Cleveland Clinic
Consent to Participate in a Research Study

Study Title: IDE# G010002: Endovascular Exclusion of Thoracoabdominal Aortic Aneurysms or Abdominal Aortic Aneurysms Utilizing Fenestrated/Branched Stent-Grafts

Sponsor/Principal Investigator: Matthew J. Eagleton, M. D.

Carefully review this consent document. The purpose of a consent document is to provide you with information to help you decide whether you wish to participate in research. Your decision is completely voluntary and will not affect your medical care if you choose not to participate. It is important for you to ask questions and understand the research risks, benefits and alternatives.

Please note:

- **You are being asked to participate in a research study**
- **Carefully consider the risks, benefits and alternatives of the research**
- **Your decision to participate is completely voluntary**

Your doctor may be an investigator in this research study, and as a research investigator, is interested in both your welfare and in the conduct of the research study. Before entering this study or at any time during this research, you may ask for a second opinion about your care from another doctor who is not involved with the research study. You are not under any obligation to participate in any research project offered by your doctor.

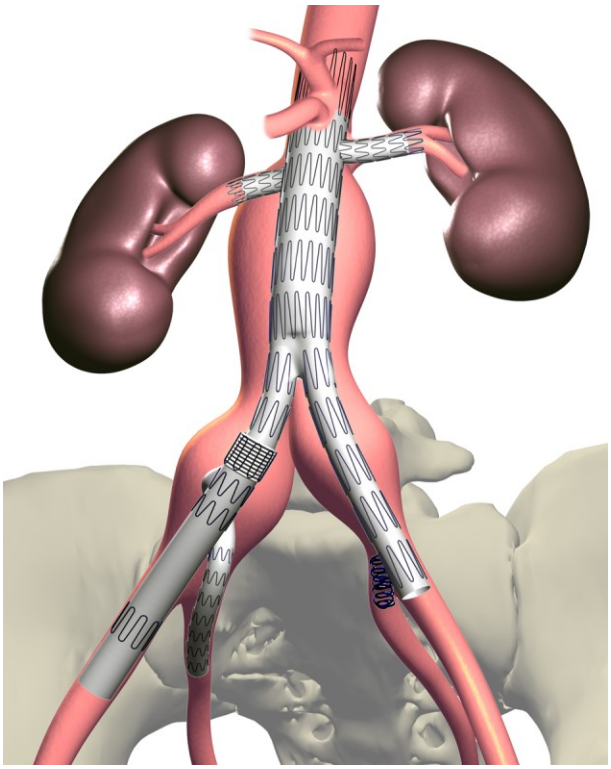
Conflict of Interest Disclosure

One or more of the Investigators conducting this study serve as paid speakers, consultants or advisory committee members for the company that is paying for this research or a company that makes products used in this study. These financial interests are within permissible limits established by the Cleveland Clinic Conflict of Interest Policy. If you have any questions regarding conflicts of interest, please ask your study doctor or call the Institutional Review Board at 216-444-2924.

INFORMATION ON THE RESEARCH

You are being asked to consider participating in this research study because you have either a Thoracoabdominal Aortic Aneurysm or Abdominal Aortic Aneurysm and may be at a high risk for standard open surgical repair. This research study will evaluate if the Endovascular Prosthesis device is safe and effective in the treatment of Thoracoabdominal Aortic Aneurysm or Abdominal Aortic Aneurysms. The Endovascular Prosthesis is an investigational device; which means it has not been approved by the FDA. The device is designed to create a sleeve through your aneurysm for blood flow to your arteries. There are several types of Endovascular

Prosthesis depending on the extent of your aneurysm and the relationship of the aneurysm to your kidney or other anatomical measurements. Your doctor will discuss which type of device you would need. We have included a picture showing an example of what a device may look like inside your aorta. The device is typically custom-made for your specific anatomy. The picture provided is not an exact picture of your specific device, but representative of what a device might look like.



