Informed consent (learning curve)

Protocal name A Prospective, Multicenter, Open, Randomized Controlled, Non Inferiority Clinical Trial to Evaluate the Safety and Efficacy the Branch-based Intraoperative Stent System in the Treatment of Stanford A Aortic Dissection

Experiment with medical device Branch type of stent system

Model Specification Full specification

The sponsor Permed Biomedical Engineering Co., Ltd

Version number V1.1(zhongshan hospital affiliated to fudan university special edition) August 10, 2022

The clinical test units Zhongshan hospital affiliated to fudan university

The principal investigator Professor chunsheng wang

Dear Sir/madam:

we are looking for you to attend a medical instrument clinical trial, the following describes the experiment in medical tests of the background, purpose, method, test process to give you the benefits and possible risks or inconvenience as well as the rights and interests of you, please be sure to read carefully before taking the clinical trials.The informed consent form for your information can help you decide whether to participate in the clinical trials, if you have any questions please ask responsible for researchers in this test, to ensure that you fully understand the content.Whether you will take part in this test is voluntary, if agreed to participate in the clinical trials, please sign in the statement of informed consent.

一、 Study background:

Aortic dissection (AD), a critically ill cardiovascular disease that seriously threatens the life health of people in a country, is due to aortic intima and media tear from various causes, separation of the intima from the media, and blood inflow occur such that the aortic lumen is divided into true and false lumens. The most widely used types of ad internationally are DeBakey typing and Stanford typing. DeBakey classification classified ad into types I, II, and III based on the location of the primary breach in AD and the extent of dissection involvement; Stanford classification based on the extent of dissection involvement, types A and B were classified. Stanford type A for those with dissection involving the ascending aorta, corresponding to DeBakey types I and II; The dissection involved only the descending thoracic aorta and its distal end was Stanford type B, which corresponds to DeBakey type III. The results of the international registry of acute ad (IRAD) show that Stanford type a ad accounts for 60% - 70%. Results from the Chinese ad Registry (Sino - RAD) showed that Stanford type a ad accounted for approximately 40% of cases in China.

The incidence of ad is about 3.5/100000 person years, according to which it is speculated that new cases are around 50000 cases every year in our country.

In recent years, the incidence of aortic dissection has shown an increasing trend and a tendency toward younger age. Stanford type A aortic dissection is the most insidious aortic disease, with a case fatality rate of approximately 1% per hour within 2 days of onset and up to 74% within 2 weeks in patients treated nonsurgically.

Stanford type a ad, once diagnosed, should in principle all be treated aggressively surgically. For aortic root involvement

Of the Stanford type A AD, aortic root reconstruction modalities mainly have ascending aortic replacement and aortic root replacement with preservation of the aortic sinus. Aortic root replacement, in turn, includes a composite aortic root replacement (such as the Bentall procedure) and a valve sparing aortic root replacement (such as the David procedure). Simple type lesions were treated with ascending aortic replacement plus partial aortic arch replacement; Complex type lesions were treated with total aortic arch replacement plus stent pictorial surgery (i.e., sun's procedure).Sun surgery has become the standard operative procedure for

Stanford type a ad, and the surgical mortality rate has decreased to less than 5%, the postoperative false lumen closure rate has improved from the past 18% - 40% to more than 95%, and the reoperation rate has decreased from 30% to less than 10%. Hybrid surgery is an important strategy for the treatment of acute Stanford type a ad involving the arch, which combines the advantages of open surgery and endoluminal repair to manage aortic root and arch lesions in the same period.

For the surgical treatment of Stanford type A dissection, its device design history can be roughly divided into four stages:

①Four branch artificial vessels for total arch replacement: an early proposed surgical treatment option for type A dissection with deep hypothermic circulatory arrest Ring conditions, a four branch artificial vessel was used to replace the patient's aortopathy vessel. ② Full arch placement Replace + elephant nose stent: a modified four branch artificial vessel procedure, namely " sun's operation ", proposed by Prof. Lizhong sun in China,The operation is under deep hypothermic circulatory arrest conditions, a straight tube type stent is implanted in the descending aorta, and the four branch artificial vessels replace the aortic arch and the upper three branch vessels of the arch, and the operation time is shortened, intraoperative brain protection is enhanced, and the probability of postoperative complications is reduced.③ Three branched scaffolds: this protocol employs a scaffold with three branches.Of stent products to treat type A dissections, also under deep hypothermic circulatory arrest conditions, stents with three branched stents are implanted into the aortic vessel, a protocol that as a whole simplifies the procedure, reduces anastomoses, and shortens the procedure time. ④ Fotus stent: this scheme employs a stent with a single branch to treat type A dissection and partial type B dissection, which has recently been marketed, and the clinical effects need to be known after a certain number of clinical applications.

A branched type intraoperative stent system developed by Permed Biomedical Engineering Co., Ltd. and mainly used for Surgical management of Stanford type A aortic dissection. Its surgical conditions, the aorta is incised, the stent is sent to the location of the lesion by a transporter, and the stent insulates high-pressure blood flow from the lesion area, eliminating the injury of blood flow pressure to the lesion area, thus achieving therapeutic purposes.

A retrospective study in China showed that a long operation time and long cardiopulmonary bypass time were associated with acute Stanford type A

Independent risk factors for operative mortality in AD patients. A branched type intraoperative stent system stent developed by Beijing Puhui Biomedical Engineering Co., Ltd. can be used intraoperatively and reduce the intraoperative anastomosis time of the left subclavian artery and left common carotid artery, which in theory can reduce the operation time and cardiopulmonary bypass time and provide convenience

for the operation. The product has been preliminarily validated for safety and efficacy by pre - liminary animal testing. This registered clinical trial, aimed to evaluate the safety and efficacy of the branched type intraoperative stent system stent for use in humans, to provide the basis for the final formal marketing and application of this product in China.

Clinical research of this project is the national multicenter study, is composed of three phase test, the first stage for the branch type structure of the branch of learning curve for clinical trials supporting system, the second stage for double branch of the structure of the branch in randomized controlled clinical trials supporting system, the third stage for single branch of the structure of the branch of a single set of supporting system in the test bed.

When a new product or new technology emerges, the learning curve is an inevitable process. The learning curve was set in the study protocol, mainly aimed to provide physicians with the difficult points and key steps to master the new product / new technology, and physicians had some experience before the new product / new technology could make effective contrast with the control group, otherwise the unfavorable bias introduced by the initial stage of the study would affect the efficacy evaluation of the new product / new technology.

The stage of the trial you are participating in is the double branched structure learning curve clinical trial, this center is one of the patients take the stage study.

二、 The test name and purpose

Study Name: evaluation of the safety of branched type intraoperative stent systems for the treatment of Stanford type A aortic dissection Efficacy and effectiveness prospective, multicentre, open label, randomised controlled non inferiority clinical trial.

Purpose of study: To evaluate the safety and efficacy of a branched type intraoperative stent system for the treatment of Stanford type A aortic dissection.

三、 Test method and content

This study is a prospective, multicenter, open, randomized design to add a single set of design.In you after signing of the informed consent, if you comply with all the inclusion criteria and do not meet any exclusion standard will be included in this study, the article use the Permed Biomedical Engineering Co., Ltd production of the structure of the branch type of support system for processing.

