

# Natrelle®

Your comprehensive portfolio  
for every curve, for every shape,  
for EVERY  
BODY<sup>2</sup>



Actual Natrelle INSPIRA® patients.  
Individual results may vary.

\*Based on surgeon survey data, September 2023 (N = 491).

Please see Important Safety Information for Natrelle® Breast Implants,  
including Boxed Warning, throughout this brochure.



# Our COMMITMENT to you and your PATIENTS

Your patients' safety is our number one priority, and our commitment to quality and satisfaction is an important part of that.<sup>3-5</sup>



Actual Natrelle INSPIRA® patients. Individual results may vary.

## Natrelle® Breast Implants IMPORTANT SAFETY INFORMATION

### WARNINGS

- Breast implants are not considered lifetime devices. The longer patients have them, the greater the chance they will develop complications, some of which will require more surgery
- Breast implants have been associated with the development of a cancer of the immune system called breast implant-associated anaplastic large cell lymphoma (BIA-ALCL). This cancer occurs more commonly in patients with textured breast implants than smooth implants, although rates are not well defined. Some patients have died from BIA-ALCL
- Patients receiving breast implants have reported a variety of systemic symptoms, such as joint pain, muscle aches, confusion, chronic fatigue, autoimmune diseases, and others. Individual patient risk for developing these symptoms has not been well established. Some patients report complete resolution of symptoms when the implants are removed without replacement

### INDICATIONS

Natrelle® Breast Implants are indicated for women for the following:

- **Breast augmentation for women at least 22 years old for silicone-filled implants and breast augmentation for women at least 18 years old for saline-filled implants.** This includes primary breast augmentation to increase the breast size, as well as revision surgery to correct or improve the result of a primary breast augmentation surgery
- **Breast reconstruction.** This 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

### CONTRAINDICATIONS

Breast implant surgery should not be performed in:

- 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

### ADDITIONAL WARNINGS

- See Boxed Warning
- **Avoid damage during surgery:** Care should be taken to avoid the use of excessive force and to minimize handling of the implant. Forcing of implants through too small an opening or applying concentrated localized pressure on the implants may result in localized weakening of the breast implant shell, potentially leading to shell damage and possible implant rupture. An incision should be of appropriate length to accommodate the style, size, and profile of the implants. Use care when using surgical instruments in proximity with the breast implant
- Follow recommended fill volumes for saline implants to decrease possibility of shell wrinkling and crease-fold failure

### PRECAUTIONS

Safety and effectiveness have not been established in patients with the following:

- Autoimmune diseases (eg, lupus and scleroderma)
- A compromised immune system (eg, currently receiving immunosuppressive therapy)
- Planned chemotherapy or radiation 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 prior to surgery. Patients with a diagnosis of depression, or other mental health disorders, should wait until resolution or stabilization of these conditions prior to undergoing breast implantation surgery

Please see additional Important Safety Information on following pages.

## NATRELLE® PORTFOLIO: A simple implant system to help you navigate your individual patient needs<sup>2</sup>



OVER  
**1.6**  
MILLION

**NATRELLE INSPIRA®** smooth gel breast implants implanted in patients since 2015 in the US<sup>6</sup>

### Simplify your selection in 3 simple steps<sup>2</sup>:

- 1 Base width
- 2 Profile
- 3 Cohesivity

- **Choose your level of fullness:** The only portfolio that offers 3 cohesivities and 5 distinct profiles to fit your patient's body<sup>2</sup>
- **Paired for precision:** 100% match between all Natrelle® tissue expanders and breast implants<sup>7a</sup>
- **For comprehensive choices:** Complete saline-filled implant portfolio of options<sup>2</sup>
- **We've got your patients covered:** Natrelle® ConfidencePlus® warranty program backs breast implants with a lifetime guarantee for certain covered events<sup>8,\*</sup>



With a demonstrated safety profile<sup>5</sup>

Actual Natrelle INSPIRA® patient. Individual results may vary.

\*See additional warranty program details on page 17.

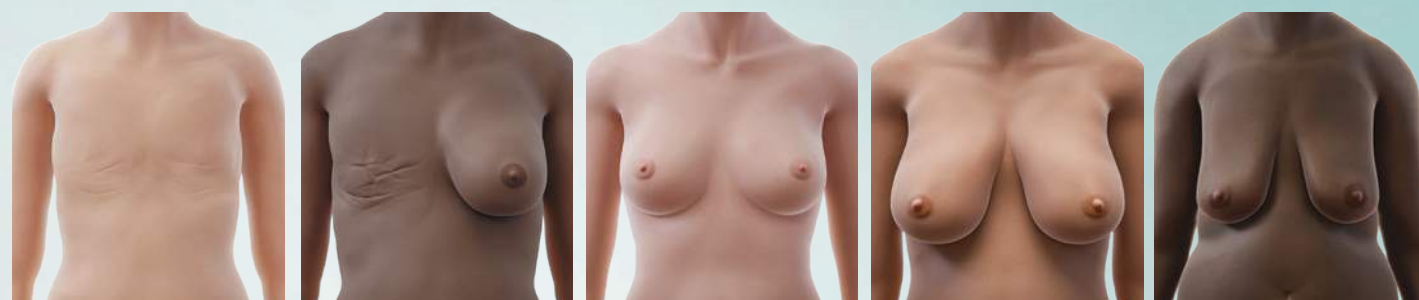
**Methodology** Tissue expanders were matched to round breast implants. A precise match was defined as a breast implant that falls within a range of 0.5 cm smaller to 1.0 cm larger in base width and 1.5 cm smaller to 2.0 cm larger in projection of a tissue expander. The percentage of precise matches was calculated for each style of tissue expander.



