VUMC Institutional Review Board
Informed Consent Document for Research

Study Title: Plunger Stroke Trial: A comparison of cyclic manual direct aspiration thrombectomy (Plunger technique) vs. static manual direct aspiration thrombectomy for treatment of acute large vessel occlusion stroke

Version Date: 10.1.2025 v2

PI: Michael T. Froehler, MD, PhD
Director of Vanderbilt Cerebrovascular Program
Associate Professor of Neurology and Neurosurgery
Vanderbilt University Medical Center

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:

You are being asked to participate in a research study evaluating two different thrombectomy techniques for removing blood clots in patients experiencing acute ischemic stroke due to large vessel occlusion. The study compares a cyclic manual aspiration method (the "Plunger" technique) with a static manual aspiration method, both using the Raptor Aspiration Catheter. Participation in this study may or may not directly benefit you; however, the information gained may help improve future stroke treatments. Risks include bleeding in the brain (symptomatic intracranial hemorrhage), vessel injury, or failure to remove the clot. The procedure is part of your standard care, and participation involves no additional visits beyond routine follow-up: a 24-hour post-procedure assessment and a 90-day telephone follow-up. There are no restrictions on daily activities, medications, or diet related to this study. All devices used are FDA-cleared, and there is no exposure to radiation or participation in sub-studies. There are no additional costs to you, and you will not receive payment for participating.

As part of the study, imaging from your procedure will be collected and reviewed by a central core lab. This includes non-contrast head CT scans (used to assess for hemorrhage and stroke severity), and angiographic images (used during the thrombectomy procedure to evaluate blood vessel blockage and reperfusion). These images will be de-identified before submission, meaning all personal identifiers will be removed and replaced with a study code. The de-identified images will be stored securely on a HIPAA-

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compliant server with encrypted access and daily backups. Only authorized study personnel and reviewers will have access to these images for research purposes.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

You are being asked to take part in this research study because you are undergoing thrombectomy for acute ischemic stroke due to a large vessel occlusion and meet the eligibility criteria for this study.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

Side effects and risks that you can expect if you take part in this study:
The risks associated with participation in this study are equivalent to those of standard of care (SOC). No additional risks are introduced by study participation.

Risks that are not known:
This protocol uses two different mechanical aspiration techniques called "Plunger" and static manual aspiration. Plunger aspiration and static aspiration techniques have not been directly compared in prior studies. While both techniques carry the same theoretical risks, it remains unknown whether one is safer or more effective than the other.
This protocol utilizes the Raptor Catheter (sizes 0.71 and 0.74) and the VacLok Syringe, both of which are FDA-approved for their intended clinical use for both the study arms.

Plunger Aspiration

- This method uses a syringe where the plunger is pulled to help remove the clot.

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- It is commonly used and may work differently depending on the doctor.
- Possible risks include changes in blood flow or needing extra steps to fully remove the clot.

Static Aspiration

- This method uses the same syringe, but without pulling the plunger.
- Possible risks are similar to the plunger method, including changes in blood flow or needing extra steps.

In both methods, the doctor may switch techniques if needed to help remove the clot safely. All procedures are done by trained medical staff using standard safety practices.

Other Risks:
No genetic testing or sample collection is involved in this study.

In addition to the risks associated with standard clinical care, there is a potential risk of breach of confidentiality or unauthorized disclosure of your protected health information (PHI). To minimize this risk, the study team will implement strict safeguards, including secure data storage, limited access to study records, and adherence to HIPAA regulations.

Good effects that might result from this study:
The benefits to science and humankind that might result from this study: The study may also help improve future stroke treatments.

Procedures to be followed:
If you agree to participate in this study, you will undergo a thrombectomy procedure to remove a blood clot from a large artery in your brain. This procedure is part of your standard medical care for acute ischemic stroke. As part of the study, you will be randomly assigned (like flipping a coin) to one of two techniques for performing the thrombectomy: the "Plunger" technique, which uses a cyclic manual aspiration method, or the standard static manual aspiration technique. Both techniques use the same FDA-cleared Raptor Aspiration Catheter.

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During the procedure, a catheter will be guided through your blood vessels to the site of the clot. Depending on your group assignment, suction will be applied either continuously (static) or in a repeated on/off fashion (Plunger). If the first attempt does not successfully remove the clot, your doctor may use other approved devices to complete the procedure.