The Endovascular Prosthesis is made up of a polyester woven material that is sewn onto a metal web, which self-expands to a predetermined size when placed into the artery. The Endovascular Prosthesis is folded tightly onto a catheter (a flexible, hollow tube) that is inserted into the aorta (large blood vessel in your abdomen) through an artery (blood vessel) in your leg. The Endovascular Prosthesis reinforces the aorta that is weakened by your aneurysm and blood flows though the prosthesis to your arteries. Additional stents may also be implanted in the arteries that supply blood to your kidneys and intestines. Depending on your anatomy, these stentgrafts may be investigational. We will continue to follow your progress yearly for the rest of your life. If your aneurysm continues to grow, you may require another procedure in the future. Other investigational stentsgrafts may be used during this procedure. If this happens, you will be asked to sign another research consent prior to this secondary procedure. Up to 1440 patients will be enrolled in this study at up to 1 study site (The Cleveland Clinic Foundation).

If your physician determines that you have a common iliac aneurysm or aneurysm involving the arteries supplying your kidneys or intestines then you may require a tube that has one or more side branches. The Endovascular Prosthesis is folded tightly onto a catheter (a flexible, hollow tube) that is inserted into the aorta (large blood vessel in your abdomen) through an artery (blood vessel) in your leg. This Endovascular Prosthesis reinforces the aorta that is weakened by your aneurysm and blood flows though the prosthesis to the arteries that go to your legs. Stents or stentgrafts will be coupled with the aortic component with the intent of preventing blood from hitting the aneurysm wall, while preserving blood flow to important organs within your abdomen or pelvis.

Your physician determines that you have an aortic aneurysm(s) which is a bulge in the aorta (blood vessels that carry blood from your heart to organs in your abdomen to your legs) caused by a weakening in the artery wall. This aneurysm involves one or more of your visceral arteries (arteries that supply blood to the organs in your abdomen, such as your kidney or intestines) and may also extend into your leg arteries. Your doctor will discuss with you the type(s) of aneurysm that you have and which type(s) of Endovascular Prosthesis(ses) can be used to treat your condition. If left untreated, these bulges may continue to grow larger, and ultimately rupture (break open), resulting in serious internal bleeding. If you decide to participate in this study, you will be carefully monitored.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U. S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Explanation of Procedures

Prior to the placement of the Endovascular Prosthetic, you will have the following: a physical examination, an ankle-brachial index that measures the blood pressure of your arms and legs, 4 tablespoons of blood will be drawn to evaluate your kidney function and blood counts, and diagnostic tests including an angiogram/intravascular ultrasound and/or a CT scan will also be performed to visualize significant arterial vessels and to obtain important information regarding the aneurysm. An angiogram uses a catheter (a hollow tube) that is placed into the artery in the groin. A dye that can be seen on x-rays is injected into the catheter into your arteries to see how the blood flows through your aneurysm and the surrounding arteries. Also, the intravascular ultrasound, an imaging catheter to visualize your aneurysm and associated vasculature (blood vessels), will be inserted via the introducer sheath. A CT scan is a special type of x-ray to see the aorta from a different view, in that x-rays are taken to image sections of your abdomen. These sections are very much like the individual slices of a loaf of bread.

The Endovascular Prosthesis procedure will be performed under either regional or general anesthesia. If regional anesthesia is used only a specific region of the body will be insensitive to pain and the nerve impulses from this area will be blocked from reaching the brain. During the procedure you will remain conscious, but may be given a sedative for relaxation. If general

anesthesia is used, your entire body including the brain is anesthetized. You will have no awareness of the surgery and feel nothing during the procedure. Your doctor, either the Anesthesiologist or Vascular Surgeon, will discuss with you the type of anesthesia to be used in your procedure.

