UNIVERSITY OF PENNSYLVANIA RESEARCH SUBJECT INFORMED CONSENT FORM AND HIPAA AUTHORIZATION

Protocol Short Title:	**Imperative Trial**
Protocol Full Title:	A prospective, multi-center, open label and single arm clinical investigation to evaluate the safety and efficacy of using the Zoom Reperfusion System in thrombectomy procedures to treat acute ischemic stroke patients (ICI-001)
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Emergency Contact:	215-349-5990

Why am I being asked to volunteer?

You are being invited to participate in a research study. Your participation is voluntary, and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the study team any questions you have related to participating before agreeing to join the study. If you have any questions about your rights as a human research participant at any time before, during or after participation, please contact the Institutional Review Board (IRB) at (215) 898-2614 for assistance.

You are invited to participate in a clinical Research Study because you have had a stroke caused by a blood clot blocking a vessel carrying blood to your brain. To treat this, your doctor has scheduled you to undergo a procedure called thrombectomy. Thrombectomy is done by threading a catheter (thin tube) through a small puncture in a leg or arm artery leading to the brain. The blocked vessel is opened by removing the blood clot through the catheter. Currently, the blood clot can be removed by a few different catheters. One type of catheter, called Stent Retrievers, is a device that "grabs" the clot so that it can be pulled back through the catheter. Another type of catheter, called Aspiration Catheters, is a device that "sucks" the clot out of the brain vessels. Both devices are effective in removing the clot from the vessels.

There is a new catheter that can be used to remove the blood clot, similar to the existing Aspiration Catheters. This new device is called the Imperative Care Zoom Reperfusion System. The purpose of this study is to evaluate the safety and effectiveness of Zoom Reperfusion System's largest size catheter, as a possible treatment in re-opening blood vessels in the brain that are blocked by blood clots. Zoom Reperfusion System's largest size catheter is investigational because it is being tested and is not approved/cleared by the United States Food and Drug Administration (FDA) for this additional way that it will be used in this study.

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The Zoom Reperfusion System has additional smaller size catheters, all of which are cleared by the U.S. Food and Drug Administration (FDA) to help other devices reach the brain vessels. In addition, for some cases based on size, it is also cleared to remove blood clots from brain vessels by using aspiration suction (vacuum) to suck the blood clot into the catheter rather than dragging the clot into a catheter. However, the device at its largest size catheter is not approved to remove (vacuum or suck) the clot into the catheter. This study is being done to expand the use of the largest size catheter (hereafter "Study Device") to include removal of the blood clot. Because the Study Device does not need to cross to the other side of the blood clot (to grab it), it may be possible that the Study Device will reduce the likelihood of the blood clot breaking off and moving deeper into the brain vessel. Researchers want to find out if use of the Study Device can achieve satisfactory removal of blood clots and improve the outcome of patients who suffer an acute ischemic stroke.

Please note that there are other factors to consider before agreeing to participate such as additional procedures, use of your personal information, costs, and other possible risks not discussed here. If you are interested in participating, a member of the study team will review the full information with you in the remainder of this form. You are free to decline or stop participation at any time during or after the initial consenting process.

Your doctor may be an investigator in this research study. You do not have to participate in any research study offered by your doctor. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. You may also decide to discuss the study with your family, friends, or family doctor. Being in a research study is different from being a patient. As an investigator, your doctor is interested both in your clinical welfare and in the conduct of this study.

If you decide to participate, you will be asked to sign this form.

This consent form is written from the point of view of a research participant. If the legally authorized representative will be providing consent, the words "you" and "your" should be read as "the research participant".

What is the purpose of this research study?

The purposes of this Research Study are:

- To evaluate the safety and effectiveness of the Study Device when used to re-open blood vessels in the brain that are blocked by blood clots.
- To receive FDA clearance for the Study Device in the U.S.

How long will I be in the study?

About 262 subjects at up to 30 sites in the United States will participate in this study. It is anticipated that enrollment will last about 12-15 months and study duration will be around 18 months. Up to 39 subjects (15% of the total enrollment) will be enrolled at this site and your participation in the study will be 3 months.

How does the Study Device work?

