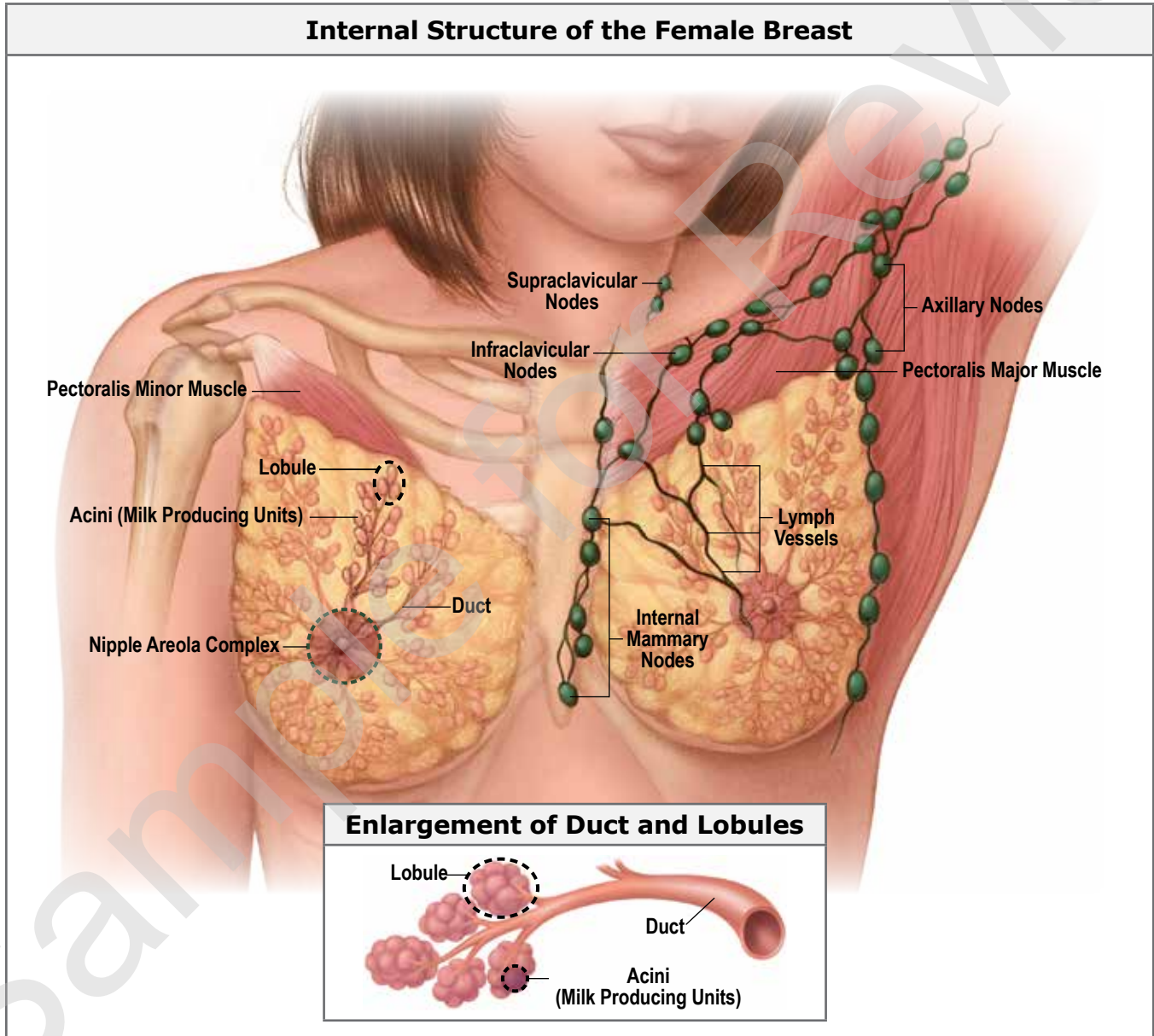


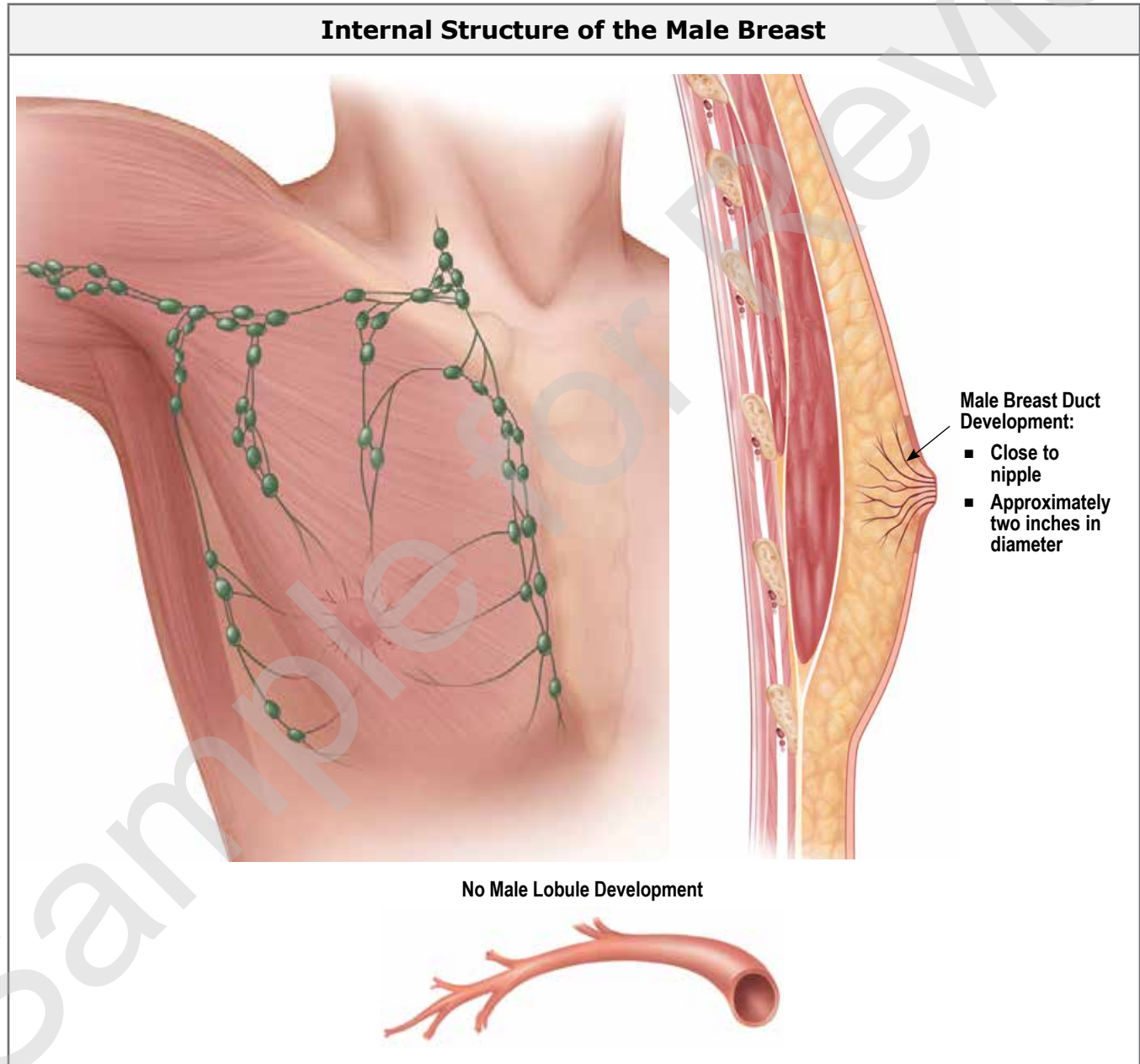
Your Breast Center Logo

Breast Anatomy - Female



Your Breast Center Logo

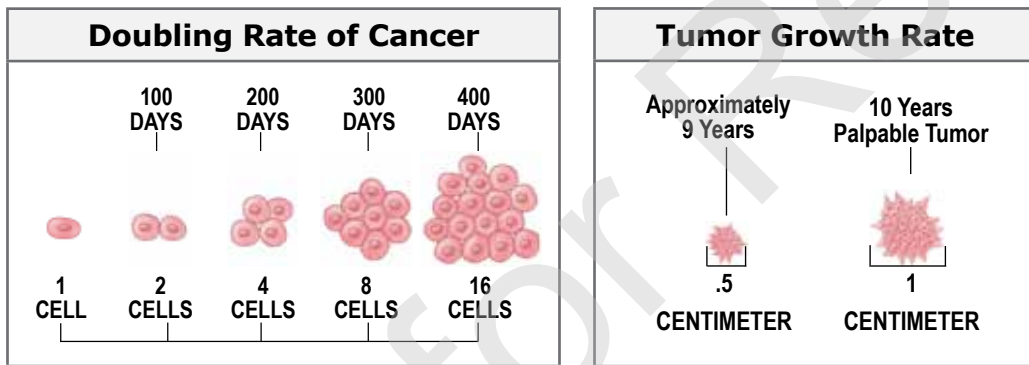
Breast Anatomy - Male



Your Breast Center Logo

Cancer Growth Rate

Cancer begins when a cell undergoes an abnormal conversion or damage that allows the cell to continue to reproduce itself. The growth process is an exponential process where the cell doubles in size with each cell division from one abnormal cell to two, then two to four, then four to eight, then eight to sixteen, etc. The growth process varies in individuals and in different types of cancer.



Some cancers grow rapidly, while others grow very slowly. Breast cancers have been shown to double in size every 23 to 209 days. A tumor that doubles every 100 days (the estimated average doubling time) would have been in your body for approximately eight to ten years when it reaches about one centimeter in size (3/8 inch) – the size of the tip of your smallest finger. By the time a one-centimeter tumor is found, the tumor has already grown from one cell to approximately 100 billion cells.

Determining Tumor Growth Rate

The percentage of cancer cells that are actively dividing in a cancerous tumor is called the proliferation rate. During the pathology evaluation of a tumor, the pathologist commonly uses the Ki-67 test to reveal the growth rate of the removed tumor. In general, the higher the proliferation rate, the more aggressive a tumor tends to be.

Additional Information:



Male Breast Cancer

