Informed Consent Form- New Clot Retrieval Device

You are having a stroke. The stroke is caused by a blood clot in the brain. You are going to have a procedure to remove the clot. You are being asked to participate in a research study for patients having a stroke. The study is about the tool doctors use to remove the clot. Several clot removal tools are available. This study is testing an additional tool that is not yet available in the United States. We need to talk with you about whether you want to be in this study.

Your doctor thinks you are an appropriate candidate for this study, but you do not have to be in it. **It is your choice. Either way you will be treated with the highest quality care.** This form tells you about the study. Please ask questions about anything that is not clear.

What is the study about?

This study is about the tool your doctor will use to remove the clot in your brain. The tool being studied is called the ClotTrap. The purpose of the study is to learn more about how well this tool works to remove blood clots and how it affects recovery from stroke.

How is this different from what would be done normally?

Other than the tool used, the procedure to remove the clot from your brain will be the same whether you are part of the study or not. If at any time your doctor decides that the ClotTrap is not appropriate for you, your doctor will use a tool that is better suited for your condition.

Has the ClotTrap tool been used before?

The ClotTrap tool has been used and approved as safe to treat strokes in Europe. It is considered investigational in the United States. This study is being done to meet requirements for approval in the United States.

What will be required of you?

As part of the study, you will have a physical exam before the procedure, 24 hours after the procedure, 7 days after the procedure, and 90 days after the procedure. These exams are in addition to ***routine*** care for your stroke. Brain scans and other tests that are part of ***routine*** care for stroke will be performed regardless of whether you decide to be a part of the study.

You can stop participating in the study at any time. Your care will not be affected.

What are the possible benefits of being in the study?

The main goal of this study is to improve care for patients with strokes. If the ClotTrap works better than other tools to remove clots safely, it is possible that your stroke may be more effectively treated. However, being in this study may not benefit you directly.

What are the possible risks of being in the study?

Your doctor will explain risks associated with the clot removal procedure. *The risks associated with clot removal are present whether you are in this study or not.* This tool is not known to have risks that are different from other clot removal tools. Although it is not expected, it is possible that additional risks may be discovered as this study goes on. A complete list of risks can be found in the accompanying study information sheet.

What is the alternative to being in the study?

The alternative to being in the study is simply to be treated with an approved tool that is selected by your doctor.

What happens if you are harmed by being in the study?

If you are harmed as a result of being in this study, the study sponsor will pay for costs associated with that injury. Additional information can be found in the study information sheet.

Will insurance cover treatment in the study?

There will be no extra charges to you or your insurance for being in this study. Payment for your stroke treatment will be handled just as it would be if you were not in the study, according to the terms of your insurance policy.

Will you be paid for being in the study?

You will not be offered payment for being in this study.

Will your information be kept private?

Your information will be kept private in accordance with research regulations. We use a special code to identify your information, and we will not identify you in research reports. However, your records may be reviewed by study sponsors or FDA, as allowed by research regulations. See the study information sheet for details on privacy rules and procedures if you have any questions.

What can you expect from the researchers?

If your doctor learns of new medical information that would affect your decision about being in the study, you will be told about that information. They will honor any decision you

make to withdraw from the study at any time. Your medical care will not be compromised in any way.

We want to answer questions you have about the study now or at any time. You do need to decide whether to be in the study before you have the clot removal. Our doctor, or someone from the study team, will also talk with you again after your procedure to answer questions you may have about the study.

Whom can you contact if you have questions or concerns?

You can contact the study doctor (_____), study team (_____), or the research review board (_____) at any time if you have questions or concerns.

A description of this study is available on http://www.ClinicalTrials.gov. This website does not identify patients. At most, it will include a summary of the results. You can search this website at any time.

Consent

Please **print** your name, **sign**, and **date** below if you agree to be in the study. By signing this consent and authorization form, you will not give up any of your legal rights.

_____

Name of Participant

_____ _____

Signature of Participant (18 or older and able to consent) **Date** **Time**

_____ _____

Signature of Legally Authorized Representative with authority for research decisions **Date** **Time**

_____

Relationship to Participant or Authority of Legally Authorized Representative

_____

Phone number for Legally Authorized Representative

_____

Name of Person Conducting Informed Consent Discussion

_____ _____

Signature of Person Conducting Informed Consent Discussion **Date** **Time**