# The right implant depends on *your* PATIENT'S NEEDS

- When patients are considering breast implants, we understand the look, the feel, and, of course, safety are important
- Since every patient has different needs and wants, we're proud to offer the most comprehensive and customizable smooth portfolio to meet your individual patients' needs<sup>2</sup>

Which types of patients are you seeing in your practice?



**6.6** women are considering breast augmentation in the next 2 years<sup>10,\*</sup>  
**MILLION**

\*Based on a survey of prospective primary augmentation patients with a mean average age of 37 (n = 200).

Nearly **140,000** women in the US undergo some form of breast reconstruction each year. **Over 100,000** of those are implant based<sup>11,12</sup>

**Natrelle® Breast Implants IMPORTANT SAFETY INFORMATION (continued)**

**ADVERSE EVENTS**

Possible adverse events with breast implant surgery include implant rupture with silicone implants, implant deflation with saline-filled implants, capsular contracture, reoperation, implant removal, pain, changes in nipple and breast sensation, infection, scarring, asymmetry, wrinkling, implant displacement/migration, implant palpability/visibility, breastfeeding complications, hematoma/seroma, implant extrusion, necrosis, delayed wound healing, infection, breast tissue atrophy/chest wall deformity, calcium deposits, and lymphadenopathy. Other systemic conditions have been reported with breast implants.

For more information, please see the full Directions for Use at [www.allergan.com/products](http://www.allergan.com/products).

To report a problem with Natrelle® Breast Implants, please call Allergan® at 1-800-624-4261.

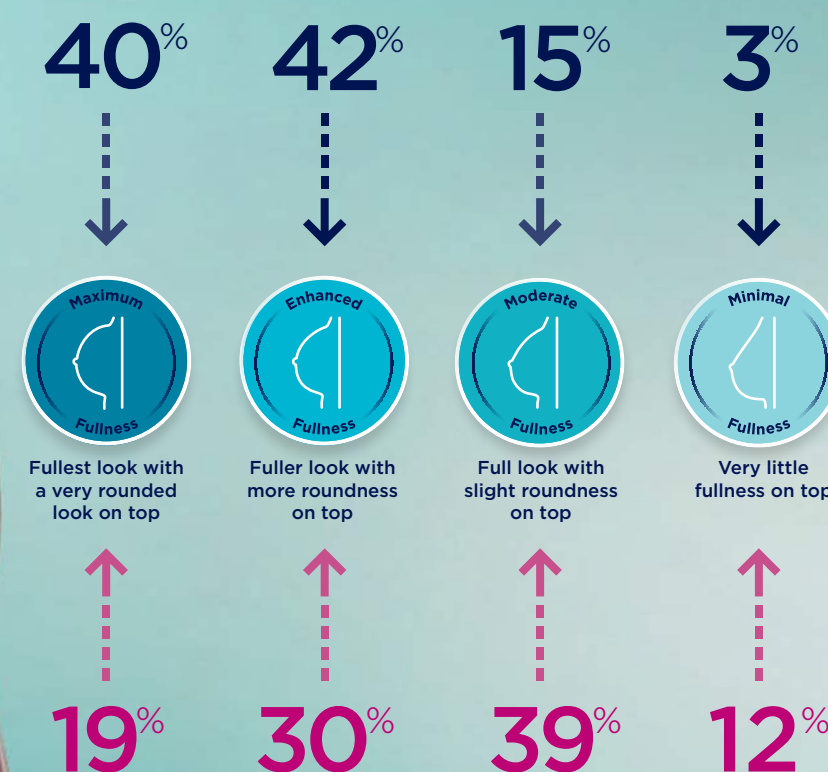
The sale and distribution of this device is restricted to users and/or user facilities that provide information to patients about the risks and benefits of this device in the form and manner specified in the approved labeling provided by Allergan®.

Please see additional Important Safety Information on following pages.