The procedure for placement of the Endovascular Prosthesis is as follows: An introducer-sheath (small tube) will be placed in your blood vessel (artery) and an angiogram will be performed. During the procedure your surgeon will use live x-ray pictures viewed on a video screen to guide a fabric and metal tube, called an Endovascular Prosthesis (or endovascular stent-graft), to the site of the aneurysm. The Endovascular Prosthesis is introduced into the body through a blood vessel in your arm or leg. This Prosthesis is factory mounted onto a delivery catheter (a flexible tube), which is inserted into the body and guided to the aneurysmal portion of your aorta for placement. The Endovascular Prosthesis self-expands to a predetermined size when placed into the artery. Additional Endovascular Prosthesis may be placed, if required, to assure that the aneurysm is isolated from blood flow. After the delivery catheter is removed, the Endovascular Prosthesis remains in place. In this section of the aorta the blood will flow through the center of the Endovascular Prosthesis. The procedure will be completed by performing diagnostic tests as described above (angiogram & intravascular ultrasound) to visualize the Endovascular Prosthesis and the associated vasculature. The procedure is expected to take about two to three hours and should result in reinforcement of the aorta where the aneurysm is located.

Follow-up Evaluations

As a participant in this clinical study, you will be expected to return for periodic follow-up evaluations so that your doctor can be sure that the Endovascular Prosthesis device is working properly. Prior to discharge from the hospital you may have a physical exam, blood work (approximately 2-4 tablespoons of blood), a CT scan and a KUB (x-ray of the abdomen), and possibly a renal/visceral aortic ultrasound. Your doctor may also perform an ankle-brachial index. Additional follow-up evaluations will be performed at 1 month, an optional 6-month examination (your doctor will decide if this visit is medically necessary*)*, 1 year and yearly after your treatment. This data will be stored in a database and used in the overall assessment of the device. Each visit will include a physical examination, blood work (approximately 2 tablespoons of blood) and you will have a CT scan, KUB and renal/visceral aortic ultrasound. You may also have an ankle-brachial index. Each follow-up will require approximately 2 ½ hours of your time.

RISKS AND DISCOMFORTS

Depending on the type of device your surgeon decides to use to treat you, the risks may differ. Because the device is typically custom-made and every aneurysm is a little different, the risk for each complication varies greatly. Your risk of the following complications could be higher or lower depending on how much of your aorta is repaired as well as your current medical condition. Your surgeon will discuss these risks with you. These effects may be mild, moderate or severe, and may be long-lasting or permanent, and may occur anytime while the device is in

your body. You will be monitored for any treatment or device-related problems that may occur after the implant of the investigational device.

The following are considered as severe risks and should be considered carefully before proceeding with the study:

- Respiratory Failure
- Death
- Renal Failure requiring hemodialysis
- Myocardial Infarction (Heart Attack)
- Cardiac Arrest during or after the procedure
- Insufficient blood flow to your intestines or other organs in your abdomen that could cause them to malfunction
- Component Separation of devices
- Rupture of aneurysm after treatment
- Paralysis
- Bleeding at the site where a catheter was inserted
- Collection of blood (hematoma) in the tissue at the site where a catheter was inserted
- Injury to an artery (blood vessel) that may or may not require surgical repair
- Misplaced Endovascular Prosthesis requiring surgical removal
- Movement of the Endovascular Prosthesis to an unacceptable place within the blood vessel
- Leaking or tear of the fabric of the prosthesis
- Stentgraft breakage, which has occurred in less than 5% of patients and may require additional surgical procedures to correct
- ongoing leakage into the aneurysm requiring additional procedures
- congestive heart failure
- wound infection at the surface or deep in the tissues where a catheter was inserted
- infection of the endovascular prosthesis
- new abnormal heart rhythm requiring therapy
- abnormality of blood clotting
- excessive or abnormal bleeding during or after the procedure and may result in the need for blood transfusions
- obstruction of the intestines due to impairment of their movement
- inflammation of the colon due to insufficient blood flow to the colon
- a possibility of intentional blockage of a branch blood vessel due to difficult anatomy resulting in loss of the vessel and decreased flow of blood to the involved organ
- insufficient blood flow to the lower extremities that may require additional procedures or even result in amputation
- Skin injury or irritation
- Low blood count affecting the red cell (oxygen carrying cells), white cells (infection fighting cells) and platelets(cells responsible for blood clotting)

- Insertion and removal difficulties – difficulties during insertion or removal of catheter used to guide placement of study device
- Reoperation – treatment may require additional investigational devices

If any of these complications are discovered in your case, they will be treated appropriately, either with a corrective operation or medical management.

A potential risk to the use of this investigational device is renal failure due to contrast media (dye) received during the Endovascular Prothesis procedure. There exists a risk of renal failure whenever contrast is used, such as regular arteriography (angiogram or live x-ray pictures). The most important predictor of renal failure caused by contrast agents is pre-existing renal disease. Other factors such as age and quantity of agent used are not predictive. The risk can be minimized by preprocedure hydration in patients with renal disease. Consequently, the risk of renal failure is extremely patient variable. If your renal arteries are involved in the aneurysm, you may have a higher risk of renal failure or need for dialysis. Likewise, if your intestinal arteries are involved, the risk of intestinal blood flow problems may be higher.

If you are receiving a standardized design (i.e. not customized to your anatomy) there is a risk that challenges may be encountered when trying to gain access into one or more vessels. This risk is minimized by the specific design of the standardized devices, but it remains a possibility.

Radiation Risk

This device requires the use of radiation in the form of x-rays in order to be placed properly. Radiation exposure carries short-term risks, intermediate risks and long term risks. Short term risks from days up to 2 years from radiation include skin injury that varies from mild skin irritation to a severe skin burn. The severity of the skin injury is determined by the length of x-ray exposure and your own sensitivity to radiation. Previous exposure to x-rays in the past 6 months also creates a situation where your skin has a heightened sensitivity to radiation. Intermediate term risks from weeks to months include the possibility of low blood counts affecting red cells (oxygen carrying cells), white cells (infection fighting cells) and platelets (cells responsible for blood clotting). This affect on blood cells is rare and would only occur in cases where radiation exposure was prolonged (greater than 3 hours of exposure), included a significant portion of your spine and is dependant on your age. Long term effects in years to decades include the possibility of cancer formation is rare and related to the amount of radiation you receive, your age and the parts of your body exposed to the radiation. The long term and short term risks of radiation are very rare and you will be closely monitored for any of the above risks. We have tracked radiation related injuries in this study though the carefully monitored follow up visits and no injuries to radiation exposure have been detected at this point and time.

As with any device undergoing clinical investigation, there may be unforeseeable risk to you that are not known at this time. If you are a woman of childbearing age, the procedure may involve unforeseeable risks to you or an embryo or fetus should you become pregnant. It is suggested

that pregnancy is avoided and birth control used. If you are unwilling to do this, we ask that you not participate in the study.

BENEFITS

You may not experience any benefits from participation in this study. Potential benefits of Endovascular Prosthesis procedure include, but may not be limited to the following: not having to undergo open surgery; less time under anesthesia and mechanical ventilation (a machine used to assist breathing); less blood transfusion; reduction of the complication that may result from open surgery; reduction in hospitalization and recovery time.

The potential benefits of follow-up procedures and exams are to identify any problems associated with the Endovascular Prosthesis. This information gained from this research may benefit future patients.

ALTERNATIVE PROCEDURES OF TREATMENT

Alternative procedures to the Endovascular Prosthesis system include standard surgical aneurysm repair.

PRIVACY AND CONFIDENTIALITY

Although every reasonable effort will be made to protect the confidentiality of your records, such protection cannot be guaranteed; agents of the Food and Drug Administration and the Cleveland Clinic Foundation may inspect the research records if needed. The data from the study may be published; however, you will not be identified by name.

The medical and research information recorded about you will be used within the Cleveland Clinic and/or disclosed outside the Cleveland Clinic as part of this research. In case of losing contact with you, we may use other means to locate you if necessary. We may contact your local physician, use public records, or we may speak with your family member to collect information.