Male breast cancer is rare, accounting for less than one percent of all diagnosed breast cancers. The diagnosis usually occurs in older men. The average age is between 60 - 70 years. The presenting characteristics and treatments given for male breast cancer are very similar to that of female breast cancer.

The cause for the majority of male breast cancer, like female breast cancer, is often not identifiable. The BRCA2 gene has been implicated in male breast cancer. It is recognized as a potential cause of breast or pancreatic cancer diagnosed in both men and women and prostate cancer in men who have a family history of cancer.

Identified Risk Factors for Male Breast Cancer:

- BRCA2 gene carrier
- Jewish heritage
- African-American heritage
- History of mumps or orchitis after age 20
- Klinefelter syndrome
- Conditions of increased or excessive estrogen levels
- Conditions causing decreased testosterone levels
- Occupational jobs that cause high environmental exposure to heat (steel mills, etc.)
- Exposure to electromagnetic fields for extended periods of time
- Exposure to ionizing radiation

Diagnosis of male breast cancer is similar to that of the female. Most male breast cancers show up as a hard lump on one breast, under the areola and anchored in surrounding tissues when examined with the hand. Some men may have nipple discharge. Infiltrating ductal carcinoma, as in female breast cancer, composes the vast majority of male breast cancer (87 percent).

Mammograms are very helpful in identifying the presenting symptom as a malignancy. Needle biopsies, FNA or core, are used to obtain a histological diagnosis.

Mastectomy is usually the surgery of choice. A modified radical is most often performed unless there is chest wall involvement of the muscle that requires a radical mastectomy with removal of the pectoralis muscles.

