

Please see inside for Indications and Important Safety Information.

## Designed for your

# Peace of Mind

# Congratulations on your new look!

Whether you have chosen *Natrelle*® Gel implants or saline, you can have the satisfaction of knowing that you're backed by the *ConfidencePlus*® warranty program.

ConfidencePlus® is the first and only warranty program that comes with FREE breast implant replacement for up to 10 years in the event of capsular contracture (Baker Grade III/IV) for all Natrelle® Gel implants. Plus, if you need an implant replacement, you may choose any Natrelle® style implant (within a comparable size range).

## Who may get breast implants (INDICATIONS)? Natrelle® Breast Implants are indicated for women for

Natrelle® Breast Implants are indicated 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.

### **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

## **Special considerations**

Each Natrelle® breast implant is covered individually. So, in the case of rupture, deflation, or capsular contracture (Baker Grade III/IV), 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.

Natrelle

ConfidencePlus® Warranty Program

## IMPORTANT SAFETY INFORMATION Who should NOT get breast implants (CONTRAINDICATIONS)?

Breast implant surgery should not be performed in women with active infection anywhere in their body, with existing cancer or pre-cancer of their breast who have not received adequate treatment for those conditions, and women who are currently pregnant or nursing.

Please see additional Important Safety Information on next page.



## ConfidencePlus® **Warranty Program**

If you elect to have surgery with Natrelle® Gel breast implants on/after November 1, 2014, you are automatically enrolled.

Register online and see complete terms and conditions at www.cppwarranty.com/termsconditions.aspx

## Uparade to ConfidencePlus® Premier

If you have Natrelle® Saline-Filled Breast Implants, you have the option of upgrading your standard warranty to ConfidencePlus® Premier. For \$200, the ConfidencePlus® Premier warranty offers financial assistance of up to \$2400 for surgery costs in the

event of an implant rupture.

With Natrelle®, you're choosing more than an implant, you're choosing a partner. And as your partner, we have the confidence to offer you one of the best warranty programs in the industry.



## **IMPORTANT SAFETY INFORMATION (continued)** What else should I consider (WARNINGS)?

Breast implants are not lifetime devices or necessarily a onetime surgery. 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 produce milk for breastfeeding. Silicone-filled implants may rupture without symptoms. MRI examinations 3 years after surgery and then 2 years after can detect ruptures. 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. Talk to your doctor about removing ruptured implants. Inform any other doctor if you have implants.

Natrelle ConfidencePlus® Warranty Program

All Natrelle® Gel breast implants come with a FREE 10-year warranty covering capsular contracture (Baker Grade III/IV).

	Saline		Gel	
	Standard	Premier	Premier	
Cost	Free	\$200	Free	
Enrollment	Automatic	Must enroll within 45 days of surgery	Automatic	
Term	10 years	10 years	10 years	
For deflation or rupture				
Financial assistance (for surgery costs)	\$0	Up to \$2400 during term	Up to \$3500 during term	
Implant (for deflation or rupture)	Lifetime replacement	Lifetime replacement	Lifetime replacement	
Contralateral implant	Lifetime replacement	Lifetime replacement	Lifetime replacement	
For capsular contracture (Baker Grade III/IV)				
Financial assistance (for surgery costs)	\$0	<b>\$</b> O	\$0	
Implant	No replacement	No replacement	10-year replacement	
Contralateral implant	No replacement	No replacement	10-year replacement	
Surgery date	Coverage valid for surgery on/after November 1, 2014			
Additionally, if you need a gel implant replacement due to rupture or capsular contracture (Baker Grade (III/IV), you can choose ANY Natrelle® Gel style (within a comparable size range).				



For Natrelle® Saline-Filled Breast Implants patients with a deflation, you can upgrade to gel implants at the time of replacement and pay the additional cost difference.

After saline implant replacement, *ConfidencePlus®* Premier coverage is optional and available for purchase at the \$200 fee. For full warranty terms and conditions, visit www.cppwarranty.com/termsconditions.aspx or call 1-800-624-4261.

## What types of conditions require more study (PRECAUTIONS)?

Caution: Notify your doctor if you have any of the following conditions, as the risks of breast implant surgery may be higher: autoimmune diseases, a weakened immune system, planned radiation therapy to the breast or planned chemotherapy following breast implant placement, conditions/medications that interfere with wound healing and blood clotting, reduced blood supply to breast tissue or a clinical diagnosis of depression, other mental health disorders, body dysmorphic disorder and eating disorders. These disorders should be resolved or stabilized prior to surgery.

## What are some complications with breast implants (COMPLICATIONS)?

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 or call the Allergan Product Support line at 1-800-433-8871.

To report a problem with Natrelle, please call Allergan Product Surveillance at 1-800-624-4261.

Natrelle® Breast Implants are available by prescription only.

## **Upgrade today!**

## To enroll in *ConfidencePlus®* Premier, complete the tear-off form or register online within 45 days of your surgery.

For patients who choose *Natrelle®* Saline-Filled Breast Implants and would like to upgrade to the *ConfidencePlus®* Premier warranty, the enrollment fee is \$200 and must be received or postmarked within 45 days of the qualifying surgery.

## Mail payment and completed form to:

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

## Or fax the completed form to:

1-888-647-4029

## Or register online at:

To pay by credit card:

www.cppwarranty.com

**DO NOT** send a personal check. Enrollment forms that include a personal check **WILL NOT** be processed.

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## To pay by certified check or money order:

Please make payable to Allergan ConfidencePlus®

Premier warranty.		
Name		
Address	_ State	Zip
Date of birth		
Home phone		
Implanting surgeon name_		
Surgeon telephone		
Date of implant surgery		
Implant serial number(s):		
Left side		

(The serial number follows the letters SN 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

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
Our promise to you

- FREE implant replacement for 10 years in the event of capsular contracture (Baker Grade III/IV) for Natrelle® Gel breast implants
- · Lifetime product replacement for all implants in the event of implant rupture or deflation
- Financial assistance up to \$2400 for 10 years in the event of implant rupture for Natrelle® saline
- Financial assistance up to \$3500 for 10 years in the event of implant rupture for Natrelle® Gel breast implants

For more information about the ConfidencePlus® warranty program, please talk to your surgeon or visit www.cppwarranty.com.

#### **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
- Adverse reactions other than implant deflation, rupture, or capsular contracture (Baker Grade III/IV)
- 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.

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 www.cppwarranty.com.

Please see Important Safety Information inside.