# The unique look *your* PATIENTS WANT

Customize to fit your patient's body<sup>2</sup>

Prospective **AUGMENTATION** patients surveyed preferred this look.<sup>3,\*</sup>



Prospective **RECONSTRUCTION** patients surveyed preferred this look.<sup>4,†</sup>

Actual Natrelle INSPIRA® patient. Individual results may vary.

\*Based on a 2022 survey of 174 prospective breast augmentation patients.

†Based on a 2022 survey of 129 prospective and existing breast reconstruction patients.





# 5 DISTINCT PROFILES AND 3 DIFFERENT GELS designed to retain upper pole fullness<sup>13,a,\*</sup>

SIMPLE SELECTION



## Navigate Natrelle<sup>®</sup> IN 3 EASY STEPS

with a simple breast implant selection system to help you meet your patients' unique needs<sup>2</sup>

**Natrelle INSPIRA<sup>®</sup>** uses consistent systematic diameter sizing increments (0.25 cm or 0.50 cm), providing an organized and predictable portfolio to allow for an optimal implant selection that best matches your patient's breast.<sup>2</sup>

**Natrelle INSPIRA<sup>®</sup>** smooth implants are designed to achieve and maintain a range of upper pole fullness.<sup>13,a,\*</sup>



**Natrelle INSPIRA<sup>®</sup>** is the only implant system with 300 options that can be easily utilized to create a customized look from **5 profiles** and **3 cohesivities** to fit your patient's body and their aesthetic goal.<sup>2</sup>

Images for representation only. In vivo significance has not been established.

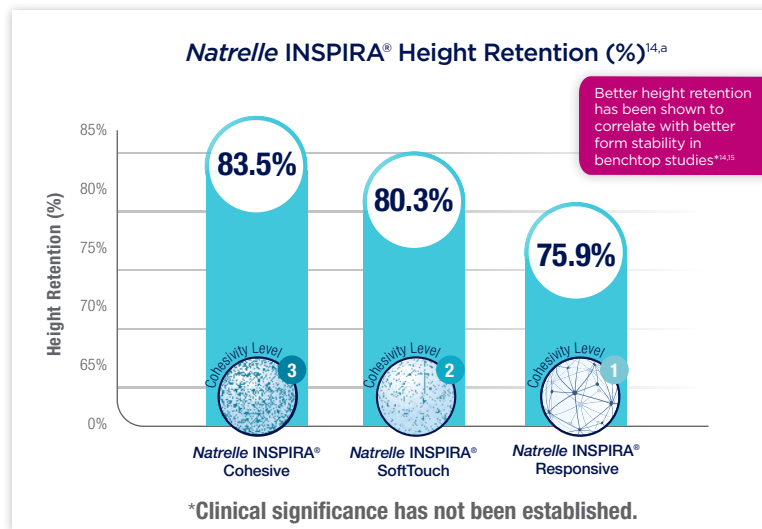
<sup>a</sup>Based on implant performance testing; clinical significance has not been established.  
<sup>1</sup>Based on surgeon survey data, September 2023 (N = 491).

<sup>2</sup>**Methodology** Breast implant devices (n = 6 per group) were placed in a horizontal orientation on a sliding stage; the width and maximum projections of the implants were measured using fixed calipers. The devices were then placed in a vertical-supported orientation using a 90° angle, and the width and maximum projections were measured again. From those measurements, the retention of dimension was calculated and the relative change was determined.

# NATRELLE INSPIRA® offers you the most form-stable implants<sup>14-16,\*</sup>

A range of form-stable options with consistent shell thickness<sup>14,17,a,b,\*</sup>

We know that form stability is important to your breast implant procedures<sup>3,+</sup>  
**Form Stability/Height Retention = Gel Cohesivity + Shell Thickness<sup>14,18</sup>**



