Protocol Number: WEIQIANG202101

Guo's visceRal artEries Reconstruction: The Prospective, Multiple Center, Objective Performance Criteria Clinical Trial About the sAfeTy and Efficacy of WeFlow-JAAA™ Stent Graft System.(GREAT Study)

Trial Medical Device Name: WeFlow-JAAA Stent Graft System

Model/Specification: See protocol for details

Management Category of Investigational Medical Device:

Class III Medical Device Requiring Clinical Trial Approval: Yes □ No ■

Similar Products in China: Yes □ No ■

Protocol Version Number and Date: V1.2/20221016

Lead Institution: The First Medical Center, Chinese PLA General Hospital

Coordinating Investigator: Professor Guo Wei

Sponsor: Hangzhou Endonom Medtech co. ltd

Study Protocol Summary

Study Name	Guo's visceRal artEries Reconstruction: The Prospective, Multiple Center, Objective Performance Criteria Clinical Trial About the sAfeTy and Efficacy of WeFlow-JAAA™ Stent Graft System. (GREAT Study)
Sponsor	Hangzhou Endonom Medtech co. ltd
Study Purpose	The purpose of this clinical trial is to evaluate the safety and efficacy of the WeFlow-JAAA Stent Graft System, developed and manufactured by Hangzhou Endonom Medtech co. ltd, in treating patients with juxtarenal and pararenal abdominal aortic aneurysms.
Investigational Device	WeFlow-JAAA Stent Graft System
Sample Size	Considering a 20% dropout rate, the total sample size is 106 cases.
Sample Size Calculation	[redacted]
Follow-up Duration	Each subject requires follow-up for 60 months post-surgery.
Subject Selection/ Inclusion/Exclusion Criteria	Inclusion Criteria 1) Age 18-80 years, regardless of gender; 2) Subjects who were diagnosed with Juxtarenal and Pararenal abdominal aortic aneurysms and needed to reconstruct the blood supply of superior mesenteric artery

	and bilateral renal arteries; 3) Have appropriate vascular conditions, mainly including: • Distance from the upper edge of the aneurysm to the lower edge of the opening of SMA ≥ 4 mm; • The angle between the proximal aneurysm neck and the aortic long axis near the opening of SMA ≤ 60°; • The aortic diameter at the opening of SMA ranges from 18 to 34 mm • The diameter range of the starting part of SMA is 5–12 mm • The diameter range of the initial part of bilateral RAs is 4.5–10 mm • Length of non-bifurcated segment of SMA and RA ≥ 10 mm • The diameter at the bifurcation of abdominal aorta ≥ 16 mm • The length of distal anchoring area of iliac artery ≥ 15 mm • The diameter range of distal anchoring area of iliac artery is 8–24 mm • Feasible iliofemoral artery and upper patent upper extremity access 4) Those who can understand the purpose of the trial, voluntarily participate in the study, sign the informed consent form by themselves or their legal representative, and are willing to complete the follow-up according to the protocol requirements. Exclusion Criteria 1) Upper edge of renal artery origin higher than the lower edge of the opening of SMA; 2) Accessory renal artery diameter ≥ 3 mm, or supplying more than 1/3 of kidney tissue; 3) Hemodynamically unstable ruptured abdominal aortic aneurysm, pseudoaneurysm, or aortic dissection; 4) Infectious aortic disease, Takayasu arteritis, Marfan syndrome (or other connective tissue diseases); 5) Presence of severe stenosis, calcification, or mural thrombus in the proximal landing zone; 6) Need to intervene on other vascular lesions (e.g., coronary, carotid) in the same procedure, affecting postoperative medication regimen; 7) History of myocardial infarction, TIA, or cerebral infarction within the past 3 months;

	8) History of previous abdominal aortic surgery or endovascular repair; 9) Pre-existing severe liver, kidney, lung, or heart dysfunction [subjects with serum creatinine > 150 umol/L; ALT or AST > 5 times the upper limit of normal; total bilirubin > 2 times the upper limit of normal; left ventricular ejection fraction < 50% on echocardiography]; 10) Acute systemic infection; 11) Contraindications to antiplatelet or anticoagulant therapy; 12) Allergy to contrast media, anesthetic drugs, stent, or delivery system materials; 13) Inability to tolerate anesthesia; 14) Pregnant, breastfeeding, or women unable to practice contraception during the trial period; 15) Life expectancy less than 12 months (e.g., advanced malignancy); 16) Concurrent participation in another drug or device clinical trial; 17) Investigator judges that the subject's vascular conditions affect branch artery revascularization or other concomitant diseases make them unsuitable for this study.
Primary Safety Endpoint	Rate of no major adverse events occurred within 30 days after operation Evaluation Time: Before discharge, 30 days after operation The main adverse events within 30 days after operation refer to all-cause death, myocardial infarction, renal failure, respiratory failure, ischemic stroke, intestinal necrosis, severe ischemia or necrosis of lower limbs and paraplegia within 30 days afteost-procedure. Renal failure refers to resulting in permanent dialysis, kidney transplantation, or other fatal outcomes. Respiratory failure refers to resulting in significantly prolonged intubation time, tracheostomy, worsening lung function, or other fatal outcomes. Intestinal necrosis refers to intestinal ischemia requiring bowel resection or resulting in other fatal outcomes. Severe lower limb ischemia refers to new-onset severe claudication or rest pain after operation.
Secondary Safety	All-cause mortality rate, abdominal aortic aneurysm-related mortality rate, serious adverse event rate, device-related adverse event rate.

Endpoints	1) Rate of all cause mortality Evaluation Time: Before discharge, Day 30, Month 6, Month 12, Months 24-60 after operation Evaluation Method: All cause death refers to death from any cause during the follow-up period. 2) Rate of abdominal aortic aneurysm related mortality Evaluation Time: Before discharge, Day 30, Month 6, Month 12, Months 24-60 after operation Evaluation Method: Rate of abdominal aortic aneurysm related death refers to death caused by aneurysm rupture or surgery for aortic aneurysm. 3) Incidence of serious adverse events Evaluation Time: Before discharge, Day 30, Month 6, Month 12, Months 24-60 after operation Evaluation Method: Serious adverse events refer to events that lead to death or serious deterioration of health status during clinical trials, including fatal diseases or injuries, permanent defects in body structure or function, and the need for medical or surgical intervention to avoid permanent defects in body structure or function. 4) Incidence of device related adverse events Evaluation Time: Before discharge, Day 30, Month 6, Month 12, Months 24-60 after operation Evaluation Method: Device related adverse events refer to adverse medical events related to the use of devices during clinical trials. However, normal postoperative stress reactions, such as fever and chest and back discomfort, should be distinguished. If they are judged as normal postoperative stress reactions by the researchers, they need not be recorded in adverse events. Recording device related adverse events refers to the situation that the investigator determines to be definitely related, possibly related or unable to determine with the test device.
Primary Efficacy Endpoint	The success rate of treatment of abdominal aortic aneurysm 12 months after operation Evaluation Time: Intraoperative, 12 months after operation Evaluation Method: The 12-month abdominal aortic aneurysm treatment success rate is a composite endpoint, including immediate technical success after operation and,

	at the 12-month after operation CT scan, an increase in the maximum diameter of the abdominal aortic aneurysm ≤ 5 mm compared to pre-surgery, absence of Type I or Type III endoleak, no stent migration, branch stent patency, and no secondary intervention during the follow-up period. Definitions: Immediate technical success after operation means the delivery system of the aortic and branch covered stents is successfully delivered to the predetermined position, the stents are accurately positioned and successfully deployed, the delivery system is safely withdrawn, and after operation angiography shows no Type I or Type III endoleak, with branch stents patent. Type I endoleak: Endoleak caused by failure of the covered stent to closely adhere to the native vessel, including proximal (Type Ia) and distal (Type Ib) interfaces. Type III endoleak: Endoleak caused by failure of close connection between the branch stent and the abdominal aortic stent interface or rupture of the stent graft. Secondary intervention refers to open or endovascular re-intervention required for the subject due to complications or adverse events related to the surgery and device, such as: aortic rupture, branch vessel occlusion, lower limb artery occlusion, persistent Type I or Type III endoleak requiring intervention. Stent migration is defined as displacement of the aortic and branch covered stents by > 10 mm compared to before discharge at follow-up time points
Secondary Efficacy Endpoints	Incidence of Type I or III endoleak, incidence of covered stent migration, branch vessel patency rate, incidence of conversion to open surgery or secondary intervention. 1) Incidence of Type I or III endoleak Evaluation Time: Intraoperative, before discharge, Month 6, Month 12 Evaluation Method: Record endoleak shown by DSA, CTA, or other imaging after operation. Endoleaks occurring intraoperatively that are treated are not recorded. For endoleaks occurring after surgery completion, if they appear in the same subject at different follow-up stages without treatment, they are counted once. 2) Incidence of aortic covered stent migration Evaluation Time: Month 6, Month 12 after operation

	Evaluation Method: Observe and record whether stent migration has occurred on CTA at 6 and 12 months after operation. Both the main body stent and branch stents are evaluated. Migration is defined as displacement of the aortic and branch covered stents by > 10 mm compared to before discharge at follow-up time points. 3) Patency rate of postoperative branches Evaluation Time: Before discharge, Month 6, Month 12 Evaluation Method: Observe and record CTA before discharge, at 6 months, and 12 months to evaluate the revascularization status of the renal arteries and superior mesenteric artery branch vessels, assessing for occlusion, stenosis, or in-stent thrombosis. After operation branch vessel stenosis ≤ 50% is considered patent. 4) Incidence of conversion to open surgery or secondary interventional surgery for abdominal aortic aneurysm Evaluation Time: Before discharge, Month 6, Month 12, Months 24-60 Evaluation Method: Evaluate whether the subject required conversion to open surgery or secondary intervention due to the abdominal aortic aneurysm.
Study Visit Plan	- Visit 1: Screening Period (-15~0 days) - Visit 2: Day of Surgery (Day 0) - Visit 3: Before Discharge - Visit 4: Day 30 (±7 days) After operation Visit - Visit 5: Month 6 (±30 days) After operation Visit - Visit 6: Month 12 (±30 days) After operation Visit - Visits 7, 8, 9, 10: Months 24 (±30 days), 36 (±30 days), 48 (±30 days), 60 (±30 days) After operation

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Main Text of the Study Protocol

1. Sponsor Information

1.1. Sponsor Name

Hangzhou Endonom Medtech co. ltd

1.2. Sponsor Address

[redacted]

1.3. Sponsor Contact Information

Company Phone: [redacted]

Company Fax: [redacted]

2. List of Clinical Trial Institutions and Investigators

See Appendix 1 of the protocol.