四、The research process and deadline

Your participation in this study will take ~ 60 months. Patients were included if they were screened preoperatively, underwent surgery intraoperatively, and were followed up at discharge or 30 days ± 7 days, 6 months ± 30 days, 12 months ± 30 days, and 2-5 years ± 30 days after surgery.

If you are participating in this study you will need to complete the following

items:

Preoperative screening: if you are willing to participate in this study, after signing an informed consent form, the investigator performed the study in accordance with the Inclusion / exclusion criteria for screening. During this time you need to cooperate to complete: as in routine medical examination section: medical history taking Set (history of allergy, infection, multiple organ failure, surgery, previous medication, etc.); Vital signs (body Temperature, blood pressure, heart rate); Laboratory tests (blood routine - take blood volume about 2ml, coagulation function - take blood volume about 3ml Blood Biochemistry - blood volume is taken to be about 4 ml), pregnancy test (receiving blood or urine pregnancy test results, suitable for non physiological periods And non menopausal women, in whom blood sampling for pregnancy was approximately 3 ml), imaging (CT angiography), Other drug combination, record.If you have done before signing the informed related inspection, and the doctor check is available, not repetitive checks to you.

Undergoing surgery intraoperatively: if you meet all the inclusion criteria and do not meet any of the exclusion criteria, You will be treated with a branched type intraoperative scaffolding system with a double branched structure produced by Beijing Permed Biomedical Engineering Co., Ltd. The operation time was projected to be 5 h, the aorta was incised intraoperatively, the stent was sent to the location of the lesion via a transporter, and the stent isolated the high pressure blood flow from the lesion area, eliminating the blood flow pressure injury to the lesion area, thus achieving the purpose of treatment. Also observe your medication and for adverse events and device defects.

Discharge or 30 ± 7 days after surgery: your condition will be closely observed by the relevant doctor, according to the requirements of the protocol, during which time you need to cooperate to complete: vital signs examination, laboratory tests (blood routine - take blood volume about 2ml, blood biochemical - take blood volume about 4ml), and record your adverse events, concomitant medication and instrument defects.

6 months ± 30 days postoperatively: as required by the protocol, during which time you need to cooperate to complete: imaging (CT Angiography), and to document your adverse events, concomitant medications and device defects.

12 months ± 30 days postoperatively: as required by protocol, during this time you need to cooperate to complete: lab tests(blood routine - take blood volume about 2ml, coagulation function - take blood volume about 3ml, Blood Biochemistry - take blood volume about 4ml),Imaging (CT angiography), as well as documenting your adverse events, concomitant medications and device defects.

2-5 years ± 30 days postoperatively: as required by the protocol, during which time you need to cooperate to complete: imaging (CT Angiography or X-ray), and to document your adverse events, concomitant medications and device defects.

The blood sample collection, will be in accordance with the requirements of hospital clinical laboratory test in time, the remaining volume will be carried out in accordance with the hospital to seek medical treatment.The above image collection to save a disc in the corresponding departments, until the end of the test to bed in the

save ten years after the destruction of test institutions.

If you participate in this study, you will need to:

- Provide accurate past medical history and current condition information.
- tell researchers about any health problems you have experienced during the study.
- tell investigators about any blood pressure control, heart rhythm control medications you take during the study and any occurrences of bad Event related medication.
- visit on request.
- do not participate in other medical research.
- follow the instruction of researchers.
- there are any unclear places you can ask at any time.

五、The test of funding sources and possible conflicts of interest

Financial support for this study was provided by Beijing Permed Biomedical Engineering Co., Ltd (the sponsor). Investigators

The examination project expenses and the medical devices for the test required by the case were provided by Beijing Permed Biomedical Engineering Co., Ltd.

The objective of the principal investigator and other team personnel with no bidders on the product research and open hair have other financial relations;Bidders also have no other research projects to give financial support to researchers or compensation;The researchers did not hold shares or other equity bidders.

六、The possible benefit

If you agree to participate in this study, your Stanford type A aortic dissection may improve or recover or may not achieve the effects of treatment you intended. Meanwhile, the investigator will provide diagnosis and treatment guidance in a timely manner after the surgery to allow you, throughout the treatment, to receive effective assistance and adequate counseling from the investigator. The data and information you have obtained from participating in this study will facilitate the approval of this medical device for marketing, potentially leading to new treatment options for patients with more homogeneous diseases.

七、The potential risk and discomfort

Your doctor will monitor adverse events during the study period.If you have any not suitable during the study period, or any unexpected happens, you should immediately report to the doctor, will provide you with effective treatment and processing.

Possible risks in this trial include anastomotic bleeding, internal leak, renal failure, hepatic insufficiency, Acute respiratory insufficiency, neurological complications, cerebral complications, gastrointestinal syndrome, spinal cord injury complications, limb paralysis, infection, arteriovenous thrombosis, arterial injury, perforation, arterial dissection formation, vascular fistula or pseudoaneurysm

formation, death, and other unpredictable adverse events. Possible risks with the test device itself include adverse events such as endoleak, thrombus, or vascular rupture due to a mismatch in the morphologic specification of the stent or rupture of the stent membrane. The above adverse events may occur in all procedures of intraoperative stent therapy for Stanford type A aortic dissection, but we will still reduce the incidence of the above adverse events by strict factory inspection of the product, strict follow of the clinical trial protocol during the process of the clinical trial, careful assessment before operation, normative operation during operation, and close monitoring after operation.

Branch type of supporting system for the embryo, fetus or nursing infants at risk not related to the clinical research evidence.If you have been pregnancy or planned pregnancy during the study, in order to ensure that you and embryo, the safety of the tire, breast-feeding infant, you will not be allowed to take part in the clinical research.

The hospital is staffed with excellent health care workers who, after an adverse event, come to timely and appropriate care and can effective in reducing the impact of adverse events.

八、With the test related injury treatment and economic compensation

The study physicians and sponsor will try their best to prevent possible harm due to this study. If you are during the study Injury, whether related or not related to the study, please contact your study doctor at the first time. The doctor will take active measures to you for your treatment, minimizing the extent and time that the injury will occur. If you occur with clinical testing A priori, the related damage or death, the sponsor will cover the costs of the treatment and the correspondin Economic compensation, except for damage caused by the fault of medical institutions and their medical staff in the diagnostic and diagnostic activities.

The sponsor has purchased insurance for this clinical trial if you experience damage related to the clinical trial or death, insurance cover will cover the corresponding portion of the sponsor.

九、May be assigned to the group

The first stage for you to attend this test (double branch of the structure of the branch learning curve type of support system of clinical tests), so you will use the Beijing Permed double branch of biomedical engineering co., LTD., the production of the structure of the branch type of support system for processing.By clinical experienced doctors to provide you with the diagnosis and treatment, and pay close attention to your therapeutic effect.

十、The expenses during the test

During the trial you will be free to use double branch of bidders production type structure of the branch of support system.surgery costs need you to pay.

