

# Natrelle®



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

*Natrelle*® *ConfidencePlus*®  
warranty program

More COVERAGE  
for peace of mind  
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)<sup>†</sup>

### **Late seroma**

- Implant replacement: 20 years for both affected and contralateral textured implants<sup>§</sup>

## **ConfidencePlus® saline warranty<sup>||</sup>**

**FREE** coverage and automatic enrollment

### **Rupture/Deflation**

- Implant replacement: Lifetime for both affected and contralateral implants

## **ConfidencePlus® Premier saline warranty<sup>||</sup>**

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

### **Breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) coverage for both gel and saline patients**

If you have breast implants, you have an increased risk of developing BIA-ALCL. If you have textured implants, Allergan will cover up to \$1000 of out-of-pocket fees toward diagnostic testing for BIA-ALCL.<sup>†</sup> In the event of a BIA-ALCL diagnosis, all Allergan implant patients are eligible for up to \$7500 of out-of-pocket surgical 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.

<sup>†</sup>Valid for procedures on or after January 1, 2019.

<sup>‡</sup>Covers one incident per patient; recurring capsular contracture is not covered.

<sup>§</sup>Valid for cases diagnosed on or after January 1, 2019.

<sup>||</sup>Valid for surgeries on or after July 1, 2014.

# 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](http://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
- **Diagnostic testing for 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.

# 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](http://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](http://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 font.

## **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](http://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.

