INFORMED CONSENT FOR RESEARCH

CONSENT TO TAKE PART IN A STUDY TITLED:
Evaluation of longer duration use of the SAVI SCOUT Surgical Guidance System for Excision of Breast and Axillary Lesions in Neo-adjuvant Therapy Patients: A Pilot Study

PLEASE READ THIS FORM CAREFULLY AND COMPLETELY BEFORE SIGNING.

NAME OF PARTICIPANT:_____

YOUR STUDY DOCTOR(S): Erica Bloomquist, MD *Surgeon*,
Heather Wright, MD *Surgeon*,
Aeisha Rivers, MD *Surgeon,*
Mary K. Hayes, MD *Radiologist*,
Michel Velez, MD *Oncologist*,
Sayeh Lavasani, MD *Oncologist,*
Marcelo Blaya, MD *Oncologist,*
Mayra Frau-Reyna, MD *Radiologist,*
Rakesh Parbhu, MD *Radiologist*
Jessica Batista, MD *Radiologist*

WHAT IS THIS STUDY ABOUT?

We are asking you to take part in a research study. This form gives you information that will help you decide. If you do decide to take part, you will be given a copy of this form to keep if you agree to take part. Please read this form carefully and take your time making your decision. Ask the researcher or study staff any words or information that you do not understand. You can take an unsigned copy home to talk with family and friends before you decide to take part.

This study will look at the performance of a medical device called the SAVI SCOUT Surgical Guidance System (SAVI SCOUT, Cianna Medical, Inc.). This device is currently on the market and is used to aid in the surgical removal of breast and/or axillary (underarm) lesions. It does not contain wires or radioactive materials. The Food and Drug Administration (FDA) has given its clearance for this device to be placed inside the breast up to 365 days before surgery to mark a lumpectomy site intended for surgical removal. There are three parts to the SAVI SCOUT guidance system. One is the SCOUT reflector, which is a device that is placed in the breast and/or axillary tumor lesion (target) by a radiologist. The second is a hand piece (magic marker sized probe) that is placed in direct contact with the skin and is used to send/receive radar signals from the device through a console (third part). The SCOUT probe makes a sound when light and radar waves bounce off of it. This sound directs the surgeon to the SAVI device at the target lesion and both are removed during the procedure.

Other available devices with a similar purpose include the radiologist placing a wire (part inside the breast and part outside the breast) or placement of radioactive seeds into the target area to mark the area before surgery.

WHY IS THIS STUDY BEING DONE?

This is a pilot (small) study to test the SAVI SCOUT system's performance over a longer duration (31 to 365 days) in women receiving or scheduled to receive chemotherapy, biologics or hormone treatment before surgery to shrink their breast and/or axillary cancer tumor. Giving chemotherapy, biologics or hormones to reduce the tumor size before surgery is called neoadjuvant treatment. The SAVI SCOUT was approved by the FDA for this use on October 31, 2017. Information about placement and removal of the device, and preliminary safety information will be collected.

In some women who receive neoadjuvant treatment, the breast and/or axillary tumor and lymph nodes can shrink completely so that no remaining cancer can be found. This cannot always be predicted in advance. While this shrinkage is good for the patient, it can result in difficulty locating the initial target lesion(s) area on imaging studies. This may result in more imaging to locate the original target area(s) and placement of wires, SAVI reflectors, or other devices to mark the spot of the original tumor(s) before surgery.

If the SCOUT device(s) is placed prior to neoadjuvant treatment when the lesion(s) is larger and more clearly seen on imaging, then the target lesion(s) may be located better after a treatment response without the need for additional imaging or devices. This may lead to a more accurate surgical procedure. If this study demonstrates that the SAVI SCOUT system can stay in its original location and be removed surgically, this may mean that future patients may require fewer and/or less expensive imaging or procedures before surgery.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

The study population consists of up to 35 adult female surgical patient volunteers who receive neoadjuvant breast cancer treatment followed by surgery. This study will be conducted within Memorial Healthcare System.

