IRB Approved Template
MUST BE APPROVED
FOR SITES BEFORE USE
AS MODIFIED
Aug 07, 2020

Informed Consent Form

TITLE:	Prospective, Multicenter, Single Arm Safety and Effectiveness Confirmatory Study of Endovascular Abdominal Aortic Aneurysm Repair using the Nellix® System (EVAS II Confirmatory Study)
PROTOCOL NO.:	CP-0008 WIRB® Protocol #20172461
SPONSOR:	Endologix, Inc.
INVESTIGATOR:	Name Address City, State, Zip Country
STUDY-RELATED PHONE NUMBER(S):	Name Number (24-hour number required)

INFORMED CONSENT FORM SUMMARY

You are being asked for your consent to take part in a research study. This section provides a concise summary of this research. It describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide all relevant details.

Endologix, Inc, is the sponsor of the study and provides support for the costs of conducting the research. In addition, study investigators are compensated for their time and effort conducting the study.

What should I know about this research?

- Someone will explain this research to you.
- Taking part in this research is voluntary. Whether you take part is up to you.
- If you don't take part, it won't be held against you.
- You can take part now and later drop out, and it won't be held against you
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

How long will I be in this research?
If you decide to consent, the Screening process will take approximately 1-2 hours. If you have been approved by the Sponsor to participate in the study, you will have the Nellix Device implanted. The procedure will take approximately 1-2 hours. You will return for follow-up visits at one month, six months, 1 year, and once a year for 5 years. Each follow-up visit will take approximately 1-2 hours.

Why is this research being done?
The purpose of the study is to evaluate the safety and effectiveness of the Nellix® System.

What happens to me if I agree to take part in this research?
If you decide to take part in this research study, you will first be fully consented and then screening may begin. After screening and if you qualify for the study, you will be implanted with the Nellix® System. You will be expected to return for follow-up visits, as described in detail later in this informed consent form.

Could being in this research hurt me?
You may experience risks or discomforts from this study which can be due to the implant procedure, standard risks to abdominal aortic aneurysm repair, standard surgical complications, and potential investigational secondary treatment risks. These potential risks or discomforts are outlined in the informed consent form in the Benefit, Risk, Safety section.

Will being in this research benefit me?
The study is not guaranteed to directly benefit you. However, your participation will help to obtain FDA approval for the Nellix system.

What other choices do I have besides taking part in this research?
Taking part in this research study is voluntary. You don't have to participate, and you can stop at any time. If you decide not to take part in this study, you have other choices such as surgical repair of the aneurysm or use of another commercially available device.

DETAILED INFORMED CONSENT FORM

INTRODUCTION
You are being asked to participate in a clinical research study because of your specific medical condition; an abdominal aortic aneurysm (known as AAA). The goal of this study is to evaluate the safety and effectiveness of the Nellix® System. This device is made by Endologix, Inc. located in the United States of America (US) and is used for the treatment and repair of AAA. The information collected from this study will be used to assess how well patients do when treated with the Nellix System both immediately after the repair of the aneurysm and over the following five (5) years.

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GENERAL INFORMATION

You have been diagnosed with an abdominal aortic aneurysm (a bulge in the aorta). The aorta is the largest blood vessel in the body and carries blood away from your heart to the rest of your body. The aneurysm is caused by a weakening in the wall of the aorta. If left untreated, this bulge may continue to grow larger and ultimately rupture (break open), resulting in serious internal bleeding.

One of the accepted treatments for an abdominal aortic aneurysm is to place a tube (called a stent graft) inside the aneurysm via an artery in the groin. Stent grafts are made of metal and commonly have a fabric covering. Once the stent graft is in place, blood will flow through the stent graft instead of against the weakened part of the aorta. The stent graft is inserted into an artery in the groin and is guided into the aorta. It is positioned so that it covers the entire aneurysm. The stent graft stays there permanently. Endovascular repair of the aneurysm may provide clinical benefits for patients because it is less invasive than standard open surgical repair, it is associated with lower complications rates, and has the potential for faster recovery time.

STUDY DEVICE INFORMATION

You are currently participating in this study because you may have the type of abdominal aortic aneurysm that could be treated by the Nellix System. The Nellix System is an investigational device in the US, which means it has not received US Food and Drug Administration (FDA) approval for marketing. The Nellix System is no longer available outside the United States, unless the physicians are participating in a clinical study. The Nellix System was voluntarily withdrawn outside the United States in early 2019, which was done as a result of poor outcomes such as migration of the device, Type I endoleaks, and/or aneurysm growth. The majority of the poor outcomes were in patients who were not selected and/or treated consistently with the Instructions for Use, which is a document that advises physicians how to implant the Nellix device within a specific patient population. Migration of the device, Type I endoleaks, and/or aneurysm growth will be explained later in this consent form (please see Clinical Study Experience in the United States and Study Questions & Answers #11 Section below).