3. Other Collaborating Units

3.1. Statistical Analysis

[redacted]

Address: [redacted]

3.2. Core Laboratory

[redacted].

Address: [redacted]

4. Objectives and Content of the Clinical Trial

4.1. Objectives

The purpose of this clinical trial is to evaluate the safety and efficacy of the WeFlow-JAAA Stent Graft System, developed and manufactured by Hangzhou Endonom Medtech co. ltd, in treating patients with juxtarenal and pararenal abdominal aortic aneurysms.

4.2. Content

This project will be conducted at qualified clinical research institutions. Investigators will use the WeFlow-JAAA Stent Graft System, developed and manufactured by Hangzhou Endonom Medtech co. ltd, for endovascular treatment of patients with juxtarenal and pararenal abdominal aortic aneurysms. This is a prospective, multi-center, single-arm, objective performance criteria clinical study. An internet-based registration system will be used to register enrolled subjects. The project is expected to start in February 2022, complete 106 clinical implants by December 2023, and conduct clinical follow-ups post-surgery before discharge, and at 30 days, 6 months, 12 months, 24 months, 36 months, 48 months, and 60 months. CTA imaging follow-up will be performed before discharge, at 6 months, 12 months, 24 months, 36 months, 48 months, and 60 months.

This trial evaluates whether the investigational device meets safety standards based on the 30-day major adverse event (MAE)-free rate endpoint, and whether it meets efficacy standards based on the 12-month abdominal aortic aneurysm treatment success rate primary endpoint. Safety of the device is reflected by all-cause mortality rate, abdominal aortic aneurysm-related mortality rate, serious adverse event rate, device-related adverse event rate, incidence of intestinal ischemia, etc. Efficacy of the device is reflected by the incidence of Type I or III endoleak, incidence of aortic covered stent migration, after operation branch vessel patency rate, aortic aneurysm growth rate, and incidence of conversion to open surgery or secondary intervention due to aortic aneurysm. The sponsor will submit a clinical trial report to NMPA after completing the 12-month primary endpoint evaluation. Subsequent annual follow-ups will continue until year 5 to observe long-term outcomes.

5. Background Information of the Clinical Trial

Abdominal aortic aneurysm (AAA) is the most common type of aortic aneurysm in humans, accounting for over 60% of all aortic aneurysms. The incidence of AAA significantly increases in males over 50, peaking in males over 65. Gender differences in AAA have been established in several large epidemiological studies, with the incidence in female patients being 4 to 6 times lower than in males [1]. The mortality rate after AAA rupture is as high as 65%-85% [2]. Traditional aortic replacement surgery is highly invasive with high mortality and complication rates, leading elderly and high-surgical-risk patients to forgo treatment due to inability to tolerate the surgery. Endovascular repair technology, being minimally invasive, safe, and effective, has gradually replaced traditional open surgery as the preferred treatment for AAA.

There is currently no unified classification for AAA. Thurnher [3] proposed the Siegfried classification, which is a relatively simple and commonly used method: Suprarenal type: AAA involves or extends above the renal artery ostia; Renal type: AAA is located within 15 mm

below the renal arteries; Infrarenal type: AAA is located more than 15 mm below the renal arteries. Suprarenal and renal types are collectively referred to as pararenal abdominal aortic aneurysms, accounting for approximately 20% of AAAs. Infrarenal AAA can be treated with conventional endovascular repair techniques, whereas for pararenal AAA, treatments currently require hybrid techniques, chimney techniques, fenestrated techniques, and branched stent techniques.

Methods combining endovascular repair and extra-anatomic bypass are collectively referred to as hybrid procedures, mainly consisting of two parts: first, unilateral or bilateral renal artery bypass using an artificial graft to the distal AAA or iliac artery, then ligation of the proximal renal artery, and finally endovascular repair. Some literature confirms the feasibility and safety of this approach. However, due to the need for open surgery, surgical trauma is increased. Additionally, due to the presence of the aneurysm, renal artery reconstruction is technically challenging, and renal artery clamping may affect renal function, thus it is not suitable for widespread application [4].

The chimney technique, also known as the parallel stent technique, involves covering the renal artery with the aortic covered stent, then implanting a stent within the covered renal artery, which is deployed parallel to the aortic stent, thereby preserving the renal artery [5]. This technique was initially used in emergency endovascular aortic repair or as a salvage measure when a renal artery was inadvertently covered during surgery. With accumulated experience, many elective cases also use this method to extend the proximal landing zone while preserving branch vessel blood supply. This technique is relatively simple to perform, but currently, there is no dedicated stent system for the chimney technique; its use is off-label. A characteristic of this technique is the inevitable gaps created between the aortic stent and branch stent, leading to a higher risk of Type I endoleak and branch vessel occlusion [6-10]. Compression between the renal artery stent and aortic stent may cause renal artery stent occlusion, thereby affecting renal function. Moreover, the chimney technique is not suitable for suprarenal AAA. In summary, the chimney technique is currently not an ideal treatment for pararenal AAA.

Custom-made fenestrated stent grafting is currently the preferred method for treating renal-type AAA [11]. This technique requires a proximal neck length ranging from 4 mm to 15 mm, with high technical success rates, low complication rates, and low perioperative mortality [12, 13]. Its main problems are that each patient requires individualized customization, making the stent system very expensive, and the customization period typically takes 6-8 weeks, making it unsuitable for emergent or time-sensitive surgeries. Additionally, the procedure is technically demanding, requiring precise alignment of both renal arteries with the fenestrations during surgery; otherwise, renal artery occlusion can occur. Furthermore, similar to the chimney technique, it is not suitable for suprarenal AAA. Therefore, although fenestrated stent grafting

has been used for many years, it has not been widely adopted.

Branched stent grafts feature branches on the main body stent to revascularize branch vessels. Currently marketed branched stent grafts are only indicated for thoracoabdominal aortic aneurysms and are not suitable for renal-type AAA. The "Octopus" technique shares similarities with branched stent grafts but is used off-label. The long-term patency rate of the branches is uncertain, and the risk of endoleak is also high [14]. In summary, endovascular treatment for juxtarenal and pararenal AAA still faces significant challenges.

To address the issues faced by the above techniques, aiming to increase the accuracy of branch stent positioning, improve long-term patency of branch vessels, and accommodate a broader range of anatomical variations, the WeFlow-JAAA Stent Graft System used in this study was designed and developed. This product consists of two parts: a double internal branch abdominal aortic covered stent and an abdominal aortic bifurcated covered stent. The former has a straight tubular shape, with a "notch" at the 12 o'clock position on the proximal stent to preserve celiac trunk blood flow. Directly below the notch is a "large fenestration" for preserving and reconstructing the superior mesenteric artery. On both sides, at the 3 o'clock and 9 o'clock positions, there is one internal branch each, shaped like atrumpet shape, facilitating alignment with both renal arteries and reducing procedural difficulty. After positioning, covered stents connect the renal arteries to the internal branches. The connection area is sufficiently long, reducing the risk of endoleak. Furthermore, each branch has a pre-loaded guidewire to reduce selective catheterization time during the procedure. The stent also features post-deployment and partial deployment capabilities, further enhancing safety. The second part is a conventional abdominal aortic bifurcated covered stent, with its proximal end connecting to the double internal branch abdominal aortic covered stent and its distal ends anchoring in both iliac arteries. This product is modular and does not require customization. Standard sizes can meet most anatomical conditions.

6. Product Structure, Working Principle, Mechanism of Action, and Trial Scope

6.1. Product Structure, Working Principle, Mechanism of Action

The WeFlow-JAAA Stent Graft System consists of the Abdominal Aortic Internal Branch Stent Graft System, the Abdominal Aortic Bifurcated Stent Graft System, the Extension Stent Graft System, and the Branch Vessel Stent Graft System. The Abdominal Aortic Internal Branch Stent Graft System consists of the Abdominal Aortic Internal Branch Stent Graft and its delivery system. The Abdominal Aortic Bifurcated Stent Graft System consists of the Abdominal Aortic Bifurcated Stent Graft and its delivery system. The Extension Stent Graft System consists of

the Extension Stent Graft and its delivery system. The Branch Vessel Stent Graft System consists of the Branch Vessel Stent Graft and its delivery system. The Abdominal Aortic Internal Branch Stent Graft, Abdominal Aortic Bifurcated Stent Graft, Extension Stent Graft, and Branch Vessel Stent Graft are pre-loaded into their respective delivery systems.

During clinical use, the WeFlow-JAAA Stent Graft System treats juxtarenal and pararenal abdominal aortic aneurysms via endovascular approach. The Abdominal Aortic Internal Branch Stent Graft reconstructs the suprarenal aortic region. Branch vessel stents connect to the circular fenestration and internal branches of the Abdominal Aortic Internal Branch Stent Graft to reconstruct the superior mesenteric artery and left/right renal arteries. The Abdominal Aortic Bifurcated Stent Graft connects to the distal end of the Abdominal Aortic Internal Branch Stent Graft, reconstructing the infrarenal aortic region. Extension stents connect to the long and short limbs of the Abdominal Aortic Bifurcated Stent Graft to reconstruct the iliac artery regions.

The Abdominal Aortic Internal Branch Stent Graft is made of a nickel-titanium metal stent and polyester fabric (see Figure 1);

The Abdominal Aortic Bifurcated Stent Graft is made of a nickel-titanium metal stent and polyester fabric (see Figure 2);

The Extension Stent Graft is made of a nickel-titanium metal stent and polyester fabric (see Figure 3);

The Branch Vessel Stent Graft is made of a nickel-titanium metal stent and e-PTFE membrane (see Figure 4).

The Abdominal Aortic Internal Branch Stent Graft Delivery System consists of a tip, sheath, sheath core assembly, push rod assembly, handle assembly, side port, pre-loaded guidewires, etc. (see Figure 5);

The Abdominal Aortic Bifurcated Stent Graft Delivery System consists of a tip, sheath, sheath core assembly, push rod assembly, handle assembly, side port, etc. (see Figure 6);

The Extension Stent Graft Delivery System consists of a tip, sheath, sheath core assembly, push rod assembly, handle assembly, side port, etc. (see Figure 7);

The Branch Vessel Stent Graft Delivery System consists of a tip, sheath, sheath core assembly, handle assembly, side port, etc. (see Figure 8).