Some men receive radiation therapy because of the close proximity of the tumor to the chest wall. Chemotherapy is used for large tumors and/or positive lymph nodes. A higher percentage of men are diagnosed in the later stages of the disease than women because of the lack of screening programs.

Chemotherapy protocol drugs are identical to female breast cancer drugs. Tamoxifen is added if the tumor tested positive for estrogen or progesterone receptors. For many years, orchiectomy (removal of the testes) was used to reduce hormones in the man's body. Now, men are more often treated with various anti-hormonal drugs. Orchiectomy is now a third-line option because of the effectiveness of anti-hormonal drugs.

Dealing with the side effects of chemotherapy is the same as in females. The use of tamoxifen causes hot flashes and reduces the sex drive.

The challenge in male breast cancer, like female breast cancer, is early detection. The earlier the stage of the disease, the better the prognosis.

Additional Information:

Your Breast Center Logo

Pathology Report

After the surgical removal of your tumor, it goes to a pathology laboratory for numerous evaluations and tests. A pathologist, a physician specializing in diagnosing diseases from tissue samples under a microscope, analyzes your tumor for a number of characteristics. These characteristics compile your pathology report.

Gross Description

The pathologist first describes the size, weight and color of the tissues removed during your surgery called the gross description. The shape of the tumor is reported as round, spherical or having irregular contours (edges), such as stellate or spiculated.