Clinical Study Experience Outside of United States

Prior to conducting a clinical trial in the US, there were a total of 55 patients in Europe, Latin America, and New Zealand that received earlier versions of the Nellix System as part of a clinical study between 2008 and 2012. Between October and December of 2012, an additional 14 patients were treated as part of a clinical study at hospitals in Europe and New Zealand. All patients are undergoing regular follow-up by their doctor using standard of care tests and evaluations similar to those required in this study.

Clinical Study Experience in the United States

Between January 2014 and September of 2016, a total of 333 patients were enrolled into the EVAS I IDE study, which is an investigational study in the US. These patients received an earlier version of the Nellix System and are currently undergoing regular follow-up visits. Of the

333 patients enrolled, 26 patients were treated at 3 centers outside of the US, while the remaining 307 were treated across 27 centers in the US. During an initial review of the 2-year follow up data on September 19, 2016, there were higher than anticipated rates of movement over time of the Nellix device after the procedure (migration), blood leaking back into the aneurysm sac (Type 1 endoleak), as well as growth of the aneurysm after treatment with the Nellix device (aneurysm enlargement). Endologix reported these events to the Food and Drug Administration (FDA) and modified the anatomy that is allowed to be treated. Subjects who did not meet the updated types of anatomies that can be treated with the Nellix device were at a higher risk of having these events. For subjects who did not meet the updated types of anatomies or for those subjects who had one of the events listed below, more frequent follow-up visits were recommended. As part of this study, only subjects who meet the updated types of anatomies will be treated. Because the criteria to participate in this study was updated, Endologix does not expect that there will be a higher than anticipated rate of these events.

VOLUNTARY PARTICIPATION

Your participation in this study is entirely voluntary. Should you decide not to participate in the study, you will continue to receive the best possible treatment from your doctor. You may withdraw from the study at any time. Your decision will not affect your future medical care and treatment. If you do agree to take part in the study, you are free to withdraw from the study at any time, without having to give a reason, and this will in no way affect your future healthcare. Your doctor may also stop your participation in the study should he/she determines that this study is not in your best medical interest.

If your doctor decides to explant (remove from your body) the devices, the explanted devices will be returned to the Sponsor.

Please read this document carefully before you make a decision about participating in this study, and ask your doctor or a member of the study team to explain anything that is unclear to you. If you decide to participate in this study, you will be asked to sign this consent form. Subject-specific research results will not be disclosed to you. By signing, you confirm that you have read and understood the information, that you will participate in this study, and that you will follow the study requirements, including the follow-up visits. If the study design changes or if there are important findings that may affect your consent decision, you will be informed as soon as possible and given another opportunity to consent.

STUDY QUESTIONS & ANSWERS

1. **How are patients selected for this study?** Your doctor will initially decide if you can be considered for this study. If you meet certain general and anatomical requirements you will be asked to read and consider this consent form.

2. **What tests are required if I agree to participate?** Tests that are considered standard-of-care for your medical condition and are also necessary to evaluate study requirements include but may not be limited to:

   - Physical Exam to check your health condition;
   - Blood drawn to test your kidney function (approximately 1 ½ tablespoonful);
   - Spiral CT Scan which is a special x-ray that allows your doctor to see your blood vessels at close range;
   - Other tests or examinations as ordered by your doctor (For example, if you are of childbearing potential, you must have a negative pregnancy test before study entry. Pregnant women are not allowed to participate in this study due to the unknown impact of CT scans on the fetus.)

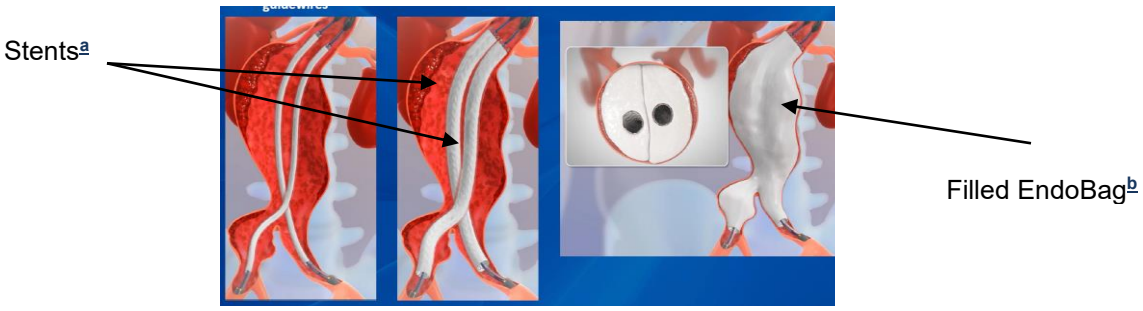
   You and your doctor will make the final decision on study participation after these test results have been evaluated

3. **How many patients will be in the study?** In response to the COVID-19 pandemic and a delay in recruiting to research studies, the Sponsor received FDA approval to decrease the number of total enrolled (enrolled means implanted and included in the study data analysis) subjects from 105 subjects to 95 subjects. Enrollment was completed on March 4, 2020 with the 95th implanted subject.

