

Natrelle®



Actual *Natrelle* INSPIRA® patient.
Individual results may vary.

Natrelle® *ConfidencePlus*®
warranty program

More **COVERAGE**
for peace of mind

September 2019 update

Please see back for Approved Uses and Important Safety Information.

MORE coverage. MORE confidence.

The *Natrelle® ConfidencePlus®* warranty offers you more coverage for your breast implants—all designed for your peace of mind and satisfaction.

Choose ANY style and size of *Natrelle®* gel breast implant for replacement in the case of any covered event with *Natrelle®* gel implants.*



ConfidencePlus® gel warranty*

FREE coverage and automatic enrollment

Rupture

- Implant replacement: Lifetime for both affected and contralateral implants
- Out-of-pocket financial assistance: Up to \$3500 for 10 years

Capsular contracture Baker Grade III/IV

- Implant replacement: 10 years for both affected and contralateral implants
- Out-of-pocket financial assistance: Up to \$2000 for 2 years (augmentation patients only)†

ConfidencePlus® saline warranty†

FREE coverage and automatic enrollment

Rupture/Deflation

- Implant replacement: Lifetime for both affected and contralateral implants

ConfidencePlus® Premier saline warranty†

You may choose to upgrade the above coverage within 45 days by submitting the attached enrollment form by mail, fax, or online at Natrelle.com/warranty.

Enrollment fee: \$200 within 45 days of surgery

Rupture/Deflation

- Out-of-pocket financial assistance: Up to \$2400 for 10 years

Late seroma

Implant replacement: 20 years for both affected and contralateral textured implants§

Late seroma diagnostic testing coverage

If you have textured gel or textured saline breast implants, Allergan will cover up to \$1000 of out-of-pocket fees toward diagnostic testing for late seroma to rule out breast implant-associated anaplastic large cell lymphoma (BIA-ALCL).

BIA-ALCL treatment coverage

In the event of a BIA-ALCL diagnosis, you are eligible for up to \$7500 out-of-pocket financial assistance toward the removal of the breast implant(s) and the associated scar tissue (complete capsulectomy).

Allergan will also provide replacement implant(s) at no charge. For coverage eligibility, surgeons are directed to contact Allergan and provide appropriate documentation. Coverage valid for cases diagnosed on or after January 1, 2018.

*Valid for surgeries on or after November 1, 2014.

†Valid for procedures on or after January 1, 2019. Covers one incident per patient; recurring capsular contracture is not covered.

‡Valid for surgeries on or after July 1, 2014.

§Valid for cases diagnosed on or after January 1, 2019.

Important TERMS and CONDITIONS to know

Products covered

The *ConfidencePlus*® warranty program applies to all FDA-approved *Natrelle*® breast implants, provided the products have been used:

- As intended by appropriately qualified and licensed surgeons, in accordance with current and accepted plastic surgery techniques
- In accordance with the current *Natrelle*® Breast Implant Directions for Use, found at www.allergan.com/labeling/usa.htm

Events covered

- **Loss of shell integrity**, resulting in implant rupture or deflation that requires surgical intervention. Valid for surgeries on or after November 1, 2014
- **Capsular contracture (Baker Grade III/IV)** with *Natrelle*® gel implants that requires surgical intervention
 - Allergan has the right to request photographs to confirm diagnosis
 - Implant replacement valid only for surgeries on or after November 1, 2014
 - Financial assistance valid only for surgeries on or after January 1, 2019
- **Late seroma** for patients with textured implants only. Previous Allergan textured implants that have since been replaced with smooth implants are not covered
 - A diagnosis qualifies as > 50 cc of fluid presented at least 12 months after surgery
 - Cases must be diagnosed by a surgeon and confirmed by photographs, pathology, or other reports deemed acceptable by Allergan
 - Valid for cases diagnosed on or after January 1, 2019
- **BIA-ALCL** diagnosis that requires surgical intervention. Valid for cases diagnosed on or after January 1, 2018
- **Late seroma diagnostic testing to rule out BIA-ALCL**, when suspected, which may include one or more of cell cytology, CD30 immunohistochemistry, or flow cytometry. Valid for cases diagnosed on or after January 1, 2019

Special considerations

Each *Natrelle*® breast implant is covered individually. So in case of any covered event above, you may choose to replace both implants or only the damaged implant. Coverage of the opposite (contralateral) implant will continue for the remaining life of the warranty.

Events not covered

- Removal for capsular contracture for saline implants
- Dissatisfaction with implant size or aesthetics
- Adverse reactions other than the covered events listed on the previous page
- Loss of product integrity caused by cosmetic revision surgery
- Loss of product integrity caused by open or closed capsulotomy
- Other manufacturers' products
- Financial reimbursement for a replacement product that is not a *Natrelle*® style breast implant in lieu of a *Natrelle*® style replacement product

To submit a claim

For coverage eligibility, your surgeon must contact the Allergan Product Surveillance team prior to surgery at 1-800-624-4261 and provide the appropriate documentation. The surgeon is required to return the explanted, disinfected *Natrelle*® breast implant(s) within 3 months of the date of explantation. Allergan requests the return of all explanted breast implants associated with a complaint to assist with evaluating and maintaining the quality and safety of *Natrelle*® breast implants. Where applicable, financial assistance will be issued upon receipt and verification of the explanted product(s), the Returned Goods Authorization (RGA), and the patient's warranty general release.

Insurance may cover procedures related to breast implants. Please contact your insurance provider to understand what may be included in your coverage.

Natrelle[®] ConfidencePlus[®] warranty program

You are automatically enrolled in the *Natrelle[®] ConfidencePlus[®]* warranty program when you choose *Natrelle[®]* gel implants on or after November 1, 2014. Fill out the information below and keep it for your records. To learn more, visit Natrelle.com/warranty.



Name _____
Surgeon's name _____
Date of implant surgery _____
Implant serial numbers
Left _____
Right _____
Reference/Catalog numbers
Left _____
Right _____

Natrelle[®] ConfidencePlus[®] Premier saline warranty enrollment

If you have saline breast implants and would like additional coverage, you may upgrade your warranty for \$200 within 45 days of your surgery.

3 easy ways to enroll:

1. Register online at Natrelle.com/warranty.
2. Fax the completed form to 1-888-647-4029.
3. Mail the completed form to:

Allergan Warranty Processing
301 West Howard Lane, Suite 100
Austin, TX 78753

NOTE: Form must be postmarked within 45 days of the qualifying surgery. DO NOT send a personal check. Enrollment forms that include a personal check will NOT be processed.

2 ways to pay:

(All fields must be completed to process payment.)

1. Pay by credit card.

("Allergan" will appear on your credit card statement.)

Visa[®] MasterCard[®] American Express[®] Discover[®]

Credit card number _____

Expiration date _____

Cardholder name _____

Cardholder signature _____

2. Pay by certified check or money order.

Please make payable to Allergan *ConfidencePlus[®] Premier* warranty.

Patient name _____

Street address _____

City _____ State _____ Zip _____

Date of birth _____

Email address _____

Phone number _____

Surgeon name _____

Surgeon phone number _____

Date of implant surgery _____

Implant serial numbers: Left _____ Right _____

(The serial number follows the "SN" letters on your device ID card provided by your surgeon.)

You will receive a certificate verifying your enrollment in the *ConfidencePlus[®] Premier* warranty. Please allow 8 to 10 weeks for processing.

Note: Enrollment in the *ConfidencePlus[®] Premier* warranty may be voided if the information provided is incorrect. The *ConfidencePlus[®] Premier* warranty is nonrefundable and nontransferable.

The Natrelle logo, featuring the brand name in a stylized, cursive script.

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.

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.

