



CHOICES IN BREAST RECONSTRUCTION

A Guide to Surgical Options
and the *Natrelle*[®] Collection

**Please see Indications and Important Safety
Information inside.**



Natrelle[®]

CHOOSING BREAST RECONSTRUCTION

The purpose of this brochure is to give you a basic understanding of breast reconstruction. It is not meant to replace a thorough consultation with a plastic surgeon. It is designed to assist you in making an informed decision.

If you are facing the loss of a breast due to cancer or other disease, you may be given the option of breast reconstruction. The decision to have breast reconstruction is an important and personal one. It requires a thorough understanding of all the options available to you. While there are several ways to perform breast reconstruction, your surgeon will ultimately decide which method is best for you based on your health, medical condition, and personal desires.

Natrelle® Breast Implants Important Information **Who may get breast implants (INDICATIONS)?**

Natrelle® Breast Implants are indicated 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.

Great strides have been made in the field of breast reconstruction in recent years, resulting in a more anatomical breast shape and appearance. It is important for you to realize that your reconstructed breast will not look or feel like your natural breast. While it is not for everyone, breast reconstruction had a positive impact on many women's emotional well-being. The best reconstruction procedure for you will depend upon your individual desired results, your physical condition, and your surgeon's advice.

This brochure will introduce you to the most common breast reconstruction procedures used today and will summarize some of the differences among them. If you are considering breast reconstruction and do not have a plastic surgeon, ask your general surgeon for a referral, call the American Society of Plastic Surgeons (ASPS) at 1-800-635-0635, or use the surgeon locator tool at www.natrelle.com for the names of experienced, board-certified and non-board-certified plastic surgeons in your area. Often, your general surgeon and plastic surgeon will work together to plan your mastectomy and reconstruction procedure to give you the best possible result.

IMPORTANT SAFETY INFORMATION **Who should NOT get breast implants** **(CONTRAINDICATIONS)?**

- Women with active infection anywhere in their body.
- Women with existing cancer or pre-cancer of their breast who have not received adequate treatment for those conditions.
- Women who are currently pregnant or nursing.

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

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THE OPTIONS OF BREAST RECONSTRUCTION

The breast reconstruction process may begin at the time of your mastectomy (immediate) or weeks to years afterward (delayed). The type of breast reconstruction procedure offered to you depends on your medical situation, your breast shape and size, your general health and lifestyle, and your goals. Every woman's situation is unique.

There are different types of breast reconstruction that are commonly performed:

1. A tissue expander, followed by a breast implant, either gel or saline filled (referred to as two-stage).
2. Your own tissues (referred to as a flap).
3. A combination of both.

Natrelle® Breast Implants IMPORTANT SAFETY INFORMATION (continued)

What else should I consider (WARNINGS)?

- Breast implants are not lifetime devices, and not necessarily a one-time surgery.
- Many of the changes to your breasts following implantation cannot be undone. If you later choose to have your implant(s) removed and not replaced, 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 breastfeed, either by reducing or eliminating milk production.

The following pages contain a brief discussion of these commonly used breast reconstruction procedures.

If you are considering breast reconstruction, your plastic surgeon can provide you with information that fully explains the risks and complications associated with breast implants, tissue flaps, and breast reconstruction surgery. It is recommended that you read all of the information provided before scheduling surgery, so that you have plenty of time to ask questions and evaluate all of your options.

- Rupture of a silicone-filled breast implant is most often silent and may not be detected by you or your doctor. You should have an MRI 3 years after your surgery and then every 2 years after that for as long as you have your breast implants to determine if rupture is present. If implant rupture is noted on an MRI, you should have the implant removed, with or without replacement.
- With breast implants, a routine screening mammography and self-examinations for breast cancer will be more difficult. Ask your doctor to help you distinguish the implant from your breast tissue. 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. Tell your doctor of these symptoms and remove ruptured implants.

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

TWO-STAGE BREAST RECONSTRUCTION WITH IMPLANTS

There is more than one method to reconstruct the breast. One technique is to use a tissue expander, followed by a breast implant. Breast reconstruction using tissue expanders and implants has been performed for over 30 years. A tissue expander is a device that is made from elastic silicone rubber. It is placed under the skin of the chest at the location of the breast. This procedure can be performed immediately (at the time of mastectomy), or it can be delayed for months or years. Over a period of time, the expander is filled with sterile saline via a small needle inserted through the skin to a "fill port" located inside the expander. Gradually, as the saline is introduced, the overlying tissues expand. This process creates a breast-shaped pocket.

Natrelle® Breast Implants IMPORTANT SAFETY INFORMATION (continued)

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

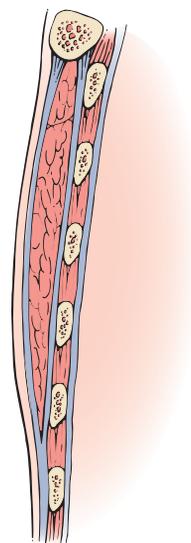
- Inform any other doctor who treats you of the presence of your implants to minimize the risk of damage to the implants.

What types of conditions require more study (PRECAUTIONS)?

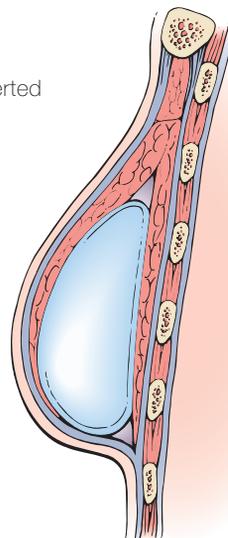
Caution: Notify your doctor if you have any of the following conditions, as the risks of breast implant surgery may be higher:

- Autoimmune diseases (for example, lupus and scleroderma).

SIDE VIEW:
Breast tissue removed.

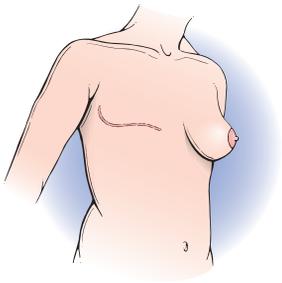


SIDE VIEW:
Expander inserted and filled.

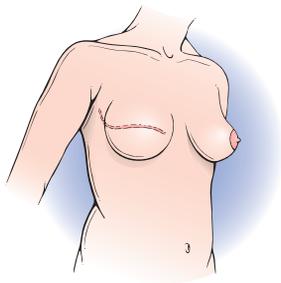


Please see additional **Natrelle® Breast Implants Important Safety Information** on next page.

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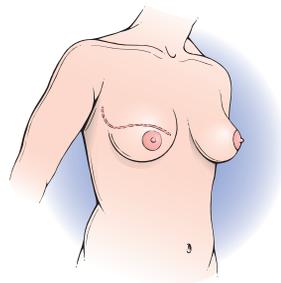


POSTMASTECTOMY



STAGE 1:

Tissue expander placed and expansion under way.



STAGE 2:

Breast implant and nipple/areola reconstruction.

How you feel after surgery depends on the extent and complexity of the procedure. Because chest skin is usually numb following mastectomy surgery, it is possible that you may not initially experience pain from the placement of the tissue expander or the needle during the expansion process. However, you may experience feelings of pressure or discomfort after each filling of the expander. These feelings may last for a few days, as the tissues stretch. The complete filling process will require a few visits to your surgeon's office over the course of weeks to months, depending on the area to be reconstructed.

After the skin over the breast area has stretched enough, the expander will be removed and replaced with a breast implant. This procedure will be performed in an operating room under anesthesia. The type of breast implant used will be determined by you and your plastic surgeon after evaluating the dimensions and shape of your desired breast. Breast implants are available in round and anatomical shapes, in a variety of sizes, and can be either saline or gel filled.

Because during many mastectomies the nipple and areola are removed, your surgeon may perform a procedure to build a new one. This procedure can be done at the time of the implant exchange or in later stages. Nipple/areola reconstruction is often performed by using a graft of skin taken from another part of the body and, after the breast heals, is frequently tattooed to enhance color.

Natrelle® Breast Implants IMPORTANT SAFETY INFORMATION (continued)

What types of conditions require more study (PRECAUTIONS)? (continued)

- A weakened immune system (for example, currently taking drugs that weaken the body's natural resistance to disease).
- Planned chemotherapy following breast implant placement.

- Planned radiation therapy to the breast following breast implant placement.
- Conditions that interfere with wound healing and blood clotting.
- Reduced blood supply to breast tissue.

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

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BREAST IMPLANT OPTIONS

Breast implants have been used worldwide for nearly 50 years by millions of women for both breast augmentation and breast reconstruction. In the United States, they have been classified by the Food and Drug Administration (FDA) as a Class III Medical Device. This means that implants have been intensely studied for both safety and effectiveness.

If you are considering breast reconstruction with implants, you should be aware that there are many options available—including the numerous options in the *Natrelle*® Collection—to help you find the fit that both you and your surgeon determine is best for you. Our latest addition to this line of breast implants is an anatomically shaped gel implant designed with a shape that mirrors a woman's breast—the *Natrelle*® 410 Shaped Gel.

***Natrelle*® Breast Implants IMPORTANT SAFETY INFORMATION (continued)**

What types of conditions require more study (PRECAUTIONS)? (continued)

- Clinical diagnosis of depression or other mental health disorders, including body dysmorphic disorder and eating disorders. Please discuss any history of mental health disorders with your surgeon prior to surgery. Patients with a diagnosis of depression or other mental health disorders should wait for resolution or stabilization of these conditions prior to undergoing breast implantation surgery.

The *Natrelle*® Collection helps you find the fit that's right for you.

When it comes to choosing the right implant for your breast reconstruction, you can never have too many choices. That's why *Natrelle*® offers different variations of breast implants. With different combinations of shape, texture, volume, and projection, the *Natrelle*® Collection has options to help you and your surgeon to match the right implant to your shape and body tissue.

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.

Please see *Natrelle*® 133 Tissue Expanders Important Safety Information on next page.

The logo for Natrelle, featuring the brand name in a stylized, cursive font inside a light blue oval.

NATRELLE® BREAST IMPLANT OPTIONS

Two approved options for breast implant fillers: gel and saline.

The gel implants in the *Natrelle*® Collection are filled with cohesive silicone. All gel-filled breast implant manufacturers currently have a consistent testing standard for gel cohesivity, which is recommended by the FDA.

You can choose a round shape or an anatomically shaped gel implant. The *Natrelle*® 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants are designed for a natural feel and with a shape that mirrors a woman's breast. Its highly cohesive gel holds together uniformly. In a clinical study, there was no migration of gel outside the capsule (the wall the body creates around the implant) in ruptured implants through 7 years.

Saline breast implants are filled with a saltwater solution, similar to the fluids in your body. While gel-filled implants are inserted prefilled, the shells of saline-filled implants are surgically placed in the body empty, and then filled with saline to achieve the desired volume.

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.



SHAPED GEL:

An anatomically shaped breast implant filled with a highly cohesive gel that is designed with a shape that mirrors a woman's breast.



ROUND GEL:

A classic, round-shaped breast implant filled with cohesive gel for a soft feel.



SALINE:

A round-shaped breast implant filled with saline.

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.

Please see additional *Natrelle*® 133 Tissue Expanders Important Safety Information on next page.



BREAST RECONSTRUCTION USING TISSUE FLAPS

The breast can also be reconstructed by surgically moving a section of skin, fat, and muscle to the chest from another area of your body. The section of tissue may be taken from such areas as your abdomen, upper back, upper hip, or buttocks. The reconstructed breast may be made from the tissue flap alone or from the tissue flap and a breast implant.

The tissue flap may be left attached to the blood supply and moved to the breast area through a tunnel under the skin called a pedicle flap, or it may be removed completely and reattached to the breast area by a microsurgical technique called a free flap.

Who is a candidate for tissue flap surgery?

Flap surgery has the advantage of being able to replace tissue in the chest area. This may be useful when the chest tissues have been damaged and are not suitable for tissue expansion, when extra tissue is desired to recreate a large breast without a breast implant, or when extra tissue coverage is needed over a breast implant.

It is important for you to be aware that tissue flap surgery, particularly the TRAM flap, requires a hospital stay of several days and a longer recovery time than tissue expander/implant reconstruction. It requires good general health and strong emotional motivation.

Natrelle® 133 Tissue Expanders IMPORTANT SAFETY INFORMATION (continued)

Who should NOT get tissue expanders? (continued)

- Are undergoing adjuvant radiation therapy.

Flap surgery also creates scars at the site where the flap was taken, and possibly additional scars on the reconstructed breast. But if the remaining tissues on your chest are insufficient or inadequate to allow breast reconstruction with a tissue expander and implant, you may be a good candidate for flap surgery.

If you are very overweight, smoke, have had previous surgery at the flap site, or have any circulatory problems, you may not be a good candidate for a tissue flap procedure. Also, if you are very thin, you may not have enough tissue on your abdomen or back to create a breast with this method.

The most common types of flap surgeries are:

THE TRAM FLAP

(fat, skin, and muscle from the abdomen)

THE DIEP FLAP

(fat and skin from the abdomen without the muscle)

THE LATISSIMUS DORSI FLAP

(skin and muscle from the upper back)

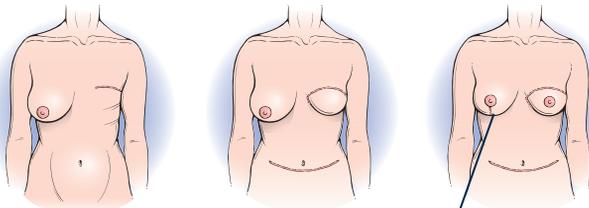
- Have a physiological condition (e.g., obesity, smoking, diabetes, autoimmune disease, hypertension, chronic lung or severe cardiovascular disease, or osteogenesis imperfecta) or use certain drugs (including those that interfere with blood clotting or affect tissue viability) that may result in a high risk of surgical and/or postoperative complications.

Please see additional Natrelle® 133 Tissue Expanders Important Safety Information on next page.

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THE TRAM FLAP (pedicle or free)

During a TRAM flap (transverse rectus abdominis musculocutaneous flap) procedure, the surgeon removes a section of tissue from your abdomen and moves it to your chest to reconstruct the breast. The TRAM flap is sometimes referred to as a “tummy tuck” reconstruction, because it may leave the stomach area flatter.



THIS RECONSTRUCTION INCLUDES A MASTOPEXY TO THE OTHER BREAST TO IMPROVE SYMMETRY.

A pedicle TRAM flap procedure typically takes 3 to 6 hours of surgery under anesthesia; a free TRAM flap procedure generally takes longer. The TRAM procedure may require a blood transfusion. Typically, the hospital stay is 2 to 5 days. You can resume daily activity after 6 to 8 weeks. However, some women report that it takes up to 1 year to resume a normal lifestyle.

Natrelle® 133 Tissue Expanders IMPORTANT SAFETY INFORMATION (continued)

What else should I consider?

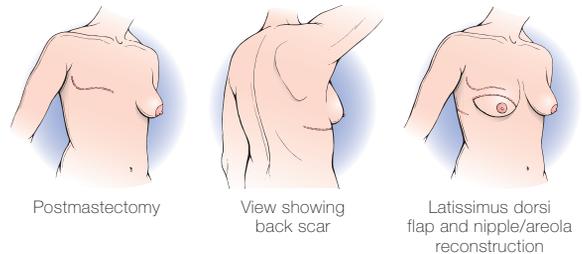
- Natrelle® 133 Tissue Expanders should NOT be used in patients who already have implanted devices that would be affected by a magnetic field.
- Active infection anywhere may increase risk of infection around the tissue expander. Certain infections may require premature removal of the device.

THE DIEP FLAP

DIEP stands for deep inferior epigastric perforator. What this surgery entails, in the simplest of terms, is a TRAM flap without using the muscle. The fat and skin of the abdomen are moved to create a new breast mound. Microsurgery is involved, due to the reattachment of blood supply to the area.

THE LATISSIMUS DORSI FLAP

During a latissimus dorsi flap procedure, the surgeon moves a section of tissue from your back to your chest to reconstruct the breast. Because the latissimus dorsi flap is usually thinner and smaller than the TRAM flap, this procedure may be more appropriate for reconstructing a smaller breast.



The latissimus dorsi flap procedure generally takes 2 to 4 hours of surgery under anesthesia. Typically, the hospital stay is 2 to 3 days. You can resume daily activity after 2 to 3 weeks. You may have some temporary or permanent muscle weakness and difficulty with movement in your back and shoulder. You will have a scar on your back, which can usually be hidden in the bra line. You may have additional scars on your reconstructed breast.

- 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.

Please see additional **Natrelle® 133 Tissue Expanders Important Safety Information** on next page.

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OTHER SURGICAL CONSIDERATIONS RELATED TO BREAST RECONSTRUCTION

Whether you have a breast implant following a tissue expander or a tissue flap reconstruction, the following surgical procedures are options your surgeon may consider in completing your breast reconstruction.

NIPPLE AND AREOLA RECONSTRUCTION

The nipple is often removed with the breast tissue during the mastectomy. Your nipple can be reconstructed by using a small skin graft or by taking part of the nipple from the opposite breast. The circle around your nipple, the areola, may be reconstructed with a skin graft, or by tattooing the area to enhance its color and match the opposite breast. Nipple and areola reconstruction is sometimes performed at the time of the implant exchange, but may be performed as a separate outpatient procedure after the initial reconstruction surgery is complete.

Natrelle® 133 Tissue Expanders IMPORTANT SAFETY INFORMATION (continued)

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.

IMPROVING SYMMETRY:

Mastopexy, reduction mammoplasty, or augmentation mammoplasty.

In one-sided or unilateral breast reconstruction, it may be difficult for the surgeon to exactly match the remaining breast, particularly if you have large breasts or if your breasts have sagged with age or from bearing children. In order to help improve symmetry between your natural and reconstructed breasts, your plastic surgeon may recommend: a breast lift, called a “mastopexy”; breast reduction, called “reduction mammoplasty”; or breast enlargement, called “augmentation mammoplasty.”

If it is important to you not to alter the unaffected breast, you should discuss this with your plastic surgeon, as it may affect the breast reconstruction method he or she is considering for your case.

It is very important that you are informed and that you discuss with your surgeon all of the potential contraindications, and warnings and precautions to consider when choosing breast reconstruction, both with and without breast implants.

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

For more information, please visit www.allergan.com/labeling/usa.htm or call the Allergan Product Support line at 1-800-433-8871.

Please see additional *Natrelle*® 133 Tissue Expanders Important Safety Information on next page.

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IMPORTANT

Factors you should consider when choosing breast implants.

For many women, breast implant surgery has the potential to bring rewards, both physically and emotionally. However, it is important to consider the risks, as well as the benefits, before making your decision. There are many important factors to consider before choosing saline-filled or gel-filled breast implants:

- Breast implants are not lifetime devices, and breast implantation is not necessarily a one-time surgery. You will likely need additional surgeries on your breasts due to complications or unacceptable cosmetic results. These additional surgeries can include implant removal, with or without replacement, or other surgical procedures.
- Many of the changes to your breasts following implantation are irreversible. If you later choose to have your implants removed and not replaced, 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 breastfeed, either by reducing or eliminating milk production.

Natrelle® 133 Tissue Expanders IMPORTANT SAFETY INFORMATION (continued)

What are possible complications? (continued)

Natrelle® 133 Tissue Expanders are available by prescription only.

Please see *Natrelle®* Breast Implants Indications and Important Safety Information on next page.

- For gel-filled breast implants, you will need regular MRI screenings over your lifetime in order to determine if silent rupture is present. Rupture of a gel-filled breast implant is most often silent. This means that neither you nor your surgeon will know that your implants have a rupture. You should have your first MRI 3 years after your initial implant surgery and then every 2 years thereafter.
- The health consequences of a ruptured gel-filled breast implant have not been fully established.
- If implant rupture is noted on an MRI, you should have the implant removed, with or without replacement.
- With breast implants, routine screening mammography for breast cancer will be more difficult. If you are of the proper age for mammography screening, you should continue to undergo routine mammography screenings as recommended by your primary care physician. The implant may interfere with finding breast cancer during mammography, and because the breast and implant are squeezed during mammography, an implant may rupture during the procedure.

***Natrelle®* Breast Implants Important Information**

Who may get breast implants (INDICATIONS)?

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

Please see additional *Natrelle®* Breast Implants Indications and Important Safety Information on next page.

The logo for Natrelle, featuring the brand name in a stylized, cursive font inside a light blue oval.

- You should perform a self-examination of your breasts every month for cancer screening. However, this may be more difficult with implants. You should ask your surgeon to help you distinguish the implant from your breast tissue.
- You should perform a self-examination of your breasts for the presence of lumps, persistent pain, swelling, hardening, or change in implant shape, which may be signs of a rupture of the implant. These signs should be reported to your surgeon and possibly evaluated with an MRI.
- After undergoing breast implant surgery (either primary or revision), your health insurance premiums may increase, your insurance coverage may be dropped, and/or future coverage may be denied. Additionally, treatment of complications may not be covered.
- You should inform any other doctor who treats you of the presence of your implants to minimize the risk of damage to the implants.
- Clinical information on the long-term safety and effectiveness of the *Natrelle*[®] Round Silicone-Filled Breast Implants is obtained from two 10-year studies: the Core Study and the Breast Implant Follow-Up Study (BIFS). BIFS was designed to address specific issues that the Allergan Core Study was not designed to fully answer, as well as to provide a real-world assessment of some end points. The end points in the large postapproval studies include long-term local complications, connective tissue disease (CTD), CTD signs and symptoms, neurological disease, neurological signs and symptoms, offspring issues, reproductive issues, lactation issues, cancer, suicide, mammography issues, and MRI compliance and results.
- Clinical information on the long-term safety and effectiveness of *Natrelle*[®] 410 Shaped Gel Breast Implants is obtained from 7-year data from the pivotal study, a prospective, 10-year, multicenter, single-arm, observational clinical study conducted across 47 investigational sites in 941 women undergoing breast augmentation, reconstruction, and revision operations.

***Natrelle*[®] Breast Implants Important Information (continued)**

Who may get breast implants (INDICATIONS)? (continued)

- **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.

IMPORTANT SAFETY INFORMATION

Who should NOT get breast implants (CONTRAINDICATIONS)?

- Women with active infection anywhere in their body.
- Women with existing cancer or pre-cancer of their breast who have not received adequate treatment for those conditions.
- Women who are currently pregnant or nursing.

What else should I consider (WARNINGS)?

- Breast implants are not lifetime devices, and not necessarily a one-time surgery.

Please see additional *Natrelle*[®] Breast Implants Important Safety Information on next page.

- The results through 7 years have been reported. Safety assessments include local complication rates, and effectiveness assessments include change in breast size (augmentation only), patient and physician satisfaction with outcome (all patients), and quality of life (augmentation and reconstruction patients).

Allergan will update its labeling on a regular basis with the results of these studies. You should also ask your surgeon if he/she has any available updated Allergan clinical information.

- It is important that you read the entire *Making an Informed Decision—Natrella® Saline-Filled Breast Implants*, or the entire *Important Information for Women About Breast Reconstruction with Natrella® Silicone-Filled Breast Implants*, or the entire *Breast Reconstruction—Natrella® 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants: Important Factors Breast Reconstruction Patients Should Consider* to have realistic expectations for your surgery, including an understanding of the risks and benefits.

Natrella® Breast Implants IMPORTANT SAFETY INFORMATION (continued)

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

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Natrella® Breast Implants IMPORTANT SAFETY INFORMATION (continued)

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

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- With breast implants, a routine screening mammography and self-examinations for breast cancer will be more difficult. Ask your doctor to help you distinguish the implant from your breast tissue. 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. Tell your doctor of these symptoms and remove ruptured implants.
- Inform any other doctor who treats you of the presence of your implants to minimize the risk of damage to the implants.

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 (for example, lupus and scleroderma).
- A weakened immune system (for example, currently taking drugs that weaken the body's natural resistance to disease).
- Planned chemotherapy following breast implant placement.

Please see Natrella® Breast Implants Important Safety Information on next page.



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Natrelle® Breast Implants IMPORTANT SAFETY INFORMATION (continued)

What types of conditions require more study (PRECAUTIONS)? (continued)

- Planned radiation therapy to the breast following breast implant placement.
- Conditions that interfere with wound healing and blood clotting.
- Reduced blood supply to breast tissue.
- Clinical diagnosis of depression or other mental health disorders, including body dysmorphic disorder and eating disorders. Please discuss any history of mental health disorders with your surgeon prior to surgery. Patients with a diagnosis of depression or other mental health disorders should wait for resolution or stabilization of these conditions prior to undergoing breast implantation 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.

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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.

Please see additional *Natrelle*® 133 Tissue Expanders Important Safety Information on next page.

Natrelle® 133 Tissue Expanders IMPORTANT SAFETY INFORMATION (continued)

What else should I consider? (continued)

- *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.

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

For more information, please visit www.allergan.com/labeling/usa.htm or call the Allergan Product Support line at 1-800-433-8871.

Natrelle® 133 Tissue Expanders are available by prescription only.

QUESTIONS TO ASK YOUR PLASTIC SURGEON ABOUT BREAST RECONSTRUCTION

The following list of questions may help remind you of topics to discuss with your plastic surgeon:

- What are all my options for breast reconstruction?
- I'm considering an implant. Which type would be right for me?
- What are the risks and complications of each type of breast reconstruction surgery, and how common are they?
- What if my cancer recurs or occurs in the other breast?
- Will reconstruction interfere with my cancer treatment?
- How many steps are there in each procedure, and what are they?
- How long will it take to complete my reconstruction?
- How much experience do you have with each procedure?
- Do you have before-and-after photos I can look at for each procedure?
- What results are reasonable for me?
- What will my scars look like?
- What kind of changes in my reconstructed breast can I expect over time?

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- Can I talk with other patients about their experiences?
 - What is the estimated total cost of each procedure?
 - How much is my insurance expected to cover?
 - How much pain or discomfort will I feel and for how long?
 - How long will I be in the hospital?
 - Will I need blood transfusions, and can I donate my own blood?
 - When will I be able to resume my normal activity (or sexual activity, or athletic activity)?
 - Where can I get more information?
 - Is there a warranty that covers my implant(s)?



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