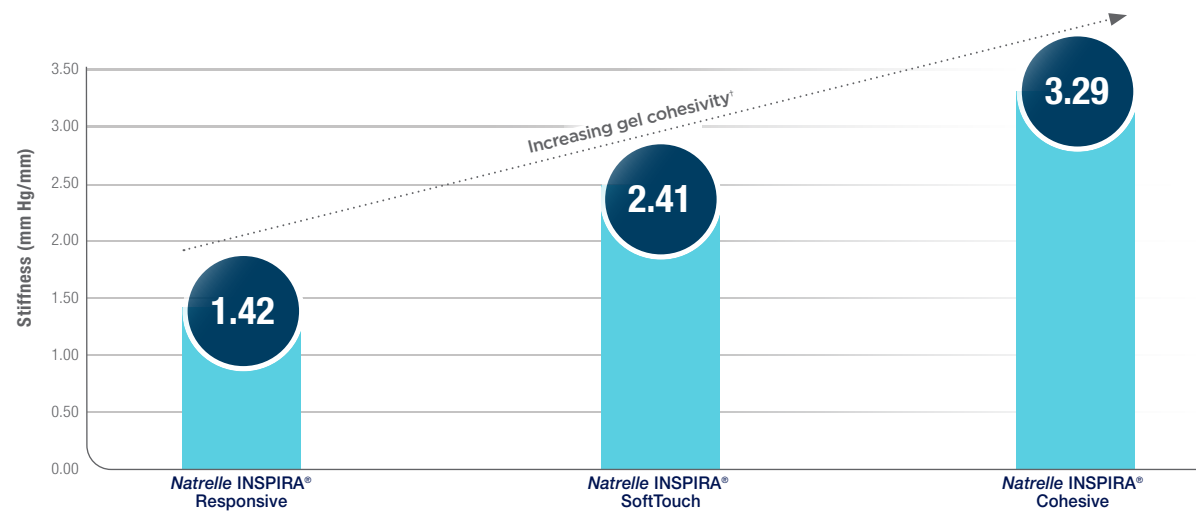
**Methodology** Breast implant devices (n = 8 per study group from DOF MD16075-DV5; n = 6 per study group from DOF MD-16075-DV1; n = 6 additional breast implant devices from 1745-D77-054: Final Report 1) were placed in a horizontal orientation on a sliding stage; the width and maximum projections of the implants were measured using fixed calipers. The devices were then placed in a vertical, supported orientation using a 90° angle, and the width and maximum projections were measured again. From those measurements, the retention of dimension was calculated and the relative change was determined.



**Methodology** Shell thickness was measured at 5 regions around the anterior shell (upper pole, left lateral, point of maximum projection [PMP], right lateral, and lower pole) per device. Shell thickness for each region was measured (mm) in triplicate with a calibrated digital thickness gauge caliper and the means and standard deviations were calculated for each region. The 5 regions were averaged to calculate the shell thickness of all sites per device (n = 8 per group) and the means were calculated per device group.

The Natrelle INSPIRA® Smooth Collection has consistent shell thickness<sup>17,b,\*</sup>

Smooth implants designed to hold their shape<sup>17,c,\*</sup>



\*Clinical significance has not been established.

<sup>1</sup>Based on Plastic Surgeon Survey Data; n = 100; August 2022.

**Methodology** Breast implant gel was measured for material properties using the BTC-2000™. The BTC-2000™ applies a controlled vacuum, or negative pressure, to the gel while measuring the dynamic response of material deformation using a synchronized target laser. The gel for each device (n = 8 per group) was tested at 3 sites, all at or near the apex of the implant (anterior side). Each gel's resistance to deformation (mm Hg/mm) was calculated from the slope of the linear region of the pressure-deformation curve. This measurement characterizes the material's dynamic response to resisting deformation, or the gel's stiffness. Higher values indicate greater gel stiffness, while lower values suggest less gel stiffness.