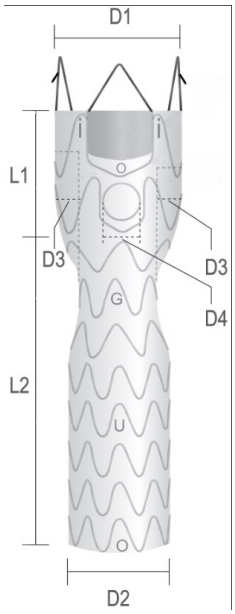

Figure 1: Abdominal Aortic Internal Branch Stent Graft Illustration

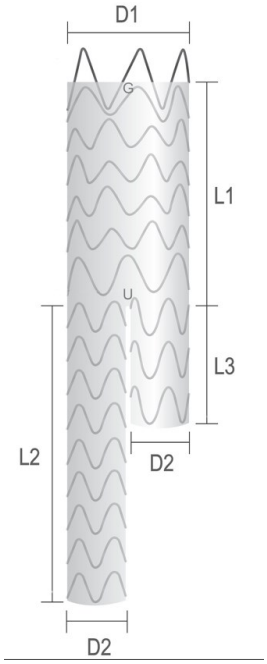

Figure 2: Abdominal Aortic Bifurcated Stent Graft Illustration

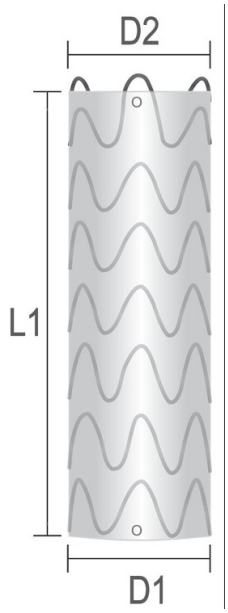

Figure 3: Extension Stent Graft Illustration

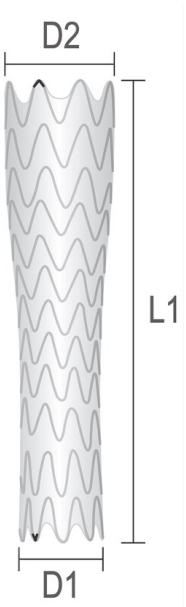

Figure 4: Branch Vessel Stent Graft Illustration

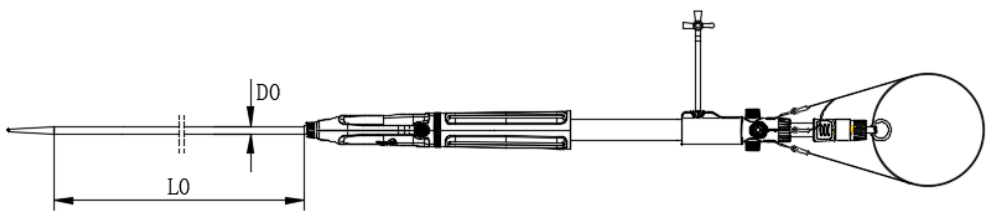

Figure 5: Abdominal Aortic Internal Branch Stent Graft Delivery System Illustration

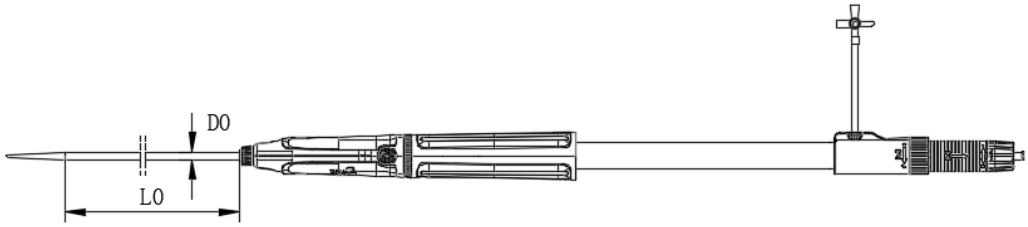

Figure 6: Abdominal Aortic Bifurcated Stent Graft Delivery System Illustration

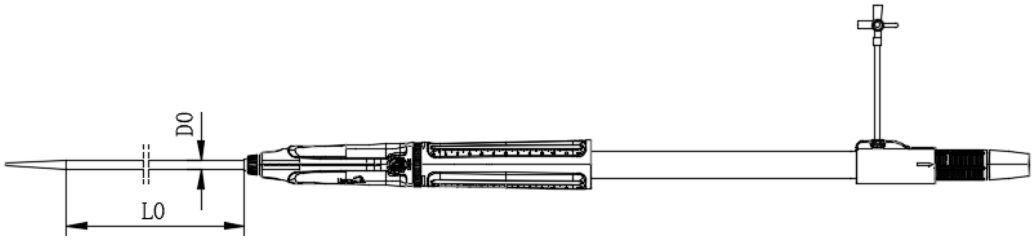

Figure 7: Extension Stent Graft Delivery System Illustration

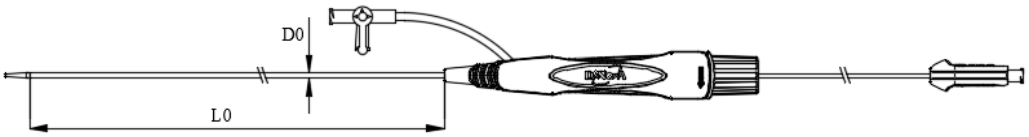

Figure 8: Branch Vessel Stent Graft Delivery System Illustration

6.2. Product Specifications

The product specification series for the Abdominal Aortic Stent Graft System are shown in the following tables:

Table 1: Abdominal Aortic Internal Branch Stent Specification Series Table (Unit: mm)

Specification	D1	D2	L1	L2	D3	D4	Delivery System Specification
20	20	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	22F
22	22						22F
24	24						22F
26	26						22F
28	28						22F
30	30						22F
32	32						24F
34	34						24F
36	36						24F
38	38						24F

Note: Refer to Figure 1.

Table 2: Abdominal Aortic Bifurcated Stent Specification Series Table (Unit: mm)

Specification	D1	D2	L1	L2	L3	Delivery System Specification
18	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	18F
20						18F
22						18F
24						18F
26						18F
28						20F
30						20F
32						20F
34						20F
36						20F

Note: Refer to Figure 2.

Table 3: Extension Stent Specification Series Table (Unit: mm)

Specification	D1	D2	L1	Delivery System Specification
10	10	[redacted]	[redacted]	16F
12	12			16F
14	14			16F
16	16			16F
18	18			16F
20	20			16F
22	22			16F
24	24			18F
26	26			18F
28	28			18F

Note: Refer to Figure 3.

Table 4: Branch Vessel Stent Specification Series Table (Unit: mm)

Specification	D1	D2	L1	Delivery System Specification
5	5	[redacted]	[redacted]	8F
				9F
		[redacted]	[redacted]	8F
				9F
6	6	[redacted]	[redacted]	8F
				9F
		[redacted]	[redacted]	8F
				9F
7	7	[redacted]	[redacted]	8F
				9F
		[redacted]	[redacted]	8F
				9F
8	8	[redacted]	[redacted]	8F
				9F

		[redacted]	[redacted]	8F
			[redacted]	9F
9	9	[redacted]	[redacted]	8F
			[redacted]	9F
		[redacted]	[redacted]	8F
			[redacted]	9F
10	10	[redacted]	[redacted]	8F
		[redacted]	[redacted]	9F
11	11	[redacted]	[redacted]	8F
			[redacted]	9F
12	12	[redacted]	[redacted]	9F
13	13	[redacted]		9F
14	14	[redacted]		9F

Note: Refer to Figure 4.

Table 5: Delivery System Specification Series Table (Unit: mm)

Specification	D0	L0	Product Modules
22F	[redacted]	[redacted]	Abdominal Aortic Internal Branch Stent Graft System
24F			
18F			Abdominal Aortic Bifurcated Stent Graft System
20F			
16F			Extension Stent Graft System,
18F			
9F			Branch Vessel Stent Graft System
8F			

Note: Refer to Figure 5、6、7、8.

6.3. Trial Scope

This trial will be conducted at multiple centers across the country, including subjects from vascular surgery wards, cardiac surgery wards, or emergency departments. Subjects must be preoperatively diagnosed with non-ruptured juxtarenal or pararenal abdominal aortic aneurysms.

7. Indications, Contraindications, and Precautions

7.1. Indications

The WeFlow-JAAA Stent Graft System is indicated for patients with non-ruptured juxtarenal and pararenal abdominal aortic aneurysms. The scope of indications is as follows:

1) Juxtarenal and pararenal abdominal aortic aneurysm requiring revascularization of the superior mesenteric artery and both renal arteries;

2) Suitable vascular conditions, primarily including:

- Distance from the upper edge of the aneurysm to the lower edge of the opening of SMA ≥ 4 mm;
- The angle between the proximal aneurysm neck and the aortic long axis near the opening of SMA ≤ 60°;
- The aortic diameter at the opening of SMA ranges from 18 to 34 mm
- The diameter range of the starting part of SMA is 5–12 mm
- The diameter range of the initial part of bilateral RAs is 4.5–10 mm
- Length of non-bifurcated segment of SMA and RA ≥ 10 mm
- The diameter at the bifurcation of abdominal aorta ≥ 16 mm
- The length of distal anchoring area of iliac artery ≥ 15 mm
- The diameter range of distal anchoring area of iliac artery is 8–24 mm
- Feasible iliofemoral artery and upper patent upper extremity access.

(Note: The proximal aneurysm neck refers to the aorta between the upper edge of the aneurysm and the lower edge of the superior mesenteric artery ostium; the proximal landing zone refers to the aortic segment >15 mm in length above the lower edge of the superior mesenteric artery; the distal iliac artery landing zone refers to the common iliac artery or external iliac artery region corresponding to the distal anchoring site of the extension stent.)

7.2. Contraindications

1) Presence of severe stenosis, calcification, or mural thrombus in the proximal landing zone that could impede stent graft apposition;

2) Allergy to contrast media, anesthetic drugs, stent, or delivery system materials;

3) Contraindications to antiplatelet or anticoagulant therapy;

4) Acute systemic infection;

7.3. Precautions

1) Before using this product, physicians must undergo appropriate specialized training and have a clear understanding of the principles, clinical application, complications, side effects, and hazards of aortic stenting procedures.

2) The Abdominal Aortic Stent Graft System uses a modular component design. During the surgical procedure, multiple stents such as the Abdominal Aortic Internal Branch Stent, Abdominal Aortic Bifurcated Stent, Extension Stent, and Branch Vessel Stent are used together. To effectively prevent endoleak, it is necessary to assess the target vessel dimensions preoperatively and select the appropriate stents.

3) The Abdominal Aortic Internal Branch Stent Graft features a double fenestration + double internal branch design. During deployment, ensure that the circular fenestration aligns with the superior mesenteric artery ostium and that the internal branch openings are located above the left and right renal arteries.