The Study Device is a thin, flexible, plastic tube (catheter) that can be used to access a blood clot in the brain vessels. Once the blood clot in the brain has been reached with the Study Device, the Study Device is hooked up

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to a vacuum source, the vacuum is turned on, and the clot is sucked into the Study Device, through the Study Device and outside of the body.

What am I being asked to do?

Before the Thrombectomy Procedure:

You will have the following tests to see if you are eligible to participate in the Research Study. Your Study Doctor will take some blood for routine blood tests and you will receive a special X-ray of your brain called a CT/CTA or MRI/MRA. This procedure takes pictures of the insides of blood vessels in your brain. This is done by putting some dye into your blood vessels. This test may take from a few minutes to a few hours, depending upon the location of your blood clot. If you had some of these tests already, they may not need to be repeated. This will be up to your Study Doctor. None of these tests are experimental.

Thrombectomy Procedure:

Before the procedure begins, you may be given some medication to make you feel sleepy. After sedation or local anesthesia, a small catheter will be inserted in an artery. As part of routine care before, during and after the procedure, medical imaging of your brain vessels will be seen on a monitor, much like an X-ray movie. This is done by injecting an X-ray dye through the body so the blood vessels of the brain can be seen in detail. This should not cause you any pain. Your doctor will use the X-ray pictures to decide if you are eligible for this Research Study. If your doctor decides that you are eligible, you will be treated with the Study Device. If the Study Device does not remove the blood clot completely, you may be treated with other available treatments, which is up to your Study Doctor.

If you are not eligible for the study, the reason will be recorded in a screening log. You will not be followed in the study (no data will be collected). You will receive the usual care and treatment for your stroke.

After Thrombectomy Procedures:

Once the thrombectomy procedure is completed, you will receive standard care. At about 12-36 hours and about 3 days after you are treated (or before you leave the hospital), you will have an exam to test how well you can move your arms and legs and talk, understand speech, and see in all directions. None of the procedures or tests are experimental.

Follow-Up Visits:

You will be required to complete a follow-up visit about 90 days after you are treated. You will come back for a follow up visit with your doctor at the hospital where you were treated. This is done to see how you have been doing. You will have an exam to test how well you can move your arms and legs and talk, understand speech, and see in all directions. You will also be asked questions about how well you are able to perform your day-to-day activities like bathing, dressing, and walking. None of the procedures or tests are experimental.

What are the possible risks or discomforts?

As with any medical procedure there is some risk associated with using a thrombectomy device. Medical treatments often cause side effects. You may have none or some of the effects listed below, and they may be mild, moderate or severe. Consequences vary and may include additional interventional (invasive) procedures, medication or hospitalization. If you have any of these side effects, or are worried about them, speak to your Study Doctor. Your Study Doctor will also be looking out for side effects.

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The Study Device may have unforeseeable risks or discomforts that the researchers do not expect or do not know about and they may be serious or severe. Tell your Study Doctor immediately about any new or unusual symptoms.

The risks related to thrombectomy will be explained by your Study Doctor. Those risks exist whether or not you take part in this Research Study. The risks associated with the study procedure are consistent with any brain vessel procedure to remove blood clots and include the risks described below:

These complications may be caused by the intervention or by the devices, or both. If any of these were to happen, you may need more treatment and it is also possible that your symptoms may get worse or you could die.

- An air bubble could enter your blood vessels
- Allergic reaction to the contrast dye. Minor allergic reactions may include a rash or hives. A serious allergic reaction could include shortness of breath and swelling, drop in blood pressure, and even death.
- Headache or pain during or following the procedure
- Bleeding or bruising where the device enters your body requiring surgery or blood transfusion
- Uncontrolled bleeding from the medicines given during the procedure to keep your blood from clotting may occur. If this cannot be controlled, it could lead to death.
- Risks due to use of anesthetics and sedative agents during the procedure include but are not limited to difficulty breathing, lowering of blood pressure, allergic reactions, and even rare life-threatening reactions. A small amount of radiation is used to obtain the pictures of your brain during the procedure. The radiation dose from this study is below the level thought to result in a significant risk of harmful effect.
- Risks to the embryo or fetus, if the subject becomes pregnant, are currently unknown
- Infection
- A piece of clot may travel further down your artery, or into a new area of your brain causing a new stroke
- Blood vessel tear or puncture
- Bleeding into the brain
- Damage to an artery causing it to form a pouch-like pocket or sac
- Artery spasm
- New clot formation (thrombosis)
- Blood vessel becomes re-blocked (re-thrombosis)
- Reduced blood flow to the brain (ischemia)
- Reduced mental functioning
- Discomfort from equipment used to monitor your condition during and immediately following the procedure
- Discomfort from frequent examinations performed before, during, and after the procedure
- A device could get stuck, or break off, and need to be left in your body.
- CT/MR pictures of the brain are considered standard medical care. The risk associated with performing a CT/MR scan is the radiation exposure. There is no increased risk of radiation because of participation in this study.