The costs of the examination items required by the study protocol, including: blood routine, coagulation tests, were all covered by the sponsor.Check up, blood biochemistry test, pregnancy test, CT angiography or X-ray. (if you have completed

the relevant exams required for the clinical study prior to signing the informed consent form for your routine clinic and have it assessed by your doctor that the exams are available for the screening phase and are not subject to repeat testing, this portion of the testing fee is at your own expense and no longer reimbursed). Investigator will take a thoughtful treatment plan for you and pay more attention during the course of the study, to complete 6 months± 30 days, 12 months±30 days, 2-5 years ± 30 days after surgery after follow-up visit, you will be at the completion of each follow-up visit,Received a transportation grant of 300 RMB, totalling 1800 RMB. This traffic grant will be on the date each time you complete the appropriate follow-up visit,Paid to you by cash; Special cases may remit by bank transfer to the silver of you or your family. In the current account (transfer is expected to be complete within 2 months). There is no remuneration other than this.

十一、Alternative diagnosis and treatment methods of this test is:

You can choose not to participate in the objective of the test, the conventional treatment for you will not bring any bad effects, the present for your health, you can also select listed the same kind of equipment or conservative treatment, your clinical doctor will discuss with you the main risk and benefit of these treatments related.

十二、Medical records confidential manner

You participate in this clinical trial of personal data is confidential, but medical instrument clinical trial institution management, ethics committee, the pharmaceutical supervisory and administrative departments, administrative departments of health or arbitrator, the inspectors in accordance with the relevant provisions when the job is need to program can refer to the personal data you to participate in this clinical trial.At any time, you can ask refer to your personal information (such as your name and address), can modify this information if necessary.

Your medical information to integrate information and others together, all information will be coded, will contain your name or any other can directly reflect your identity information.Encoded information to send in electronic form to bidders (Permed biomedical engineering co., LTD.), as evidence of this product safety and efficacy data.During the research, we may find that your new medical information, if it's important for your health, I will inform you immediately.We would advise you to do some check to make sure the new information.You can refer to any medical information about yourself.

When you signed the informed consent, on behalf of you agree to your personal and medical information is used in the description above.

十三、Voluntary participation, withdrawal from the trial:

You to participate in this study is completely voluntary, hope you can stick to this study.Before you attend study decision, please as soon as possible to your doctor about problem, until you to fully understand the study.You can exit this study at any

time without any reasons, not discrimination or revenge, you and will not lead to any medical treatment and the rights and interests of the affected.

If you decide to quit this study, in order to ensure the safety of your study doctor may ask you to accept some end research program.

If you need other diagnosis/treatment, or you do not comply with the test plan, or any other reasonable the original cause, the doctors can terminate your continue to participate in this test.

You may at any time to understand information related to this test and research progress, if you have any questions related to this test, or your any discomfort and injuries occurred in the process of test, or have questions about this test participants on the surface of the rights and interests of parties you can with your researchers (the researchers name: phone:).

As the research subjects of rights issues or you have questions about this study, concerns or dissatisfaction, you can contact: 021-31587871 contact in our hospital ethics committee (phone:).

In addition to signing the informed consent of the present study, you still need to sign and other operation with the consent of the surgery and other conventional medical documents.

Thank you for carefully reading the above materials. If you decided to take part in this study, please sign "informed consent", you will get a has signed and dated copy of this informed consent form.

Informed consent signed page

【Participants statement】

I have carefully read the informed consent form, I have the opportunity to ask and all questions have been answered.I understand the cords and the study is voluntary, I can choose not to participate in the study, or at any time notify the researchers after exit without discrimination or revenge, and will not lead to any of my medical treatment and the rights and interests are affected.If I need other diagnosis/treatment, or I didn't obey the research program, or any other reasonable reasons, researchers can study in the end I continue to participate in this bed.I voluntarily agreed to participate in the clinical study, I will receive a signed copy of the "informed consent".

Subjects signature: date: year month day

Contact phone number 1: contact phone number 2:

Such as subjects with no capacity or with limited capacity reason can't sign the informed consent form, signed by the guardian.

Guardian signature: date: year month day

relations with subjects:

contact phone number 1: contact phone number 2:

The reason of subjects can't sign the informed consent:

☐Subjects of conscious obstacle problem

☐Subjects due to causes such as upper limb paralysis disabled or unable to write

☐Subjects were illiterate, or had been unable to write for various reasons

☐Other please describe:

Such as subjects or phase of care per capita has no ability to read or write, can ask witnesses familiar with the process, studies the doctor explained after informed consent, witness read the informed consent and oral knowledge content is consistent, by the participants or their prison guard verbally agreed to after, witness in the informed consent form signed and dated.

Witness signature: date: year month day

Contact phone number 1: contact phone number 2:

【The researchers declared】

I have accurately the content of the informed consent and inform the participants to answer questions from participants, the participants voluntarily join this clinical study.

The signature: date: year month day

contact phone number 1: contact phone number 2:

Informed consent (RCT)

Protocal name Controlled,A Prospective, Multicenter, Open, Randomized Non Inferiority Clinical Trial to Evaluate the Safety and Efficacy the Branch-based Intraoperative Stent System in the Treatment of Stanford A Aortic Dissection

Experiment with medical device Branch type of stent system

Model Specification Full specification

The sponsor Permed Biomedical Engineering Co., Ltd

Version number V1.1(zhongshan hospital affiliated to fudan university special edition) August 10, 2022

The clinical test units Zhongshan hospital affiliated to fudan university

The principal investigator Professor chunsheng wang

Dear Sir/madam:

we are looking for you to attend a medical instrument clinical trial, the following describes the experiment in medical tests of the background, purpose, method, test process to give you the benefits and possible risks or inconvenience as well as the rights and interests of you, please be sure to read carefully before taking the clinical trials.The informed consent form for your information can help you decide whether to participate in the clinical trials, if you have any questions please ask responsible for researchers in this test, to ensure that you fully understand the content.Whether you will take part in this test is voluntary, if agreed to participate in the clinical trials, please sign in the statement of informed consent.

一、 Study background:

Aortic dissection (AD), a critically ill cardiovascular disease that seriously threatens the life health of people in a country, is due to aortic intima and media tear from various causes, separation of the intima from the media, and blood inflow occur such that the aortic lumen is divided into true and false lumens. The most widely used types of ad internationally are DeBakey typing and Stanford typing. DeBakey classification classified ad into types I, II, and III based on the location of the primary breach in AD and the extent of dissection involvement; Stanford classification based on the extent of dissection involvement, types A and B were classified. Stanford type A for those with dissection involving the ascending aorta, corresponding to DeBakey types I and II; The dissection involved only the descending thoracic aorta and its distal end was Stanford type B, which corresponds to DeBakey type III. The results of the international registry of acute ad (IRAD) show that Stanford type a ad accounts for 60% - 70%. Results from the Chinese ad Registry (Sino - RAD) showed that Stanford type a ad accounted for approximately 40% of cases in China.

The incidence of ad is about 3.5/100000 person years, according to which it is speculated that new cases are around 50000 cases every year in our country.

In recent years, the incidence of aortic dissection has shown an increasing trend and a tendency toward younger age. Stanford type A aortic dissection is the most insidious aortic disease, with a case fatality rate of approximately 1% per hour within 2 days of onset and up to 74% within 2 weeks in patients treated nonsurgically.

