

Informed Consent for Mammotome (vacuum-assisted) Breast Biopsy

Patient Name _____

PAMC# _____

PRE-BIOPSY MEDICATION INSTRUCTIONS:

Please inform us **BEFORE MAKING A BREAST BIOPSY APPOINTMENT** if you are:

- **Taking anti-coagulants** (“blood thinners” such as **COUMADIN** and **HEPARIN**). Let us know if you are taking such a drug. It **MUST** be stopped for several days for us to do a biopsy. We will contact the physician who prescribed the drug and seek approval for stopping it. We will then contact you.
- **Taking ASPIRIN, ADVIL, any similar drugs** (those taken mainly for pain or arthritis), **or large doses of vitamin E or fish oil**. They can affect blood clotting. **DO NOT TAKE THOSE DRUGS FOR 7 DAYS BEFORE THE BIOPSY OR FOR 2 DAYS AFTER THE BIOPSY**. Instead take acetaminophen (Tylenol) for pain. Multi- vitamins are OK.
- Allergic or unresponsive to local anesthetic injections, such as Lidocaine.

DAY OF BIOPSY INSTRUCTIONS:

Eat a light breakfast or lunch prior to the biopsy, limiting fluids. Wash your breasts and underarms thoroughly with soap and water. Wear loose-fitting, two-piece clothes to simplify undressing and dressing. Wear a brassiere. Be prepared to spend about 2 hours in the X-Ray Department.

DESCRIPTION OF THE PROCEDURE:

For Stereotactic Biopsy: You will lie face down with the breast to be biopsied protruding through an opening in the biopsy table. The x-ray technologist firmly compresses the breast, takes x-ray pictures to locate the mammographic abnormality, and cleanses the skin. The radiologist injects a local anesthetic (Lidocaine) and inserts a special biopsy needle into your breast. A stereotactic breast biopsy machine, using x-rays in conjunction with a computer, is used by the radiologist to guide the needle to the area of abnormality seen on your mammogram. Multiple tissue samples are removed.

For Ultrasound Guided Biopsy: You will lie on your back on the biopsy table. The technologist locates the abnormality using the ultrasound machine, takes pictures and cleanses the skin. The radiologist injects a local anesthetic (Lidocaine) and inserts a special biopsy needle into your breast, using ultrasound to guide the needle to the area of abnormality. Multiple tissue samples are removed.

After the biopsy, one or two 1/8-inch metal markers (with or without associated gelatin pellets) are usually placed in the breast (through the same biopsy needle) for future surgical reference. No marker is placed if part of the mammographic abnormality is clearly still evident after the biopsy. If a marker is placed, a two-view, upright mammogram is obtained after the biopsy to measure the distance from the biopsy site to the marker. The marker does not set off metal detectors at the airport or elsewhere. It only shows up on future mammograms.

RISK OF PROCEDURE:

During the biopsy, most patients experience only mild discomfort. Rarely patients may experience significant bleeding or pain during the biopsy. Following the biopsy, bruising is common. Discomfort, tenderness, and bleeding at the biopsy site are all usually mild, but occasionally they are significant. Post-biopsy breast infection and other risks and complications rarely occur. Complications, from this biopsy or any other type of breast biopsy, can delay subsequent breast surgery. The metal marker sometimes attaches to breast tissue too far from the biopsy site to be useful as a future reference. Rarely patients may have an allergic reaction to the local anesthetic.

ALTERNATIVES TO THIS PROCEDURE:

The abnormal area can be removed by surgical excision, which is a somewhat more extensive and costly procedure, with approximately the same accuracy as a Mammotome biopsy. A Mammotome biopsy is an advanced form of core biopsy

that allows multiple tissue samples to be removed with each needle insertion. The biopsy can be done by core biopsy or fine-needle aspiration techniques, which usually give a less definitive diagnosis. Alternatively, the abnormality can be followed on serial mammograms, and not biopsied at all. That approach is used when there is deemed to be a very low likelihood of breast cancer.

BENEFIT OF PROCEDURE:

A definitive diagnosis of the breast abnormality can usually, but not always, be made. Most women who have had both a surgical excisional biopsy and a Mammotome biopsy state that the Mammotome biopsy is far less stressful physically and emotionally. Cancer that is first diagnosed by a Mammotome biopsy can usually be treated with one operation instead of two.

POST-BIOPSY INSTRUCTIONS:

1. Place an ice pack (which we will provide) inside your brassiere, on top of the dressing. Keep the ice pack in place for **ONE HOUR AFTER THE BIOPSY** and then for 10 minutes per hour until bedtime. Be prepared to add fresh ice.
2. If an elastic bandage is used instead of an ice pack, keep the elastic bandage on **for 24 or 48 hours**, as instructed at the end of the biopsy.
3. If you need medication for discomfort, take Tylenol. Do **NOT** take aspirin, Advil or similar drugs for 2 days after the biopsy. Contact your physician if you need a stronger pain medication.
4. Do **NOT** take **HEPARIN** shots or **COUMADIN** pills until the fourth day after the biopsy.
5. Do not participate in strenuous activities for 48 hours following the biopsy.
6. Watch for excessive bleeding or pain. If either occurs, contact the Palo Alto Medical Clinic and ask for the "x-ray doctor on call" – (650) 321-4121. If significant bleeding occurs, apply **firm pressure** with both hands to the biopsy area for 10 minutes.
7. Don't shower or bathe until the dressing is removed, the next day.
8. We will call you the day after the biopsy to check on the status of your breast.
9. After you remove the pressure dressing, which may or may not cause the steri-strip (tape) to come off, you may bathe or shower .
10. If the steri-strip (tape) does not come off with the pressure bandage, remove it 2 days after the biopsy.
11. If there is slight bleeding at the biopsy site after the pressure bandage is removed, cover the area with a Band-Aid.

BIOPSY RESULTS:

The results of the microscopic examination of the biopsy tissue samples will be called to your doctor within 3 working days from the time of the biopsy. Your doctor will relay those biopsy results to you. Please call your doctor on the fourth working day after the biopsy if you have not received the results by then.

If the breast tissue is benign (not malignant), **BREAST FOLLOW-UP IS VERY IMPORTANT** since there is a small chance of inaccuracy with any type of breast biopsy. Breast follow-up will be done by mammography (usually 6 or 12 months and then once a year post-biopsy) and by physical examination (as recommended by your doctor). If the tissue sample is malignant (cancer) or atypical (precancerous), your doctor will recommend appropriate treatment. In the occasional case where a definitive diagnosis is not possible from the tissue sample, your doctor will discuss appropriate diagnostic alternatives, which may include surgical excision.

CONSENT:

From reading "A Woman's Guide to Breast Cancer Diagnosis and Treatment", from reading this form, and from discussion with the radiologist, I have been informed of the nature, risks, and benefits of this procedure, am aware of the alternatives, and know that no guarantee has been made as to the results which may be obtained.

PATIENT SIGNATURE _____ DATE _____
(or legally authorized person for minor or person who is incapacitated)

Relationship of legally authorized person to patient _____

WITNESS TO SIGNATURE _____ DATE _____