BRONSON

Affix Patient Label	
Patient Name:	Date of Birth:

Informed Consent: Needle Core Biopsy with Possible Clip Placement and/or Needle Aspiration of the Breast/Axilla

This information is given to you so that you can make an informed decision about having a **needle core biopsy with possible clip placement and/or needle aspiration of the breast/axilla**.

Reason and Purpose of this Procedure:

This procedure is done to assist your physician in diagnosing and treating an abnormality that was seen on your imaging exams of the breasts or axilla.

Using a needle, a small incision may be necessary, the physician will attempt to remove or take a small piece of tissue, cells or fluid in your breast and/ or axilla. The physician will use a mammogram, Ultrasound or MRI machine to help guide them directly to the area that is abnormal. Tissue removed will be sent to the pathologist for examination. Fluid may or may not be sent to the lab.

At the time of the tissue sampling, a tiny marker or clip may be placed in your breast at the biopsy site. This is done so that your doctor or surgeon can easily find the area biopsied, for future monitoring, to confirm a mammogram and ultrasound abnormally are the same, or if a follow-up procedure is needed to remove more tissue. If the biopsied abnormality does not need to be surgically removed, the clip will remain permanently.

Local anesthetic will be injected. For most patients, the procedure is well tolerated. Some patients will have moderate discomfort.

Benefits of this Procedure:

You might receive the following benefits. Your doctor cannot promise you will receive any of these benefits. Only you can decide if the benefits are worth the risk.

- To assist your physician to diagnose an abnormality. This will help them determine any further need of treatment.
- Treatment for pain or infection.

Risks of this Procedure:

No procedure is completely risk free. Some risks are well known. There may be risks not included in the list that your doctor cannot expect.

- **Pain**: At incision or needle placement site. Your doctor can discuss how best to treat the pain with you.
- **Infection**: Could occur in the skin, soft tissue under the skin or at the internal biopsy site. These infections are rare. You may need antibiotics. In rare cases, an infection may need to be drained with a needle or by surgery.
- **Bleeding**: At the incision or internal biopsy site. This usually resolves on its own. In severe cases, you may need further treatment.
- **Pneumothorax**: The needle may puncture the lung causing collapse. This may resolve on its own, or you may need a chest tube to re-expand the lung.
- **Reaction to Local Anesthetic**: The most common reactions are hives and rash. You may need medication to treat.
- **Inconclusive result**: You may need a surgical biopsy if the needle biopsy does not fully explain the abnormality
- **Skin necrosis (death of skin tissue)**: At the injection site. This is rare. You may need treatments with medication or surgery.

Risks Associated with Smoking:

Smoking is linked to an increased risk of infections. It can also lead to heart and lung complications and clot formation.

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Risks Associated with Obesity:

Obesity is linked to an increased risk of infections. It can also lead to heart and lung complications and clot formation.

Risks Specific to You:

_____

_____

_____

_____

Alternative Treatments:

Other choices:

- You and your physician can decide whether surgery with general anesthesia is an option.
- Do nothing. You can decide not to have the procedure.

If you Choose not to have this Treatment:

- The reason for your breast abnormally will not be completely known.
- Your doctor will not be able to treat the abnormality.
- If the abnormality is cancerous and goes undiagnosed, you may die.

General Information

During this procedure, the doctor may need to perform more or different procedures than I agreed to.

During the procedure, the doctor may need to do more tests or treatment.

Tissues or organs taken from the body may be tested. They may be kept for research or teaching. I agree the hospital may discard these in a proper way.

Students, technical sales people and other staff may be present during the procedure. My doctor will supervise them.

Pictures and videos may be done during the procedure. These may be added to my medical record. These may be published for teaching purposes. My identity will be protected.

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By signing this form, I agree:

- I have read this form or had it explained to me in words I can understand.
- I understand its contents.
- I have had time to speak with the doctor. My questions have been answered.
- I want to have this procedure: ☐ **Left,** ☐ **Right, or** ☐ **Bilateral - Needle Core Biopsy with Possible Clip Placement and/or Needle Aspiration of the Breast/Axilla** _____
- I understand that my doctor may ask a partner to do the procedure.
- I understand that other doctors, including medical residents or other staff may help with procedure. The tasks will be based on their skill level. My doctor will supervise them.

Provider: This patient may require a type and screen or type and cross prior to procedure. If so, please obtain consent for blood/products.

Patient Signature: _____ Date: _____ Time: _____

Relationship: ☐ Patient ☐ Closest relative (relationship) _____ **☐ Guardian/POA Healthcare**

Interpreter's Statement: I have interpreted the doctor's explanation of the consent form to the patient, a parent, closest relative or legal guardian.

Interpreter's Signature: _____ ID #: _____ Date: _____ Time: _____

For Provider Use ONLY:

I have explained the nature, purpose, risks, benefits, possible consequences of non-treatment, alternative options, and possibility of complications and side effects of the intended intervention, I have answered questions, and patient has agreed to procedure.

Provider signature: _____ Date: _____ Time: _____

Teach Back:

Patient shows understanding by stating in his or her own words:

_____ Reason(s) for the treatment/procedure: _____

_____ Area(s) of the body that will be affected: _____

_____ Benefit(s) of the procedure: _____

_____ Risk(s) of the procedure: _____

_____ Alternative(s) to the procedure: _____

OR

_____ Patient elects not to proceed: _____ Date: _____ Time: _____
(Patient signature)

Validated/Witness: _____ Date: _____ Time: _____