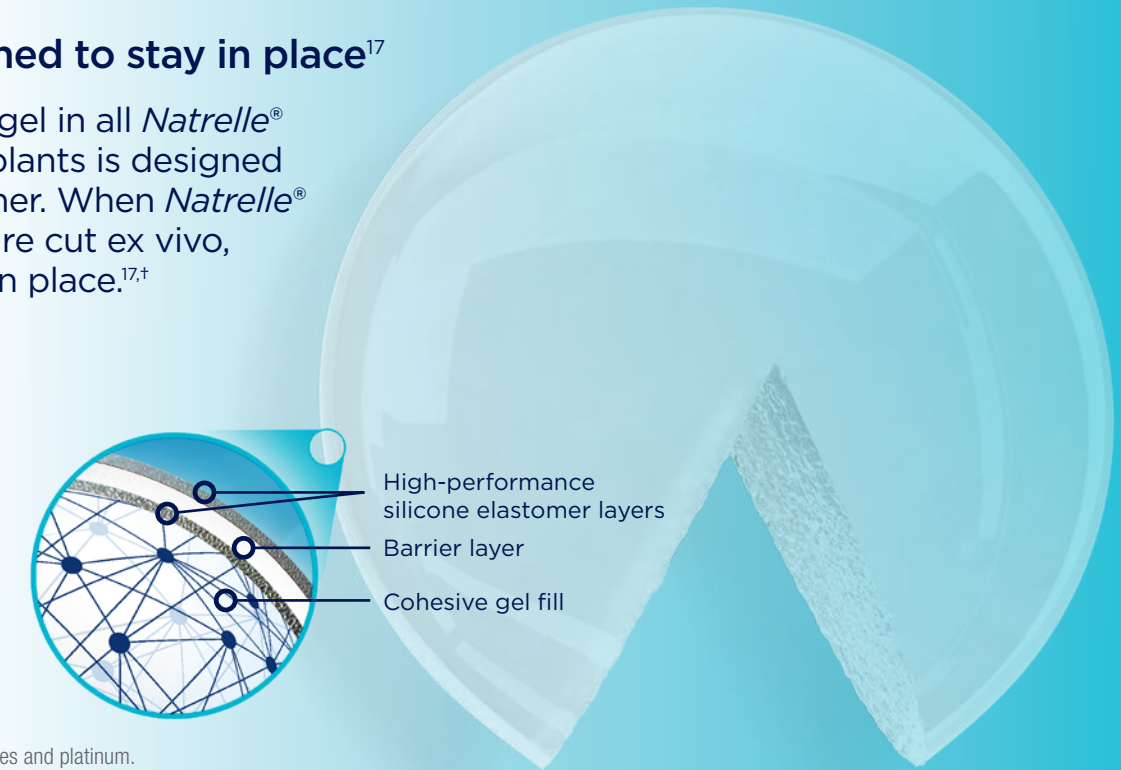
# ADVANCED Implant Technology

A shell designed to protect<sup>5</sup>

The Natrelle INSPIRA® Collection is designed with patented INTRASHIEL™ SHELL TECHNOLOGY providing a barrier layer which minimizes gel diffusion through the shell (<1% gel diffusion rate).<sup>5,\*</sup>

A gel designed to stay in place<sup>17</sup>

The cohesive gel in all Natrelle® gel breast implants is designed to hold together. When Natrelle® gel implants are cut ex vivo, the gel stays in place.<sup>17,+</sup>



\*Low molecular weight silicones and platinum.  
<sup>+</sup>In vivo significance has not been established.

Natrelle INSPIRA® Cohesive

The most cohesive round gel breast implant in the US.<sup>17</sup>

A patch created with a special tapered cut<sup>19</sup>





# Customized looks for YOUR UNIQUE PATIENTS

A little to a lot, the choice is hers



## Revision Augmentation With Breast Lift With *Natrelle* INSPIRA® Cohesive

BEFORE



AFTER



***Natrelle* INSPIRA® Cohesive Style SCM-445**  
Implant dimensions: 445 cc volume, 13.50 cm diameter, 4.5 cm projection

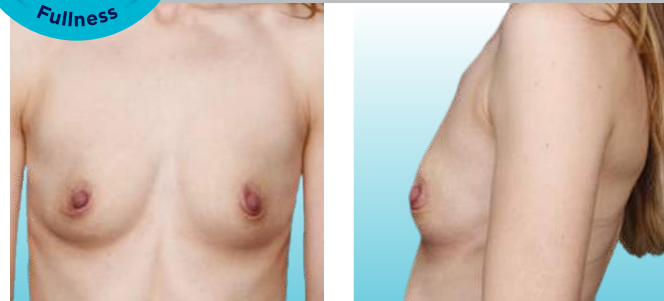
Photos provided by Dr Allen Gabriel.  
**Individual results may vary.**

*Natrelle* INSPIRA® SoftTouch is the  
**#1** selected implant for breast augmentation in the US<sup>1,\*</sup>

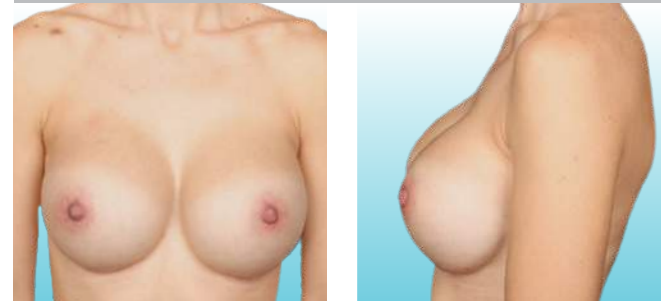


## Primary Augmentation With *Natrelle* INSPIRA® Cohesive

BEFORE



AFTER



***Natrelle* INSPIRA® Cohesive Style SCX-580**  
Implant dimensions: 580 cc volume, 13.50 cm diameter, 6.4 cm projection

Photos provided by Dr Allen Gabriel.  
**Individual results may vary.**

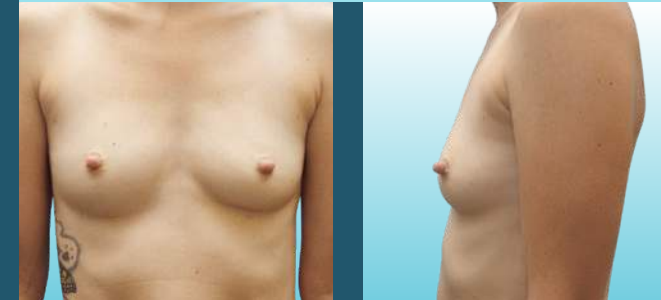
94%

of women who had breast augmentation with *Natrelle*® Breast Implants were satisfied with their implants at 10 years<sup>5,\*</sup>



## Primary Augmentation With *Natrelle* INSPIRA® SoftTouch

BEFORE



AFTER



***Natrelle* INSPIRA® SoftTouch Style SSM-310**  
Implant dimensions: 310 cc volume, 12.00 cm diameter, 4.0 cm projection

Photos provided by Dr Gaurav Bharti.  
**Individual results may vary.**



## Primary Augmentation With *Natrelle* INSPIRA® Cohesive

BEFORE



AFTER



***Natrelle* INSPIRA® Cohesive Style SCM-310**  
Implant dimensions: 310 cc volume, 12.00 cm diameter, 4.0 cm projection

Photos provided by Dr Allen Gabriel.  
**Individual results may vary.**

<sup>1</sup>Based on surgeon survey data, September 2023 (n = 283). Based on a 3-month rolling average.

