

# Natrelle®



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

*Natrelle*® *ConfidencePlus*®  
warranty program

More **COVERAGE**  
for peace of mind

Please see inside for Approved Uses and Important Safety Information.

# MORE coverage. MORE confidence.








## Natrelle® ConfidencePlus® warranty

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.\*



### Gel breast implant coverage

-  **FREE** coverage and automatic enrollment
-  Implant replacement (for rupture): Lifetime for both affected and contralateral implants
-  Surgery cost assistance (for rupture): Up to \$3500 for 10 years
-  Implant replacement (for capsular contracture Baker Grade III/IV): 10 years for both affected and contralateral implants
-  Valid for surgeries on or after November 1, 2014

### Saline breast implant coverage


-  **FREE** coverage and automatic enrollment
-  Implant replacement (for deflation): Lifetime for both affected and contralateral implants
-  Valid for surgeries on or after July 1, 2014

### ConfidencePlus® Premier saline warranty

-  Enroll within 45 days of surgery: \$200
-  Surgery costs assistance (for deflation): Up to \$2400 for 10 years

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

## 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. In the event of a BIA-ALCL diagnosis, Allergan implant patients are eligible for up to \$7500 of out-

of-pocket surgical cost 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.

## 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.

### Who may get breast implants? (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?

- Women with active infection anywhere in their body.

Please see additional Important Safety Information on following pages.

# 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

The **ConfidencePlus**® warranty program applies only to cases of:

- Loss of shell integrity, resulting in implant rupture or deflation that requires surgical intervention
- Capsular contracture (Baker Grade III/IV) with *Natrelle*® Gel implants that requires surgical intervention
- A BIA-ALCL diagnosis that requires surgical intervention. Valid for cases diagnosed on or after January 1, 2018

## 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

The **ConfidencePlus**® warranty program does not apply to the following:

- Removal for capsular contracture for saline implants
- Dissatisfaction with implant size or aesthetics

## IMPORTANT SAFETY INFORMATION (continued)

### Who should NOT get breast implants? (continued)

- 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.

## Events not covered (continued)

- Adverse reactions other than implant deflation, rupture, capsular contracture (Baker Grade III/IV), or a BIA-ALCL diagnosis
- 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

Your surgeon must contact the Allergan Product Surveillance Team at 1-800-624-4261 prior to replacement surgery. 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.

## Enrollment

For *Natrelle*® Gel patients, enrollment in the **ConfidencePlus**® Premier warranty is automatic and free. You do not need to do anything.

For *Natrelle*® saline patients, the **ConfidencePlus**® Standard warranty is automatic and free. However, if you would like to upgrade to the **ConfidencePlus**® Premier warranty, the enrollment fee is \$200 and must be completed within 45 days of surgery by submitting the completed enrollment form by mail, fax, or online at [Natrelle.com/warranty](http://Natrelle.com/warranty).

## IMPORTANT SAFETY INFORMATION (continued)

### What should I know before getting breast implants? (continued)

- 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 Important Safety Information on following pages.**

# 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. Complete the information below and keep it for your records. For additional information, please 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 \_\_\_\_\_

## IMPORTANT SAFETY INFORMATION (continued)

### What should I know before getting breast implants? (continued)

- 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.

**Please see additional Important Safety Information on back cover.**

## Saline patients: Upgrade TODAY!

### *Natrelle® ConfidencePlus® Premier for Natrelle® Saline-Filled Breast Implants*

For patients who choose *Natrelle®* Saline-Filled Breast Implants and would like additional coverage, the enrollment fee is \$200.

### Three convenient ways to enroll within 45 days of your surgery:

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.

### PAYMENT OPTIONS

(All fields must be completed to process payment.)

#### 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 \_\_\_\_\_

#### 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.

# Natrelle®



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

## *Natrelle*® ConfidencePlus® warranty program

**With *Natrelle*®, you're choosing more than an implant, you're choosing a lifetime partner.**

To learn more, talk to your surgeon or  
visit [Natrelle.com/warranty](http://Natrelle.com/warranty).

### **IMPORTANT SAFETY INFORMATION (continued)**

#### **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.