4) The Abdominal Aortic Internal Branch Stent Graft System comes with three pre-loaded guidewires to facilitate establishing tracks for reconstructing the superior mesenteric artery, left renal artery, and right renal artery.

5) When using the Branch Vessel Stent Graft System to reconstruct the superior mesenteric artery and renal arteries, it is recommended to use a long sheath to advance to the lesion site. During deployment, the long sheath should be fixed to prevent displacement.

6) When positioning the Branch Vessel Stent Graft System, the proximal radiopaque marker should be considered in relation to the proximal radiopaque ring of the internal branch; also, the distal radiopaque marker should be considered concerning the position within the viscera.

7) The Abdominal Aortic Bifurcated Stent Graft connects to the distal end of the Abdominal Aortic Internal Branch Stent Graft. When advancing and positioning the Abdominal Aortic Bifurcated Stent Graft System, the positional relationship between the bifurcated stent body and the distal end of the Abdominal Aortic Internal Branch Stent Graft must be assessed via radiopaque markers, while also considering the relationship between the bifurcated stent limbs and the iliac arteries.

8) The Extension Stent connects to the distal limb of the Abdominal Aortic Bifurcated Stent Graft to reconstruct the iliac artery. When advancing and positioning the Extension Stent Graft System, the proximal and distal deployment positions of the stent should be assessed via radiopaque markers.

9) This product includes: the Abdominal Aortic Internal Branch Stent Graft System, the Abdominal Aortic Bifurcated Stent Graft System, the Extension Stent Graft System, and the Branch Vessel Stent Graft System. They are pre-loaded into their respective delivery systems and individually packaged.

10) The Abdominal Aortic Stent Graft System has been sterilized with ethylene oxide before shipment.

11) This product is for single use only. Any unauthorized reuse of the covered stents, delivery systems, or any other components may lead to cross-infection or other adverse consequences, for which the company assumes no responsibility. Do not use if the sealed packaging is found to be damaged before opening.

8. Overall Design

8.1. Trial Design

8.1.1. Trial Objective

This study is a pre-market clinical trial for the WeFlow-JAAA Stent Graft System. The objective is to evaluate the safety and efficacy of the WeFlow-JAAA Stent Graft System, developed and manufactured by Hangzhou Endonom Medtech co. ltd, for endovascular treatment of patients with juxtarenal and pararenal abdominal aortic aneurysms, providing clinical evidence for the formal application of this product in China.

8.1.2. Trial Methodology and Justification

This trial is designed as a prospective, multi-center, single-arm, objective performance criteria clinical study.

1) Multi-center: Selecting over 20 clinical trial centers facilitates enrollment and healthy competition, allowing faster completion of enrollment targets. Moreover, as subject data collection from multi-center trials comes from different regions and centers, completed by different investigators, the conclusions are broadly representative.

2) Single-arm with Objective Performance Criteria (OPC): Endovascular aortic repair is currently a mature technique widely used in clinical practice. Given that medical device studies are often open-label and the product is visually distinguishable, blinding is not feasible. The patient populations for surgical and hybrid procedures are inconsistent with the study population; this study enrolls patients at high risk for surgery. As there is no domestically marketed multi-branch stent product for endovascular treatment of juxtarenal and pararenal AAA, a randomized controlled trial is not feasible. Currently, there is no standard pharmacotherapy for AAA, and the efficacy and safety of drug therapies in the investigational stage have not been confirmed [15]. A control group comparing the investigational device intervention with conservative medical therapy would present significant disparities in risk and benefit for subjects, making such a control ethically unacceptable. Therefore, the trial design adopts a single-arm OPC design. This involves pre-specifying clinically meaningful performance goals and evaluating the safety and efficacy of the investigational device in a single-arm trial without a concurrent control group. According to the "Guideline for Clinical Trials of Aortic Covered Stent Systems" (No. 8, 2019) [16], although branched aortic stent grafts involving renal artery branches are excluded from this specific guideline, this study simultaneously considers a primary safety endpoint and a primary efficacy endpoint. The two primary endpoints for evaluating the abdominal aortic stent graft system are the 30-day major adverse event (MAE)-free rate and the 12-month abdominal aortic aneurysm endovascular treatment success rate. The performance goal should be based on current sufficient, scientific,

and reasonable evidence from similar products, considering the development of technology in this product category, and should be forward-looking.

[redacted]Considering a 20% dropout rate, approximately 103 subjects are expected to be enrolled.

[redacted]

Considering a 20% dropout rate, approximately 100 subjects are expected to be enrolled.

8.1.3. Measures to Reduce/Avoid Bias

1) The clinical study will be conducted in accordance with the study protocol, relevant national regulations for medical device clinical trials, GCP principles, and the company's Standard Operating Procedures (SOPs).

2) The sponsor will provide training on the study protocol and the investigational device operation to investigators participating in the study, ensuring they fully understand the study procedures and device instructions.

3) The company will appoint qualified Clinical Research Associates (CRAs) to conduct regular visits and monitoring at study centers, ensuring quality control and maintaining monitoring records, and will promptly communicate issues identified during monitoring to the investigators.

4) Communicate patiently with subjects or their families to ensure compliance, encourage follow-up visits within the scheduled windows, and prevent missing data.

5) Ensure proper data management and organization. When data issues are identified, data analysts will use data query forms to verify and confirm the data, avoiding recording errors.

8.1.4. Investigational Medical Device

Device Name: WeFlow-JAAA Stent Graft System

Manufacturer: Hangzhou Endonom Medtech co. ltd

Product Specifications: See Section 6.2 of the protocol for details.

8.1.5. Subject Selection

8.1.5.1. Inclusion Criteria (All of the following criteria must be met for enrollment)

1) Age 18-80 years, regardless of gender;

2) Subjects who were diagnosed with Juxtarenal and Pararenal abdominal aortic aneurysms and needed to reconstruct the blood supply of superior mesenteric artery and bilateral renal arteries;

3) Have appropriate vascular conditions, mainly including:

- Distance from the upper edge of the aneurysm to the lower edge of the opening of SMA ≥ 4 mm;
- The angle between the proximal aneurysm neck and the aortic long axis near the opening of SMA ≤ 60°;
- The aortic diameter at the opening of SMA ranges from 18 to 34 mm
- The diameter range of the starting part of SMA is 5–12 mm
- The diameter range of the initial part of bilateral RAs is 4.5–10 mm
- Length of non-bifurcated segment of SMA and RA ≥ 10 mm
- The diameter at the bifurcation of abdominal aorta ≥ 16 mm
- The length of distal anchoring area of iliac artery ≥ 15 mm
- The diameter range of distal anchoring area of iliac artery is 8–24 mm
- Feasible iliofemoral artery and upper patent upper extremity access

4) Those who can understand the purpose of the trial, voluntarily participate in the study, sign the informed consent form by themselves or their legal representative, and are willing to complete the follow-up according to the protocol requirements.

8.1.5.2. Exclusion Criteria (Meeting any one of the following criteria excludes the subject)

1) Upper edge of renal artery origin higher than the lower edge of the opening of SMA;

2) Accessory renal artery diameter ≥ 3 mm, or supplying more than 1/3 of kidney tissue;

3) Hemodynamically unstable ruptured abdominal aortic aneurysm, pseudoaneurysm, or aortic dissection;

4) Infectious aortic disease, Takayasu arteritis, Marfan syndrome (or other connective tissue diseases);

5) Presence of severe stenosis, calcification, or mural thrombus in the proximal landing zone;

6) Need to intervene on other vascular lesions (e.g., coronary, carotid) in the same procedure, affecting postoperative medication regimen;

7) History of myocardial infarction, TIA, or cerebral infarction within the past 3 months;

8) History of previous abdominal aortic surgery or endovascular repair;

9) Pre-existing severe liver, kidney, lung, or heart dysfunction [subjects with serum creatinine > 150 umol/L; ALT or AST > 5 times the upper limit of normal; total bilirubin > 2 times the upper limit of normal; left ventricular ejection fraction < 50% on echocardiography];

10) Acute systemic infection;

11) Contraindications to antiplatelet or anticoagulant therapy;

12) Allergy to contrast media, anesthetic drugs, stent, or delivery system materials;

13) Inability to tolerate anesthesia;

14) Pregnant, breastfeeding, or women unable to practice contraception during the trial period;

15) Life expectancy less than 12 months (e.g., advanced malignancy);

16) Concurrent participation in another drug or device clinical trial;

17) Investigator judges that the subject's vascular conditions affect branch artery revascularization or other concomitant diseases make them unsuitable for this study.

8.1.5.3. Dropout Criteria

All subjects who sign the informed consent form and are deemed eligible for enrollment in this clinical trial, regardless of when or why they withdraw from the study (except those who reach the primary endpoint), are considered dropouts.

1) Subject voluntarily withdraws from the trial for various reasons;

2) Due to adverse events, especially serious adverse events, the Ethics Committee terminates the study based on ethical considerations;

3) The investigator determines that the subject must be terminated from the study for medical reasons;

4) Serious violation of the trial protocol;

5) Subject lost to follow-up due to changes in work, living environment, or accidents. However, if an accident occurs (e.g., traffic accident, death, fracture), follow-up should be conducted

promptly to determine causality with the investigational device;

6) Incomplete or absent informed consent process;

7) Other reasons necessitating termination of the study.

Note: If a subject drops out, the investigator should make every effort to contact the subject using various methods to ascertain the reason. If the dropout is due to an adverse event, and follow-up ultimately determines a causal relationship with the investigational device, this must be recorded in the eCRF and reported to the sponsor. All enrolled subjects who have started the study, regardless of dropout status, must have all source data and documents retained for analysis (i.e., archived), as required for Intention-to-Treat (ITT) analysis.

8.1.5.4. Criteria and Procedures for Terminating the Trial

Study termination refers to the premature cessation of the entire clinical study before completing the protocol. Except for condition (5), the sponsor and investigators will jointly decide whether to terminate the trial.

1) If serious safety issues occur during the clinical study, the trial should be terminated promptly.

2) If significant errors are found in the protocol during the study, or if serious deviations occur during protocol implementation that make it difficult to evaluate the product's efficacy, the trial should be terminated.

3) If the product shows poor or ineffective results during the study, lacking clinical value, the trial should be terminated.

4) The sponsor requests termination of the trial.

5) The National Medical Products Administration (NMPA) orders termination of the trial for specific reasons.

Premature termination of the trial must receive written consent from the principal investigator and the sponsor. All trial materials must be retained for reference.

8.1.5.5. Enrollment Time

Subjects can be enrolled once the informed consent form has been obtained, the subject meets all inclusion criteria, and does not meet any exclusion criteria.