<sup>5</sup>Patient satisfaction based on primary augmentation patients (n = 279; 86.0% definitely satisfied and 8.2% somewhat satisfied) and primary reconstruction patients (n = 43; 67.4% definitely satisfied and 23.3% somewhat satisfied) using round implants in the Allergan® Core Study.

*Natrelle*  
133S smooth tissue expander

# SMOOTH, COMPACT, SECURE<sup>20,21,\*†</sup>

Tailor your tissue expander to the specific needs of each patient.



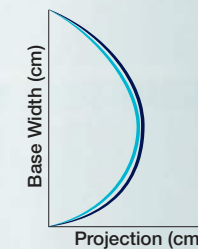
Features the **FOURTE™** Expander Fill System<sup>b</sup>

## PAIRED FOR PRECISION for the breast shape you envision<sup>7</sup>



**Natrelle®** 133S Smooth Tissue Expanders deliver a seamless match between smooth tissue expanders and round breast implants.<sup>7,a</sup>

100% match between all **Natrelle®** smooth tissue expanders and **Natrelle INSPIRA®** breast implants (in both tissue width and projection).<sup>7,a</sup>



### 100% MATCH

between all **Natrelle®** smooth tissue expanders and **Natrelle INSPIRA®** Breast Implants (in both base width and projection)<sup>7,a</sup>

Actual patient with **Natrelle®** tissue expanders. **Individual results may vary.**

**Methodology** Tissue expanders were matched to round breast implants. A precise match was defined as a breast implant that falls within a range of 0.5 cm smaller to 1.0 cm larger in base width and 1.5 cm smaller to 2.0 cm larger in projection of a tissue expander. The percentage of precise matches was calculated for each style of tissue expander.

\*Clinical significance has not been established.

<sup>†</sup>Based on tissue expanders comparable in size: **Natrelle®** Style 133MX, 500 cc and Mentor Artoura High Profile, 500 cc.

<sup>a</sup>When used with **Natrelle®** 133S Tissue Expanders.

<sup>b</sup>**Methodology** Tissue expanders were matched to round breast implants. A precise match was defined as a breast implant that falls within a range of 0.5 cm smaller to 1.0 cm larger in base width and 1.5 cm smaller to 2.0 cm larger in projection of a tissue expander. The percentage of precise matches was calculated for each style of tissue expander.

<sup>c</sup>**Methodology** The **FOURTE™** Expander Fill System and 21-gauge needle are attached to 60-cc syringes filled with water. The injector starts the injection at maximum effort while the time is tracked. When the plunger reaches the end of the syringe barrel, the time is stopped and recorded. This is repeated 20 times, recorded, and compared.

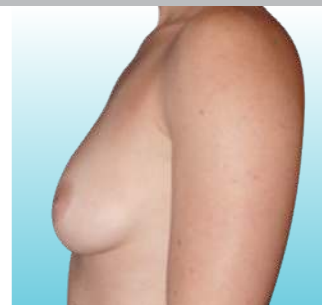


# Breast Implants MADE TO MATCH<sup>7</sup>



## Breast Reconstruction With Pre-Pec Placement and Fat Transfer

BEFORE



AFTER

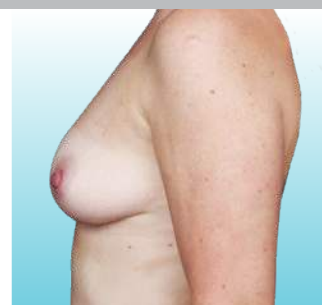


**Natrelle INSPIRA® Cohesive Style SCF-650**  
Implant dimensions: 650 cc volume, 14.50 cm diameter, 5.9 cm projection  
Photos provided by Dr Ritu Chopra.  
**Individual results may vary.**

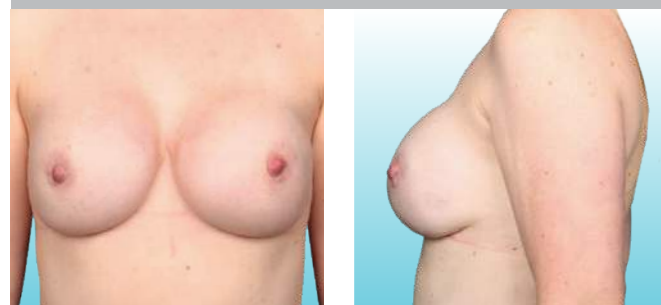


## Breast Reconstruction With Pre-Pec Placement and Fat Transfer

BEFORE



AFTER



**Natrelle INSPIRA® Cohesive Style SCF-415**  
Implant dimensions: 415 cc volume, 12.50 cm diameter, 5.1 cm projection  
Photos provided by Dr Allen Gabriel.  
**Individual results may vary.**

