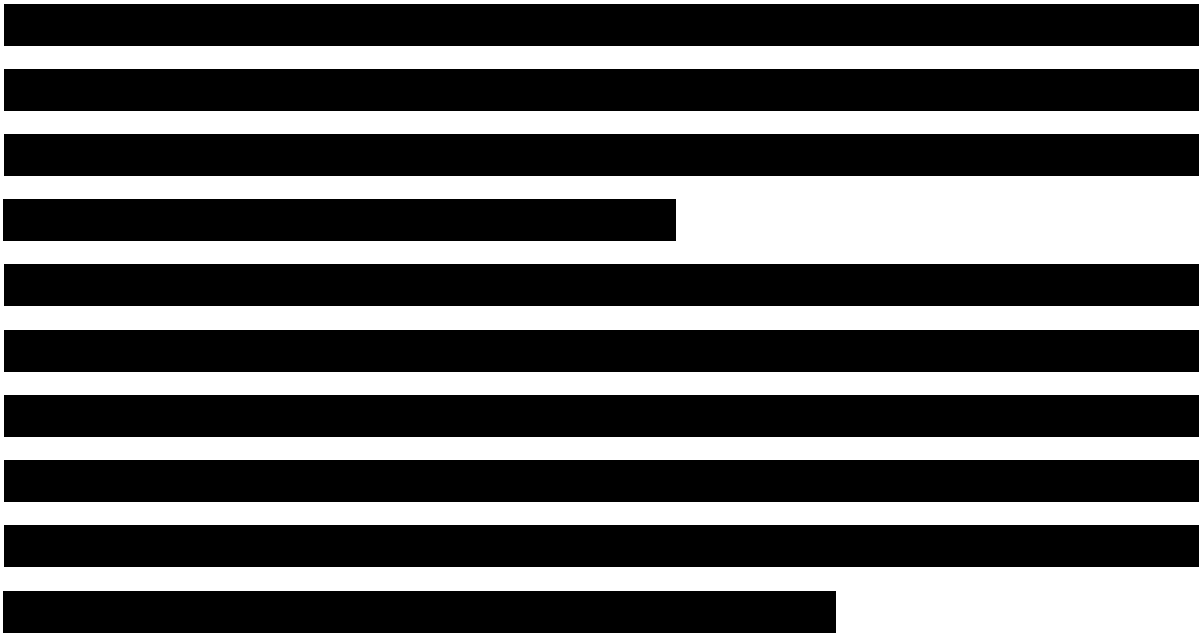
systemic heparinization.。

2) Confirmation of true and false lumens. Through one vascular sheath, advance a Rosen guidewire with a pigtail catheter into the true lumen of the descending aorta, confirmed by angiography.Through the contralateral vascular sheath, advance a Rosen guidewire with a Judkins catheter to select an appropriate entry tear into the false lumen, confirmed by angiography.

3) Guidewire exchange in the false lumen and insertion of the steerable delivery sheath. Withdraw the Rosen guidewire prepositioned in the false lumen and replace it with a stiff guidewire; remove the Judkins catheter to leave the stiff guidewire in the false lumen.Advance the steerable delivery sheath over the stiff guidewire to the intended deployment site of the Aorta Vascular Plug, then withdraw the stiff guidewire and dilator.

4) Insertion of the Aorta Vascular Plug. Advance the Aorta Vascular Plug with its delivery cable slowly to the predetermined position at the distal end of the delivery sheath.

5) Deployment of the Aorta Vascular Plug. After confirming the deployment position and orientation, fix the delivery cable, retract the delivery sheath, and slowly deploy the Aorta Vascular Plug into the false lumen.



6) Detach the delivery cable. Rotate counterclockwise to unscrew the threaded connection between the delivery cable and the Aorta Vascular Plug, then withdraw the delivery system.

7) Angiography is performed again to evaluate the occlusion effect of the Aorta Vascular Plug and assess for any device migration.

8.4.5. 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.

8.5. 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 adopts a randomized controlled design. The 12-month clinical success rate postoperatively is used as the primary efficacy endpoint, which includes: [redacted].

A significance level of $\alpha = 0.025$ (one-sided) and power of $1-\beta = 0.80$ are used. A 20% dropout rate at 12 months is considered for the clinical success rate. The final total sample size is 256 subjects, with 128 subjects in each group.

The sample size calculation formula is as follows:

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 Thereof

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 α = 0.025 (single tailed), 1-β = 0.80.

9.1.5. Expected Dropout Rate

The dropout rate for the 12-month clinical success rate in 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: $P_T - P_C > \Delta$

$\alpha = 0.025$ (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 Aorta Vascular Plug 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 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.

14. Clinical Trial Ethical Issues and Informed Consent

14.1. 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.

14.2. 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.

14.3. 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.

15. Provisions for Reporting Adverse Events and Device Defects

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 Aorta Vascular Plug, 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

21.1. 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.

21.2. 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.

21.3. 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.

21.4. 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)

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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Annex 1.

NYHA Functional Classification.

Class	Patient Symptoms
I	No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation or shortness of breath.
II	Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, shortness of breath or chest pain.
III	Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, shortness of breath or chest pain.
IV	Symptoms of heart failure at rest. Any physical activity causes further discomfort.