

Breast reconstruction—words to know

Throughout your breast reconstruction journey, you may hear words and terms that you're not familiar with. To help you better understand your surgeon, we've put together this list of the most common terminology.

Asymmetry

Lack of proportion in shape, size, and/or position between the two breasts.

Biopsy

The removal and examination of tissues, cells, or fluid from the body.

Breast mass

A lump in the breast.

Capsule

Scar tissue which forms around the breast implant. Sometimes this capsule squeezes the implant, resulting in capsular contracture.

Capsular contracture

A tightening of the tissue capsule surrounding an implant, resulting in firmness or hardening of the breast and squeezing of the implant if severe. Capsular contracture is classified by Baker Grades. Baker Grades III and IV are the most severe. Baker Grade III often results in the need for additional surgery (reoperation) because of pain and possible abnormal appearance. Baker Grade IV usually results in the need for additional surgery (reoperation) because of pain and unacceptable appearance. Capsular contracture Baker Grade II may also result in the need for additional surgery. Capsular contracture is a risk for implant rupture. Below is a description of each Baker Grade.

- **Baker Grade I**—Breast is soft and natural in appearance
- **Baker Grade II**—Breast is slightly firm, but looks normal
- **Baker Grade III**—Breast is more firm than normal, and looks abnormal (change in shape)
- **Baker Grade IV**—Breast is hard, with obvious distortion, and is painful

Natrelle® Breast Implants Important Information

Who may get breast implants (INDICATIONS)?

Natrelle® Breast Implants are approved for women for the following:

- **Breast reconstruction.** Breast reconstruction includes primary reconstruction to replace breast tissue that has been removed due to cancer or trauma or that has failed to develop properly due to a severe breast abnormality. Breast reconstruction also includes revision surgery to correct or improve the result of a primary breast reconstruction surgery.

Please see **Natrelle® Breast Implants Important Safety Information** on following pages.

Capsulotomy, closed

An attempt to break the scar tissue capsule around the implant by pressing or pushing on the outside of the breast. This method does not require surgery, but is a known risk for rupture of the implant and is not recommended.

Capsulotomy, open

An attempt to break the scar tissue capsule around the implant by surgical incision into the capsule.

Contralateral

Opposite side.

Extracapsular rupture

A type of rupture in which the silicone gel has leaked outside of the scar tissue capsule surrounding the implant.

Fat injection

When fat tissue is removed from parts of the body—usually the thighs, belly, or buttocks—by liposuction. The tissue is then processed into liquid and injected into the breast area to enhance the breast.

Flap

A portion of tissue (which may include muscle, fat, or skin) moved from one part of the body to another. The tissue flap may or may not have its blood supply attached.

Inframammary

Below the breast.

Inframammary fold

The crease at the base of the breast.

Inframammary incision

An incision made in the fold below the breast.

Intracapsular rupture

A type of rupture in which the silicone gel remains within the scar tissue capsule surrounding the implant.

The Natrelle logo is written in a large, elegant, cursive script font. The 'N' is particularly large and stylized, with a long tail that loops under the 'a'. The 't' is also stylized with a long, thin tail. The 'r' and 'e' are connected, and the 'l' is a simple vertical stroke. The 'l' and 'l' are connected, and the 'e' has a small loop at the end. The logo is followed by a registered trademark symbol (®).

Latissimus dorsi

Two triangular muscles that run from the spinal column to the shoulder.

Magnetic resonance imaging (MRI)

A radiographic examination that currently has the best ability to detect rupture of silicone-filled breast implants.

Malposition

Implant malposition or displacement is when the implant is not in the desired spot in the breast. This could be due to incorrect placement of the implant during the surgery or due to shifting of the implant position over time.

Mammography

A type of X-ray examination of the breasts used for detection of cancer.

- Screening mammography—X-ray examination of the breast that is performed on women with no complaints or symptoms of breast cancer; the goal is to detect breast cancer when it is still too small to be felt by a physician or the patient
- Diagnostic mammography—X-ray examination in order to evaluate a breast complaint or abnormality detected by a physical exam or screening mammography; additional views of the breast are usually taken

Periareolar

Around the darkened or pigmented area surrounding the nipple of the breast.

Reoperation

An additional surgery after the first breast implantation.

Rupture

A tear or hole in the implant shell. Silicone implant ruptures may occur with or without symptoms. Ruptures can be intracapsular (where the silicone does not leak past the scar tissue capsule) or extracapsular (where the silicone leaks past the scar tissue capsule into the surrounding tissue).

Natrelle® Breast Implants IMPORTANT SAFETY INFORMATION

Who should NOT get breast implants (CONTRAINDICATIONS)?

Breast implant surgery should not be performed in women with active infection anywhere in their body, with existing cancer or pre-cancer of their breast who have not received adequate treatment for those conditions, and women who are currently pregnant or nursing.

Saline

A solution that is made up of water and a small amount of salt.

Seroma

A pocket of clear fluid that sometimes develops in the body after surgery.

Silent rupture

A breast implant rupture without symptoms, which is not apparent except through appropriate imaging techniques such as MRI. Most silicone-filled breast implant ruptures are silent. (See symptomatic rupture.)

Silicone gel

A gel made from polymerized organic silicon oxide, used as a filling in breast implants.

Subglandular placement

Placement of a breast implant underneath and within the breast glands, but on top of the chest muscle.

Submuscular placement

Placement of a breast implant wholly or partially underneath the chest muscle.

Symptomatic rupture

A breast implant rupture that is associated with symptoms such as lumps, persistent pain, swelling, hardening, or change in implant shape. Some silicone breast implant ruptures are symptomatic, but most are silent. (See silent rupture.)

Tissue expander

A temporary, adjustable implant that can be inflated with saline over a period of weeks or months to slowly stretch the tissue at the mastectomy site. Stretching the tissue over time allows surgeons to create a pocket to hold a permanent breast implant. (See two-stage reconstruction.)

Transaxillary

Through the axilla (armpit); an incision made under the arm.

What else should I consider (WARNINGS)?

Breast implants are not lifetime devices or necessarily a one-time surgery. You may experience unacceptable dimpling, puckering, wrinkling, or other cosmetic changes of the breast, which may be permanent. Breast implants may affect your ability to produce milk for breastfeeding. Silicone-filled implants may rupture without symptoms. You should have MRI examinations 3 years after surgery and then every 2 years thereafter in order to detect ruptures.

Please see additional *Natrelle®* Breast Implants Important Safety Information on following pages.

The logo for Natrelle, featuring the brand name in a stylized, cursive script font with a registered trademark symbol (®) at the end.

Types of surgery

Breast reconstruction

A surgical procedure to replace breast tissue that has been removed due to cancer or trauma or that has failed to develop properly due to a severe breast abnormality.

Delayed reconstruction

Delayed reconstruction is performed several months or even years after a mastectomy and after other cancer treatments are completed. It is preferable to wait a minimum of 6 to 9 months following the completion of radiation therapy to allow time for the chest skin to heal before performing breast reconstruction.

Mastectomy

The removal of breast tissue due to the presence of a cancerous or precancerous growth. There are 4 types of mastectomies, which are defined below.

- Subcutaneous mastectomy: Surgical removal of breast tissue, but sparing the skin, nipple, and areola
- Total mastectomy: Surgical removal of the breast including the nipple, areola, and most of the overlying skin
- Modified radical mastectomy: Surgical removal of the entire breast including the nipple, areola, and overlying skin, as well as the lymphatic-bearing tissue in the axilla
- Radical mastectomy: Surgical removal of the entire breast including the nipple, areola, and overlying skin, as well as the pectoral muscles, lymphatic-bearing tissue in the axilla, and various other neighboring tissue

One-stage immediate reconstruction

In this type of reconstruction, the breast mound creation is done at the same time as the mastectomy. For this, the final implant is put in at the same time as the mastectomy is done. After the surgeon removes the breast tissue, a plastic surgeon places a breast implant. The implant is usually placed beneath the chest muscle.

Primary breast reconstruction

The first time a breast implant is placed for the purpose of a breast reconstruction.

Revision reconstruction

Refers to the correction or improvement of a primary reconstruction surgery. In the context of this document, it refers to surgical removal and replacement of breast implants that were placed originally for primary breast reconstruction.

Natrelle® Breast Implants IMPORTANT SAFETY INFORMATION (continued)

What else should I consider (WARNINGS)? (continued)

Symptoms of a ruptured implant may be hard knots or lumps surrounding the implant or in the armpit, change or loss of size or shape of the breast or implant, pain, tingling, swelling, numbness, burning or hardening. Talk to your doctor about removing ruptured implants. Inform any other doctor if you have implants.

Please see additional **Natrelle® Breast Implants Important Safety Information on following page.**

Tissue-based reconstruction

Also called tissue flap reconstruction, this type of procedure uses the body's own tissue to form new breasts. The tissue is commonly transferred from the abdomen or upper back to the chest. Tissue flap surgery, particularly the TRAM flap, requires a hospital stay of several days and a longer recovery time than implant-based reconstruction.

There are 3 common types of tissue-based reconstruction:

1. Transverse rectus abdominis muscle (TRAM) flap

The TRAM flap procedure uses tissue and muscle from the lower abdominal wall (tummy). Some women have enough tissue in this area to shape the breast, so an implant may not be needed. The skin, fat, blood vessels, and at least one abdominal muscle are moved from the abdomen (belly) to the chest. The TRAM flap can decrease the strength in the abdomen, and may not be possible in women who have had abdominal tissue removed in previous surgeries. The procedure also results in a tightening of the lower abdomen, also known as a tummy tuck.

2. Deep inferior epigastric perforator (DIEP) flap

The DIEP flap uses fat and skin from the same area as the TRAM flap, but does not use the muscle to form the breast shape. This results in less skin and fat in the lower abdomen (belly), also known as a tummy tuck. This method uses a free flap, which means that the tissue is completely cut free from the abdomen and then moved to the chest. A microscope is needed to connect the tiny blood vessels. There's less risk of a bulge or hernia because no muscle is taken.

3. Latissimus dorsi flap

The latissimus dorsi flap tunnels muscle, fat, skin and blood vessels from the upper back, under the skin, and to the front of the chest. This provides added coverage over an implant and makes a more natural-looking breast than just an implant alone. It can sometimes be used without an implant. It's a very reliable flap and can even be used in women who smoke (smoking can delay healing). Though it's not common, some women have weakness in their back, shoulder, or arm after this surgery.

The Natrelle logo is written in a stylized, cursive script font. The letters are dark blue or black, and the overall appearance is elegant and flowing. A registered trademark symbol (®) is located at the top right of the logo.

Types of surgery (continued)

Two-stage reconstruction

In two-stage reconstruction, a short-term tissue expander is implanted after the mastectomy. The expander is a balloon-like implant that's slowly expanded to the desired size to allow the skin flap to stretch. It's used when the surgeon believes that the mastectomy skin is not healthy enough to immediately support a full-sized breast implant. Through a tiny valve under the skin, the surgeon injects a saltwater solution at regular intervals to fill the expander over a period of about 2 to 3 months. After the skin over the breast area has stretched enough, a second surgery will replace the expander with the permanent implant.

- Two-stage reconstruction is sometimes called delayed-immediate reconstruction because it allows time for other treatment options. If radiation therapy is needed, the final placement of the implant is delayed until radiation treatment is completed. If radiation is not needed, the surgeon can immediately place the tissue expander

Natrelle® Breast Implants IMPORTANT SAFETY INFORMATION (continued)

What types of conditions require more study (PRECAUTIONS)?

Caution: Notify your doctor if you have any of the following conditions, as the risks of breast implant surgery may be higher: autoimmune diseases, a weakened immune system, planned radiation therapy to the breast or planned chemotherapy following breast implant placement, conditions/medications that interfere with wound healing and blood clotting, reduced blood supply to breast tissue or a clinical diagnosis of depression, other mental health disorders, body dysmorphic disorder or eating disorders. These disorders should be resolved or stabilized prior to surgery.

What are some complications with breast implants (COMPLICATIONS)?

Key complications are reoperation, implant removal with or without replacement, implant rupture with silicone-filled implants, implant deflation with saline-filled implants, and severe capsular contracture (severe scar tissue around the implant). Other complications include asymmetry, nipple/breast/skin sensation changes, scarring or wrinkling/rippling. Talk to your doctor about other complications.

Talk to your doctor. For more information see the Patient Brochures at www.allergan.com/labeling/usa.htm or call the Allergan Product Support line at 1-800-433-8871.

To report a problem with *Natrelle*®, please call Allergan Product Surveillance at 1-800-624-4261.

Natrelle® Breast Implants are available by prescription only.

Natrelle® 133 Tissue Expanders Important Information

Approved Uses

Natrelle® 133 Tissue Expanders are approved for breast reconstruction following mastectomy, treatment of underdeveloped breasts and treatment of soft tissue deformities.

IMPORTANT SAFETY INFORMATION

Who should NOT get tissue expanders?

Do not use if you:

- Already have implanted devices that would be affected by a magnetic field.
- Have tissue unsuitable for expansion.
- Have an active infection or a residual gross tumor at the expansion site.
- Are undergoing adjuvant radiation therapy.
- Have a physiological condition (e.g., obesity, smoking, diabetes, autoimmune disease, hypertension, chronic lung or severe cardiovascular disease, or osteogenesis imperfecta) or use certain drugs (including those that interfere with blood clotting or affect tissue viability) that may result in a high risk of surgical and/or postoperative complications.

What else should I consider?

- *Natrelle*® 133 Tissue Expanders should NOT be used in patients who already have implanted devices that would be affected by a magnetic field.
- Active infection anywhere may increase risk of infection around the tissue expander. Certain infections may require premature removal of the device.
- *Natrelle*® 133 Tissue Expanders are temporary devices, and are not to be used for permanent implantation or beyond 6 months. Tissue expansion in breast reconstruction typically requires 4 to 6 months.

What are possible complications?

Deflation, tissue damage and/or appearance of the implant through the skin, infection, unwanted shape, unintended blood or fluid collection, capsular contracture (tightening of scar tissue that causes the breast to harden), premature device removal, bone/pain/sensation changes, and inflammation.

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