Some of the tests and procedures done solely for this research study also may be placed in your medical record so your other doctors know you are in this study. Your access to research information about you will be limited while the study is in progress. Preventing this access during the study keeps the knowledge of study results from affecting the reliability of the study. This information will be available should an emergency arise that would require your treating physician to know this information to treat you best.

Your research information may be disclosed to the Cleveland Clinic, Cook Inc., Cook Australia, Cook Research, Inc. (formerly known as Med Institute), a data management group within Cook Inc., data entry personnel inside and outside of the Cleveland Clinic, the research study Sponsor and its agents, the Cleveland Clinic research review staff, the U.S. Food and Drug

Administration, and other outside collaborators or laboratories that are participating in this study, if any, that are listed as above. The Cleveland Clinic also may use and disclose this information for treatment and payment reasons. The Cleveland Clinic must comply with legal requirements that mandate disclosure in unusual situations. Otherwise, the information recorded about you as part of this research will be maintained in a confidential manner. It is possible that information disclosed about you outside the Cleveland Clinic could be re-disclosed and no longer protected by federal privacy laws.

Your research information may be used and disclosed indefinitely, but you may stop these uses and disclosures at any time by writing to Matthew Eagleton, M.D., at The Cleveland Clinic Foundation, 9500 Euclid Avenue, Cleveland, Ohio 44195. If you do so, any information previously disclosed cannot be withdrawn. The Cleveland Clinic will not use or disclose the information collected in this study for another research purpose without your written permission; unless the Cleveland Clinic Institutional Review Board gives permission after ensuring that appropriate privacy safeguards are in place. The Institutional Review Board is a committee whose job is to protect the safety and privacy of research subjects.

If you choose not to sign this consent form, you will not be permitted to participate in this research study.

RESEARCH-RELATED INJURIES

If physical injury occurs due to your involvement in this research, medical treatment is available, but you or your insurance company must pay the cost of treatment. Compensation for lost wages and/or direct or indirect losses is not available. The Cleveland Clinic Foundation will not voluntarily provide compensation for medical expenses or any other compensation for research-related injuries. Further information about research-related injuries is available from the Office of the Institutional Review Board (216/444-2924).

QUESTIONS ABOUT RESEARCH

If you have any questions about the research or develop a research-related problem, you should contact Matthew Eagleton, M.D., of the Department of Vascular Surgery at the Cleveland Clinic Foundation (216/445-1167). During non-business hours, please call 216/444-2200 and have the CCF page operator page Dr. Eagleton or you may reach the vascular surgery fellow on call. If you have questions about your rights as a research subject, you should contact the Institutional Review Board (216/444-2924).

VOLUNTARY PARTICIPATION

Your participation in this study is voluntary. Your refusal to participate will not prejudice your future treatment or benefits here at The Cleveland Clinic Foundation. You are free to discontinue participation in the study at any time without fear of penalty or loss of medical care.

Your physician may terminate your participation in this study without your prior consent if it is in the best interest of your health and welfare. If any significant new findings develop during the course of the study, which may affect your willingness to participate, you will be informed.

COSTS

The Cleveland Clinic Foundation will not pay for any items or services you receive as part of your routine medical care, or as part of this research. You or your insurance carrier will be billed the usual and customary charges for all such items and services. The Cleveland Clinic Foundation will assist you as reasonably as possible in seeking reimbursement for the costs of these items and services from your private or commercial insurance carrier, and will hold you personally responsible for any charges not paid by your insurance plan. You will also be personally responsible for any deductibles or co-insurance related to your insurance plan.

SIGNATURE

I have read and have had verbally explained to me the above information and have had all my questions answered to my satisfaction. I understand that my participation is voluntary and that I may stop my participation in the study at any time. Signing this form does not waive any of my legal rights. I understand that a copy of this consent will be provided to me. By signing below, I agree to take part in this research study.

_____
Printed name of Subject

_____ _____
Subject Signature Date

Statement of Person Conducting Informed Consent Discussion

I have discussed the above points with the subject. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

_____
Printed name of person obtaining consent

_____ _____
Signature of person obtaining consent Date