Stanford type a ad, once diagnosed, should in principle all be treated aggressively surgically. For aortic root involvement

Of the Stanford type A AD, aortic root reconstruction modalities mainly have ascending aortic replacement and aortic root replacement with preservation of the aortic sinus. Aortic root replacement, in turn, includes a composite aortic root replacement (such as the Bentall procedure) and a valve sparing aortic root replacement (such as the David procedure). Simple type lesions were treated with ascending aortic replacement plus partial aortic arch replacement; Complex type lesions were treated with total aortic arch replacement plus stent pictorial surgery (i.e., sun's procedure).Sun surgery has become the standard operative procedure for

Stanford type a ad, and the surgical mortality rate has decreased to less than 5%, the postoperative false lumen closure rate has improved from the past 18% - 40% to more than 95%, and the reoperation rate has decreased from 30% to less than 10%. Hybrid surgery is an important strategy for the treatment of acute Stanford type a ad involving the arch, which combines the advantages of open surgery and endoluminal repair to manage aortic root and arch lesions in the same period.

For the surgical treatment of Stanford type A dissection, its device design history can be roughly divided into four stages:

①Four branch artificial vessels for total arch replacement: an early proposed surgical treatment option for type A dissection with deep hypothermic circulatory arrest Ring conditions, a four branch artificial vessel was used to replace the patient's aortopathy vessel. ② Full arch placement Replace + elephant nose stent: a modified four branch artificial vessel procedure, namely " sun's operation ", proposed by Prof. Lizhong sun in China,The operation is under deep hypothermic circulatory arrest conditions, a straight tube type stent is implanted in the descending aorta, and the four branch artificial vessels replace the aortic arch and the upper three branch vessels of the arch, and the operation time is shortened, intraoperative brain protection is enhanced, and the probability of postoperative complications is reduced.③ Three branched scaffolds: this protocol employs a scaffold with three branches.Of stent products to treat type A dissections, also under deep hypothermic circulatory arrest conditions, stents with three branched stents are implanted into the aortic vessel, a protocol that as a whole simplifies the procedure, reduces anastomoses, and shortens the procedure time. ④ Fotus stent: this scheme employs a stent with a single branch to treat type A dissection and partial type B dissection, which has recently been marketed, and the clinical effects need to be known after a certain number of clinical applications.

A branched type intraoperative stent system developed by Permed Biomedical Engineering Co., Ltd. and mainly used for Surgical management of Stanford type A aortic dissection. Its surgical conditions, the aorta is incised, the stent is sent to the location of the lesion by a transporter, and the stent insulates high-pressure blood flow from the lesion area, eliminating the injury of blood flow pressure to the lesion area, thus achieving therapeutic purposes.

A retrospective study in China showed that a long operation time and long cardiopulmonary bypass time were associated with acute Stanford type A

Independent risk factors for operative mortality in AD patients. A branched type intraoperative stent system stent developed by Beijing Puhui Biomedical Engineering Co., Ltd. can be used intraoperatively and reduce the intraoperative anastomosis time of the left subclavian artery and left common carotid artery, which in theory can reduce the operation time and cardiopulmonary bypass time and provide convenience

for the operation. The product has been preliminarily validated for safety and efficacy by pre - liminary animal testing. This registered clinical trial, aimed to evaluate the safety and efficacy of the branched type intraoperative stent system stent for use in humans, to provide the basis for the final formal marketing and application of this product in China.

Clinical research of this project is the national multicenter study, is composed of three phase test, the first stage for the branch type structure of the branch of learning curve for clinical trials supporting system, the second stage for double branch of the structure of the branch in randomized controlled clinical trials supporting system, the third stage for single branch of the structure of the branch of a single set of supporting system in the test bed.

This time, you will participate in the second phase of the randomized controlled clinical trial of the bifurcated intraoperative stent system,There are no less than 10 hospitals in China, including 212 subjects in the group.

二、 The test name and purpose

Study Name: evaluation of the safety of branched type intraoperative stent systems for the treatment of Stanford type A aortic dissection Efficacy and effectiveness prospective, multicentre, open label, randomised controlled non inferiority clinical trial.

Purpose of study: To evaluate the safety and efficacy of a branched type intraoperative stent system for the treatment of Stanford type A aortic dissection.

三、 Test method and content

This study is a prospective, multicenter, open, randomized design to add a single set of design.In you after signing of the informed consent, if you comply with all the inclusion criteria and do not meet any exclusion standard will be included in this study, according to the random results, they were assigned to the test group or the control group, and the test group used Beijing Permed intraoperative stent system with dual branch structure produced by Permed biomedical engineering co., LTD. was used for treatment, while the control group was treated with CRONUS® intraoperative stent system (listed) produced by Shanghai MicroPort Endovascular MedTech Co., Ltd.

四、The research process and deadline

Your participation in this study will take ~ 60 months. Patients were included if they were screened preoperatively, underwent surgery intraoperatively, and were followed up at discharge or 30 days ± 7 days, 6 months ± 30 days, 12 months ± 30 days, and 2-5 years ± 30 days after surgery.

If you are participating in this study you will need to complete the following items:

Preoperative screening: if you are willing to participate in this study, after signing an informed consent form, the investigator performed the study in accordance with the Inclusion / exclusion criteria for screening. During this time you need to

cooperate to complete: as in routine medical examination section: medical history taking Set (history of allergy, infection, multiple organ failure, surgery, previous medication, etc.); Vital signs (body Temperature, blood pressure, heart rate); Laboratory tests (blood routine - take blood volume about 2ml, coagulation function - take blood volume about 3ml Blood Biochemistry - blood volume is taken to be about 4 ml), pregnancy test (receiving blood or urine pregnancy test results, suitable for non physiological periods And non menopausal women, in whom blood sampling for pregnancy was approximately 3 ml), imaging (CT angiography), Other drug combination, record.If you have done before signing the informed related inspection, and the doctor check is available, not repetitive checks to you.

Undergoing surgery intraoperatively: if you meet all the inclusion criteria and do not meet any of the exclusion criteria, According to the random results, You will be assigned to the test group or the control group, and the test group used Beijing Permed intraoperative stent system with dual branch structure produced by Permed biomedical engineering co., LTD. was used for treatment, while the control group was treated with CRONUS® intraoperative stent system (listed) produced by Shanghai MicroPort Endovascular MedTech Co., Ltd.The operation time was projected to be 5 h, the aorta was incised intraoperatively, the stent was sent to the location of the lesion via a transporter, and the stent isolated the high pressure blood flow from the lesion area, eliminating the blood flow pressure injury to the lesion area, thus achieving the purpose of treatment. Also observe your medication and for adverse events and device defects.

Discharge or 30 ± 7 days after surgery: your condition will be closely observed by the relevant doctor, according to the requirements of the protocol, during which time you need to cooperate to complete: vital signs examination, laboratory tests (blood routine - take blood volume about 2ml, blood biochemical - take blood volume about 4ml), and record your adverse events, concomitant medication and instrument defects.

6 months ± 30 days postoperatively: as required by the protocol, during which time you need to cooperate to complete: imaging (CT Angiography), and to document your adverse events, concomitant medications and device defects.