8.1.5.6. Expected Overall Duration of the Clinical Trial and Justification

This clinical study is expected to involve over 20 research centers. Based on the patient volume at each center, the complexity of the inclusion/exclusion criteria, and the difficulty of obtaining informed consent, the enrollment period is estimated to be 30 months. Each subject will be

followed for 60 months. The first subject is expected to be enrolled in March 2022, and the last subject is expected to be enrolled in December 2023. The final follow-up for the last subject is expected to be completed around December 2028.

8.1.5.7. Expected Duration of Participation for Each Subject

From screening and surgery to the end of post-operative follow-up, each subject is expected to participate for 60 to 62 months.

8.1.5.8. Number of Subjects Required for the Clinical Trial

This study plans to have 82 evaluable cases. Considering a 20% dropout rate and to facilitate subject allocation across centers, the total planned enrollment is 106 cases.

8.1.6. Primary Endpoints

8.1.6.1. Primary Safety Endpoint

Rate of no major adverse events occurred within 30 days after operation

Evaluation Time: Before discharge, 30 days after operation

The main adverse events within 30 days after operation refer to all-cause death, myocardial infarction, renal failure, respiratory failure, ischemic stroke, intestinal necrosis, severe ischemia or necrosis of lower limbs and paraplegia within 30 days after operation. Among them, renal failure leads to lasting dialysis, renal transplantation or other fatal results. Respiratory failure leads to significantly prolonged intubation time, tracheotomy, deterioration of pulmonary function or other fatal results. Intestinal necrosis refers to intestinal ischemia that requires intestinal resection or leads to other fatal results. Severe ischemia of lower limbs refers to new severe claudication or resting pain after operation.

8.1.6.2. Primary Efficacy Endpoint

The success rate of treatment of abdominal aortic aneurysm 12 months after operation

Evaluation Time: Intraoperative, 12 months after operation

Evaluation Method: The 12-month abdominal aortic aneurysm treatment success rate is a composite endpoint, including immediate technical success after operation and, at the 12-month after operation CT scan, an increase in the maximum diameter of the abdominal aortic aneurysm ≤ 5 mm compared to pre-surgery, absence of Type I or Type III endoleak, no stent migration, branch stent patency, and no secondary intervention during the follow-up period.

Definitions: Immediate technical success after operation means the delivery system of the aortic and branch covered stents is successfully delivered to the predetermined position, the stents are

accurately positioned and successfully deployed, the delivery system is safely withdrawn, and after operation angiography shows no Type I or Type III endoleak, with branch stents patent. Type I endoleak: Endoleak caused by failure of the covered stent to closely adhere to the native vessel, including proximal (Type Ia) and distal (Type Ib) interfaces. Type III endoleak: Endoleak caused by failure of close connection between the branch stent and the abdominal aortic stent interface or rupture of the stent graft. Secondary intervention refers to open or endovascular re-intervention required for the subject due to complications or adverse events related to the surgery and device, such as: aortic rupture, branch vessel occlusion, lower limb artery occlusion, persistent Type I or Type III endoleak requiring intervention. Stent migration is defined as displacement of the aortic and branch covered stents by > 10 mm compared to before discharge at follow-up time points.

8.1.7. Secondary Endpoints

8.1.7.1. Secondary Safety Endpoints

All-cause mortality rate, abdominal aortic aneurysm-related mortality rate, serious adverse event rate, device-related adverse event rate.

1) Rate of all cause mortality

Evaluation Time: Before discharge, Day 30, Month 6, Month 12, Months 24-60 after operation

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

2) Rate of abdominal aortic aneurysm related mortality

Evaluation Time: Before discharge, Day 30, Month 6, Month 12, Months 24-60 after operation

Evaluation Method: Abdominal aortic aneurysm-related death refers to death caused by aneurysm rupture or related to the aortic aneurysm treatment surgery.

3) Incidence of serious adverse events

Evaluation Time: Before discharge, Day 30, Month 6, Month 12, Months 24-60 after operation

Evaluation Method: Serious adverse events are events occurring during the clinical trial that lead to death or serious deterioration in health, 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

Evaluation Time: Before discharge, Day 30, Month 6, Month 12, Months 24-60 after operation

Evaluation Method: Device-related adverse events are adverse medical events occurring during

the clinical trial that are related to the use of the device. Distinction should be made from normal postoperative stress responses, such as fever, chest/back discomfort, etc. If judged by the investigator as a normal postoperative stress response, it does not need to be recorded as an adverse event. Device-related adverse events recorded refer to those judged by the investigator as definitely related, probably related, or with an unknown relationship to the investigational device.

8.1.7.2. Secondary Efficacy Endpoints

Incidence of Type I or III endoleak, incidence of covered stent migration, branch vessel patency rate, incidence of conversion to open surgery or secondary intervention.

1) Incidence of Type I or III endoleak

Evaluation Time: Intraoperative, before discharge, Month 6, Month 12

Evaluation Method: Record endoleak shown by after operation DSA, CTA, or other imaging. Endoleaks occurring intraoperatively that are treated are not recorded. For endoleaks occurring after surgery completion, if they appear in the same subject at different follow-up stages without treatment, they are counted once.

2) Incidence of aortic covered stent migration

Evaluation Time: Month 6, Month 12 after operation

Evaluation Method: Observe and record whether stent migration has occurred on CTA at 6 and 12 months after operation. Both the main body stent and branch stents are evaluated. Migration is defined as displacement of the aortic and branch covered stents by > 10 mm compared to before discharge at follow-up time points.

3) Patency rate of postoperative branches

Evaluation Time: Before discharge, Month 6, Month 12

Evaluation Method: Observe and record CTA before discharge, at 6 months, and 12 months to evaluate the revascularization status of the renal arteries and superior mesenteric artery branch vessels, assessing for occlusion, stenosis, or in-stent thrombosis. After operation branch vessel stenosis ≤ 50% is considered patent.

4) Incidence of conversion to open surgery or secondary interventional surgery for abdominal aortic aneurysm

Evaluation Time: Before discharge, Month 6, Month 12, Months 24-60

Evaluation Method: Evaluate whether the subject required conversion to open surgery or

secondary intervention due to the abdominal aortic aneurysm.

8.1.8. Standardization of Subject Screening and Enrollment Review Committee

A Clinical Expert Review Committee will be established for this clinical trial. Each trial center must strictly adhere to the screening criteria when selecting subjects. Investigators must clearly document the medical reasons for their conclusions. Additionally, the risks for these patients should be identified and approved by the Expert Review Committee.

8.1.9. Imaging Examinations

Imaging examinations, including echocardiography, angiography, and CT angiography, should use unified measurement methods, such as for measuring angles, data to be collected, and reporting formats. CT examination is required to provide information on vascular anatomy and potential lesions. For trial evaluation, a qualified independent third-party core laboratory will be selected to assess the imaging data.

8.2. Trial Procedures

1) Sign the informed consent form;

2) Subject Screening: Screen subjects according to inclusion and exclusion criteria;

3) Subject Enrollment;

4) Selection of Investigational Product: The investigator determines the required product specifications for the subject; the sponsor provides them free of charge;

5) Perform Surgery: The surgery is performed by the investigator;

6) Post-operative Follow-up: The investigator conducts clinical follow-ups before discharge, at 30 days, 6 months, 12 months, 24 months, 36 months, 48 months, and 60 months. CTA follow-up is required before discharge, at 6 months, 12 months, 24 months, 36 months, 48 months, and 60 months. The sponsor covers the cost of CTA examinations;

7) Data Analysis and Summary: The sponsor collects all relevant data and commissions a third-party organization for data evaluation, management, statistical analysis, and summary.

8.2.1. Trial Flowchart

Procedure Screening Surgery Follow-up

Trial Procedure	**Screening Period**	Intraoperatively	**Follow-Up**					
Visit	V1	V2	V3	V4	V5	V6	V7-10	Unschedul

Days	-15~0d	0	Discharge	30 ± 7 days after surgery	6 months ± 30 days after surgery	12 months ± 30 days after surgery	24-60 months±30d days after surgery	ed Visit
Signing of Informed Consent Form	X							
Inclusion/Exclusion Criteria	X							
Medical History/ Demographic data	X							
Pregnancy Test	X							
Physical Examination	X	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							
Chest X-ray	X							
CTA*	X		X		X	X	X	
DSA		X						
Surgical Records		X						
Medication Records**	X	X	X	X	X	X	X	X
Adverse Event Records	X	X	X	X	X	X	X	X
Phone follow-up ***				X				

Notes:

- Pregnancy Test: Performed during screening for women of childbearing age; also performed if pregnancy is suspected during the trial.

- Physical Examination: Heart rate, respiration, blood pressure, body temperature, upper and lower limb pulses.

- Blood Routine: Red blood cells, white blood cells, platelet count, hemoglobin.

- Urinalysis: pH, leukocytes, erythrocytes, protein.

- Liver/Kidney Function: Creatinine (Cr), Alanine Aminotransferase (ALT), Aspartate Aminotransferase (AST), Total Bilirubin (TBIL), Direct Bilirubin (DBIL).

- Coagulation Function: Activated Partial Thromboplastin Time (APTT), Prothrombin Time (PT), International Normalized Ratio (INR), Fibrinogen (FIB), Thrombin Time (TT), D-Dimer.

- Concomitant medications and medical history collect data from within 3 months prior to subject's informed consent.

- Screening CTA measurements require verification and approval by the lead institution before enrollment.

- Before Discharge (Visit 3): Refers to a visit on any day between surgery and discharge; the final laboratory results before discharge are collected.

- Collect CTA data preoperatively, before discharge, at 6 M±30d post-op, and 12 M±30d post-op. During follow-up, if the investigator assesses any condition making CTA unsuitable for a subject, a CT plain scan plus abdominal ultrasound may be substituted at the investigator's discretion.

- Collect medication records preoperatively, intraoperatively, before discharge, at 30d±7d, 6 M±30d, and 12 M±30d post-op, and adverse event records post-consent, intraoperatively, before discharge, at 30d±7d, 6 M±30d, and 12 M±30d post-op.

- If available, laboratory data from within 7 days before enrollment (prior to signing ICF), CTA data from within 6 months before enrollment, and ultrasound, 12-lead ECG, chest X-ray, or CT chest plain scan data from within 30 days before enrollment may be used as baseline assessment data without repeating.

- Post-operative antiplatelet therapy should follow medical advice.

- Phone follow-up at 30d±7d post-op to record adverse events and related medications, focusing on MAE events from discharge to 30d±7d. Long-term follow-up visits at 24, 36, 48, and 60 months (±30d) require recording adverse events and related medications, as well as CTA outpatient follow-up (follow-up at other hospitals is acceptable for special reasons).