# 91%

of women who had breast reconstruction with *Natrelle*® Breast Implants were satisfied with their implants at 10 years<sup>5,\*</sup>

## Revision Reconstruction With *Natrelle* INSPIRA®

BEFORE



AFTER



**Natrelle INSPIRA® Responsive Style SRL-110 (right)**  
Implant dimensions: 110 cc volume, 10.00 cm diameter, 2.0 cm projection  
**Natrelle INSPIRA® Cohesive Style SCF-415 (left)**  
Implant dimensions: 415 cc volume, 12.50 cm diameter, 5.1 cm projection  
Photos provided by Dr Hani Sbitany.  
**Individual results may vary.**



## Breast Reconstruction With Pre-Pec Placement

BEFORE



AFTER



**Natrelle INSPIRA® SoftTouch Style SSF-520**  
Implant dimensions: 520 cc volume, 13.25 cm diameter, 5.5 cm projection  
Photos provided by Dr Maurice Nahabedian.  
**Individual results may vary.**



\*Patient satisfaction based on primary reconstruction patients using round implants (n = 43; 67.4% definitely satisfied and 23.3% somewhat satisfied).





# Natrella® ConfidencePlus® GEL WARRANTY PROGRAM

Give your patients the benefit of lifetime coverage<sup>8,\*</sup>

\*For certain covered events. See full warranty program terms and conditions by scanning the QR code below.

## ConfidencePlus® gel warranty

**FREE** coverage and automatic enrollment<sup>8</sup>

### Rupture<sup>8</sup>

- 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<sup>8,†</sup>

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

### Late seroma<sup>8</sup>

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

### Late seroma diagnostic testing coverage<sup>8</sup>

If the patient has textured gel or textured saline breast implants, Allergan Aesthetics 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<sup>8</sup>

In the event of a BIA-ALCL diagnosis, the patient is 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 Aesthetics will also provide replacement implant(s) at no charge. For coverage eligibility, surgeons are directed to contact Allergan Aesthetics and provide appropriate documentation.

†Covers one incident per patient; recurring capsular contracture is not covered.



Visit [NatrellaSurgeon.com](https://www.NatrellaSurgeon.com)  
to download the brochure.



Actual Natrella INSPIRA® patients.  
Individual results may vary.



**Natrelle® 133S Smooth Tissue Expanders With MAGNA-SITE® Injection Sites**  
**IMPORTANT SAFETY INFORMATION**

**INDICATIONS**

Natrelle® 133S Smooth Tissue Expanders are indicated for:

- Breast reconstruction following mastectomy
- Treatment of underdeveloped breasts
- Treatment of soft tissue deformities

**IMPORTANT SAFETY INFORMATION**

**CONTRAINDICATIONS**

Natrelle® 133S Smooth Tissue Expanders **should not** be used in patients:

- Who already have implanted devices that would be affected by a magnetic field (eg, pacemakers, drug infusion devices, and artificial sensing devices)
- Whose tissue at the expansion site is determined to be unsuitable
- Who have an active infection or a residual gross tumor at the expansion site
- Who are undergoing adjuvant radiation therapy
- Whose physiological condition (eg, sensitive over- or underlying anatomy, obesity, smoking, diabetes, autoimmune disease, hypertension, chronic lung or severe cardiovascular disease, or osteogenesis imperfecta) or use of certain drugs (including those that interfere with blood clotting or affect tissue viability) poses an unduly high risk of surgical and/or postoperative complications
- Who are psychologically unsuitable

**WARNINGS**

- **Do not** use Natrelle® 133S Smooth Tissue Expanders in patients who already have implanted devices that would be affected by a magnetic field (see *Contraindications*) because the MAGNA-SITE® integrated injection site contains a strong rare-earth, permanent magnet. Diagnostic testing with Magnetic Resonance Imaging (MRI) is contraindicated in patients with Natrelle® 133S Smooth Tissue Expanders in place
- **Do not** alter the tissue expander or use adulterated fill. Fill only with sterile saline for injection as described in INSTRUCTIONS FOR USE. **Do not** expose to contaminants
- **Do not** expand if the pressure will compromise wound healing or vasculature of overlying tissue, or beyond patient or tissue tolerance. Stop filling immediately if tissue damage, wound dehiscence, abnormal skin pallor, erythema, edema, pain, or tenderness are observed
- **Do not reuse explanted products**
- Active infection anywhere may increase risk of periprosthetic infection. **Do not expose the tissue expander or injection needles to contaminants.** Postoperative infections should be treated aggressively