12 months ± 30 days postoperatively: as required by protocol, during this time you need to cooperate to complete: lab tests(blood routine - take blood volume about 2ml, coagulation function - take blood volume about 3ml, Blood Biochemistry - take blood volume about 4ml),Imaging (CT angiography), as well as documenting your adverse events, concomitant medications and device defects.

2-5 years ± 30 days postoperatively: as required by the protocol, during which time you need to cooperate to complete: imaging (CT Angiography or X-ray), and to document your adverse events, concomitant medications and device defects.

The blood sample collection, will be in accordance with the requirements of hospital clinical laboratory test in time, the remaining volume will be carried out in accordance with the hospital to seek medical treatment.The above image collection to save a disc in the corresponding departments, until the end of the test to bed in the save ten years after the destruction of test institutions.

If you participate in this study, you will need to:

- Provide accurate past medical history and current condition information.
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五、The test of funding sources and possible conflicts of interest

Financial support for this study was provided by Beijing Permed Biomedical Engineering Co., Ltd (the sponsor). Investigators

The examination project expenses and the medical devices for the test required by the case were provided by Beijing Permed Biomedical Engineering Co., Ltd.

The objective of the principal investigator and other team personnel with no bidders on the product research and open hair have other financial relations;Bidders also have no other research projects to give financial support to researchers or compensation;The researchers did not hold shares or other equity bidders.

六、The possible benefit

If you agree to participate in this study, your Stanford type A aortic dissection may improve or recover or may not achieve the effects of treatment you intended. Meanwhile, the investigator will provide diagnosis and treatment guidance in a timely manner after the surgery to allow you, throughout the treatment, to receive effective assistance and adequate counseling from the investigator. The data and information you have obtained from participating in this study will facilitate the approval of this medical device for marketing, potentially leading to new treatment options for patients with more homogeneous diseases.

七、The potential risk and discomfort

Your doctor will monitor adverse events during the study period.If you have any not suitable during the study period, or any unexpected happens, you should immediately report to the doctor, will provide you with effective treatment and processing.

Possible risks in this trial include anastomotic bleeding, internal leak, renal failure, hepatic insufficiency, Acute respiratory insufficiency, neurological complications, cerebral complications, gastrointestinal syndrome, spinal cord injury complications, limb paralysis, infection, arteriovenous thrombosis, arterial injury, perforation, arterial dissection formation, vascular fistula or pseudoaneurysm formation, death, and other unpredictable adverse events. Possible risks with the test

device itself include adverse events such as endoleak, thrombus, or vascular rupture due to a mismatch in the morphologic specification of the stent or rupture of the stent membrane. The above adverse events may occur in all procedures of intraoperative stent therapy for Stanford type A aortic dissection, but we will still reduce the incidence of the above adverse events by strict factory inspection of the product, strict follow of the clinical trial protocol during the process of the clinical trial, careful assessment before operation, normative operation during operation, and close monitoring after operation.

Branch type of supporting system for the embryo, fetus or nursing infants at risk not related to the clinical research evidence.If you have been pregnancy or planned pregnancy during the study, in order to ensure that you and embryo, the safety of the tire, breast-feeding infant, you will not be allowed to take part in the clinical research.

The hospital is staffed with excellent health care workers who, after an adverse event, come to timely and appropriate care and can effective in reducing the impact of adverse events.

八、With the test related injury treatment and economic compensation

The study physicians and sponsor will try their best to prevent possible harm due to this study. If you are during the study Injury, whether related or not related to the study, please contact your study doctor at the first time. The doctor will take active measures to you for your treatment, minimizing the extent and time that the injury will occur. If you occur with clinical testing A priori, the related damage or death, the sponsor will cover the costs of the treatment and the correspondin Economic compensation, except for damage caused by the fault of medical institutions and their medical staff in the diagnostic and diagnostic activities.

The sponsor has purchased insurance for this clinical trial if you experience damage related to the clinical trial or death, insurance cover will cover the corresponding portion of the sponsor.

九、May be assigned to the group

Because you were enrolled in the second phase of this trial (a randomized controlled clinical trial of a branched intraoperative stent system with a double branched structure). Randomization was performed with the use of a central randomization system. Randomization is an experimental way to avoid trials being affected by human factors, as if a coin were to be cast in the same way it was possible for a coin to appear both face up and reverse up, and the probability of obtaining both the front and the reverse faces was the same. I.e., you have an equal chance of getting into the trial or control group and a 50% probability of being assigned to both the trial and control groups. When you will be enrolled in this clinical trial, the trial center investigators log into the randomization website for randomization, and the system displays your grouping arrangements immediately after randomization to determine which group you are doing based on the randomized results. You may be assigned to the test or control group, which was treated with a branched type intraoperative stent system with a double branched structure produced by Permed biomedical engineering

co., LTD and the control group, which was treated with a cronus® intraoperative stent system (listed) produced by Shanghai MicroPort Endovascular MedTech Co., Ltd.

十、The expenses during the test

During the trial period, you will use the test or control products provided by the sponsor free of charge. Surgery costs need you to pay.

The costs of the examination items required by the study protocol, including: blood routine, coagulation tests, were all covered by the sponsor.Check up, blood biochemistry test, pregnancy test, CT angiography or X-ray. (if you have completed the relevant exams required for the clinical study prior to signing the informed consent form for your routine clinic and have it assessed by your doctor that the exams are available for the screening phase and are not subject to repeat testing, this portion of the testing fee is at your own expense and no longer reimbursed). Investigator will take a thoughtful treatment plan for you and pay more attention during the course of the study, to complete 6 months± 30 days, 12 months±30 days, 2-5 years ± 30 days after surgery after follow-up visit, you will be at the completion of each follow-up visit,Received a transportation grant of 300 RMB, totalling 1800 RMB. This traffic grant will be on the date each time you complete the appropriate follow-up visit,Paid to you by cash; Special cases may remit by bank transfer to the silver of you or your family. In the current account (transfer is expected to be complete within 2 months). There is no remuneration other than this.

十一、Alternative diagnosis and treatment methods of this test is:

You can choose not to participate in the objective of the test, the conventional treatment for you will not bring any bad effects, the present for your health, you can also select listed the same kind of equipment or conservative treatment, your clinical doctor will discuss with you the main risk and benefit of these treatments related.

十二、Medical records confidential manner

You participate in this clinical trial of personal data is confidential, but medical instrument clinical trial institution management, ethics committee, the pharmaceutical supervisory and administrative departments, administrative departments of health or arbitrator, the inspectors in accordance with the relevant provisions when the job is need to program can refer to the personal data you to participate in this clinical trial.At any time, you can ask refer to your personal information (such as your name and address), can modify this information if necessary.

Your medical information to integrate information and others together, all information will be coded, will contain your name or any other can directly reflect your identity information.Encoded information to send in electronic form to bidders (Permed biomedical engineering co., LTD.), as evidence of this product safety and efficacy data.During the research, we may find that your new medical information, if it's important for your health, I will inform you immediately.We would advise you to

do some check to make sure the new information.You can refer to any medical information about yourself.

When you signed the informed consent, on behalf of you agree to your personal and medical information is used in the description above.