WHAT WILL HAPPEN TO ME ON THIS STUDY?

Your breast surgeon will determine if you are eligible for this study. Once you decide to take part, you will be asked to read and sign this consent. You will be scheduled for the SAVI SCOUT device(s) procedure (31-365 days prior to surgery). The SCOUT device is placed using a needle. The breast and/or axillary area is injected with numbing medication before placing the device. One to four SCOUT devices may be placed based on your surgeon's choice. In this research study we will collect data on up to four SCOUT device(s) placed. Your medical oncologist will determine which neoadjuvant treatment is right for you. Your participation in this study will not affect which treatment is given to you. Upon completion of your neoadjuvant treatment, you will be scheduled for surgery.

Approximately 30 days before surgery, you will return to the radiology department for a recheck of the SAVI SCOUT device(s) and routine pre-operative skin marking. The SCOUT probe will be placed over the breast and/or axillary area to listen for the sound that the device is in place. If the device is found, no further device placement will be needed other than routine imaging prior to the surgery. You will then have the surgery, and the surgeon will remove the device and the breast and/or axillary target tissue. Information will be collected from your health and imaging records to look at the performance of the device(s) and any problems from the device.

If the device(s) cannot be located, the radiologist will talk with your surgeon to see if another device(s) (SAVI SCOUT or wire) should be placed. This will be done at no additional cost to you. If you have surgery at another location then we will collect information from the surgical record to see if the SAVI SCOUT system was used and the SAVI device(s) removed and problems from the device(s). Imaging scans and pathology results will be captured.

HOW LONG WILL I BE ON THIS STUDY?

Your participation will be completed after your surgical procedure to remove the SCOUT device(s). Information from your medical record will be collected including your treatment, tumor results, imaging, and surgical procedures.

WHAT ARE THE RISKS OF THE STUDY?

Medicine is not an exact science. No one can promise that you will have a good result from taking part in this study. There is a risk of rare bad results. There is a risk of bad results that were not known before.

The risks of SCOUT device(s) placement are similar to or less than wire placement: bleeding, injury to vessels, nearby tissue injury, pain, infection and repeating the procedure.

The most significant risk for this study is if the surgeon may not be able to successfully remove the device(s) and/or target lesion(s). This has not occurred to date in our clinical (greater than 150 patients; greater than 200 devices) experience at Memorial Healthcare System with our experienced breast surgeons. If this happens another surgery may be needed to remove the target lesion. The device(s) may be able to be removed during the next surgery or by the radiologist with a needle.

Another potential risk to the patients is that the SCOUT device(s) might move during the 31-365 day time period. This could possibly require a longer procedure to remove the lesion(s) and/or retrieve the device(s). This has occurred to date in our clinical experience in less than 1% of our initial 150 patients, which is less than half of the risk of the wire device risk (2-3%), which has been reported in the United States for over 30 years.

If the SCOUT device(s) is not detected (no sound) at the 0 to 30 days prior to surgery visit, you may end up having the standard of care procedure (wire or SAVI SCOUT as determined by surgeon). This standard of care procedure will be done at no additional cost. However, this may result in a slight increased procedure time since the first SCOUT device(s) will need to be removed in addition to the subsequent selected device(s). We anticipate this risk to be less than 1% (1/150 patients), which is less than routine standard of care (2-3%) wire procedure done before surgery. Fainting or mild light-headedness (vasovagal)

risks can occur with wire placement before surgery (2-3%). To date, our local experience has not identified this risk with SAVI SCOUT.
In a small percentage of patients following neoadjuvant treatment, the tumor has not shrunk completely. The surgeon may be able to locate the target lesion without the need for any devices to assist the location of the target. If this were to happen, you may not have needed the SAVI SCOUT procedure or other procedures (example: wire) before surgery. This cannot be predicted in advance.