- Medication Recording: Record only medications related to the treatment of medical history, adverse events, and cardiovascular/cerebrovascular diseases. Other health supplements and solvents (e.g., normal saline, glucose injection) are not recorded.

8.2.2. Visit Plan

1) Visit 1: Screening Period (-15~0d)

For ethical considerations, interventional examinations performed before signing the ICF can be used as trial data: CTA within 6 months, other imaging data within 1 month, and laboratory results within 7 days can be used without requiring the patient to repeat the examination.

During this visit, after full explanation, the subject is required to sign the ICF. Baseline data and baseline examinations are collected. Based on the results, the subject is screened according to inclusion/exclusion criteria. Eligible subjects are enrolled and registered, and the investigator

selects an appropriate surgery time. Ineligible subjects end the trial. Specific items collected are:

• Demographic information: age, gender, height, weight

• Physical examination: heart rate, respiration, blood pressure, body temperature, upper/lower limb pulses

• Family history, medical history: including surgical history, concomitant diseases, concomitant medications, and treatments

• Routine laboratory tests:

  o Blood routine: RBC, WBC, platelet count, hemoglobin

  o Urinalysis: pH, leukocytes, erythrocytes, protein

  o Liver/kidney function: Cr, ALT, AST, TBIL, DBIL

  o Coagulation function: APTT, PT, INR, FIB, TT, D-Dimer

• Pregnancy test (for female subjects of childbearing potential)

• 12-lead ECG

• CTA angiography

• Chest X-ray or CT chest plain scan

• Echocardiography

• Concomitant medications

• Adverse events

2) Visit 2: Day of Surgery (Day 0)

This is an intraoperative visit, recording the surgical procedure. Specific items collected are:

• Physical examination

• DSA imaging data

• Surgery-related records (selected stent model/specification, access route, intervention time [from sheath insertion to removal], deployment status, immediate success, etc.)

• Concomitant medications

• Adverse events

• Device deficiencies

3) Visit 3: Before Discharge

• Physical examination

• Blood routine: RBC, WBC, platelet count, hemoglobin

• Urinalysis: pH, leukocytes, erythrocytes, protein

• Liver/kidney function: Cr, ALT, AST, TBIL, DBIL

• Coagulation function: APTT, PT, INR, FIB, TT, D-Dimer

• 12-lead ECG

• CTA angiography / Abdominal ultrasound + CT plain scan

• Concomitant medications

• Adverse events

• Device deficiencies

4) Visit 4: (Day 30 ± 7 days After operation)

This is a post-discharge phone follow-up, collecting the following information from the subject:

• Concomitant medications

• Adverse events

• Device deficiencies

5) Visit 5: (Month 6 ± 30 days After operation)

This is a post-discharge follow-up, collecting the following information from the subject:

• CTA angiography / Abdominal ultrasound + CT plain scan

• Concomitant medications

• Adverse events

• Device deficiencies

6) Visit 6: (Month 12 ± 30 days After operation)

This is a post-discharge follow-up, collecting the following information from the subject:

• CTA angiography / Abdominal ultrasound + CT plain scan

• Concomitant medications

• Adverse events

• Device deficiencies

7) Visits 7, 8, 9, 10: (Months 24 ~ 60 ± 30 days After operation, one visit every 12 months)

These are post-discharge follow-ups, collecting the following information from the subject:

• CTA angiography / Abdominal ultrasound + CT plain scan

• Adverse events and related medications

8.3. Device Usage Specifications

The sponsor, after obtaining ethics committee approval, is responsible for providing the investigational medical device to the clinical trial institutions and investigators, and for determining its transport conditions, storage conditions, storage duration, expiry date, etc.

The investigational medical device must be of acceptable quality, with easily identifiable, correctly coded, and "For Investigational Use" labeling, and must be appropriately packaged and stored according to the clinical trial protocol.

The sponsor is responsible for the safety of the investigational medical device during the clinical trial. If issues that may affect subject safety or trial implementation, potentially altering the ethics committee's approval for continuation, are discovered, the sponsor must immediately notify all clinical trial institutions and investigators and take appropriate action.

8.4. Monitoring Plan

According to the requirements of the "Medical Device Clinical Trial Quality Management Practices," the sponsor will select qualified monitors to perform monitoring duties at all participating institutions. The number of monitors and the frequency of monitoring will be determined based on the specific visit requirements of the trial and confirmed with the monitors. Specific responsibilities include:

1) Before the trial, confirm that the clinical trial institution has adequate conditions, including appropriately trained personnel, adequate and functioning laboratory equipment, an expected sufficient number of subjects, and that participating researchers are familiar with the trial requirements.

2) Monitor whether the clinical trial institution and investigators comply with relevant regulations, the "Medical Device Clinical Trial Quality Management Practices," and the clinical

trial protocol before, during, and after the trial.

3) Confirm that each subject signed the ICF before participating in the clinical trial, understand subject enrollment status and trial progress; clearly and accurately document any missed follow-ups, tests not performed, or examinations not completed by the investigator, and any corrections made to errors or omissions; confirm that subjects affected by revised ICFs who have not yet completed the trial process have re-signed.

4) Confirm that all CRFs are correctly completed and consistent with source data; all errors or omissions are corrected or noted, signed and dated by the investigator; confirm and record the disease type, total cases, gender, age, treatment outcomes, etc., for each trial case.

5) Confirm that subjects who withdraw from the clinical trial or do not comply with ICF requirements are documented and discussed with the investigator.

6) Confirm that all adverse events, complications, and other device deficiencies are documented, and that serious adverse events and device deficiencies that could lead to serious adverse events are reported within the specified timeframe and documented.

7) Monitor the supply, use, maintenance, transport, receipt, storage, distribution, handling, and return of the investigational device.

8) Supervise the regular maintenance and calibration of relevant equipment during the clinical trial.

9) Ensure that investigators receive the most current versions of all clinical trial-related documents.

10) Provide a written report to the sponsor after each monitoring visit, including the monitor's name, monitoring date, time, location, content, investigator's name, project completion status, existing problems, conclusions, and corrections made for errors or omissions.

9. Statistical Considerations

9.1. Statistical Design, Methods, and Analysis Procedures

9.1.1. Statistical Design

The statistical design for this clinical trial is a prospective, multi-center, single-arm, objective performance criteria (OPC) design to evaluate the safety and efficacy of the investigational device.

9.1.2. Statistical Methods and Analysis Procedures

a) General Principles

The analysis in this study is primarily descriptive. Quantitative variables will be described by calculating the mean, standard deviation, median, minimum, maximum, lower quartile (Q1), and upper quartile (Q3). Categorical variables will be described by the count and percentage of each category.

b) Completion and Demographic Analysis

Summarize enrollment and completion numbers by center. List dropouts and provide a detailed list of reasons for non-completion. Describe patient demographics (age, gender, etc.), relevant medical history, and treatment. Demographic analysis will be based on the Full Analysis Set (FAS).

c) Primary Endpoint Analysis

Primary Safety Endpoint: 30-day Major Adverse Event (MAE)-Free Rate. Hypothesis:

> Null Hypothesis: H~0~: $P1 \leq P0$;

> Alternative Hypothesis: H~1~: $P1 > P0$.

> $\alpha = 0.025$ (one-sided)

The 30-day MAE-free rate will be described statistically, and its two-sided 95% confidence interval (CI) will be estimated. The upper limit of the 95% CI will be compared with the performance goal (OPC) to draw statistical conclusions. If the upper limit of the 95% CI is greater than the performance goal P0, the primary endpoint meets the trial requirements, and the investigational device can be considered to meet the requirements for clinical application.

Primary Efficacy Endpoint: 12-month Abdominal Aortic Aneurysm Treatment Success Rate. Hypothesis:

> Null Hypothesis: H0: $\mu 2 \leq \mu 0$;

> Alternative Hypothesis: H1: $\mu 2 > \mu 0$.

> $\alpha = 0.025$ (one-sided)

The 12-month AAA treatment success rate will be described statistically, and its two-sided 95% CI will be estimated. The upper limit of the 95% CI will be compared with the performance goal (OPC) to draw statistical conclusions. If the upper limit of the 95% CI is greater than the performance goal $\mu 0$, the primary endpoint meets the trial requirements, and the investigational device can be considered to meet the requirements for clinical application.

d) Secondary Endpoint Analysis

Secondary Safety Endpoints: All-cause mortality rate, AAA-related mortality rate, serious adverse event rate, device-related adverse event rate.

All-cause mortality rate, AAA-related mortality rate: Survival rates and their 95% CIs will be estimated using the Kaplan-Meier method, and Kaplan-Meier curves will be plotted.

Serious adverse event rate, device-related adverse event rate: Descriptive analysis of the indicator data.

Descriptive statistical analysis of changes in laboratory test indicators before and after the trial will be performed. All adverse events occurring during the trial will be documented, and descriptive statistical analysis of adverse events will be performed along with a listing.

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

Secondary Efficacy Endpoints: Incidence of Type I or III endoleak, incidence of covered stent migration, branch vessel patency rate, incidence of conversion to open surgery or secondary intervention.

Secondary efficacy endpoints will be described statistically, calculating frequencies and percentages.

Secondary efficacy endpoints will be analyzed using both the FAS and Per Protocol Set (PPS).

9.2. Sample Size Calculation

9.2.1. Total Sample Size

This trial has two primary endpoints, and the overall power needs to reach 80%. Therefore, the Type II error rate for each endpoint must be adjusted. Assuming these endpoints are completely independent, a conservative estimate is $\beta = 0.20/2$ to achieve the overall power requirement. Taking the significance level $\alpha = 0.025$ (one-sided) and power $1-\beta = 0.90$, the sample sizes calculated for the 12-month AAA treatment success rate and the 30-day MAE-free rate are 82 and 80 cases, respectively. Considering a 20% dropout rate, at least 103 patients need to be enrolled. To facilitate allocation across centers, the planned enrollment is 106 cases. The sample

size formula is as follows:

$$n = \frac{\left[Z_{1-\alpha/2}\sqrt{P_0(1-P_0)} + Z_{1-\beta}\sqrt{P_T(1-P_T)}\right]^2}{(P_T - P_0)^2}$$

Where: PT is the expected rate for the investigational device, P0 is the performance goal.

9.2.2. Number of Cases per Disease Type and Justification

This study does not involve multiple disease types, so only the total number of clinical trial cases is specified.

9.2.3. Minimum and Maximum Number of Subjects per Clinical Trial Institution in a Multi-center Trial and Justification

This trial will be conducted at over 20 clinical trial institutions simultaneously. In principle, enrollment will be distributed as evenly as possible across centers to ensure adequate representativeness. However, considering feasibility and enrollment timelines, the enrollment numbers may be adjusted based on actual conditions. The goal is to maintain a relatively balanced enrollment across sites, ensuring that no single center's final enrollment exceeds 50% of the total cases.

9.3. Significance Level and Power of the Clinical Trial

$\alpha = 0.025$ (one-sided), $1-\beta = 0.90$

9.4. Expected Dropout Rate

The expected dropout rate for this trial is no more than 20%.

9.5. Criteria for Success/Failure of Clinical Trial Results

If the lower limits of the 95% confidence intervals for both primary endpoints are higher than the pre-specified performance goals, the study results are considered successful.

9.6. Criteria and Justification for Terminating the Trial Based on Statistical Reasons

As this clinical trial does not include interim analyses, it will not be terminated early for statistical reasons.

9.7. Statistical Methods for All Data, Including Handling of Missing, Unused, or Erroneous Data (Including Withdrawals and Dropouts) and Unreasonable Data

A Statistical Analysis Plan (SAP) will be developed before the trial starts. After the database is locked, statistical analysis will be performed according to the SAP, and a statistical analysis

report will be generated.

(1) Handling of Missing Values: Missing data will be handled according to the specific analysis set definition. For primary efficacy data, the Worst Observation Carried Forward (WOCF) method will be used for imputation.

(2) Handling of Unreasonable Data: During data management, logical checks will be performed on the database. Unreasonable data will be addressed by issuing queries to the investigator. Adjustments will be made based on the investigator's written responses until all unreasonable data are resolved before database lock.

(3) Handling of Erroneous Data: During data management, quality checks will be performed on the database. Erroneous data will be addressed by issuing queries to the investigator. Corrections will be made based on the investigator's written responses until all erroneous data are corrected before database lock.

9.8. Procedures for Reporting Deviations from the Original Statistical Plan

If changes to the protocol necessitate changes to the original statistical analysis plan, consensus must be reached among the sponsor, investigators, data management/statistical analysis team, ethics committee, etc., and the changes must strictly follow clinical trial operational procedures. Changes should not be made lightly.

9.9. Criteria and Justification for Selecting Subjects for Inclusion in the Analysis

Statistical analysis will be based on the following analysis populations. The analysis populations will be clearly defined before statistical analysis begins. The analysis populations in this study include:

1. Full Analysis Set (FAS): The set of subjects as close as possible to the intention-to-treat (ITT) principle. This dataset is derived from all enrolled subjects after minimal and reasonable exclusions, including all subjects who were enrolled and used the investigational device at least once. The FAS will be used for evaluating primary and secondary endpoints.

2. Per Protocol Set (PPS): A subset of subjects who complied with the protocol, had good compliance, completed the protocol-specified treatment, and had no missing primary efficacy data. The PPS will be used for evaluating primary and secondary endpoints.

3. Safety Set (SS): All enrolled subjects who used the investigational device and had safety evaluations. The SS will be used for safety endpoint analysis.

10. Data Management

10.1. Data Management System

The data collection/management system for this project is an Electronic Data Capture (EDC) system. This system has undergone system validation and has audit trail and user permission management functions.

10.2. eCRF Design

The Data Manager designs the eCRF according to the protocol. The eCRF includes all data points specified in the protocol except for external data. The eCRF (PDF format) will be exported directly from the EDC system.

10.3. Data Management Plan

The Data Manager will develop a Data Management Plan (DMP) based on the final protocol and project requirements. The DMP will be finalized after discussion with all parties involved in the clinical trial.

10.4. Data Verification Plan

The Data Manager will develop a Data Verification Plan (DVP) based on the clinical trial protocol and eCRF. The DVP will be finalized after discussion with all parties involved in the clinical trial.

10.5. Electronic Database Construction and Testing

The Database Builder constructs the database, including configuring logical check rules, system function settings, etc. The Data Manager will manage permissions based on user roles. Database testing includes data entry, export, logical checks, eCRF interface, and system functionality testing.

10.6. Database Training and Go-Live

Before the project database goes live, the Data Manager will provide training to relevant personnel. Training content includes: system operation skills and/or project-specific requirements. The specific training content will be determined based on the roles and past experience of the personnel. Database Go-Live: After the database passes testing and other preparatory work is completed, the database will go live upon confirmation by the sponsor.

10.7. Data Verification

Data verification is jointly conducted by data management personnel and medical personnel according to the DVP. For issues identified during verification, queries are issued as needed.

The investigator or authorized CRC responds to the queries. After confirmation by the query issuer, the query is closed. If issues remain, new queries are issued until resolved.

10.8. Medical Coding

Medical terms in the clinical trial data need to be standardized before statistical analysis. Medical coding may be performed manually or via a system, using standard medical coding dictionaries commonly used in clinical trials. Data that do not meet the dictionary requirements or have questions will be clarified with the clinical investigator via data queries. Medical coding may include: medical history, concomitant medications, and adverse events. Specific requirements for coding will be defined in the Data Management Plan.

10.9. External Data Management

If the clinical trial involves external data, the Data Manager will pre-specify an External Data Management Plan to define the process for managing external data throughout the clinical trial.

10.10. Data Backup

The system automatically backs up daily to a data management cloud server. The database administrator will perform manual periodic backups to a backup cloud server.

10.11. Data Review

Data generated during the clinical trial may violate the clinical trial protocol. A clinical data review at the overall trial level is required. Issues identified during the data review can be addressed by appropriate actions, such as protocol amendments or subject data exclusion.

10.12. Database Lock

At the end of the study, after completing the review of the database lock checklist, the database will be locked upon approval by the principal investigator, sponsor, statistician, data manager, monitor, and other relevant personnel. If data errors are found after database lock, the principal investigator, sponsor, statistician, data manager, and other relevant personnel will jointly assess the potential impact of these data errors on safety and efficacy analyses. If the impact is significant, they will jointly sign to unlock the database for data correction. If the impact is not significant, the errors will be documented in the statistical analysis report and clinical study report.

10.13. Data Management Report

The Data Manager will prepare a Data Management Report summarizing the data management execution process, operational specifications, and management quality.

11. Feasibility Analysis

11.1. Analysis of Likelihood of Success

The manufacturing of the investigational device complies with the requirements of a medical device quality management system. The investigational device has undergone analysis and evaluation of physical, chemical, biological properties, and risks. The analysis results demonstrate the feasibility and safety of the product, and all risks are within acceptable limits. The clinical benefits outweigh the risks of use, potentially improving patient health and quality of life.

Animal experiments have been conducted with this investigational product, yielding complete experimental data with no adverse events. The animal experiment results indicate the product is safe and effective. Please refer to the animal experiment study report.

11.2. Analysis of Likelihood of Failure

- Occurrence of serious adverse events leading to excessive subject withdrawals;

- Labeling information failing to adequately guide operators;

- Excessive loss to follow-up.

However, these factors are generally controllable. Measures such as training to improve operator proficiency and skills, and the development of a comprehensive protocol tailored to the specificities of this study by investigators, can mitigate these risks.

Furthermore, as the clinical institutions involved in this trial possess complete equipment and technical resources, and the principal investigators have excellent clinical experience, the likelihood of trial failure is low.

12. Quality Control of the Clinical Trial

To ensure the accuracy and completeness of data in the eCRF, the sponsor or its designated monitor(s) will conduct regular monitoring visits to the research centers. During these monitoring visits, data submitted by the center will be compared with source data. The investigator's compliance with relevant regulations and the study guide will also be assessed.

Investigators must ensure that medical records are completely and properly preserved. Study documents should be available for inspection by the sponsor and/or regulatory authorities. Investigators must confirm that the rights and welfare of subjects are protected, and that the study adheres to GCP guidelines and the trial protocol.

13. Ethical Issues and Informed Consent in the Clinical Trial

13.1. Ethical Considerations

This clinical trial adheres to the principles of the Declaration of Helsinki and relevant national regulations. The study meets the requirements of ISO 14155 (Clinical investigation of medical devices for human subjects - Good clinical practice), GCP, and EU Medical Device Regulation (MDR).

Investigators are responsible for providing the clinical trial protocol, informed consent form, and information to be provided to subjects to the Ethics Committee to obtain independent approval for conducting the trial. Ethics Committee approval must be obtained before the clinical trial begins. The Ethics Committee approval must be provided in writing to the investigator, who will then provide a copy to the sponsor. The Ethics Committee approval document must include a list of all committee members who participated in the approval discussion and their respective affiliations.

During the clinical study, any issues related to clinical study safety, such as changes to the protocol or subject ICF, as well as serious adverse events occurring during the study, must be promptly reported to the Ethics Committee. The conclusion or early termination of the clinical study must also be reported to the Ethics Committee.

13.2. Approval of the Trial Protocol

Before the clinical study begins, the investigator must submit the clinical study protocol, ICF, and other relevant documents to the Medical Ethics Committee of the institution leading the clinical study. The clinical study can only begin after obtaining Ethics Committee approval. Any modifications to the study protocol must be approved by the Ethics Committee before implementation. Serious adverse events occurring during the clinical study must be promptly reported in writing to the Ethics Committee.

13.3. Informed Consent Process

The investigator is responsible for explaining the purpose, methods, benefits, and potential risks of the clinical trial to each subject and for obtaining the subject's signed ICF. The subject's ICF must be obtained before any clinical trial-related procedures begin. For subjects unable to sign the ICF themselves for any reason, a legal guardian or witness must sign the ICF. By signing the ICF, the subject also authorizes clinical study monitors/auditors/health investigation organizations to verify the original data obtained regarding the clinical study to ensure data reliability.

14. Provisions for Reporting Adverse Events and Device Deficiencies

14.1. Adverse Events

An adverse event is any untoward medical event occurring during the clinical trial, regrdless of whether it is related to the investigational medical device.

Any pre-existing condition recorded as part of the physical examination or ongoing illness is not considered an adverse event unless its nature, severity, or frequency changes.

A. Classification of Adverse Event Severity

• Mild: Does not affect daily activities.

• Moderate: Affects daily activities.

• Severe: Unable to perform daily activities.

B. Assessment of Relationship between Adverse Event and Investigational Product/Surgery

The investigator should assess the relationship between the adverse event and the investigational product/surgery using the following classification:

• Definitely Related: The reaction is consistent with the known reaction pattern of the product or surgery.

• Probably Related: The reaction is consistent with the known reaction pattern of the product or surgery; the patient's clinical status or treatment could reasonably have produced the reaction.

• Possibly Related: The reaction is consistent with the known reaction pattern of the product or surgery; the patient's clinical status or other treatments could also have produced the reaction.

• Possibly Unrelated: The reaction is not entirely consistent with the known reaction pattern of the product or surgery; the patient's clinical status or other treatments could have produced the reaction.

• Unrelated: The reaction is not consistent with the known reaction pattern of the product or surgery; the patient's clinical status or other treatments could have produced the reaction; the reaction resolves with improvement of the disease state or cessation of other treatments, and reappears with re-use of other treatments.

• Unknown: Insufficient or conflicting information to determine causality.

14.2. Serious Adverse Events

A serious adverse event is any untoward medical event that:

- Results in death; or

- Leads to serious deterioration in the subject's health, resulting in:

  - A life-threatening illness or injury; or

  - Permanent impairment of a body structure or body function; or

  - Hospitalization or prolongation of existing hospitalization; or

  - Medical or surgical intervention to prevent permanent impairment of body structure or body function; or

- Leads to fetal distress, fetal death, congenital abnormality, or birth defect.

Hospitalizations planned due to pre-existing conditions or surgeries specified in the clinical study protocol that do not result in serious deterioration of health are not considered serious adverse events.

14.3. Device Deficiencies

A device deficiency is any unreasonable risk of harm to human health and safety that exists during the clinical trial under normal use of the medical device, such as labeling errors, quality issues, malfunctions, etc.

14.4. Reporting Procedures

14.4.1. Adverse Events

Adverse event information will be collected throughout the study. The investigator will record and monitor all adverse events in the eCRF until resolution or stabilization.

14.4.2. Serious Adverse Events

The investigator must promptly report safety information during the medical device clinical trial:

(i) When a serious adverse event occurs during the medical device clinical trial, the investigator must immediately take appropriate treatment measures for the subject. Additionally, within 24 hours of becoming aware of the serious adverse event, the investigator must report it to the sponsor, the medical device clinical trial institution management department, and the Ethics Committee; and follow up on the serious adverse event according to the clinical trial protocol, submitting follow-up reports.

(ii) If it is discovered that the risks of the medical device clinical trial outweigh the potential benefits, requiring suspension or termination of the clinical trial, the principal investigator must report this to the sponsor, the medical device clinical trial institution management department, and the Ethics Committee, promptly notify the subjects, and ensure they receive appropriate

treatment and follow-up.

The sponsor is responsible for evaluating and reporting safety information during the medical device trial:

(i) Within 7 days of becoming aware of a death or life-threatening medical device-related serious adverse event, and within 15 days of becoming aware of a non-death or non-life-threatening medical device-related serious adverse event or other serious safety risk information, the sponsor must report to other medical device clinical trial institutions, Ethics Committees, and principal investigators involved in the trial. Reports must also be made to the provincial-level drug regulatory authority where the sponsor is located, as well as to the provincial-level drug regulatory and health administrative authorities where the medical device clinical trial institution is located. Risk control measures must be taken. If information arises that may affect subject safety, the implementation of the medical device clinical trial, or change the Ethics Committee's approval opinion, the sponsor must promptly organize modifications to the clinical trial protocol, ICF, other information provided to subjects, and other related documents, and submit them to the Ethics Committee for review.

(ii) If a large-scale medical device-related serious adverse event or other major safety issue occurs, the sponsor must suspend or terminate the medical device clinical trial, report to all medical device clinical trial institution management departments, Ethics Committees, and principal investigators, and report to the provincial-level drug regulatory authority where the sponsor is located, as well as to the provincial-level drug regulatory and health administrative authorities where all medical device clinical trial institutions are located.

14.4.3. Potential Adverse Events

Allergy, fever, arterial/venous thrombosis, arterial injury, arterial perforation, arteriovenous fistula, pseudoaneurysm, bleeding/hematoma, ischemic intestinal necrosis, respiratory failure, heart failure/myocardial infarction, renal insufficiency/failure, stroke, spinal cord ischemia, severe lower limb ischemia, wound syndrome, air embolism, conversion to open surgery, death, device complications, including: incorrect deployment position, stent migration, stent fracture, endoleak, graft rupture.

14.4.4. Device Deficiencies

If a device deficiency occurs during the trial, the investigator must document the deficiency found during the clinical trial, analyze the cause with the sponsor, prepare a written analysis report, and propose an opinion on whether to continue, suspend, or terminate the trial. This report must be submitted to the Ethics Committee via the medical device clinical trial institution management department.

For device deficiencies that could lead to serious adverse events, the sponsor must report to the filed food and drug administration department and the same-level health and family planning authority within 5 working days of becoming aware. Simultaneously, the sponsor must notify other clinical trial institutions and investigators involved in the trial, and promptly notify the Ethics Committee of the institution via its medical device clinical trial institution management department.

15. Provisions for Protocol Deviations and Amendments

15.1. Protocol Deviation

A protocol deviation is non-compliance with the protocol requirements, resulting in data that is unusable or cannot be obtained.

Protocol deviations include, but are not limited to:

- Procedures not performed within the allowed follow-up window

- Required data not obtained

- Follow-up procedures performed at an unapproved center

15.2. Protocol Violation

A protocol violation is non-compliance with protocol requirements and/or regulatory guidelines. Protocol violations are considered likely to 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

- Violation of subject inclusion/exclusion criteria

- Non-compliance with protocol requirements that affects the main purpose of the study design

In some cases, compliance issues may arise during the informed consent process. The investigator should seek guidance from the research center's Ethics Committee to ensure subjects receive appropriate information to consider participation. The investigator is obligated to take any measures deemed necessary by the EC, including subject withdrawal. Deviations in the consent process for subjects that the EC deems able to continue participation will be considered protocol violations.

All protocol deviations and violations must be reported to the appropriate EC. If necessary, protocol violations will be reported to the medical device clinical trial institution management

department in progress reports, and the investigator must promptly notify the sponsor and report to the Ethics Committee.

15.3. Provisions for Clinical Trial Protocol Amendments

The medical device clinical study protocol should be designed jointly by the responsible clinical study institution and the sponsor, prioritizing the protection of subject rights, safety, and health. It must be approved by the Ethics Committee before implementation. If, during the study, the investigator needs to modify the clinical study protocol, ICF, or CRF, approval from the Ethics Committee must be obtained before the clinical study can continue.

16. Direct Access to Source Data and Documents

All clinical results, observations, and other activities throughout the clinical study must be documented and preserved in each enrolled subject's medical record, either as originals or certified copies. The medical record (source document) must contain corresponding source data for data recorded in the eCRF.

The medical record (source document) must include, but is not limited to, the following information:

- Date of informed consent

- Subject's participation in the clinical study

- Demographic characteristics

- Dated discharge summary

- Medical/surgical history records and prior medications

- Vessel and lesion dimensions and characteristics

- Description of device operation (all materials, intraoperative medications, dates, times, etc.)

- All adverse events: diagnosis and symptoms, start and end dates, severity, actions taken, outcome

- Concomitant medications

- Clinical study results or date of withdrawal

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

- Serious adverse event reports

Clinical trial institutions must retain clinical trial data for 10 years after the trial concludes. Sponsors must retain clinical trial data until the medical device is no longer in use.

17. Financial and Insurance Information

The research funding for this study is provided by Hangzhou Endonom Medtech co. ltd For specific costs and details, please refer to the Clinical Study Agreement.

To protect subject rights and safety, the sponsor will purchase human clinical trial liability insurance for subjects participating in this study. For specific content and terms, please refer to the Insurance Policy.

18. Content of the Clinical Trial Report

Upon completion of the clinical trial, the clinical trial institution(s) must prepare a clinical trial report in accordance with the format specified in the medical device clinical trial protocol. The clinical trial report must include the name and specifications of the device, main content of the clinical protocol, list of participating centers, statistical analysis populations, documentation and handling of adverse events during the clinical study, analysis of clinical trial results, product indications, contraindications, precautions, clinical trial conclusions, and opinions from the investigator and clinical institution clinical trial management department.

19. Confidentiality Principles

All personal information of subjects is considered private. Access to this information is permitted only for relevant research personnel, the sponsor (Hangzhou Endonom Medtech co. ltd), members of the Ethics Committee, and relevant national/local drug regulatory authorities. The investigator and sponsor must maintain the confidentiality of subject personal information.

20. Agreement on Publication of Trial Results

The sponsor and investigator(s) agree on the final study report.

Hangzhou Endonom Medtech co. ltd has the right to include the report of this clinical study in any registration documents, registration applications, or any prepared medical professional information materials.

Before the overall results of the multi-center clinical study are published, data from individual centers may not be published separately. All research papers must be reviewed by Hangzhou Endonom Medtech co. ltd before submission.

All information related to the investigational device (e.g., patent applications, previously undisclosed manufacturing processes, basic scientific data provided by the sponsor to investigators) is considered confidential and owned by the sponsor. Investigators may not use it for other purposes without the sponsor's written permission.

21. Responsibilities of Each Party

21.1. Sponsor Responsibilities

1) Design and develop the medical device clinical trial protocol together with the investigator(s), and sign the mutually agreed protocol and contract.

2) Provide qualified investigational products to the medical institution free of charge.

3) Provide relevant training to medical device clinical trial personnel before the trial begins.

4) Bear the costs associated with the trial, including subject examination fees, compensation for trial-related injury treatment, and remuneration for the trial unit.

5) In the event of a serious adverse event, report according to section 14.4.2.

6) If the sponsor terminates the medical device clinical trial, they must notify the medical institution, the Ethics Committee, and the NMPA that accepted the medical device registration application, stating the reasons.

7) If the investigational product causes harm to a subject, the sponsor must compensate the subject according to the medical device clinical trial contract.

21.2. Responsibilities of Investigators Conducting the Clinical Trial

1) Must be familiar with the information provided by the sponsor and the use of the investigational product.

2) Design and develop the clinical trial protocol together with the sponsor, and sign the protocol and contract.

3) Truthfully explain details of the investigational product to subjects. Before starting the clinical trial, subjects must be given sufficient time to consider participation.

4) Accurately record side effects and adverse events of the investigational product and analyze the causes. In the event of a serious adverse event, the investigator must make a prompt clinical judgment, take measures to protect subject interests, immediately report to the Ethics Committee and sponsor, complete the "Serious Adverse Event Report Form," and report according to section 14.4.2.

5) If the clinical trial is terminated, the investigator must notify the subjects, sponsor, Ethics Committee, and the NMPA that accepted the medical device registration application, stating the reasons.

6) Prepare the clinical trial report and be responsible for its correctness and reliability.

7) Have an obligation to maintain confidentiality regarding information provided by the sponsor.

Other responsibilities of each party are detailed in the Clinical Trial Agreement.

22. 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)

23. References

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