十三、Voluntary participation, withdrawal from the trial:

You to participate in this study is completely voluntary, hope you can stick to this study.Before you attend study decision, please as soon as possible to your doctor about problem, until you to fully understand the study.You can exit this study at any time without any reasons, not discrimination or revenge, you and will not lead to any medical treatment and the rights and interests of the affected.

If you decide to quit this study, in order to ensure the safety of your study doctor may ask you to accept some end research program.

If you need other diagnosis/treatment, or you do not comply with the test plan, or any other reasonable the original cause, the doctors can terminate your continue to participate in this test.

You may at any time to understand information related to this test and research progress, if you have any questions related to this test, or your any discomfort and injuries occurred in the process of test, or have questions about this test participants on the surface of the rights and interests of parties you can with your researchers (the researchers name: phone:).

As the research subjects of rights issues or you have questions about this study, concerns or dissatisfaction, you can contact: 021-31587871 contact in our hospital ethics committee (phone:).

In addition to signing the informed consent of the present study, you still need to sign and other operation with the consent of the surgery and other conventional medical documents.

Thank you for carefully reading the above materials. If you decided to take part in this study, please sign "informed consent", you will get a has signed and dated copy of this informed consent form.

Informed consent signed page

【Participants statement】

I have carefully read the informed consent form, I have the opportunity to ask and all questions have been answered.I understand the cords and the study is voluntary, I can choose not to participate in the study, or at any time notify the researchers after exit without discrimination or revenge, and will not lead to any of my medical treatment and the rights and interests are affected.If I need other diagnosis/treatment, or I didn't obey the research program, or any other reasonable reasons, researchers can study in the end I continue to participate in this bed.I voluntarily agreed to participate in the clinical study, I will receive a signed copy of the "informed consent".

Subjects signature: date: year month day

Contact phone number 1: contact phone number 2:

Such as subjects with no capacity or with limited capacity reason can't sign the informed consent form, signed by the guardian.

Guardian signature: date: year month day

relations with subjects:

contact phone number 1: contact phone number 2:

The reason of subjects can't sign the informed consent:

☐Subjects of conscious obstacle problem

☐Subjects due to causes such as upper limb paralysis disabled or unable to write

☐Subjects were illiterate, or had been unable to write for various reasons

☐Other please describe:

Such as subjects or phase of care per capita has no ability to read or write, can ask witnesses familiar with the process, studies the doctor explained after informed consent, witness read the informed consent and oral knowledge content is consistent, by the participants or their prison guard verbally agreed to after, witness in the informed consent form signed and dated.

Witness signature: date: year month day

Contact phone number 1: contact phone number 2:

【The researchers declared】

I have accurately the content of the informed consent and inform the participants to answer questions from participants, the participants voluntarily join this clinical study.

The signature: date: year month day

contact phone number 1: contact phone number 2:

Informed consent (single-arm trial)

Protocal name Controlled,A Prospective, Multicenter, Open, Randomized Non Inferiority Clinical Trial to Evaluate the Safety and Efficacy the Branch-based Intraoperative Stent System in the Treatment of Stanford A Aortic Dissection

Experiment with medical device Branch type of stent system

Model Specification Full specification

The sponsor Permed Biomedical Engineering Co., Ltd

Version number V1.1(zhongshan hospital affiliated to fudan university special edition) August 10, 2022

The clinical test units Zhongshan hospital affiliated to fudan university

The principal investigator Professor chunsheng wang

Dear Sir/madam:

we are looking for you to attend a medical instrument clinical trial, the following describes the experiment in medical tests of the background, purpose, method, test process to give you the benefits and possible risks or inconvenience as well as the rights and interests of you, please be sure to read carefully before taking the clinical trials.The informed consent form for your information can help you decide whether to participate in the clinical trials, if you have any questions please ask responsible for researchers in this test, to ensure that you fully understand the content.Whether you will take part in this test is voluntary, if agreed to participate in the clinical trials, please sign in the statement of informed consent.

一、 Study background:

Aortic dissection (AD), a critically ill cardiovascular disease that seriously threatens the life health of people in a country, is due to aortic intima and media tear from various causes, separation of the intima from the media, and blood inflow occur such that the aortic lumen is divided into true and false lumens. The most widely used types of ad internationally are DeBakey typing and Stanford typing. DeBakey classification classified ad into types I, II, and III based on the location of the primary breach in AD and the extent of dissection involvement; Stanford classification based on the extent of dissection involvement, types A and B were classified. Stanford type A for those with dissection involving the ascending aorta, corresponding to DeBakey types I and II; The dissection involved only the descending thoracic aorta and its distal end was Stanford type B, which corresponds to DeBakey type III. The results of the international registry of acute ad (IRAD) show that Stanford type a ad accounts for 60% - 70%. Results from the Chinese ad Registry (Sino - RAD) showed that Stanford type a ad accounted for approximately 40% of cases in China.

The incidence of ad is about 3.5/100000 person years, according to which it is speculated that new cases are around 50000 cases every year in our country.

In recent years, the incidence of aortic dissection has shown an increasing trend and a tendency toward younger age. Stanford type A aortic dissection is the most insidious aortic disease, with a case fatality rate of approximately 1% per hour within 2 days of onset and up to 74% within 2 weeks in patients treated nonsurgically.

Stanford type a ad, once diagnosed, should in principle all be treated aggressively surgically. For aortic root involvement

Of the Stanford type A AD, aortic root reconstruction modalities mainly have ascending aortic replacement and aortic root replacement with preservation of the aortic sinus. Aortic root replacement, in turn, includes a composite aortic root replacement (such as the Bentall procedure) and a valve sparing aortic root replacement (such as the David procedure). Simple type lesions were treated with ascending aortic replacement plus partial aortic arch replacement; Complex type lesions were treated with total aortic arch replacement plus stent pictorial surgery (i.e., sun's procedure).Sun surgery has become the standard operative procedure for

Stanford type a ad, and the surgical mortality rate has decreased to less than 5%, the postoperative false lumen closure rate has improved from the past 18% - 40% to more than 95%, and the reoperation rate has decreased from 30% to less than 10%. Hybrid surgery is an important strategy for the treatment of acute Stanford type a ad involving the arch, which combines the advantages of open surgery and endoluminal repair to manage aortic root and arch lesions in the same period.

For the surgical treatment of Stanford type A dissection, its device design history can be roughly divided into four stages:

①Four branch artificial vessels for total arch replacement: an early proposed surgical treatment option for type A dissection with deep hypothermic circulatory arrest Ring conditions, a four branch artificial vessel was used to replace the patient's aortopathy vessel. ② Full arch placement Replace + elephant nose stent: a modified four branch artificial vessel procedure, namely " sun's operation ", proposed by Prof. Lizhong sun in China,The operation is under deep hypothermic circulatory arrest conditions, a straight tube type stent is implanted in the descending aorta, and the four branch artificial vessels replace the aortic arch and the upper three branch vessels of the arch, and the operation time is shortened, intraoperative brain protection is enhanced, and the probability of postoperative complications is reduced.③ Three branched scaffolds: this protocol employs a scaffold with three branches.Of stent products to treat type A dissections, also under deep hypothermic circulatory arrest conditions, stents with three branched stents are implanted into the aortic vessel, a protocol that as a whole simplifies the procedure, reduces anastomoses, and shortens the procedure time. ④ Fotus stent: this scheme employs a stent with a single branch to treat type A dissection and partial type B dissection, which has recently been marketed, and the clinical effects need to be known after a certain number of clinical applications.