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- During an MRI or MRA no harmful radiation is involved. The MR contrast dye could cause one of the following in rare cases: mild to moderate headaches; coldness in the arm where dye is being injected; infection; nausea; dizziness; changes in heart rate and/or blood pressure; sneezing; dry mouth; or rash.
- Increase or decrease in blood pressure
- Slow, fast or irregular heartbeat (including abnormal heartbeat)
- Death
- There could be other risks that are not yet known.

What if new information becomes available about the study?

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

Also, upon receiving new information, your Study Doctor might consider it to be in your best interests to withdraw you from the Research Study. If this happens, he/ she will explain the reasons and arrange for your regular health care to continue.

What are the possible benefits of the study?

The Study Device stays on the nearest side of the blood clot and is used to suck the blood clot outside of your body. Because the Study Device does not need to cross to the other side of the blood clot, it is possible that the Study Device will reduce the likelihood of the blood clot breaking off and moving deeper into the brain vessel. Because this is still unknown, there may be no direct benefit in participating in the trial.

It is possible that you may have no direct benefit from being in this Research Study; however, the knowledge gained from your part in this Research Study may be used to help others in the future with brain clots similar to yours and reduce healthcare costs related to stroke.

What other choices do I have if I do not participate?

You may choose not to participate in this study. Your decision to participate or not will not affect your regular medical care in any way. There are other effective alternative treatment options outside of this research study. Discuss with the study doctor all of the available treatment options to you.

Will I be paid for being in this study?

You will not be paid to participate in this study.

Will I have to pay for anything?

You will not have to pay for any study related activities. You and/or your health insurance will be billed for the costs of the thrombectomy procedure and any standard medical care (not study related) received during your participation in the study. You are still responsible for any deductibles or applicable co-pays for routine office visits, scans and blood work. Please talk to your doctor and study team about putting you in touch with a financial counselor to determine exactly what the deductible and co-pay will be for you; this is highly variable depending on your type of insurance.

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What happens if I am injured from being in the study?

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the University of Pennsylvania to pay you or give you other compensation for the injury. Additionally, no funds have been set aside by the study sponsor to provide financial compensation or assistance for additional medical care or other costs associated. The costs of such medical treatments will be billed to you or your insurance company. If you feel this injury was caused by medical error on the part of the study doctors or others involved in the study, you have the legal right to seek payment, even though you are in a study. You do not give up your legal rights by signing this form.

If you think you have been injured as a result of taking part in this research study, tell the person in charge of the research study as soon as possible. The researcher's name and phone number are listed in the consent form.

When is the Study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. This study and/or your participation may also be stopped at any time by your Study Doctor, the study Sponsor, or the Food and Drug Administration (FDA) without your consent because:

- The Study Doctor feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The Sponsor, the study Principal Investigator, or the Food and Drug Administration (FDA) has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. Withdrawal will not interfere with your future care. Prior to your withdrawal in the study, your doctor may ask you to come in for a final study visit to make sure that you are okay.

How will my personal information be protected during the study?

We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. If this study is being overseen by the Food and Drug Administration (FDA), they may review your research records.

We will take every measure to protect your privacy and confidentiality. Any information will be coded by a study-specific identification number to protect your confidentiality. Study documentation will be kept and securely archived. Your identity will be kept confidential when the results of this study are published.

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Will information about this study be available to the public?

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 website at any time.

What information about me may be collected, used or shared with others?

- Name, address, telephone number, date of birth
- Personal and family medical history
- Results from any physical examinations, tests or procedures

Why is my information being used?

Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to:

- do the research
- oversee the research
- to see if the research was done right
- to evaluate and manage research functions.

Where may my information be stored?

Information related to your participation in clinical research will be contained in a clinical trial management system (CTMS). A clinical trial management system (CTMS) is used to register your information as a participant in a study. This allows for your research data to be entered and stored for the purposes of study operational and financial applications and other activities required as part of the conduct of the research. Once placed in the CTMS your information may be accessible to other authorized personnel at Penn Medicine that support research operations. Your information may be held in other research databases.

Who may use and share information about me?

The following individuals may use or share your information for this research study:

- The investigator for the study and the study team
- Other authorized personnel at Penn Medicine and the University of Pennsylvania, including offices that support research operations
- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB.

Who, outside of Penn Medicine, might receive my information?

It is possible that some oversight organizations may receive your information:

- The Food and Drug Administration
- The Office of Human Research Protections (OHRP)
- Imperative Care, Inc. (Sponsor and manufacturer of the Study Device)
- Contract Research Organization (People who work for the Sponsor)
- Independent Safety Board and Steering Committee (A group of doctors who will review side effects reported in the study)

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- Core Lab (A group of doctors who will review the x-rays or images taken of your blocked artery before and after the study procedure)

Once your personal health information is disclosed to others outside of Penn Medicine, it may no longer be covered by federal privacy protection regulations. The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

How long may Penn Medicine use or disclose my personal health information?

Your authorization for use of your personal health information for this specific study does not expire.

Your information may be held in a research database. However, Penn Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law

Can I change my mind about giving permission for use of my information?

Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the investigator for the study. If you withdraw your permission, you will not be able to stay in this study. To note, any data collected from the time of consent until notification of study withdraw will be retained as a part of study data. When your participation ends, no new information will be collected about you.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

You will be given a copy of this Research Subject HIPAA Authorization describing your confidentiality and privacy rights for this study.

By signing this document, you are permitting Penn Medicine to use and disclose personal health information collected about you for research purposes as described above.

Electronic Medical Record and Release of Study Related Information

What is an Electronic Medical Record?

An Electronic Medical Record (EMR) is an electronic version of your medical chart within a health system. An EMR is simply a computerized version of a paper medical record.

If you have never received care within Penn Medicine and are participating in a University of Pennsylvania research study that uses Penn Medicine healthcare related services, an EMR will be created for you for the purpose of maintaining any information produced from your participation. The creation of this EMR is a requirement of your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a

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hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have). If you have been a patient at Penn Medicine in the past, information from your research participation will be added to your existing medical record.

What may be placed in the EMR?

Information related to your participation in the research will be placed in your EMR maintained by Penn Medicine.

Once placed in your EMR your information may be accessible to appropriate Penn Medicine workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by Penn Medicine to be appropriate to have access to your EMR (e.g. Health Insurance Company, disability provider, etc.).

Penn Medicine also participates in automated information sharing through Health Information Exchanges (HIEs). HIEs securely share parts of your electronic health record, including research information, with other healthcare organizations involved in your care. This information is shared to improve the quality, safety and efficiency of your healthcare. To request that your health information not be shared through HIEs, please call 215-662-4484.

Will I, as a subject, have access to research related information within the EMR?

The 21st Century Cures Act requires healthcare institutions to allow patients increased access to their electronic medical record. As part of your participation in this research, you will have access to research related information within your EMR through Penn Medicine's patient portal – called MyPennMedicine (MPM). Results from all of your standard-of-care tests, procedures, notes and orders will be included in your EMR.

What may happen to my information collected on this study?

Future Use of Data:

While your identity will be stored in the study records, it will not be shared. For any future use, your information will be de-identified. De-identified means that all identifiers have been removed. The information could be stored and shared in this de-identified fashion. The information may be shared with other researchers within Penn, or other research institutions, as well as pharmaceutical, device, or biotechnology companies. It would not be possible for future researchers to identify you as we would not share any identifiable information about you with future researchers. This can be done without again seeking your consent in the future, as permitted by law. The future use of your information only applies to the information collected on this study.

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any question, concerns or complaints at the University of Pennsylvania by calling (215) 898-2614.

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When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that personal health information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you.

Name of Subject (Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Print)	Signature	Date

For subjects unable to give authorization,
the authorization is given by the following authorized subject representative:

Authorized Subject Representative (Print)	Authorized Subject Representative Signature	Date

Provide a brief description of above person authority to serve as the subject's authorized representative:

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