4. **Where will the study be held?** This study is being conducted at a maximum of 38 US sites under an investigational device exemption. A total of 35 US sites were initiated in the study.

5. **How long is the study?** You will be followed through hospital discharge and then seen at one month, six months, 1 year and annually through 5 years.

6. **What is required at the time of my surgery?** Your endovascular repair and device implant is generally done in an operating room under general anesthesia. The procedure is expected to take one to two hours. Your doctor will determine how long you will need to stay in the hospital after the procedure. Repair of your AAA with the Nellix System involves the placement of specially designed stent grafts (stents[a]) in your aorta. The Nellix System is delivered through a catheter (a long, flexible tube) and inserted into your aorta through small incisions (cuts) in arteries in your legs. The stents are then placed in the correct position. The stents each have an attached bag to fill the aneurysm sac (EndoBags[b]). Once the stents are inside your aorta, a medical grade polymer material is delivered into each bag to fill your aneurysm. The bags, once filled, will reinforce the part of your aorta that is weakened and bulging from the aneurysm. In this section of the aorta, blood will now flow through the center of the graft and will no longer contact the inside walls of the aneurysm. The picture below shows the Nellix System implanted in the aorta:



Sometimes, your doctor may use an additional stent (without a bag) to lengthen the implanted Nellix device to ensure the aneurysm is sealed (distal extension with Ovation iX Iliac Stent Graft).

7. **What happens if the device is not implanted during my surgery?** If the surgeon inserts the Nellix System into your blood vessel, but it is removed for any reason, then the study doctor will collect information on the other surgical repair method that is used. Information will also be collected at a 30 day follow-up visit. Following the 30 day follow-up visit, you will exit the study.

8. **What is done before I leave the hospital?** You will have a physical examination, blood pressure, and blood will be drawn for standard testing (approximately 1 ½ tablespoonful).

9. **What happens if the device needs to be removed?** The study doctor will collect information on the surgical repair method that is used. Information will also be collected at a 30 day follow-up visit. Following the 30 day follow-up visit, you will exit the study.

10. What is expected of me through the five-year follow-up?
You will be seen at your doctor's office at 1-month, 6-months and 1, 2, 3, 4 and 5 years.

The following tests will be done at each follow-up visit:

- A physical examination;
- Blood pressure
- A blood test (approximately 1 ½ tablespoonful);
- A CT Scan.

Your doctor may also perform other tests as he/she determines as necessary. After 5 years, you will no longer participate in this study; however, your doctor will schedule follow-up visits per the standard-of-care for patients with endovascular stent grafts.

11. What were the events that some subjects experienced in the EVAS I IDE study, that started being observed in September 2016? The following events were observed:

- Movement of the device (migration),
- Blood leaking back into the aneurysm sac at the top of the device (Type 1A endoleak),
- Progressive (continued) aneurysmal enlargement.

The occurrence of any of these events may increase your risk of aneurysm rupture and may occur after any AAA endovascular procedure. For more information, please review the list of events that may occur in section ***Standard Risks to AAA Repair***.

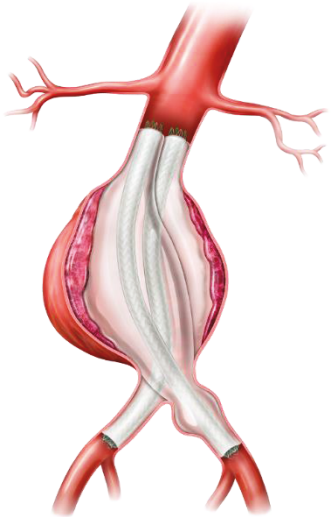
12. What will happen if I experience any of the same events that started being observed in the EVAS I IDE study in September 2016? Although these events can occur after any AAA procedure, Endologix will be closely monitoring outcomes and should any of the previous events occur at a rate that is more than expected, Endologix will report this to the FDA and each of the participating study centers. You will then be notified by your doctor. There are recommended investigational secondary procedures to treat these events. These recommended investigational secondary procedures are described below:

- Your doctor may use a new stent to lengthen the implanted Nellix device and prevent further aneurysm enlargement (distal extension with Ovation iX Iliac Stent Graft)
- To treat blood leaking back into the aneurysm sac at the top of the device (Type 1A endoleak), your doctor may use the Chimney Endovascular Aneurysm Sealing (ChEVAS) technique to lengthen the top of the Nellix device by using stents that will go into visceral arteries to help seal the leak (Secondary ChEVAS technique)
- Your doctor may place a new Nellix device inside the implanted Nellix device to prevent the device from moving further (Nellix Relining treatment)

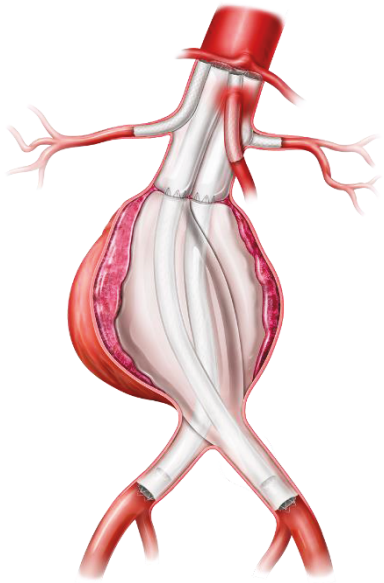
- Your doctor may use glue (Onyx®) and coils to reestablish the seal around the aneurysm sac and treat the leak (Onyx® and coils; the selected coils will be recommended by your doctor)
- Your doctor may use glue (Onyx®) and coils along with using stents to lengthen the top of the Nellix device to reestablish the seal around the aneurysm sac and treat the leak (proximal extension)
- Your doctor may surgically remove (explant) the Nellix device and repair the aneurysm

Your study doctor may perform any of the investigational secondary procedures to treat these events, if they occur, and will advise you of which of these procedures is best for your case. Your study doctor may ask you to return for an optional visit every 6 months if an investigational secondary procedure occurs or to monitor adverse events. Having additional follow-up visits may allow your study doctor to find any of the adverse events earlier and therefore treat you sooner.

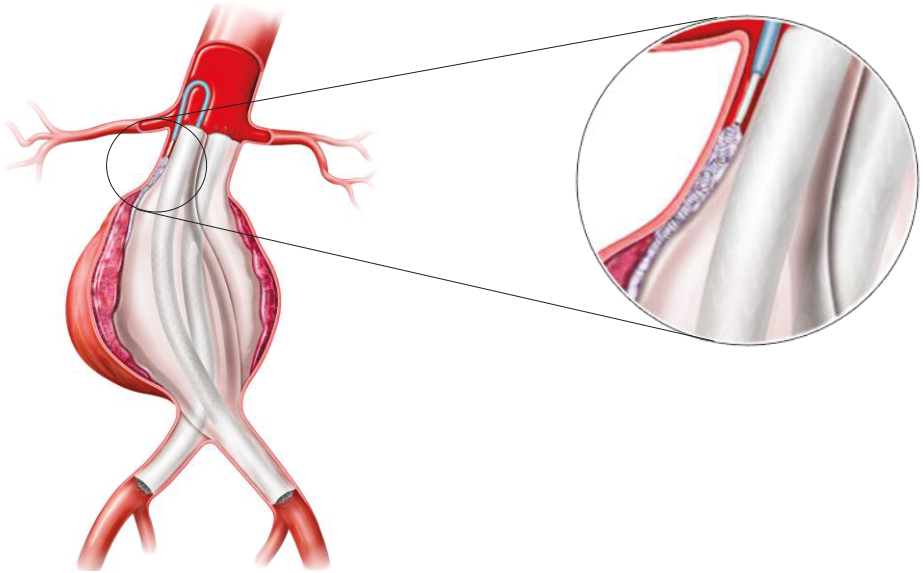
The pictures below show these recommended investigational secondary treatment options:



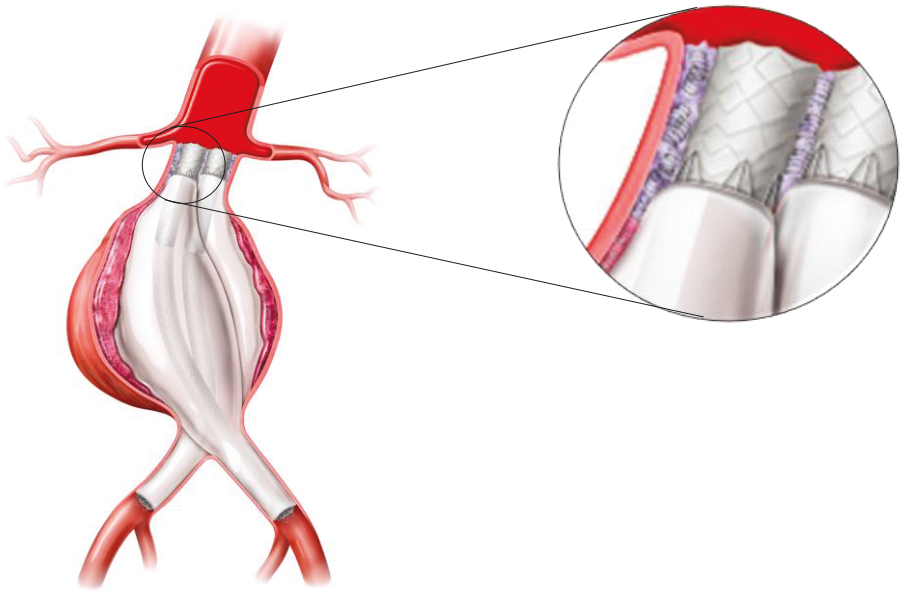
Nellix Relining Treatment



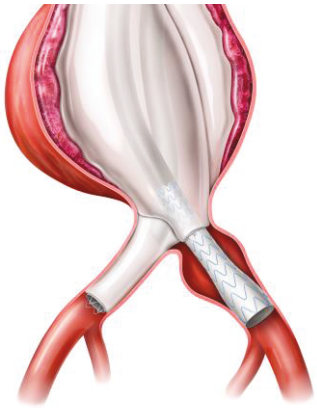
Secondary Chimney Endovascular Aneurysm Sealing
(ChEVAS) Technique



Onyx® and Coils



Onyx® and Coils with Proximal Extension



Distal Extension

13. **What is expected of me for follow-up if I need to have any of the recommended investigational secondary procedures mentioned above?** Your doctor may ask you to return for a follow up visit every 6 months to monitor your progress using the same CT method that will be used for a regular follow-up visit.

    The following tests will be done at each follow-up visit:
    - A physical examination;
    - Blood pressure;

- A blood test (approximately 1 ½ tablespoonful);
- A CT Scan.

Because of the more frequent CT scanning, these participants will be exposed to more radiation. Please see the ***Radiation & Injection of Contrast Agents*** section for further information. Your study doctor will answer any questions you may have regarding the increased radiation.

Your doctor may also perform other tests as he/she determines as necessary. You will complete the study in the same amount of time you would complete if you do not experience any of the events mentioned above. This means, that after 5 years, you will no longer participate in this study; however, repair with an endovascular graft requires lifelong visits with your doctor. Your doctor will schedule follow-up visits per the standard-of-care for patients with endovascular stent grafts.

14. **Who should I contact if I have any questions about the study?** If you have any questions, concerns or complaints about the study, please contact your study doctor. If you have questions about research subjects' rights, you may call your study doctor at any time or you can contact the Ethic Committee/Institutional Review Board (EC/IRB). If you have questions, concerns or complaints about the study contact Western Institutional Review Board® (WIRB®) 1019 39th Avenue SE Suite 120, Puyallup Washington 98374-2115, Telephone: 1-800-562-4789 or 360-252-2500, E-mail: Help@wirb.com. WIRB is a group of people who perform independent review of research. WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

RADIATION & INJECTION OF CONTRAST AGENTS

This study requires computerized tomography (CT) scans. A CT scan is a type of x-ray. The CT scan combines multiple x-rays taken from different angles around your body. There is a risk to radiation exposure from CT scans. The radiation exposure from CT scans may or may not be more than the standard of care to treat or monitor your aneurysm. This includes the CT scans that are done during your follow-up study visits. If you need additional CT scans to be monitored more closely, you will receive extra radiation that might increase your risk of cancer. Care will be taken to minimize your radiation exposure. Please confirm with your study doctor.

One of the risks associated with radiation exposure is cancer. Each CT scan could deliver 1 to 20 msV of radiation, depending on the part of your body that is being scanned. Everyday radiation exposure from natural occurring background radiation (including sun exposure and exposure in the home) is approximately 3 mSv per year.

During the CT scan, you may also receive extra contrast agents (dye placed in the vein), which might increase your risk of kidney function impairment or kidney failure. There is also a risk of a serious allergic reaction to the extra contrast agent. Care will be taken to minimize your exposure to the contrast agent.

If you have questions, you may call your study doctor at any time or you can contact the Ethic Committee/Institutional Review Board (EC/IRB). The address and phone number of the study doctor are provided on page one of this consent. The address and phone number of WIRB are provided on the preceding page of this consent.

