

Natrelle[®] **WARRANTY**

**The *Natrelle*[®]
ConfidencePlus[®]
Warranty Program**

Offering you
more *coverage*
for your
peace of mind

Nikki
Natrelle INSPIRA[®] Responsive Style SRF-415
Individual results may vary.

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.

ConfidencePlus® Premier for Natrelle® Gel implants

- **FREE** breast implant replacement in the event of capsular contracture (Baker Grade III/IV)
- **FREE** coverage for primary AND revision surgeries in the event of capsular contracture (Baker Grade III/IV)
- Choose **ANY** style and size of Natrelle® Gel breast implant for replacement in the event of capsular contracture (Baker Grade III/IV) or rupture

Gel breast implant coverage

ConfidencePlus® Premier Warranty

-  Automatic enrollment: **FREE**
-  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

Additional rare event coverage for both gel and saline patients:

If you have breast implants, you have a very small but increased risk of developing breast implant-associated anaplastic large cell lymphoma (BIA-ALCL). In the unlikely event of a BIA-ALCL diagnosis, Allergan implant




Choose additional coverage with ConfidencePlus® Premier for saline breast implants.

If you have Natrelle® Saline-Filled Breast Implants, you have the option to choose additional coverage for \$200, which includes financial assistance for surgery costs.





Saline breast implant coverage

ConfidencePlus® Warranty

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

ConfidencePlus® Premier Warranty

-  Enroll within 45 days of surgery for ConfidencePlus® Premier warranty: \$200
-  ConfidencePlus® Premier surgery cost assistance (for deflation): Up to \$2400 for 10 years

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.

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

Who may get breast implants? (continued)

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.

Please see 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

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 rare event of BIA-ALCL diagnosis that requires surgical intervention*

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

*Valid for cases diagnosed on or after January 1, 2018.

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.

Events not covered (continued)

- Adverse reactions other than implant deflation, rupture, capsular contracture (Baker Grade III/IV), or rare event of 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*[®] breast implant in lieu of a *Natrelle*[®] 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*[®] 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.

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

Please see additional Important Safety Information on following pages.

Natrelle® warranty information

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 for your records. For additional information, please visit 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 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.

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.

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 in order 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 weeks 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® ConfidencePlus® warranty program

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

- **FREE** lifetime product replacement for all implants in the event of implant rupture or deflation
- **FREE** financial assistance up to \$3500 for 10 years in the event of implant rupture of *Natrelle*® Gel breast implants
- **FREE** financial assistance up to \$7500 for rare event of BIA-ALCL diagnosis*
- **FREE** gel breast implant replacement for 10 years in the event of capsular contracture (Baker Grade III/IV) for *Natrelle*® Gel implants (valid for both **primary AND revision** surgeries)†
- Choose **ANY** style and size of *Natrelle*® Gel breast implant for replacement in case of any covered event with *Natrelle*® Gel implants†
- Financial assistance up to \$2400 for 10 years in the event of implant deflation of *Natrelle*® Saline-Filled Breast Implants (\$200 upgrade to *ConfidencePlus*® Premier required)

For more information about the *ConfidencePlus*® warranty program, please talk to your surgeon or visit Natrelle.com/warranty.

*Valid for cases diagnosed on or after January 1, 2018.

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

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

Natrelle® Breast Implants are available by prescription only.



The Natrelle logo features the word "Natrelle" in a large, elegant, cursive script font, with a registered trademark symbol (®) to the upper right.