Your participation in the study will not require any additional procedures beyond what part of your clinical care is already. However, the study team will collect information about your procedure and recovery. This includes a follow-up assessment approximately 24 hours after the procedure and a phone call about 90 days later to complete a short questionnaire about your recovery and overall health.
As part of the study, images from your procedure (such as angiograms) will be collected and reviewed by a central core laboratory. These images will be de-identified before submission, meaning all personal identifiers will be removed and replaced with a study code. The de-identified images will be stored securely on a HIPAA-compliant server with encrypted access and daily backups. Only authorized study personnel and reviewers will have access to these images for research purposes.

Payments for your time spent taking part in this study or expenses:
You will not be paid for participating in this study.

Costs to you if you take part in this study:

If you agree to take part in this research study, you and/or your insurance will not have to pay for the tests and treatments that are being done only for research. However, you are still responsible for paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non-research) further before choosing to be in the study. You may choose

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not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

Payment in case you are injured because of this research study:
If it is determined by Vanderbilt and the Investigator with Sponsor, Balt (Sponsor) that an injury occurred, then you and/or your insurance may be billed for the cost of medical care provided at Vanderbilt to treat the injury. You will be responsible for any copayments or deductibles associated with the treatment of that injury.

There are no plans for Vanderbilt or Balt (Sponsor) costs for any additional care. There are no plans for Vanderbilt or Balt to give you money for the injury.

Who to call for any questions or in case you are injured:
If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact at 615-421-6059 or my Faculty Advisor**,** Michael E Froehler at 615-322-7417 If you cannot reach the research staff, please page the study doctor at 615-322-7417

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Reasons why the study doctor may take you out of this study:
You develop a new medical condition or complication that could interfere with the study procedures or increase the risk of harm. The study doctor determines that continuing participation may negatively affect your well-being based on new information or test results.

What will happen if you decide to stop being in this study?
If you decide to stop being part of the study, you should tell your study doctor.

Clinical Trials Registry:

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A description of this clinical trial will be available on 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 Web site at any time.

Confidentiality:
All records and data collected during this study, including procedural imaging, will be stored securely and maintained in compliance with HIPAA regulations. Imaging data (such as angiograms) will be submitted to a central core laboratory (Oculus Imaging, LLC) for analysis. These images will be de-identified before submission, meaning all personal identifiers will be removed and replaced with a unique study code. The de-identified images will be uploaded via a secure, HIPAA-compliant web portal using 2048-bit encryption and stored on encrypted servers with daily backups. Only authorized study personnel and core lab reviewers will have access to these images for research purposes.
In addition to imaging, other study data will be entered into a secure electronic data capture system (Redcap), which maintains an audit trail and access controls to ensure data integrity and confidentiality. There are no study-specific procedures that increase the risk of a breach of confidentiality beyond standard clinical research practices. However, as with any research study, there is a minimal risk that confidentiality could be compromised despite all efforts to protect your information.

Privacy:
Information collected about you during this study, including procedural imaging and clinical data, may be shared with other researchers for scientific purposes. To protect your privacy, your name and other identifying information will not be released. All shared data will be de-identified, meaning it will be coded and stripped of personal identifiers before being used or shared.

You will not receive any direct benefit from the use of your data or images. However, the information collected may help researchers better understand the causes, risks, treatments, and prevention of stroke and other health conditions.

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No biological samples will be collected or stored as part of this study. Therefore, there will be no future use of specimens, no creation of new products or tests from samples, and no whole genome or exome sequencing.

Study Results:
The results of this study may be published or presented at scientific meetings; however, your identity will not be disclosed in any publication or presentation. You will not receive individual results from this study. The information collected from all participants will be combined and analyzed as a group to evaluate the effectiveness and safety of the thrombectomy techniques being studied.

Authorization to Use/Disclose Protected Health Information
What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?
The people who may request, receive or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers, insurance providers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

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Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may withdraw your authorization at any time. To do so, you must notify the Principal Investigator of writing using the contact information provided in this consent form. Please note that withdrawing your authorization will not affect information that has already been collected or shared prior to your withdrawal.

If you decide not to participate in this study, or if you withdraw later, it will not affect your medical care, insurance coverage, or eligibility for benefits. You will receive a copy of this signed consent form for your records.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

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STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form, and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

Date _____ Signature of patient/volunteer/legally authorized representative (LAR) _____

Consent obtained by:

Date _____ Signature _____

Printed Name and Title _____

Date of IRB Approval: 11/04/2025
Date of Expiration: 11/03/2026