We do not know how the device will interfere with pacemakers, so notify the Principal Investigator if you have one placed. Surgery and neoadjuvant treatments may affect an unborn child. We do not know if this device will affect an unborn child. Please discuss your participation in this study with the Study doctor if you are pregnant. You agree to notify the study doctor if you become pregnant during this study.

The risk of being in any study is a loss of the privacy of your information. Several means will be used to minimize this risk, as described below in the section "**WILL MY MEDICAL INFORMATION BE KEPT PRIVATE?"**

WILL I BENEFIT FROM THIS STUDY?

We cannot guarantee that you will benefit from taking part in this study. If the target lesion(s) is more easily seen, this may help with surgical removal. Your taking part may help patients in the future.

ARE THERE OTHER OPTIONS?

You do not have to take part in this study. You can have the standard of care procedure done (wire or SAVI SCOUT) just before surgery depending on what your surgeon chooses. You do not have to give your permission to use or give out your health information. Your healthcare providers' attitude about you or your care will not be affected by this decision.

WILL MY MEDICAL INFORMATION BE KEPT PRIVATE?

AUTHORIZATION (PERMISSION) TO USE OR DISCLOSE (RELEASE) IDENTIFIABLE HEALTH INFORMATION FOR RESEARCH

This research study will use records of current and/or future identifiable health information. This information will come from the records of your hospital, doctors' offices, clinics, or other places you get healthcare. This information also comes from your healthcare billing records. It includes information about your treatments and care. This information will be used for the purpose of meeting the goals of this study and is included in the "What will happen to me on this study: section of this consent for this study.

In order to protect the privacy of study participants, all study data will be restricted to password protected computers and servers on the protected Memorial Healthcare System and Sheridan networks. Any study data will have your personal identifying information removed before being sent to a third party.

Other people or organizations that help with this research may also get your medical information. Scout

devices that have been removed and would otherwise be discarded by pathology department after 3-4 weeks may be shared with the device manufacturer for purposes of scientific review.
You allow the use and disclosure of this information to:

- the researchers, doctors taking part in the study and their assistants;
- Cianna Medical Inc. (sponsor) or their agents or contractors:
- Memorial Healthcare System Study Monitor;
- Memorial Healthcare System Institutional Review Board;
- the Food and Drug Administration;
- People and organizations acting for any of the above.

You are letting Memorial Healthcare System and your healthcare facilities and providers give this information to the people, organizations, and parties listed above.
If it applies to your case, you give permission to use or disclose information about:

- Acquired Immunodeficiency Syndrome (AIDS)
- Human Immunodeficiency Virus (HIV) infection
- mental or behavioral health or psychiatric care
- or treatment for drug or alcohol abuse.

The term "Protected Health Information" means the information about your health that is protected under the law. It includes new and existing medical records and test results that contain information that could be used to identify you. It means medical records that include ways to identify you, such as your name; address; telephone number; date of birth; and medical record number. This may include information in your medical record and information created or collected during this study.

Federal and state laws require your records to be kept private. However, no one can promise complete confidentiality. Your Protected Health Information will sometimes be used or disclosed in the ways described in this form. In addition, after the researcher discloses your records to others then the law may no longer protect the privacy of your records listed above.

The results of this study may be published, but those publications will not identify you. Scientific data from this study may be presented at meetings. It may be published so that the information may be used to help others. Your participation in the study will not be made known and will be kept strictly confidential.

This authorization is voluntary. You do not have to give it. But, if you will not allow the use and disclosure of your identifiable health information, you will not be allowed to be part of this study. You can cancel this authorization at any time. But if you cancel after you have started the study, you will be removed from the study. Your canceling this authorization will not affect any use or disclosure made before the cancellation. That information will continue to be used in the study. It will not change any action that anyone had made because he or she relied on your authorization. It means that no new Protected Health Information about you will be used or disclosed. You may cancel this authorization by giving a written notice to:

Mary K. Hayes, MD
Chief of Women's Imaging, 3rd Floor -Dept. of Radiology,

Memorial Healthcare System
3501 Johnson St.
Hollywood, FL 33021

You have the right to see and copy your records related to the study for as long as the study doctor has this information. You do not have the right to review or copy records kept by researchers associated with this study.

This authorization does not have a fixed ending date. It stays in effect until it is canceled.

WHAT ARE THE COSTS (PAYMENTS) ASSOCIATED WITH THIS STUDY?

You will not be paid to take part in this study. There will be no anticipated additional costs to you or your insurance. The SAVI SCOUT procedure and device(s) placed prior to neoadjuvant treatment will be billed to you or your insurance. You or your insurer will be billed for routine medical and surgery care. Cianna Medical (sponsor) is providing funding for this study to your healthcare provider. These payments are anticipated to cover the costs of conducting the study. If this is of concern, please feel free to discuss this with study doctor or study staff.

WHAT IF I AM INJURED FROM TAKING PART IN THIS STUDY?

There is a risk that taking part in this study may hurt you. If you are hurt, medical care will be provided to you. All of that medical care will be charged and paid for in the same way it would be if you were not part of the study. Neither the study sponsor, nor the investigating doctors, nor the Hospital will pay for that care. Signing this form does not take away any of your legal rights. It does not release anyone from liability for negligence.

Funds to pay for pain, expenses, lost wages, and other damages caused by the injury are not routinely available. If you need help paying for losses or care caused by such an injury, ask the study doctor or a social worker about how you might get help.

WHAT ARE MY RIGHTS AS A STUDY PARTICIPANT?

You do not have to participate in this research study. You can agree to be in the study now and change your mind later. Your decision will not affect your regular care. Your doctor's attitude toward you will not change. There will be no penalty or loss of benefits. You are free to seek care from a doctor of your choice at any time. You will continue to receive medical care. If you decide to withdraw from the study after the device has been placed, please contact the Principal Investigator, so that arrangements can be made to remove the device or notify the surgeon performing your procedure.

You may be taken out of the study if:

1. Staying in the study would be harmful to you.
2. You need treatment not allowed in the study.
3. You fail to follow instructions.

4. The study is canceled.
5.

We may learn about new things that might make you want to stop being in the study. If this happens, you will be informed. You can then decide if you want to continue to be in the study.

WHAT IF I HAVE QUESTIONS OR PROBLEMS?

The Principal Investigator, Mary K. Hayes, MD, can be contacted at Women's Imaging, 3rd Floor - Dept. of Radiology, Memorial Healthcare System, 3501 Johnson St., Hollywood, FL 33021 **(954-265-6311) or mhayes@mhs.net.** Ask the Principal Investigator any questions you have about the research. Let the Principal Investigator know if you have a research-related problem or injuries at any time during the study.

If you have any questions about your rights in this study, you may contact in writing or by telephone:

The Chairman of the Institutional Review Board
Memorial Healthcare System
3501 Johnson Street, Hollywood, Florida 33021
Telephone number (954) 265-1857.

WHERE CAN I GET MORE INFORMATION?

You may also visit the following Web site for information on SAVI SCOUT at: http://www.ciannamedical.com/

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.

If you want more information about this study, ask your study doctor.

STATEMENT OF CONSENT:

You have read and fully understand this form. The study has been explained to you. All of your questions were answered to your satisfaction. You sign this form freely and voluntarily. You agree to freely take part in this study. **A copy of this signed form will be given to you if you decide to take part.**

_____
PRINT NAME OF PARTICIPANT

_____ _____
SIGNATURE OF PARTICIPANT (18 and older) DATE*

_____ _____
SIGNATURE OF CONSENTING PERSONNEL DATE*

STATEMENT OF INVESTIGATOR:

I have discussed the nature of this research study and its possible benefits, risks, and alternatives with the participant. The participant stated that this information was understood to their satisfaction.

_____
PRINT NAME OF INVESTIGATOR

_____ _____
SIGNATURE OF INVESTIGATOR DATE*

*Each person who signs the consent must personally enter the date for his/her signature.