BENEFITS, RISKS AND SAFETY

Potential Benefits of the Procedure: There is a possible benefit that the Nellix System may prevent the aneurysm from growing or rupturing (breaking open). The procedure using the Nellix System is also less invasive than standard surgical open repair of the aneurysm, which may be of benefit to you, as well. No benefit from your participation in the procedure can be guaranteed. However, your participation will be contributing to the advancement of this technique, which may prove beneficial to you and to future patients.

Standard Risks to AAA Repair: Complications common to standard surgical aneurysm repair or endovascular repair include, but may not be limited to the following:

- Bleeding during the procedure
- Hematoma (clotted blood) at the access sites in the groin
- Infection at the access sites in the groin
- Progressive growth of the aneurysm
- Blood clots in the graft
- Infection in the graft
- Stretching of the graft
- Development of a hole between the aorta (main artery of the body) and the intestines
- Development of a hole between the aorta (main artery of the body) and the vena cava (major blood vessel carrying blood to the heart)
- Separation of the walls of the aorta (main artery of the body)
- False aneurysm developing at the attachment site of the graft
- Aortic occlusion (blockage of the blood flow in your aorta) from blood clots
- Additional procedure to fix blood leaking back into the aneurysm sac
- Additional procedure to fix aneurysm growth
- Additional procedure to fix aneurysm movement
- Vessel (carries blood away from the heart) puncture, injury, or rupture

Standard surgical complications: Any patient undergoing surgery may be at risk for the following complications:

- Bleeding
- Respiratory failure (lack of oxygen in the blood)
- Pneumonia (infection that inflames air sacs in the lungs and may fill with fluid)
- Pulmonary embolism (blood clots in the lung)
- Low blood pressure
- High blood pressure
- Myocardial infarction (heart attack)
- Congestive heart failure (heart muscle does not pump blood as well as it should)
- Irregular heart-beat, requiring therapy
- Kidney failure
- Wound infection
- Bowel complications such as paralysis of the bowel
- Bowel ischemia (poor blood flow to the small intestines)
- Lower extremity ischemia (reduced blood flow to the lower limbs)
- Lower extremity claudication (pain/cramping in the lower limbs due to poor blood flow to the muscles)
- Numbing
- Tingling
- Paralysis (loss of the ability to move)
- Amputation (removal of a limb)
- Stroke (damage to the brain due to interruption of blood supply)
- Impotence (inability to have an erection)
- Death

Standard endovascular device risks: Other device-related risks include, but may not be limited to following:

- Movement of the device
- Blood leaking back into the aneurysm sac at the top of the device (Type 1A endoleaks)
- Progressive aneurysm growth
- Additional procedures to fix the movement of the device, blood leaking back into the aneurysm sac at the top of the device (Type 1A endoleaks), progressive aneurysm growth

Investigational Secondary Treatment Risks: If you need an investigational secondary procedure, your study doctor will discuss all risks with you before the procedure. The risks specific to the use of the investigational secondary procedures include, but may not be limited to the following:

Nellix Relining Risks:

- Narrowing of the stent where blood flows which may result in:
  - Partial Thrombosis (partial blockage of blood flow or clotting of the blood)
  - Complete Occlusion (blockage of blood flow in the blood vessels that supply blood)
  - Insufficient blood flow to various organs
  - Additional procedures
- Damage or the wearing down of the stents in the overlapped area which may result in:
  - Partial Thrombosis (partial blockage of blood flow or clotting of the blood)
  - Complete Occlusion (blockage of blood flow in the blood vessels that supply blood)
  - Insufficient blood flow to various organs
  - Artery Tear
  - Vessel (carries blood away from the heart) puncture, injury or rupture
  - Additional procedures

Secondary ChEVAS Treatment Risks:

- Narrowing of the stent where blood flows which may result in:
  - Partial Thrombosis (partial blockage of blood flow or clotting of the blood)
  - Complete Occlusion (blockage of blood flow in the blood vessels that supply blood)
  - Insufficient blood flow to various organs
  - Additional procedure
- Damage or the wearing down of the stents in the overlapped area which may result in:
  - Partial Thrombosis (partial blockage of blood flow or clotting of the blood)
  - Complete Occlusion (blockage of blood flow in the blood vessels that supply blood)
  - Insufficient blood flow to various organs
  - Artery Tear
  - Vessel puncture, injury or rupture
  - Additional procedures
- Bulging of the attached bag over the top of the stent or rupture of the attached bag from overfilling that may result in:
  - Insufficient blood flow to various organs
  - Partial or complete occlusion (blockage of blood flow in the blood vessels that supply blood)
  - Additional procedures
- Artery stent stenosis (narrowing) which may result in:
  - Insufficient blood flow to various organs
  - Additional procedures

Distal Extension Treatment Risks:

- Narrowing of the stent where blood flows which may result in:
  - Partial Thrombosis (partial blockage of blood flow or clotting of the blood)
  - Complete Occlusion (blockage of blood flow in the blood vessels that supply blood)
  - Insufficient blood flow to various organs
  - Additional procedure
- Damage or the wearing down of the stents in the overlapped area which may result in:
  - Partial Thrombosis (partial blockage of blood flow or clotting of the blood)
  - Complete Occlusion (blockage of blood flow in the blood vessels that supply blood)
  - Insufficient blood flow to various organs
  - Artery Tear
  - Vessel puncture, injury or rupture
  - Additional procedures

Coil and Glue Treatment Risks:

- Coil or glue may block blood flow in the vessels or arteries
- Coil or glue may block blood flow in the Nellix grafts
- Coil detachment and migration leading to:
  - Kidney damage (Renal infarction)
  - Limb (arms or legs) occlusion (blockage of blood flow in the blood vessels that supply blood to your arms or legs)
- Narrowing of the stent occurring in the overlap of additional stents
- Partial blockage of blood flow or clotting of the blood in the overlap of additional stents

If complications develop during the Nellix System procedure, it may be necessary to stop the procedure and proceed with a standard surgical open repair of your aortic abdominal aneurysm.

UNFORESEEABLE RISKS

Most complications can be treated with medication or conversion to an open surgical repair, which will be available as standby at your doctor's discretion. Complications could also result in serious injury or death. You understand that a serious complication or injury may require further treatment, for an example, the stent grafts may need to be removed. In the event of death, you understand that the stent grafts may be removed for analysis. If the grafts are removed for any reason, they will be sent to an independent laboratory for analysis. This will provide important information regarding the performance of each graft in these procedures. Your decision of not authorizing the removal of the stent grafts for evaluation will not affect your continued participation in the study.

Additional procedures may be performed at a later follow-up if there are issues noted with the device (for example, if blood continues to leak back into the aneurysm sac). In this case, an additional graft or stent may be placed to correct the leak and stabilize the implanted devices or the implanted devices may be removed by conversion to an open surgical repair.

All these potential risks are treatable, and if treated timely, your life should not be at risk. Your doctor will discuss with you all the signs and symptoms so that you pay attention to them. If you experience any of the signs and symptoms discussed with your doctor, contact the office immediately.

There may be risks or side effects related to the study device that are unknown at this time. You will be notified of any significant new findings that become known that may affect your willingness to continue in the study.

MEDICATION
Due to your condition, you may already be on blood thinning medication. Patients on blood thinning medications have been known to have a higher incidence of bleeding complications, such as ulcers, or strokes, both of which can be fatal. Blood thinning medications also increase the risk of bleeding at the site (groin or upper limb area) where instruments are inserted into the arteries. After your AAA procedure, your doctor may change your medicines. Your doctor will discuss with you all the necessary medications with you before you are released from the hospital. If you experience any problems or symptoms, call your doctor immediately.

COST
You will not receive any payments for participating in this study. The Sponsor has agreed to pay the doctor for study-related follow-up activities that you will not have to pay for. You and/or your insurance company(s) must pay for standard of care medical care, including services, supplies and procedures. The investigational procedure and devices will be billed to your insurance/Medicare by your doctor. You will be responsible for any co-payments and/or deductibles, or for any portion of the bill that your insurance does not cover. You may want to discuss these costs with your insurance company before agreeing to participate in the study.

INJURIES
There is a chance that you could become injured while being in this study.

The Sponsor will pay for your reasonable medical costs if the injury is a direct result of the study device or the study procedure. You are responsible for any medical costs for injuries that occur that are not a direct result from the study procedure. You may be billed for any leftover balance that your insurance does not pay, such as any deductibles and co-payments, or if you do not have insurance.

You are not giving up any of your legal rights to pursue a claim through the legal system by signing this form or by accepting medical care.

If your doctor decides you need an investigational secondary procedure, then the doctor will bill your insurance/Medicare for the investigational secondary procedure.

Please contact your study doctor for any research-related injuries. The address and phone number for your study doctor are provided on page one of this consent.

STUDY ALTERNATIVES
Your participation in this study is voluntary. You have the option to not participate. Your doctor will discuss alternatives such as open surgical repair of the aneurysm or use of another commercially available endovascular device.

CONFIDENTIALITY AND PROTECTION OF PERSONAL DATA
Any information obtained as a result of your participation in this study will be kept as confidential as legally possible. A copy of your signed Informed Consent form will be part of your permanent medical record and will be subject to confidentiality policies within the hospital/institution, as well as regulations and national policies already in place. The results of the study may be disclosed to contribute to future scientific research and for general scientific purposes. The study information collected will be disclosed to the study sponsor and affiliated organizations (e.g., core lab, clinical events committee, data safety monitoring board) and may be reported to other countries and their respective regulatory agencies. In addition, if videotapes or photographs are taken during your procedure and later used for publications or teaching materials, patients will not be identified by name nor will your face be shown.

By signing this consent, you agree to permit Endologix, its agents, subcontractors and your study doctors (Researchers), and your other health care providers (together “Providers”), to use and disclose health information about you as described below.

1. The health information that may be used and disclosed includes:
    - All information collected during the research described in the Informed Consent Form for this study;
    - Information that can identify you, including, but not limited to your initials, name, age;
    - Health information in your medical records that is relevant to the research, including, but not limited to the following: a) your entire medical chart; b) health information from other doctors’ offices or clinics where you have been seen; c) reports from your laboratory or other tests or x-rays; d) your medical history; e) the physical exam done by the study doctor; f) reports from other procedures;
    - Health economic data (information to help evaluate the cost-effectiveness of the Nellix System such as but not limited to procedure time, time to discharge, secondary procedures, hospitalization time, and DRG codes applied for hospital reimbursement).

2. The Providers and Researchers may disclose health information in your medical records and health information to:
   - The sponsor of the research, Endologix Inc., and its agents, contractors, designees ("Sponsor"), and third party data administrators; and,
   - Representatives of government agencies including the Department of Health and Human Services and the FDA (in the US), the governing Ethics Committee (EC) or Institutional Review Board (IRB), its agents and subcontractors and other persons who watch over the safety, effectiveness, and conduct of research.
   - Among themselves and with other participating researchers to conduct the research;
   - As permitted by the full Informed Consent Form; and,
   - With Endologix Inc., (the Sponsor), its agents, and subcontractors, and
   - With your Providers.

3. Once your health information has been disclosed to a third party by any of the parties above, it may be further disclosed under national/international privacy laws other providers cannot promise your privacy will always be protected. Privacy laws may no longer protect it from further disclosure.

4. You acknowledge that:
   - You do not have to sign this Authorization, but if you do not, you will not be permitted to move forward with the study or any additional procedures, if applicable.
   - You may change your mind and revoke (take back or withdraw) this Authorization at any time and for any reason. However, if you revoke this Authorization, you will not be allowed to continue taking part in the study, but you will still be able to continue to receive medical care from your doctor. Also, even if you revoke this Authorization, the Providers, Researchers and Sponsor and other parties above may continue to use and disclose the information they previously collected as permitted by the Informed Consent Form. Health information that has already been sent to the Sponsor cannot be taken back.
   - To maintain the integrity of this study, you generally will not have access to your health information related to this research until the study is complete. At the conclusion of the research and at your request, you generally will have access to your health information that is maintained in a designated record set, which means a set of data that includes medical information or billing records used in whole or in part by your doctors or other health care providers at the hospital listed on page one this consent to make decisions about individuals.
   - If all information that does or can identify you is removed from my health information, the remaining information will no longer be subject to this Authorization and may be used or disclosed for other purposes.
   - Your health information will be used or disclosed when required by law.

- If you have questions about the use of your information, you can call your study doctor, institution or Ethics Committee listed on page one of this consent or otherwise listed above.

This Authorization does not have an expiration (ending) date [or for sites located in CA, DE, IL, IN, WA, or WI, "This Authorization expires on December 31, 2060"]

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

CONSENT TO TAKE PART IN THIS STUDY
Patient Acknowledgment:
By signing this Informed and Voluntary Consent Form, I acknowledge that I have read the abovementioned trial-related information. I authorize the disclosure of my medical records to the Sponsor and the EC/IRB and others described above for the uses and purposes described above.

The purpose of this clinical research, the procedures, the risks and benefits and my rights have been explained to me, It was also explained that I can withdraw from the study at any moment.

I sign this Informed and Voluntary Consent Form voluntarily. I am not being forced by anyone to sign this consent. I understand that I a*m not waiving any of my legal rights.*

Any important findings regarding the study device relating to this trial that may affect my health or well-being will be told to me immediately.

I am receiving a signed copy of the present Inform Consent Form.

I agree to work together with the doctor and his team and also to participate in all the follow-up visits, as detailed in the information I received.

Participant's full name (PRINT NAME)

Participant's signature **Date**

IRB Approved Template
MUST BE APPROVED
FOR SITES BEFORE USE
AS MODIFIED
Aug 07, 2020

Certification:
I have talked to the subject, about the clinical trial and the Nellix System. I have answered all his/her questions. I strongly believe that the subject understands the information contained in this document and gives his/her consent to take part in this clinical trial.

Full name of the authorized person explaining the Informed and Voluntary Consent Form (PRINT NAME)

Signature of the authorized person explaining form

Date