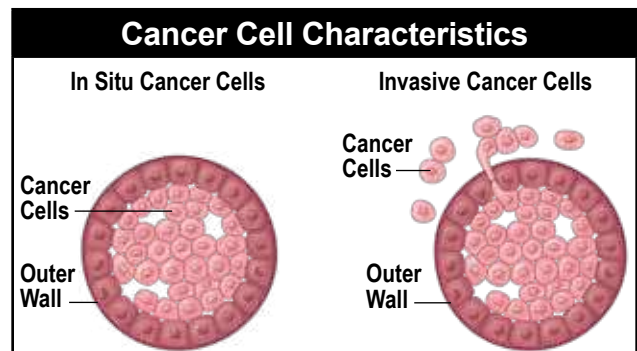
Tumor Preparation

The tumor is prepared for study under a microscope by cutting the tissue into very thin slices. Each slice is then mounted on a slide for microscopic study. These studies provide critical information about your tumor's biology (how it behaves in your body). A pathology report containing your unique characteristics is prepared and sent to your physician. The characteristics identified in this report provide foundational information on which your physician makes treatment decisions. In the future, if additional studies are needed or if research unfolds new tissue diagnostic tests, your pathology slides will be available at the pathology lab.

Type of Breast Cancer Identified

Normal ducts and lobules are lined with one or more layers of cells in an orderly pattern. When normal cells become cancerous, they change their appearance from a normal cell to an abnormal cell. Cancerous cells may lose some, or all, of their normal cell characteristics. Cancer cells behave in an abnormal way. Unlike a normal cell, cancer cells do not stop dividing but continue to divide and grow in size. They can also leave the breast duct or lobule where they started and grow through the wall into surrounding tissues. The first step in evaluating your cancer is to determine if your tumor has grown through the wall where your cancer started.

- **In Situ Cancer:** Cancer cells are contained within the duct or lobule where they originated. The cancer cells have **not** grown through the walls and invaded healthy surrounding tissues. In situ cancer is non-invasive. This type of cancer has a good prognosis.
- **Invasive (Infiltrating) Cancer:** Cancer cells have grown through the wall of the duct or lobule and are growing in healthy surrounding tissues. Micro-invasive means that only a small number of cells have grown through the duct or lobular walls.



Histological Name Of Your Breast Cancer

There are over 15 types of breast cancer (histological types) based on the pattern of tumor cell arrangement when viewed under a microscope. Pathologists identify the histology pattern, and your pathology report provides the histological name of your breast cancer. The most common histological types and names of breast cancer are listed below along with the approximate percentage of occurrence.

■ In Situ Cancers Histological Names:

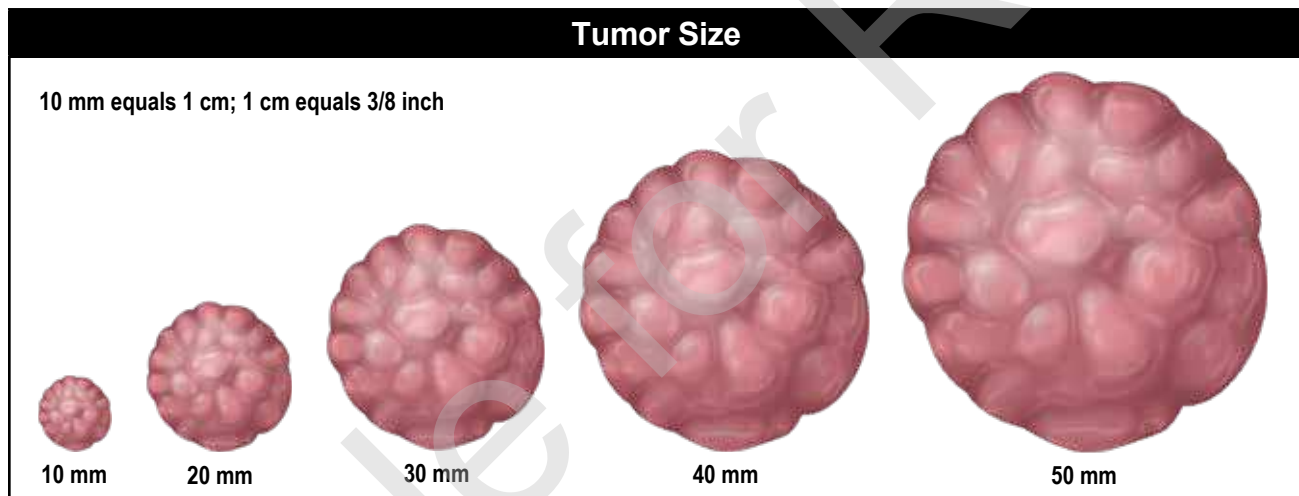
- Ductal carcinoma in situ (20%)

■ Invasive Cancers Histological Names:

- Invasive (infiltrating) ductal (52%)
- Invasive lobular (10%)
- Medullary (6%)
- Inflammatory breast cancer (5%)
- Mucinous or Colloid (3%)
- Tubular (2%)
- Paget disease with intraductal (1%)
- Cribiform (1% or less)
- Papillary (1% or less)
- Micropapillary (1% or less)
- Adenoid Cystic (1% or less)
- Secretory (1% or less)
- Mixed Ductal and Lobular

Tumor Size

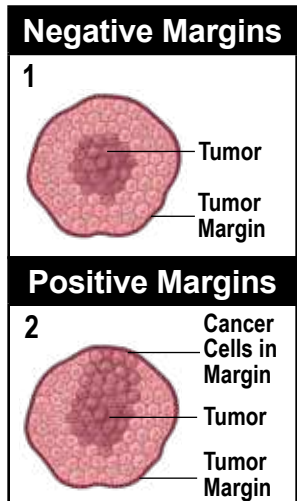
Tumor size is measured at the widest diameter and reported in millimeters (mm) or centimeters (cm).



Surgical Margins

Surgical margins report the shortest distance between the tumor edge and the surgical edge of the tissue removed during surgery. This distance is called the margin of resection. The margin of resection is looked at closely to determine if cancer cells are present. Pathology margins are reported as:

- **Negative, Clear, Clean or Uninvolved:** There was no evidence of cancer cells in the margins (*illustration 1*)
- **Positive, Involved or Residual Cancer:** Cancer was found in the margins and will probably require more surgery (*illustration 2*)
- **Close:** Cancer cells are close to margins and may require more surgery
- **Indeterminate:** Pathologist could not determine margin status



Lymph Node Status

If your surgery included lymph node removal, the report states the removal area, the number of nodes removed and how many nodes tested positive for cancer cells. Pathology reports lymph nodes as:

- **Lymph Node-Negative:** No cancer found in the lymph nodes
- **Lymph Node-Positive:** Cancer found in the lymph nodes

Breast Cancer Biomarkers

Biomarkers play a significant role in the management of breast cancer. These biomarkers include estrogen (ER) and progesterone (PR) receptor status, and HER2 receptor status. Each biomarker is evaluated for its degree of impact on a tumor. Biomarkers provide essential treatment guidance by predicting the future sensitivity to different treatments.

Determining Biomarkers Status

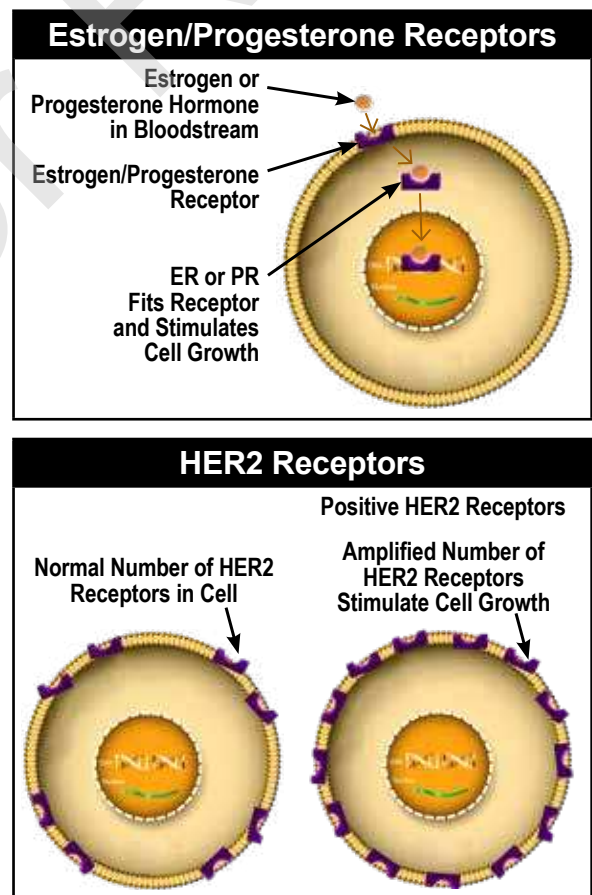
During pathology examination, your tumor is tested for estrogen (ER), progesterone (PR) and HER2 **receptors** located on the cell surface. If present, receptors for ER, PR or HER2 stimulate your tumor growth. Receptors are like little chairs with different shapes that sit on the surface of breast cancer cells. When blood passes a cell, an element in the blood may be a perfect match in size and shape to fit into the chairs. When an element fits a cell chair, it sends a signal to stimulate cell growth. Your pathology report will state if you are positive or negative for ER, PR or HER2 receptors and the degree of positivity.

- **Estrogen/Progesterone Receptors:** If ER or PR receptors are present, your tumor is stimulated by the female hormones estrogen or progesterone to grow. The number of receptors for ER/PR may range from none (negative) to high. ER and PR are studied and documented separately. One may test positive and the other negative or both may be negative or positive. ER/PR receptor status is a determining factor for treatment decisions. The status of your hormone receptors determines if you will benefit from endocrine (hormonal) therapy. Hormone receptor status is reported as:

- ER positive (+) PR positive (+)
- ER positive (+) PR negative (-)
- ER negative (-) PR positive (+)
- ER negative (-) PR negative (-)

Some reports may show the number of cell receptors out of 100 that test positive for ER or PR, called the Allred score. The score is reported on a scale from 0 to 8. The higher the score, the higher the number of positive receptors found.

- **HER2:** The HER2 gene makes a protein that controls how a cell grows, divides and repairs itself. If HER2 receptors are amplified (increased), it causes the breast cells to grow and divide in an abnormal way, stimulating cancer growth. Positive tumors have over-expressed or amplified HER2. Approximately 25 percent of diagnosed patients have elevated HER2 levels. Although elevation of HER2 indicates a more aggressive cancer, targeted drugs, like Herceptin®, block its influence on tumor growth. Having a positive HER2 means that a HER2-targeted drug will be included in your chemotherapy regimen.

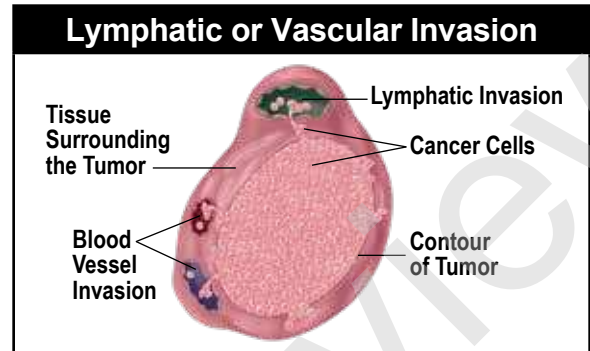


Tumor Growth Rate

Ki-67 is a proliferation (how fast a tumor is growing) study that measures a protein in a cell that increases prior to dividing. Study results below 10 percent are considered low; counts of 10 to 20 percent are considered borderline; counts over 20 percent are considered high. Higher Ki-67 levels indicate a more aggressive tumor.

Blood Vessel or Lymphatic Invasion

Vessel invasion is determined by microscopic examination of the tumor. No blood vessel or lymphatic vessel invasion offers a better prognosis. Evidence of invasion means cancer cells have entered into systemic circulation. *Note: Lymphatic invasion is different than lymph node involvement.*



Histological Grade

The histological grade of a tumor is determined by the Nottingham Scale (Scarff-Bloom-Richardson Grading System). The grading system evaluates the three tumor characteristics listed below on a scale from 1 – 3:

- **Tubular Formation:** How much of the tumor is arranged as tubules (Grading Scale range 1 – 3)
- **Nuclear Grade:** Size, shape and color of the nucleus in the tumor cells (Grading Scale range 1 – 3)
- **Mitotic Rate:** How fast the tumor cells are growing and dividing (Grading Scale range 1 – 3)

Final Histological Grade: The score of each tumor characteristic is added together to produce a final grade. The final grade may range from 3 – 9. A lower score (3) indicates a less aggressive tumor. A higher score (9) indicates an aggressive tumor and a need to consider more aggressive treatment.

Breast Cancer Subtypes

In some cancer centers, breast cancer is placed into categories based on ER, PR, HER2 and Ki-67 **combined status**, which indicate cancer aggressiveness. Breast cancer subtype categories include Luminal A, Luminal B, HER2 Positive and Triple Negative (Basal). Each subtype category has different gene expressions, metastatic potential and sensitivity to existing therapies. Subtype characteristics are profiled in the following chart.

Breast Cancer Subtypes Characteristics				
	Estrogen	Progesterone	HER2	Ki-67
Luminal A	Positive	Positive or Negative	Negative	Less than 14%
Luminal B	Positive	Positive or Negative	Positive or Negative	Greater than 14%
HER2 Positive	Negative	Negative	Positive	Greater than 14%
Triple Negative (Basal)	Negative	Negative	Negative	Greater than 14%

Triple-Negative Breast Cancer

Triple-negative breast cancer (TNBC) describes a cancer when three different breast cancer markers are all negative. TNBC tests negative for (1) estrogen receptors (ER-), (2) progesterone receptors (PR-), and (3) amplified human epidermal growth factor (HER2-). Traditionally, TNBC did not respond to existing **targeted** therapies for other breast cancers and treatment was limited to chemotherapy. However, new treatment options have recently become available, which include immunotherapy, PARP inhibitors and antibody drugs. Clinical trials are also currently studying other therapies for TNBC.

Pathology Report

The pathologist prepares a written report that is sent to your physician. If the hospital or cancer center conducts multidisciplinary conferences, the pathologist presents the findings at the conference. Time varies as to when the final report will be available. Many pathologists have a commitment to report within 24 hours after receiving the specimen. Ask your physician when you can expect to receive your pathology report. If the diagnosis reveals cancer, the pathologist's findings will help the physician(s) determine what further treatments will be needed. Additional diagnostic tests, such as a bone scan, liver scan, chest X-ray, CT scan or an MRI (magnetic resonance imaging), may be ordered. When all the results are received from the tests, your cancer will be staged on a scale from zero (in situ cancer) to four (a cancer with distant metastasis). Stage zero cancer is the least aggressive and has the best prognosis.

Pathology Report Summary

The bottom-line information is contained in the summary or final diagnosis section of your pathology report. Combining information from all of the other sections of the pathology report will provide a synopsis of the most important information regarding your cancer.

Pathology Report Questions

When you discuss the findings of your pathology report with your physician, you may want to ask the following questions and write down the answers. Some doctors will provide a copy of your pathology report for your records.

- What is the name of the type of cancer I have?
- Was my tumor in situ (inside ducts or lobules) or invasive (grown through the walls of the ducts or lobules)?
- What size was my tumor? (The size is in millimeters (mm) or centimeters (cm). 10 mm equals 1 cm. 1 cm equals 3/8 inch. 1 inch equals approximately 2.5 cm.)
- Was the cancer found anywhere else in my breast tissue?
- How many lymph nodes were removed? How many levels of lymph nodes did you sample or remove? (You have three levels of nodes.)
- Were any nodes positive with cancer cells?
- Was my tumor estrogen or progesterone receptor positive?
- Was my tumor HER2/neu positive?
- Did you grade my tumor on a grading scale and if so, what was the final cumulative score? (Grade 1: least aggressive; Grade 3: most aggressive)
- Is there anything else that I need to know about my cancer?

After the Pathology Report

Obviously, you have no control over the findings described in your pathology report. However, you can become an active participant with your physicians to help defeat the disease.

Remember:

- Breast cancer is a treatable disease. It certainly is not an illness you would choose, but it is an illness with many proven treatments.
- Acquire an understanding of the treatment options. This will allow you to communicate with your healthcare team and become an active participant in decisions. Understanding will alleviate many irrational fears and restore a sense of control over your life.

Employ the best of all medicines—your attitude. The most productive approach you can bring, and one which the physician cannot provide, is a positive, cooperative attitude. Determination, combined with optimism, creates a healing environment that only you can provide.

Your Breast Center Logo

EnCapsule Biopsy

Procedure Scheduled:

Patient Name _____

Procedure Date _____ Time _____ Facility _____

Facility Address _____ Telephone _____

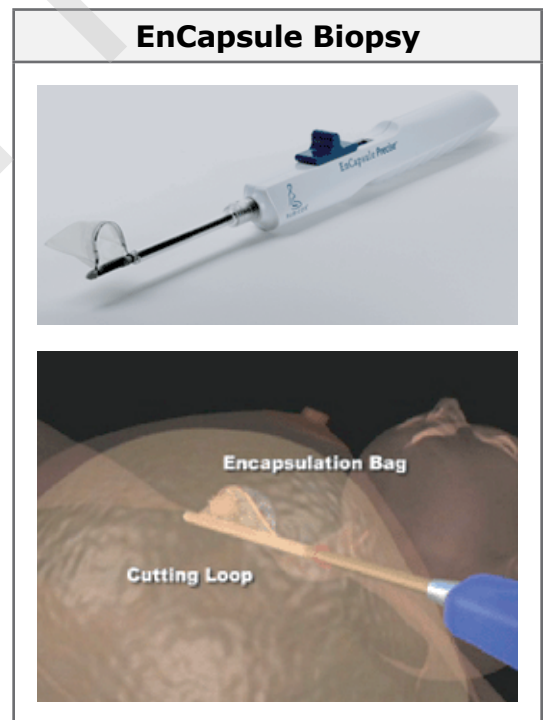
Physician _____

Definition of Terms:

- **Anesthetic** — Medication that produces loss of sensation for pain, local or general.
- **Antiseptic** — An agent to disinfect or to remove bacteria and other microorganisms.
- **Benign** — Not cancerous; of no danger to the body.
- **Biopsy** — The removal of tissue from the body to study the cells' structure.
- **Hematoma** — An accumulation of blood under the skin.
- **Malignant** — Cancerous; a threat to the body.
- **Pathology** — The study of disease processes and consequences.
- **Ultrasound** — The use of sound waves delivered by a machine to produce pictures of area, using no radiation.

Procedure Overview

The Rubicor® EnCapsule breast biopsy is a procedure that removes a lesion found in your breast in one piece. This minimally invasive biopsy is designed to take a single sample of the lesion in a matter of seconds. The physician makes one small nick in your breast and inserts the Rubicor® breast biopsy needle. The advantage of this type of biopsy is that it removes a larger sample of the lesion instead of multiple cores (strips) of tissue like some other biopsy methods. The specimen is enclosed in a small bag-like container. The larger biopsy sample gives a better representation of the lesion and surrounding breast tissue, helping the pathologist make a more definitive assessment.



Precautions:

- Tell your healthcare provider if you are taking blood-thinning medications such as Coumadin®, Plavix®, Eliquis®, Pradaxa®, Xeralto®, Effient®, Brilinta®, prednisone, aspirin or over-the-counter supplements such as fish oil or ginkgo.

Day of Biopsy:

- The biopsy is performed in a physician’s office.
- Allow one to two hours at the physician’s office for the entire procedure.
- Wear a comfortable two-piece outfit for the procedure.

Before the Biopsy:

- You will be asked to sign an informed consent document. This form states that a member of the healthcare team has thoroughly explained the risks and benefits of the procedure. Before signing, ask any questions you may have.

During the Biopsy:

- Your physician will find the lesion location in your breast using ultrasound or radiographic guidance.
- Numbing medication will be injected into the skin and breast.
- Once the area is numb, a small surgical nick will be made in the skin of your breast to allow insertion of the biopsy device. The biopsy probe is advanced to the lesion as the physician views the location of the biopsy probe on a screen.
- When the physician is assured that the device is in the right place, the EnCapsule loop and bag assembly is deployed to completely encircle the target. The handle is rotated, simultaneously cutting and collecting the breast biopsy specimen.
- During the procedure you may feel pressure, a tingling sensation or a slight burning sensation. Tell your healthcare provider if you experience pain.
- The biopsy probe is removed from your breast and the biopsy specimen is sent to a pathology lab.
- The surgical nick in your skin is closed with an adhesive strip or with a small adhesive bandage.

After the Biopsy:

- Unless your healthcare provider instructs you otherwise, you can return to normal, non-strenuous activities the same day.

Telephone number to call during office hours: _____

Telephone number to call after office hours: _____

Procedure Results:

- The pathologist informs your physician of the results of the biopsy, whether it is benign (not cancerous) or malignant (cancerous).
- Ask your physician when and how you can expect to receive the biopsy results.

Your results/report will be available: _____

You will receive the results/report from: _____

If you have not received your results/report by the date indicated, please call the office.

Things You Need to Know After A Breast Biopsy:

- No Yes A very small surgical marker or clip was placed at the site of your biopsy before the biopsy instrument was removed from your breast. This will be used to help identify the biopsied area on future mammograms or diagnostic studies. It will cause no future pain or disfigurement.

- No Yes A follow-up mammogram will be performed in 6 months to evaluate the breast and biopsied site.

- No Yes Ice pack: Fill a small Ziploc plastic bag with ice cubes or a small bag of frozen peas and place it over the biopsy site for 20 to 30 minutes to reduce swelling and discomfort. Repeat the process until _____

Special Instructions:
