RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: Breast Compression: Evaluating Image Quality and Comfort of an Investigational Curved Paddle Compared to a Standard Paddle

PROTOCOL NO.: 2016-03 (NCT03611543)
WIRB® Protocol #20162084

SPONSOR: Hologic, Inc.

INVESTIGATOR: Name
Address
City, State, Zip
Country

STUDY-RELATED PHONE NUMBER(S): Name
Name (24-hour number required)

SUMMARY

You are being asked to be in a research study. The purpose of this consent form is to help you decide if you want to be in the research study.

You should not join this research study until all of your questions are answered.

Things to know before deciding to take part in a research study:

- The main goal of a research study is to learn things to help patients in the future.
- The main goal of regular medical care is to help each patient.
- Taking part in a research study is entirely voluntary.
- If you decide to take part, you can change your mind later on and withdraw from the research study.
- The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.
- Parts of this study may involve standard medical care. Standard care is the treatment normally given for a certain condition or illness.
- Other parts of this study may involve experimental (investigational) drugs or procedures that are being tested for a certain condition or illness. Investigational means the device, procedure, and software have not been approved by the U.S. Food & Drug Administration (FDA).
- Your medical records may become part of the research record. If that happens, your medical records may be looked at and/or copied by the sponsor of this study and government agencies or other groups associated with the study.

If you take part in this research study, you will be given a copy of this signed and dated consent form.

PURPOSE OF THE STUDY
The purpose of this study is to evaluate an investigational compression paddle and compare it to the standard mammography paddle. The compression paddle is the part of the mammography machine that applies pressure to the breast to enable the best imaging. The data from this study will be used to further develop and understand the feasibility of the paddle design for clinical adoption.

PROCEDURES
If you qualify and agree to participate in this research study, you will first sign this consent form before any study-related procedures are performed. During this study, you will undergo the below investigational procedure in addition to your scheduled breast examination. The investigational procedure will take approximately ten to fifteen minutes.

The investigational procedure may be performed before or after your standard prescribed mammography exam.

If you are presenting for an annual screening mammogram, you will have two additional mammogram images with the investigational paddle. The mammogram technologist will apply compression and acquire images on one breast in both the CC (horizontal or top to bottom view) and MLO (angle or side) view.

If you are presenting for a diagnostic mammogram, you will have one additional mammogram image with the standard paddle and one additional mammogram image with the investigational paddle. The mammogram technologist will position the breast with the lesion (if there are lesions in both breasts, the technologist will choose a breast) in the CC (horizontal or top to bottom) view or MLO (angled or side) view. The chosen breast will undergo up to two compressions in the same view using both the standard and investigational paddle.

After the images have been taken, you will be asked to answer a few questions rating any discomfort you may have experienced using a pain scale that will be provided to you. You will also be asked a few questions about your overall experience and which paddle you preferred while being imaged for this study.

Once the technologist has completed both your scheduled mammogram images and the investigational images, your participation in the study will be complete.

Approximately 500 women will participate in this research study at 4 – 5 centers. Approximately 100 women will be enrolled at [Site].

RISKS AND DISCOMFORTS
You participation in this study will involve some risks or possible discomfort to you.

Although the 2D and 3D mammograms are FDA approved imaging modalities, a risk of the proposed study is the additional radiation exposure you will received in having an additional two 2D plus 3D images. In addition to the radiation you would exposed to as part of your clinical care, the equivalent whole body radiation dose that you will receive as a result of the additional study images will be approximately 0.35 mSv. In comparison, we are exposed to radiation on a daily basis both from natural (sun and earth) and man-made sources. The average radiation dose from these sources for those living in the United States is approximately 1.5 mSv per year in the US. Thus, the additional radiation does from this study is therefore equivalent to about 3 months of the average background radiation dose or less.

You should be aware that the risk of effects from radiation is believed to increase with each exposure you receive (including procedures performed as part of your medical care).

Other potential risks of the research mammograms include the possibility of bruising, discomfort, or pain from compression of your breasts. Skin irritation and abrasion wounds are also potential risks.

Women who are pregnant or nursing a child may not take part in this study. If you have reason to believe you might be pregnant or think that you have gotten pregnant during the study, you must tell your study doctor immediately. Pregnant women will be taken out of the study.

NEW INFORMATION
You will be told about any new information that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

BENEFITS
This study does not involve the administration of a drug or therapeutic agent. Therefore, subjects will see no direct health benefit from this study. If anything is seen on the study images that is not seen on the current standard of care, additional standard of care imaging will be conducted in order to confirm or nullify the finding in the study images. The additional standard of care images will not be charged to you or your insurance company. You are under no obligation to have the additional testing conducted.

Information learned in this study may help others in the future.

COSTS
There are no associated costs for the investigational imaging in this study. Your standard of care images will be billed to you or your insurance as normal. If anything is seen on the study images that is not seen on the current standard of care, additional standard of care imaging will be conducted in order to confirm or nullify the finding in the study images. The additional standard of care images will not be charged to you or your insurance company.

The Sponsor, Hologic, Inc. will provide the study imaging free of charge during this study. Tests and procedures that are done only for the study will not be billed to you or your insurance company.

You or your insurance company may be billed for:

- Any standard medical care given during this research study.

PAYMENT FOR PARTICIPATION
[To be completed by site]

ALTERNATIVE TREATMENT
This is not a treatment study. Your alternative is not to be in this study. You will still receive your scheduled screening or diagnostic mammogram exam if you decide not to participate in this research study.

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES
What information may be used and given to others?
The study doctor will get your personal and medical information. For example:

- Past and present medical records
- Research records
- Records about your study visits
- Information gathered for this research about:
  - Physical exams
  - X-ray and other test results
- Records about the study device

Who may use and give out information about you?
The study doctor and the study staff.

Who might get this information?
The sponsor of this research. "Sponsor" means any persons or companies that are:

- working for or with the sponsor, or
- owned by the sponsor.

A copy of the tomosynthesis, ultrasound, and other associated breast images and reports will be provided to Hologic, Inc. (Marlborough, MA), a manufacturer of the Selenia Dimensions for research and development. However, your name and other identifiers will be removed from the images.

Your information may be given to:

- The U.S. Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS) agencies,
- Governmental agencies in other countries,
- Governmental agencies to whom certain diseases (reportable diseases) must be reported, and
- Western Institutional Review Board® (WIRB®).

Why will this information be used and/or given to others?

- to do the research,
- to study the results, and
- to see if the research was done right.

If the results of this study are made public, information that identifies you will not be used.

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.

May I review or copy my information?
Yes, but only after the research is over.

May I withdraw or revoke (cancel) my permission?
Yes, but this permission will not stop automatically.

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 study doctor. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
There is a risk that your information will be given to others without your permission.

Absolute confidentiality cannot be guaranteed because of the need to give information to the parties listed above. The results of this research study may be presented at meetings or in publications. Your identity will not be disclosed in those presentations.

COMPENSATION FOR INJURY
If you are injured or get sick as a result of being in this study, call the study doctor, [Study Doctor Name], at [Phone Number;] or the study coordinator, [Study Coordinator Name;], at [Phone Number] immediately. Your study doctor will treat you or refer you for treatment. Your insurance will be billed for this treatment. The sponsor will pay any charges that your insurance does not cover. No other payment is routinely available from the study doctor or sponsor.

VOLUNTARY PARTICIPATION AND WITHDRAWAL
Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent for any reason, including:

- if it is in your best interest
- if you do not consent to continue in the study after being told of changes in the research that may affect you
- your study doctors determines that you should no longer participate in the study

If you leave the study before the planned final visit, you may be asked by the study doctor to have some tests or procedures done so that you leave the study safely.

SOURCE OF FUNDING FOR THE STUDY
The sponsor Hologic, Inc. will pay for this research study.

QUESTIONS
Contact [Name] at [Phone Number] for any of the following reasons:

- if you have any questions about your participation in this study,
- if you feel you have had a research-related injury or a reaction to the study device, or
- if you have questions, concerns or complaints about the research.

If you have questions about your rights as a research subject or if you have questions, concerns or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com

WIRB is a group of people who independently review research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Do not sign this consent form unless you have had a chance to ask questions and have gotten satisfactory answers.

If you agree to be in this study, you will receive a signed and dated copy of this consent form for your records.

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.

CONSENT
I have read this consent form (or it has been read to me). All my questions about the study and my part in it have been answered. I freely consent to be in this research study.

I authorize the release of my medical and research records for the purpose of this study.
By signing this consent form, I have not given up any of my legal rights.

By signing this consent form, I have not given up any of my legal rights.

CONSENT SIGNATURES:

_____
Subject Name (printed)

_____ _____
Signature of Subject Date

_____ _____
Signature of Person Conducting the Informed Consent Discussion Date