- Adverse reactions may require premature explantation
- When using suturing tabs be careful to avoid piercing the shell. Use a new one if damage occurs
- **Natrelle® 133S Smooth Tissue Expanders are temporary devices and are not to be used for permanent implantation or beyond 6 months.** Tissue expansion in breast reconstruction typically requires 4 to 6 months

**PRECAUTIONS**

Active infections may need to be treated and resolved before surgery. Follow proper surgical procedures and carefully evaluate patient suitability using standard practice and individual experience. Avoid damage to the tissue expander and use a **sterile backup** in case of damage. Pay careful attention to tissue tolerance and hemostasis during surgery. Expansion should proceed moderately and never beyond patient or tissue tolerance. Avoid contamination in any postoperative procedure.

**ADVERSE REACTIONS**

Possible adverse reactions include deflation, tissue damage, infection, extrusion, hematoma/seroma, capsular contracture, premature explantation, displacement, effects on bone, pain, sensation, distortion, inadequate tissue flap, and inflammatory reaction.

**For more information, please see the full Directions for Use at [www.allergan.com/products](http://www.allergan.com/products).**

**To report a problem with Natrelle® 133S Smooth Tissue Expanders, please call Allergan® at 1-800-624-4261.**

Natrelle® 133S Smooth Tissue Expanders are restricted to sale by or on the order of a licensed physician.

Natrelle®



# Natrelle® is the #1 SELECTED breast implant portfolio in the US<sup>1,\*</sup>



- **Navigate Natrelle®:** a simple selection system for breast implants<sup>2</sup>
- With **Natrelle®**, you can choose your level of fullness with 3 cohesivities and 5 distinct profiles resulting in a unique, customized look that fits your patient's body<sup>2</sup>
- **Natrelle INSPIRA®** smooth implants are designed to achieve and maintain a range of upper pole fullness, with upper pole retention at Cohesive 97%; SoftTouch 91%; Responsive 84%<sup>13</sup>
- 100% match between all **Natrelle®** tissue expanders and breast implants<sup>7</sup>

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

\*Based on surgeon survey data, September 2023 (N = 491).

Please see Important Safety Information for **Natrelle®** Breast Implants, including Boxed Warning, on Page 2 of this brochure.

Visit [NatrelleSurgeon.com](https://www.NatrelleSurgeon.com) to learn more.



@NatrelleBreastAugmentation  
@NatrelleBreastReconstruction



Visit [NatrelleSurgeon.com](https://www.NatrelleSurgeon.com)  
for more information

References: 1. Data on file, Allergan Aesthetics, Monthly Tracker, September 2023. 2. Data on file, Allergan Aesthetics, Hospital Order Form Update, January 2022. 3. Data on file, Allergan Aesthetics, PLS Aug AU Report 2022. 4. Data on file, Allergan Aesthetics, PLS Recon AU Report 2022. 5. **Natrelle®** Silicone-filled Breast Implants and **Natrelle INSPIRA®** Breast Implants: Smooth Surface Implants Directions for Use, 2022. 6. Data on file, Allergan Aesthetics, May 2023. 7. Data on file, Allergan Aesthetics, January 6, 2017; Study Report MD16076-DV. 8. Data on file, Allergan Aesthetics, Warranty Brochure, 2021. 9. FDA Section 510(k) marketing approval letter, Allergan, July 14, 1986. 10. Data on file, Allergan Aesthetics, Breast Augmentation Consumer AU 2022. 11. Cleveland Clinic website, 2022. 12. Data on file, Allergan Aesthetics, Recon Brand Plan, May 2023. 13. Data on file, Allergan Aesthetics, February 3, 2017; Study Report MD16075-DV1. 14. Data on file, Allergan Aesthetics, March 9, 2018; Study Report MD16075-DV5. 15. Data on file, Allergan Aesthetics, November 2022; Mentor BOOST Final Report 1745-D77-054. 16. Sientra breast Products Portfolio Guide, 2022. 17. Data on file, Allergan Aesthetics, February 2018; Study Report MD16075-DV6. 18. Jewell ML, Bengtson BP, Smither K, Nuti G, Perry TA. Physical properties of silicone gel breast implants. *Aesthet Surg.* 2019;39(3):264-275. 19. Data on file, Allergan Aesthetics, April 2005; INAMED. 20. O'Shaughnessy K. Evolution and update on current devices for prosthetic breast reconstruction. *Gland Surg.* 2015;4(2):97-110. 21. Data on file, Allergan Aesthetics, June 6, 2016; Study Report MD15017-DV. 22. Data on file, Allergan Aesthetics, September 2014; Technical Report TR-1121. 23. Data on file, Allergan Aesthetics, July 2010.

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