The Cleveland Clinic Foundation
Consent to Participate in a Research Study

Name of Trial: 3D Holographic Guidance, Navigation, and Control (3D GN&C) for Endovascular Aortic Repair (EVAR)

Sponsor: Centerline Biomedical Inc. funded by NIH National Heart, Lung, and Blood Institute

Principal Investigator: Dr. Francis Caputo 216-445-9580
After hours phone contact #: **216-444-2200 for Vascular Surgery Fellow on call**

KEY INFORMATION

The following is a short summary of this research study to help you decide whether or not to be a part of this research study. More detailed information is included later on in this document.

What should I know about a research study?

- Someone will explain this research study to you.
- You can choose whether or not to take part.
- You can agree to take part and then later change your mind.
- Your decision whether or not to participate will not be held against you.
- You can ask all the questions you want before you decide.

What is the purpose, procedures, and duration of this study?

You are being asked to participate in this research study because you have an abdominal aortic aneurysm (AAA) which is a balloon-like bulge in your aorta and are scheduled to have an endovascular aneurysm repair (EVAR). The EVAR procedure uses x-ray fluoroscopy, an imaging technique that uses pulses of x-rays, to provide a two-dimensional (2D) image for the surgeon as he/she guides the repair tools to the aneurysm site.

The purpose of this study is to see if a three-dimensional (3D) visualization system can be used as an addition to standard 2D imaging to provide more accurate guidance to the aneurysm site and decrease procedure time, limiting x-ray exposure.

You will be asked to allow both 2D and 3D imaging to be used during your EVAR procedure. Other activities such as data collection (i.e. medical and surgical history), physical exam and follow-up visit are part of the standard care for any patient that is having EVAR.

Your participation in the research will last about one month (through the standard care follow-up visit one month after your EVAR procedure).

More detailed information can be found under the section labeled: "Information on the Research**."**

Why might you choose not to participate in this research study?
You may not want to have both the 2D and 3D imaging options during your procedure. You may not want your information to be collected for research purposes.

More detailed information about the risks of this study can be found in the section labeled "Risks."

Why might you choose to volunteer for this study?
You may not receive direct benefit from being in this study. However, taking part may help patients undergoing EVAR receive better care in the future.

More detailed information about the benefits of this study can be found in the section labeled "Benefits."

What are my other choices if I do not take part in this study?
If you decide not to take part in this study, you will still receive the routine EVAR procedure using 2D fluoroscopic imaging.

Do the researchers or institution have any conflicts of interest relating to this study?
Cleveland Clinic and one or more of the investigators conducting this study may receive royalties and other revenues for a product that is used in this study. Cleveland Clinic and those investigator(s) may benefit financially if this research is successful. These financial interests are being managed and are within permissible limits established by the local institutional Conflict of Interest Policy. If you have any questions regarding conflict of interests, please ask your doctor or call the Cleveland Clinic Institutional Review Board at (216) 444-2924.

DETAILED INFORMATION

The following is more detailed information about this study in addition to the information listed above.

1. INFORMATION ON THE RESEARCH

Why is the research study being done?
The purpose of this research study is to evaluate the safety and functionality of 3D holographic guidance, navigation, and control (3D-GNC) software developed by Centerline Biomedical, Inc. (Cleveland, Ohio, USA) during endovascular aortic repair. 3D-GNC has been studied extensively in animals and its effectiveness is now being evaluated in humans. You are being asked to participate in this research study because you have an abdominal aortic aneurysm and are scheduled to have EVAR.

In the standard EVAR procedure, fluoroscopy is used to provide 2D visualization of the aneurysm site. This imaging technique includes the use of contrast dye, a solution that accentuates specific structures when looking at an image of the body, in this case your blood vessels.

3D-GNC is an experimental software that runs on a special system (described below) to create a 3D image (or hologram) of your aorta and surrounding blood vessels and project this hologram over your body during the procedure using a mixed reality headset (the Microsoft HoloLens 2). This study will evaluate whether the addition of 3D-GNC to the standard 2D imaging will improve visualization for the surgeon, provide more accurate guidance to the aneurysm site and decrease procedure time, x-ray exposure and use of contrast dye.

Below are examples of 3D and 2D images of an AAA.

Figure 1: 3D imaging of AAA.

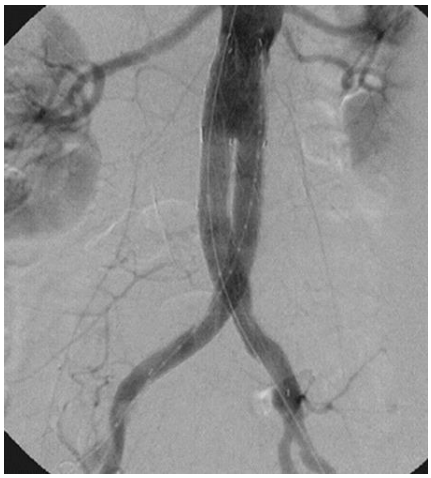

Figure 2: 2D imaging of AAA.

The 3D-GNC software runs on Centerline Biomedical's Intra-Operative Positioning System (IOPS) which has been cleared for use by the FDA. The IOPS uses a prior CT scan to create a 3D map of your blood vessels. During your surgery, the IOPS tracks the position and direction of the guidewires and catheters that are used to deliver the stent graft to the aneurysm site. This tracking is done in real-time, and the 3D image is displayed on a monitor for use in addition to 2D fluoroscopic imaging.

The figure below illustrates the output of 3D-GNC software: a 3D hologram of a patient's blood vessels, the target area for the stent graft and the position and location of the guidewires and catheters which has been projected over the patient's abdomen using the Microsoft HoloLens 2.

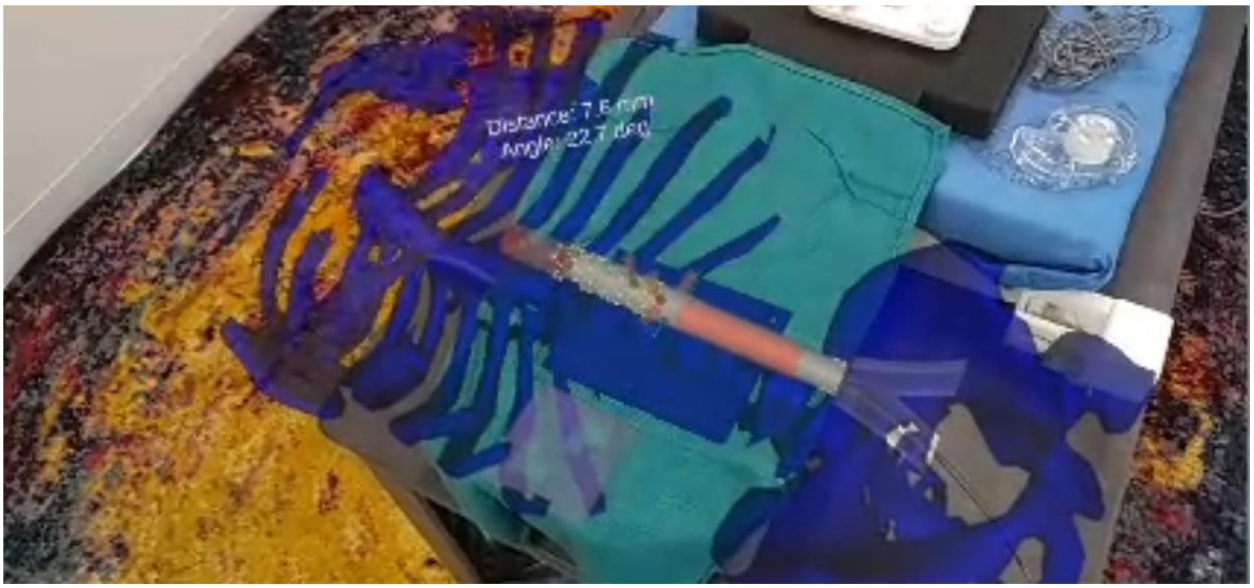

Figure 3: 3D hologram projection using Microsoft HoloLens 2 and 3D-GNC software

How Many People Will Take Part in this Study?
Approximately 3 people will take part in this study at Cleveland Clinic.

What is involved if you decide to take part in this research study?
If you agree to participate in this study, the tests and procedures that you will have during specific time periods throughout the study are described below and are the standard for any patient that is undergoing the EVAR procedure. Demographic data including but not limited to age, sex, race and ethnicity will also be collected.

	Screening/Baseline	Procedure	Discharge	1 Month Follow-Up
History and Physical Exam	X			
Blood Tests	X			
Pregnancy Test	X			
CT scan	X		X*	X*
EVAR Procedure		X		

*Routine CT scan will take place either at discharge or 1 month follow-up visit, but not both

- History and Physical Exam: collection of your medical and surgical history along with a routine exam to include height, weight, blood pressure, heart rate, and oxygen saturation which is the amount of oxygen in your blood
- Blood Tests: routine pre-surgical blood draw/testing
- Pregnancy test for women with childbearing potential
- CT (Computerized Tomography) scan: a diagnostic imaging procedure that uses a combination of x-rays and computer technology to produce images of the inside of the body

- EVAR Procedure: surgical method used to correct abdominal aortic aneurysms in which the 3D holographic guidance, navigation, and control (3D-GNC) software will be used

It is very important to complete the discharge and follow-up visits, even if you are feeling well and without symptoms. It is also very important that you contact your study doctor if you have any symptoms that could be related to the procedure so your condition can be properly checked. Once you complete the study or withdraw, your physician may ask you to come back for follow up per standard of care.

Role of the Sponsor Representative
In this study, and at the request of your doctor, a representative of the sponsor, who is obligated to maintain your privacy, may:

- provide technical expertise on device during the procedure.
- be present and may have some direct contact with you during procedure and other study related visits at your doctor's request.
- assist and review the collection of information about your procedure and study documents for completeness and accuracy.
- be aware of the outcome of your procedure and other study information.

Please talk to your doctor if you have any questions.

How will my data be used?
Your data and images may be sent outside of the Cleveland Clinic for evaluation of the accuracy and usability of the 3D-GNC software. Any personal information that could identify you will be removed before data and images are shared.

Will I be notified of the study results?
The tests/studies described are for research purposes only. It is not the purpose of these tests/studies to look for or provide you with any medical information or diagnoses relating to your present condition or any other disease or illness. Therefore, you will not receive results from these research tests/studies.

2. ALTERNATIVES

What are the alternatives to participation in the research study?
If you choose not to participate, you will receive routine EVAR surgical procedure using fluoroscopy.

3. RISKS

What are the risks of participating in the research study?
3D-GNC/IOPS risks are the same as the EVAR procedure itself. In the event of a system malfunction, the surgeon can continue using 2D fluoroscopy which is the current standard of care.

Confidentiality Risks
There is a potential risk of loss of confidentiality of your data. Every effort will be made to keep your information confidential. If you decide to be in this study, the study researchers will get information that identifies you and your personal health information. This may include information that might directly identify you, such as your name and address. This information will be kept for the length of the study. After that time, it will be destroyed or de-identified, meaning we will replace your identifying information with a code that does not directly identify you. The principal investigator will keep a link that identifies you to your coded information, but this link will be kept secure and available only to the principal investigator or selected member of the research team. Any information that can identify you will remain confidential. Any personal information that could identify you will be removed or changed before files are shared with other researchers or results are made public.

Unknown Risks
There may be risks or side effects related to the study drug/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.

4. BENEFITS

What are possible benefits of participating in the research?
There is no personal benefit to you by participating in this research study. The knowledge to be gained from this research may be beneficial for other patients, society, or science.

5. COSTS

Are there any costs to you if you participate in this study?
The following research study activities are being done only because you are participating in this research study and **will be paid for by the study sponsor** and will not be billed to you or your health insurance plan. These "research only" activities include 3D imaging.

Some of the services you will receive during this research study **are considered to be conventional routine clinical services that you would have received even if you were not participating in the research** study and will be billed to you or your health insurance plan. Examples of these routine services include physical examination, blood work, CT scans, and EVAR procedure. **You are responsible for paying any deductibles, copayments or co-insurance** that are a normal part of your health insurance plan.

7. PRIVACY AND CONFIDENTIALITY

What will happen to your information that is collected for this research?
Cleveland Clinic may share your study information, without anyone knowing that it is related to you specifically, with others or use it to research projects not listed in this form. Your data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your data, we will no longer be able to identify and destroy them.

Study results may be shared in medical journals, at scientific meetings, and in other mediums without your identifying information. Your records will be confidential, and your identity will not be shared in medical journals, at scientific meetings, and in other mediums without your express consent.

Authorization to Use/Disclose Protected Health Information
Cleveland Clinic has rules and procedures to protect information about you. Federal and State laws also protect your privacy.

The research team working on the study will collect information about you. This includes your health information, data collected for this research study and personal identifying information including your name, address, date of birth and other identifying information.

Generally, only people on the research team will know your identity and that you are in the research study. However, sometimes other people at Cleveland Clinic may see or give out your information. These include people who review research studies including the Institutional Review Board and Research Compliance, their staff, lawyers, or other Cleveland Clinic staff.

People outside Cleveland Clinic may see your information for this study. Examples include government groups (such as the Food and Drug Administration), safety monitors, other hospitals in the study and the sponsor of the research, Centerline Biomedical Inc., and the NIH National Heart, Lung, and Blood Institute, and their agents. Cleveland Clinic will do our best to ensure your information is kept confidential and that only the health information which is minimally required to conduct the study is used or disclosed to people outside Cleveland Clinic; however, people outside Cleveland Clinic who receive your information may not be covered by this promise.

You do not have to give this permission to use and give out your information; however, you will not be able to participate in this research study without providing this permission by signing this consent form. The use and disclosure of your information has no expiration date.

You may cancel your permission to use and disclose your information at any time by notifying the Principal Investigator in writing, Dr. Francis Caputo, 9500 Euclid Avenue Desk F30, Cleveland, Ohio 44195. If you do cancel your permission to use and disclose your information, your participation in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in the study.

Certificate of Confidentiality

To further protect your identifiable data and/or identifiable bio-specimens (for example, blood or tissue) collected and used under this research, a Certificate of Confidentiality from the United States Department of Health, and Human Services (DHHS) and the National Institutes of Health (NIH) has been obtained.

This added protection to your privacy, limits the re-disclosure of your private identifiable data by the researchers without your permission in any federal, state, or administrative proceedings.

The Certificate will not prevent the researchers from notifying the appropriate authorities when there is a federal, state, or local law that requires reporting, such as reporting communicable diseases or child/elderly abuse. The Certificate cannot be used during required auditing or evaluation of federally funded projects or when required by the Federal Food and Drug Administration (FDA).

This Certificate does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer or employer learns about your participation, and obtains your consent to receive research information, we may not use the Certificate of Confidentiality to withhold this information. This means you must actively protect your own privacy.

If you have any questions about what this notice means and would like to speak to someone, you may call the study's Principal Investigator, Dr. Francis Caputo 216-445-9580 or Study Coordinator, Emily Sprankle 216-444-8327, or the Institutional Review Board (216-444-2924). If you would like to read more about Certificate of Confidentiality, the NIH has a website you can visit online at: https://grants.nih.gov/policy/humansubjects/coc.htm.

Clinical Trials Registration

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 the Website at any time.

8. QUESTIONS

Who do you call if you have any questions or problems?

If you have any questions or concerns about the research, or develop a research-related problem, you should contact Dr. Francis Caputo at 216-445-9580. During non-business hours, weekends and holidays, please call 216-444-2200 and ask for the Vascular Surgery Fellow on call. If you have questions about your rights as a research subject, you should contact the Institutional

Review Board at (216) 444-2924.

9. VOLUNTARY PARTICIPATION

What are your rights as a research participant?
Taking part in this study is voluntary. You will be told of any new, relevant information from the research that may affect your health, welfare, or willingness to continue in this study. You may choose not to take part or may leave the study at any time. Withdrawing from the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to withdraw from the study, you should discuss with your study doctor your decision to ensure a safe withdrawal.

If you leave the study early, Cleveland Clinic may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

Your study doctor may stop your participation in this study if he/she feels it would be in the best interest of your health. In addition, the Sponsor of the study (Centerline Biomedical, Inc.) may suspend or prematurely terminate the study. Your withdrawal may be done without your consent, but alternative treatment options will be discussed with you. Significant new findings discovered during this study, or reasons for any amendment to the clinical investigational plan (CIP), which may affect your willingness to continue participating in the study, will be provided to you.

10. SIGNATURES

Statement of Participant
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 Participant

_____ _____
Participant Signature Date

Statement of Person Conducting Informed Consent Discussion
I have discussed the information contained in this document with the participant and it is my opinion that the participant understands the risks, benefits, alternatives, and procedures involved with this research study.

_____
Printed name of person obtaining consent

_____ _____
Signature of person obtaining consent Date