

We listened to what matters to you...**that's why we offer the**

Natrelle® **DIFFERENCE**

3 cohesivities. 5 profiles. 300 options.^{1,*}

HIGH FILL RATE

100% gel fill rate^{2,3,*†}

[†]Per predefined product specification criteria.

HIGH PROJECTION

Up to **6.7 cm**^{1,*}

UPPER POLE RETENTION

97% *Natrelle* INSPIRA® Cohesive^{4,*†§}

91% *Natrelle* INSPIRA® SoftTouch^{4,*†§}

[†]In vivo significance has not been established.

10 YEARS of proven data²

LOW RUPTURE RATE

7.7% at 10 years^{2,||,¶}

Combined MRI cohort only (n = 264).

HIGH PATIENT SATISFACTION

94% for augmentation at 10 years^{2,§}

91% for reconstruction at 10 years^{2,§}

Primary augmentation cohort (n = 279), primary reconstruction cohort (n = 43).

Natrelle® offers the most comprehensive smooth implant portfolio.^{1,5,6}

**Natrelle* INSPIRA® Collection.

§**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.

¶The Allergan® core study MRI cohort included women who received implants for breast augmentation, revision augmentation, reconstruction, and revision reconstruction (n = 264) through 10 years.

||Kaplan-Meier risks rates for key complications in the Allergan® core study through 10 years for the primary augmentation cohort (n = 455) included reoperation (36.1%); implant removal (20.9%); capsular contracture III/IV (18.9%); non-MRI cohort implant rupture (13.7%); and MRI cohort implant rupture (9.3%); and for the primary reconstruction cohort (n = 98) included reoperation (71.5%); implant removal (53.5%); MRI cohort implant rupture (35.4%); capsular contracture III/IV (24.6%); and asymmetry (23.2%).

§Patient satisfaction based on primary augmentation patients using round implants (n = 279, 86% definitely satisfied and 8% somewhat satisfied) and primary reconstruction patients using round implants (n = 43, 67.4% definitely satisfied and 23.3% somewhat satisfied).

Natrelle® Breast Implants IMPORTANT SAFETY INFORMATION

WARNINGS

- **Breast implants are not considered lifetime devices. The longer people have them, the greater the chances are that 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

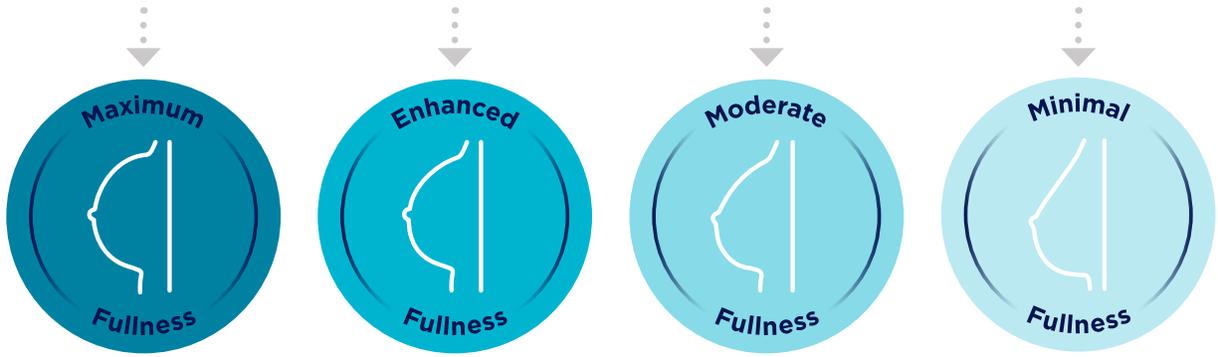
Natrelle® Silicone-Filled Breast Implants and *Natrelle* INSPIRA® Breast Implants are indicated for women for the following:

- **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

Please see additional Important Safety Information on back.

The desired smooth look your **PATIENTS WANT**

19% **61%** **11%** **9%**
of prospective **AUGMENTATION** patients surveyed preferred this look^{7,*}



Fullest look with a very rounded look on top

Fuller look with more roundness on top

Full look with slight roundness on top

Very little fullness on top

30% **40%** **14%** **17%**
of prospective **RECONSTRUCTION** patients surveyed preferred this look^{8,†}

*Based on a survey of 141 prospective breast augmentation patients.
†Based on a survey of 125 prospective breast reconstruction patients.

Visit NatrelleSurgeon.com to learn more.



IMPORTANT SAFETY INFORMATION (continued) 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 in bold type above
- **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

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 uncommon systemic conditions have been reported with breast implants.

For more information, please see the full Directions for Use at 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®.

References: 1. Data on file, Allergan, January 2020. 2. *Natrelle®* Silicone-Filled Breast Implants and *Natrelle* INSPIRA® Breast Implants: Smooth Surface Implants Directions for Use, 2021. 3. Data on file, Allergan. 4. Data on file, Allergan, February 2017. 5. *Mentor®* Product Catalog: Tissue Expanders, Breast Implants and Sizers, January 2020. 6. *Sientra®* Round Breast Implant Product Catalog, July 2019. 7. Data on file, Allergan, October 2017. 8. Data on file, Allergan, May 2018.