To be printed on hospital letter head

CEDAR STUDY

PATIENT INFORMATION SHEET AND CONSENT FORM

Researcher: XXXXXXXXXXXXXXXXXX
Consultant Vascular Surgeon

Site: XXXXXXXXXXXXX

Study Title: European Multi-Centre Castor™ Branched EnDovascular Arch Repair registry (Study ID: CEDAR Registry)

Study summary: Multi-centre, observational, registry to assess outcomes of patients treated with the Castor™ endograft system for endovascular aortic aneurysm repair.

Protocol #: Version 0

Sponsor: Shanghai MicroPort Endovascular MedTech (Group) Co., Ltd. (Endovastec™)

Dear Patient,

You are being invited to participate in the CEDAR clinical study because your doctor has determined that you have a thoracic aortic aneurysm (TAA) for which repair with the Castor™ stent graft is planned. Please read the following information and ask your Doctor any questions you may have. Your participation in this study is voluntary, and it is important that you carefully consider the following information before deciding whether participating in this research is right for you.

About TAA and Castor™

Thoracic aortic aneurysm is a swelling of the aorta which is the major artery (blood vessel) in your chest. If it is not repaired, the aneurysm can get bigger to the point of bursting or tearing at which time, blood leaks from the vessel, which can be a life-threatening event. In order to try to prevent this happening, your surgeon has advised you to have treatment for your aneurysm.

Aortic aneurysms are often treated with endovascular stent grafts, a type of minimally invasive "keyhole" surgery. This is called TEVAR (Thoracic Endo Vascular Aneurysm Repair). Your aneurysm is felt to be suitable for TEVAR.

There are several different types of TEVAR stent grafts available and it is a rapidly advancing field of modern surgery. Just like all modern devices we use in everyday life, changes are

designed to improve the function of the device and this happens with the stent grafts used to repair aneurysms. As new stents become available, they go through rigorous testing to ensure safety and function. After this initial period of study, further information can only be gathered by following patients who are treated with the new stents for many years to see if further improvements can be made.

The Castor™ stent graft is a classified as a custom-made device (CMD) under EU MDR, with a certificate from the manufacturer's Notified Body accordingly. It is available for clinical use in Europe on this basis.

What is the purpose of this study?

The purpose of this study is to gather information about the use of the Castor™ stent graft. The study aims to gathering long term data on patients who are treated with the Castor™ stent graft in a real-world situation. The aim is to study approximately 100 patients in European hospitals.

Are there any benefits to you from participating in this study?

As an individual, your treatment will be exactly the same whether you decide to go into the study or not. You will have your assessment, operation and follow up at your chosen hospital. You will have the same scans and investigations that would have happened had you not been in the study. By participating in the study, you are allowing the study team to record the information we gather routinely during your care and amalgamate this into a large database which can then be analysed. It is hoped that this will identify any specific strengths or weaknesses of the device which may then benefit future patients by helping us in understanding the Castor™™™ stent graft and the treatment of aortic aneurysms.

What does this study involve?

If you decide to join in this study, the care you receive and treatment of your aneurysm will be the same as if you were not a participant. This is referred to as Standard of Care. Information on your health following the aneurysm repair will be collected for a period of up to 5 years. You will be followed up for life, as all patients who are treated by TEVAR are, but data will not be added to the study after 5 years.

Prior to the procedure to treat your aneurysm, you will undergo the following:

- A routine physical examination, including blood tests
- A review of your medical history
- CT scan

Following the aneurysm repair you will have a further review and CT scan, and in some hospitals an ultrasound scan (duplex). These will occur between 1- and 6-months' post procedure.

You will then have annual scans which will either be duplex scans or CT scans depending on your hospital's own policy.

All of the above is standard care for anyone that has a thoracic aortic stent graft (TEVAR) implanted and will be done whether you participate in the study or not. By being in the study,

we will record this information in a database. There is no additional time or effort required on your part.

How is this different from what will happen if you do not participate in this study?

Decisions for treatment of a TAA are based on the size and shape of your aneurysm.
If you enroll in this study, you will receive standard procedures for insertion of a stent graft device, and you will receive the Castor™ stent graft (if a stent is determined to be the best option for you). If you do not receive the Castor™ stent graft, your treating physician will discuss the other treatment options available to you. The treatment options will be clinically decided by you and your surgeon; this study will not impact on the treatment or care you receive.

What are the risks involved with being enrolled in this study?

Your doctor will discuss the risks and benefits associated with the use of a thoracic aortic stent graft as is their usual practice. These risks will be the same whether or not you elect to participate in the study. There are no anticipated risks from taking part in this study. This study does not involve any change to the standard of care you would normally receive.

As this is a non-interventional study, participating in this study should not affect your life insurance status, but the condition for which you are being treated, or other conditions detected during the study might. If you have private medical insurance, you should contact your insurer to make sure that participation will not affect your cover.

Radiation Exposure:

During your normal care in the study, you would be exposed to x-rays during the insertion of the stent-graft, and with follow up x-rays and CT scans. It is not anticipated that you will be exposed to more radiation as a result of being in the study itself. In total, for adults in the general population, the radiation dose when being treated with a stent-graft is estimated to correspond to a cancer risk of around 1 in 145. This risk can be compared with the natural lifetime risk of cancer in Europe of about 1 in 3.

Withdrawal from the study:

You may choose to stop your participation in this study at any time by providing a written request to your doctor, or a call to the study team. Your decision to stop your participation will have no effect on the quality of your medical care. Your doctor may stop your participation if continuing in the study does not appear to be in your best medical interests, or if the sponsor terminates the study. If you decide not to participate further, your medical care and rights will not be affected; however, if you have received the Castor™ stent, it will remain inside your body.

Data Collection, Use, and Disclosure:

The data collected in this study includes your age, gender, height, weight, medical history, the results of procedures and tests you will have done during the study or had before the study,

information about your response to treatment you receive under the study, and other medical information relating to you. The research team will record some of this information in an electronic research database, or on data collection forms provided by the study sponsor. Your name or address will not appear in the database. Instead, you will be assigned a unique participant identification number. Representatives from the groups identified below may also need to look at your records (which identify you) to make sure that the information collected is correct. Reviews like that will take place at the hospital site or where the records are stored and can take place after the study is over.

No patient identifiable data (full name, phone number, e-mail address, home address etc.) will leave the hospital site. By signing this form, you are authorizing the hospital team to access your medical records and other health information and are authorizing that non-identifiable information to be disclosed by your doctors and other providers who provide health care to you. Your medical scans will be shared with the study sponsor in anonymized format in order that any subtle changes in the stent graft over time can be analyzed.

If you choose to leave the study, you may withdraw your approval for the use of your future medical information. Data which have already been collected will be maintained with the study records and may be used and disclosed in order to maintain the integrity and reliability of the study. Data gathered from this study will be maintained for the duration of the study and retained for at least 5 years following completion.

Confidentiality and Privacy:

This study is being conducted in accordance with relevant European data Protection laws. Researchers are required to get your authorization (permission) to use and disclose (share with others) any health information that could identify you.

The research team may use your health information to conduct, review, and determine the results of the study. The research team may also use your information to prepare reports or publications about the study. However, your name will not appear in any report or publication. Your data will instead be identified only by a generic study specific identification number. The data may be transferred to countries outside the EU in which privacy laws may not provide the same level of protection as within Europe.

It is important to note that in addition, the research team, the Sponsor, or its representatives, auditors, and regulatory agencies may require access to your personal identifiable data, but only in circumstance where this is required to carry out their obligations as required by law. An example of this is if the information is demanded by regulatory authorities.

If you sign this informed consent form, you are giving permission for the use and disclosure of your health information for purposes of this study. You do not have to give this permission. However, if you do not, you will not be able to participate in the study.

Who Will Receive My Health Information?

Your information may be shared with the following people or groups:

- The study sponsor (MicroPort Endovastec) or its representatives, including companies it hires to provide research-related services
- Researchers who are conducting this study at other research sites
- Government health agencies
- The Hospital Site Research and Development (R&D) Department

Funding:

Microport Endovastec. is responsible for organizing this study and it will reimburse the hospital for the costs associated of running it. No member of the study team will be paid for your entry into the study.

Number of Participants:

This European multicentre study will involve approximately 100 patients.

Whom should you contact with questions about this study?

Principal Investigator:
XXXXXXXX
Consultant Vascular Surgeon
XXXXXXXXX Hospital
XXXXXXXX
Tel:

What are the costs of this study?

The costs that result from the medical care associated with the implant of an endovascular stent graft system are considered standard care and are not covered by Microport Endovastec.

Will you be paid to participate in this study?

You will not receive any financial payments for participating in this study. However, should any additional clinic visits be required, the reason for this will be explained fully to you, and you will reimburse reasonable costs incurred as a direct result of the visit.

What if there is a problem or I want to make a complaint?

If you have a concern or complaint about any aspect of this study, you should ask to speak with the research team who will do their best to answer your questions (see contact details above).

However, If you remain unhappy and wish to complain formally, details about how to make a complaint can be obtained from your treating hospital.

CONSENT:

Please Initial Box

1. I confirm that I have read and understand the information sheet dated _____, Version____ for the above study and have had the opportunity to consider the information, ask questions, and have these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that sections of any of my medical notes and data collected during the study may be looked at by responsible individuals from the Sponsor. or from regulatory authorities or from the hospital, where it is relevant to my taking part in research. I give permission for these individuals to have access to my records. ☐
4. I understand that the research team, the Sponsor, or its representatives, auditors, and regulatory agencies may require access to my personal identifiable data, but only in circumstance where this is required to carry out their obligations as required by law. An example of this is if the information is demanded by regulatory authorities. I give permission for these individuals to have access to my personal identifiable data if required, in these circumstances. ☐
5. I understand that my medical scans will be shared with the study sponsor MicroPort Endovastec in anonymized format. ☐
6. I agree that any data collected may be included in anonymous form in publications/conference presentations. I agree to my medical scans and images being published as part of the findings of this research, but the images will be anonymized and will not include any identifiable information about me. ☐
7. I agree to my General Practitioner being informed of my participation in the study ☐
8. I agree to take part in the above study. ☐

_____	_____	_____
Print Name of Patient	Date	Signature
_____	_____	_____
Name of Person taking consent (if different from researcher)	Date	Signature
_____	_____	_____
Print Name of Researcher	Date	Signature

1 for patient; 1 for researcher; 1 to be kept with hospital notes