A branched type intraoperative stent system developed by Permed Biomedical Engineering Co., Ltd. and mainly used for Surgical management of Stanford type A aortic dissection. Its surgical conditions, the aorta is incised, the stent is sent to the location of the lesion by a transporter, and the stent insulates high-pressure blood flow from the lesion area, eliminating the injury of blood flow pressure to the lesion area, thus achieving therapeutic purposes.

A retrospective study in China showed that a long operation time and long cardiopulmonary bypass time were associated with acute Stanford type A

Independent risk factors for operative mortality in AD patients. A branched type intraoperative stent system stent developed by Beijing Puhui Biomedical Engineering Co., Ltd. can be used intraoperatively and reduce the intraoperative anastomosis time of the left subclavian artery and left common carotid artery, which in theory can reduce the operation time and cardiopulmonary bypass time and provide convenience

for the operation. The product has been preliminarily validated for safety and efficacy by pre - liminary animal testing. This registered clinical trial, aimed to evaluate the safety and efficacy of the branched type intraoperative stent system stent for use in humans, to provide the basis for the final formal marketing and application of this product in China.

Clinical research of this project is the national multicenter study, is composed of three phase test, the first stage for the branch type structure of the branch of learning curve for clinical trials supporting system, the second stage for double branch of the structure of the branch in randomized controlled clinical trials supporting system, the third stage for single branch of the structure of the branch of a single set of supporting system in the test bed.

This time you participate in the phase III, single branch structure of branched type intraoperative stent system single group clinical trial, a total of 30 subjects were counted in the group.

二、 The test name and purpose

Study Name: evaluation of the safety of branched type intraoperative stent systems for the treatment of Stanford type A aortic dissection Efficacy and effectiveness prospective, multicentre, open label, randomised controlled non inferiority clinical trial.

Purpose of study: To evaluate the safety and efficacy of a branched type intraoperative stent system for the treatment of Stanford type A aortic dissection.

三、 Test method and content

This study is a prospective, multicenter, open, randomized design to add a single set of design.In you after signing of the informed consent, if you comply with all the inclusion criteria and do not meet any exclusion standard will be included in this study, A branched type intraoperative stent system with a single branched structure produced by Permed biomedical engineering co., LTD. was used for procedure.

四、The research process and deadline

Your participation in this study will take ~ 60 months. Patients were included if they were screened preoperatively, underwent surgery intraoperatively, and were followed up at discharge or 30 days ± 7 days, 6 months ± 30 days, 12 months ± 30 days, and 2-5 years ± 30 days after surgery.

If you are participating in this study you will need to complete the following items:

Preoperative screening: if you are willing to participate in this study, after signing an informed consent form, the investigator performed the study in accordance with the Inclusion / exclusion criteria for screening. During this time you need to cooperate to complete: as in routine medical examination section: medical history taking Set (history of allergy, infection, multiple organ failure, surgery, previous medication, etc.); Vital signs (body Temperature, blood pressure, heart rate);

Laboratory tests (blood routine - take blood volume about 2ml, coagulation function - take blood volume about 3ml Blood Biochemistry - blood volume is taken to be about 4 ml), pregnancy test (receiving blood or urine pregnancy test results, suitable for non physiological periods And non menopausal women, in whom blood sampling for pregnancy was approximately 3 ml), imaging (CT angiography), Other drug combination, record.If you have done before signing the informed related inspection, and the doctor check is available, not repetitive checks to you.

Undergoing surgery intraoperatively: if you meet all the inclusion criteria and do not meet any of the exclusion criteria, According to the random results, You will be processed using a branched type intraoperative scaffold system with a single branched structure produced by Permed biomedical engineering co., LTD. The operation time was projected to be 5 h, the aorta was incised intraoperatively, the stent was sent to the location of the lesion via a transporter, and the stent isolated the high pressure blood flow from the lesion area, eliminating the blood flow pressure injury to the lesion area, thus achieving the purpose of treatment. Also observe your medication and for adverse events and device defects.

Discharge or 30 ± 7 days after surgery: your condition will be closely observed by the relevant doctor, according to the requirements of the protocol, during which time you need to cooperate to complete: vital signs examination, laboratory tests (blood routine - take blood volume about 2ml, blood biochemical - take blood volume about 4ml), and record your adverse events, concomitant medication and instrument defects.

6 months ± 30 days postoperatively: as required by the protocol, during which time you need to cooperate to complete: imaging (CT Angiography), and to document your adverse events, concomitant medications and device defects.

12 months ± 30 days postoperatively: as required by protocol, during this time you need to cooperate to complete: lab tests(blood routine - take blood volume about 2ml, coagulation function - take blood volume about 3ml, Blood Biochemistry - take blood volume about 4ml),Imaging (CT angiography), as well as documenting your adverse events, concomitant medications and device defects.

2-5 years ± 30 days postoperatively: as required by the protocol, during which time you need to cooperate to complete: imaging (CT Angiography or X-ray), and to document your adverse events, concomitant medications and device defects.

The blood sample collection, will be in accordance with the requirements of hospital clinical laboratory test in time, the remaining volume will be carried out in accordance with the hospital to seek medical treatment.The above image collection to save a disc in the corresponding departments, until the end of the test to bed in the save ten years after the destruction of test institutions.

If you participate in this study, you will need to:

- Provide accurate past medical history and current condition information.
- tell researchers about any health problems you have experienced during the study.
- tell investigators about any blood pressure control, heart rhythm control

medications you take during the study and any occurrences of bad Event related medication.

- visit on request.
- do not participate in other medical research.
- follow the instruction of researchers.
- there are any unclear places you can ask at any time.

五、The test of funding sources and possible conflicts of interest

Financial support for this study was provided by Beijing Permed Biomedical Engineering Co., Ltd (the sponsor). Investigators

The examination project expenses and the medical devices for the test required by the case were provided by Beijing Permed Biomedical Engineering Co., Ltd.

The objective of the principal investigator and other team personnel with no bidders on the product research and open hair have other financial relations;Bidders also have no other research projects to give financial support to researchers or compensation;The researchers did not hold shares or other equity bidders.

六、The possible benefit

If you agree to participate in this study, your Stanford type A aortic dissection may improve or recover or may not achieve the effects of treatment you intended. Meanwhile, the investigator will provide diagnosis and treatment guidance in a timely manner after the surgery to allow you, throughout the treatment, to receive effective assistance and adequate counseling from the investigator. The data and information you have obtained from participating in this study will facilitate the approval of this medical device for marketing, potentially leading to new treatment options for patients with more homogeneous diseases.

七、The potential risk and discomfort

Your doctor will monitor adverse events during the study period.If you have any not suitable during the study period, or any unexpected happens, you should immediately report to the doctor, will provide you with effective treatment and processing.

Possible risks in this trial include anastomotic bleeding, internal leak, renal failure, hepatic insufficiency, Acute respiratory insufficiency, neurological complications, cerebral complications, gastrointestinal syndrome, spinal cord injury complications, limb paralysis, infection, arteriovenous thrombosis, arterial injury, perforation, arterial dissection formation, vascular fistula or pseudoaneurysm formation, death, and other unpredictable adverse events. Possible risks with the test device itself include adverse events such as endoleak, thrombus, or vascular rupture due to a mismatch in the morphologic specification of the stent or rupture of the stent membrane. The above adverse events may occur in all procedures of intraoperative stent therapy for Stanford type A aortic dissection, but we will still reduce the incidence of the above adverse events by strict factory inspection of the product, strict follow of the clinical trial protocol during the process of the clinical trial, careful

assessment before operation, normative operation during operation, and close monitoring after operation.

Branch type of supporting system for the embryo, fetus or nursing infants at risk not related to the clinical research evidence.If you have been pregnancy or planned pregnancy during the study, in order to ensure that you and embryo, the safety of the tire, breast-feeding infant, you will not be allowed to take part in the clinical research.

The hospital is staffed with excellent health care workers who, after an adverse event, come to timely and appropriate care and can effective in reducing the impact of adverse events.

八、With the test related injury treatment and economic compensation

The study physicians and sponsor will try their best to prevent possible harm due to this study. If you are during the study Injury, whether related or not related to the study, please contact your study doctor at the first time. The doctor will take active measures to you for your treatment, minimizing the extent and time that the injury will occur. If you occur with clinical testing A priori, the related damage or death, the sponsor will cover the costs of the treatment and the correspondin Economic compensation, except for damage caused by the fault of medical institutions and their medical staff in the diagnostic and diagnostic activities.

The sponsor has purchased insurance for this clinical trial if you experience damage related to the clinical trial or death, insurance cover will cover the corresponding portion of the sponsor.

九、May be assigned to the group

Because you are going to enroll in phase III of this trial (branching type intraoperative stent system with single branch structure single group clinical trial). Therefore, you will be treated with a branched type intraoperative scaffold system with a single branched structure produced by Permed biomedical engineering co., LTD. Be diagnosed and treated by a doctor experienced in the clinic and keep your treatment in check.

十、The expenses during the test

You will have free access to the sponsor produced branched type intraoperative stent system with a single branch structure during the trial. Surgery costs need you to pay.

The costs of the examination items required by the study protocol, including: blood routine, coagulation tests, were all covered by the sponsor.Check up, blood biochemistry test, pregnancy test, CT angiography or X-ray. (if you have completed the relevant exams required for the clinical study prior to signing the informed consent form for your routine clinic and have it assessed by your doctor that the exams are available for the screening phase and are not subject to repeat testing, this portion of the testing fee is at your own expense and no longer reimbursed). Investigator will take a thoughtful treatment plan for you and pay more attention during the course of the study, to complete 6 months± 30 days, 12 months±30 days,

2-5 years ± 30 days after surgery after follow-up visit, you will be at the completion of each follow-up visit,Received a transportation grant of 300 RMB, totalling 1800 RMB. This traffic grant will be on the date each time you complete the appropriate follow-up visit,Paid to you by cash; Special cases may remit by bank transfer to the silver of you or your family. In the current account (transfer is expected to be complete within 2 months). There is no remuneration other than this.

十一、Alternative diagnosis and treatment methods of this test is:

You can choose not to participate in the objective of the test, the conventional treatment for you will not bring any bad effects, the present for your health, you can also select listed the same kind of equipment or conservative treatment, your clinical doctor will discuss with you the main risk and benefit of these treatments related.

十二、Medical records confidential manner

You participate in this clinical trial of personal data is confidential, but medical instrument clinical trial institution management, ethics committee, the pharmaceutical supervisory and administrative departments, administrative departments of health or arbitrator, the inspectors in accordance with the relevant provisions when the job is need to program can refer to the personal data you to participate in this clinical trial.At any time, you can ask refer to your personal information (such as your name and address), can modify this information if necessary.

Your medical information to integrate information and others together, all information will be coded, will contain your name or any other can directly reflect your identity information.Encoded information to send in electronic form to bidders (Permed biomedical engineering co., LTD.), as evidence of this product safety and efficacy data.During the research, we may find that your new medical information, if it's important for your health, I will inform you immediately.We would advise you to do some check to make sure the new information.You can refer to any medical information about yourself.

When you signed the informed consent, on behalf of you agree to your personal and medical information is used in the description above.

十三、Voluntary participation, withdrawal from the trial:

You to participate in this study is completely voluntary, hope you can stick to this study.Before you attend study decision, please as soon as possible to your doctor about problem, until you to fully understand the study.You can exit this study at any time without any reasons, not discrimination or revenge, you and will not lead to any medical treatment and the rights and interests of the affected.

If you decide to quit this study, in order to ensure the safety of your study doctor may ask you to accept some end research program.

If you need other diagnosis/treatment, or you do not comply with the test plan, or any other reasonable the original cause, the doctors can terminate your continue to

participate in this test.

You may at any time to understand information related to this test and research progress, if you have any questions related to this test, or your any discomfort and injuries occurred in the process of test, or have questions about this test participants on the surface of the rights and interests of parties you can with your researchers (the researchers name: phone:).

As the research subjects of rights issues or you have questions about this study, concerns or dissatisfaction, you can contact: 021-31587871 contact in our hospital ethics committee (phone:).

In addition to signing the informed consent of the present study, you still need to sign and other operation with the consent of the surgery and other conventional medical documents.

Thank you for carefully reading the above materials. If you decided to take part in this study, please sign "informed consent", you will get a has signed and dated copy of this informed consent form.

Informed consent signed page

【Participants statement】

I have carefully read the informed consent form, I have the opportunity to ask and all questions have been answered.I understand the cords and the study is voluntary, I can choose not to participate in the study, or at any time notify the researchers after exit without discrimination or revenge, and will not lead to any of my medical treatment and the rights and interests are affected.If I need other diagnosis/treatment, or I didn't obey the research program, or any other reasonable reasons, researchers can study in the end I continue to participate in this bed.I voluntarily agreed to participate in the clinical study, I will receive a signed copy of the "informed consent".

Subjects signature: date: year month day

Contact phone number 1: contact phone number 2:

Such as subjects with no capacity or with limited capacity reason can't sign the informed consent form, signed by the guardian.

Guardian signature: date: year month day

relations with subjects:

contact phone number 1: contact phone number 2:

The reason of subjects can't sign the informed consent:

☐Subjects of conscious obstacle problem

☐Subjects due to causes such as upper limb paralysis disabled or unable to write

☐Subjects were illiterate, or had been unable to write for various reasons

☐Other please describe:

Such as subjects or phase of care per capita has no ability to read or write, can ask witnesses familiar with the process, studies the doctor explained after informed consent, witness read the informed consent and oral knowledge content is consistent, by the participants or their prison guard verbally agreed to after, witness in the informed consent form signed and dated.

Witness signature: date: year month day

Contact phone number 1: contact phone number 2:

【The researchers declared】

I have accurately the content of the informed consent and inform the participants to answer questions from participants, the participants voluntarily join this clinical study.

The signature: date: year month day

contact phone number 1: contact phone number 2: