A Continued Commitment to Patients

BIOCELL® Replacement Warranty

Allergan™

On July 24, 2019, Allergan announced a voluntary worldwide withdrawal of unused BIOCELL® textured breast implants from doctors' offices and hospitals, and a suspension of any future sales.

THE US FOOD AND DRUG ADMINISTRATION (FDA) STATES THAT WOMEN WHO HAVE BIOCELL® IMPLANTS BUT NO SPECIFIC SYMPTOMS DO NOT NEED TO HAVE THEIR IMPLANTS OR EXPANDERS REMOVED.

As a result of this product withdrawal, if you and your plastic surgeon decide to remove your textured breast implants, Allergan will cover the cost of new, smooth replacement devices under the **BIOCELL® Replacement Warranty**. As part of this program, Allergan will not be providing surgical fee assistance.

We're Here to **Answer Your Questions**

What devices are included in this warranty coverage?

The BIOCELL® Replacement Warranty covers all BIOCELL® textured implants that may have been originally manufactured under the brands McGHAN, INAMED, ALLERGAN, or *Natrelle*®. Both saline and silicone gel–filled textured implants are covered. This coverage will be available through July 24, 2021. Please note that *Natrelle*® smooth breast implants are not subject to this withdrawal.

What are my options if I decide to replace my devices?

The FDA recommends not to remove devices in asymptomatic patients. However, if you and your plastic surgeon decide that replacing your device is the best option for you, you can choose any Allergan smooth implant(s) as a replacement on or before July 24, 2021.

Bring your current patient ID card or any other information available about your implants with you to your appointment. You and your plastic surgeon will decide on the best size and style as a replacement option for you. Your plastic surgeon will request your replacement implants from Allergan on your behalf.

Are surgery fees covered?

No. As part of this program, Allergan will not be providing surgical fee assistance. This decision is aligned with the FDA's recommendation not to remove textured implants or other types of breast implants in patients who have no symptoms of BIA-ALCL.

What if I choose NOT to explant my textured device?

If you choose not to explant your BIOCELL® textured devices, you will continue to be covered under the *Natrelle*® *ConfidencePlus*® Warranty, which includes comprehensive coverage including rupture, capsular contracture and late seroma. More information about the *Natrelle*® *ConfidencePlus*® Warranty can be found at www.allergan.com.

How do I find out if my Allergan implants are textured?

Please visit Allergan.com to understand how to read your product ID card. If you don't have a card, or would like to speak to someone at Allergan, please contact **Allergan Medical Information at 1-800-678-1605**, option #2, or email IR-Medcom@allergan.com.

Does my plastic surgeon know about the BIOCELL® Replacement Warranty?

Plastic surgeons are being informed about this additional coverage and how to assist their patients in getting it. You may direct them to Allergan.com for more information. Plastic surgeons may contact the Allergan Product Surveillance team prior to surgery at 1-800-624-4261 and provide the appropriate documentation.

How do I learn more about BIA-ALCL?

To learn more about BIA-ALCL, please visit www.fda.gov/medical-devices/implants-and-prosthetics/breast-implants.

Natrelle® 133S Smooth Tissue Expanders Important Information

Approved Uses

Natrelle® 133S Smooth 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 (eg, 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*® 133S Smooth 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*® 133S Smooth 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 months 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.

For more information, please visit www.allergan.com/labeling/usa.htm. To report a problem *with Natrelle*®, please call Allergan at 1-800-433-8871.

Natrelle® 133S Smooth Tissue Expanders are available by prescription only.

Natrelle® Breast Implants Important Information

Who may get breast implants?

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

- **Breast augmentation for women at least 22 years old for silicone-filled implants.**
  Breast augmentation for women at least 18 years old for saline-filled implants.
  Breast augmentation includes primary breast augmentation to increase breast size, as well as revision surgery to correct or improve the result of a primary breast augmentation surgery.
- **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.

Natrelle® Breast Implants IMPORTANT SAFETY INFORMATION

IMPORTANT SAFETY INFORMATION

Who should NOT get breast implants?

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

What should I know before getting breast implants?

- 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 breast-feed, either by reducing or eliminating milk production.
- 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.
- Inform any other doctor who treats you of the presence of your implants to minimize the risk of damage to the implants.

What should I tell my doctor?

Tell 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.
- Planned radiation therapy to the breast following breast implant placement.
- Conditions or medications 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?

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. To report a problem with *Natrelle*® Breast Implants, please call Allergan at 1-800-433-8871.

Natrelle® Breast Implants are available by prescription only.

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