Smooth surface.
PRECISE EXPANSION.

The tissue expander with over 30 years of clinical experience is available in a smooth surface.[1]

Featuring the
FOURTÉ® Expander Fill System

Natrelle®
133S smooth tissue expander

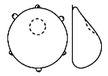
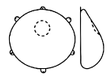
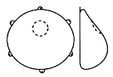
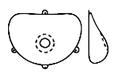
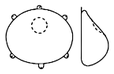
Please see inside for Important Safety Information, including Boxed Warning.

EXPLORE your options

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

Smooth tissue expanders are available in 36 options and 6 profiles.[2]

Natrelle® 133S smooth tissue expander

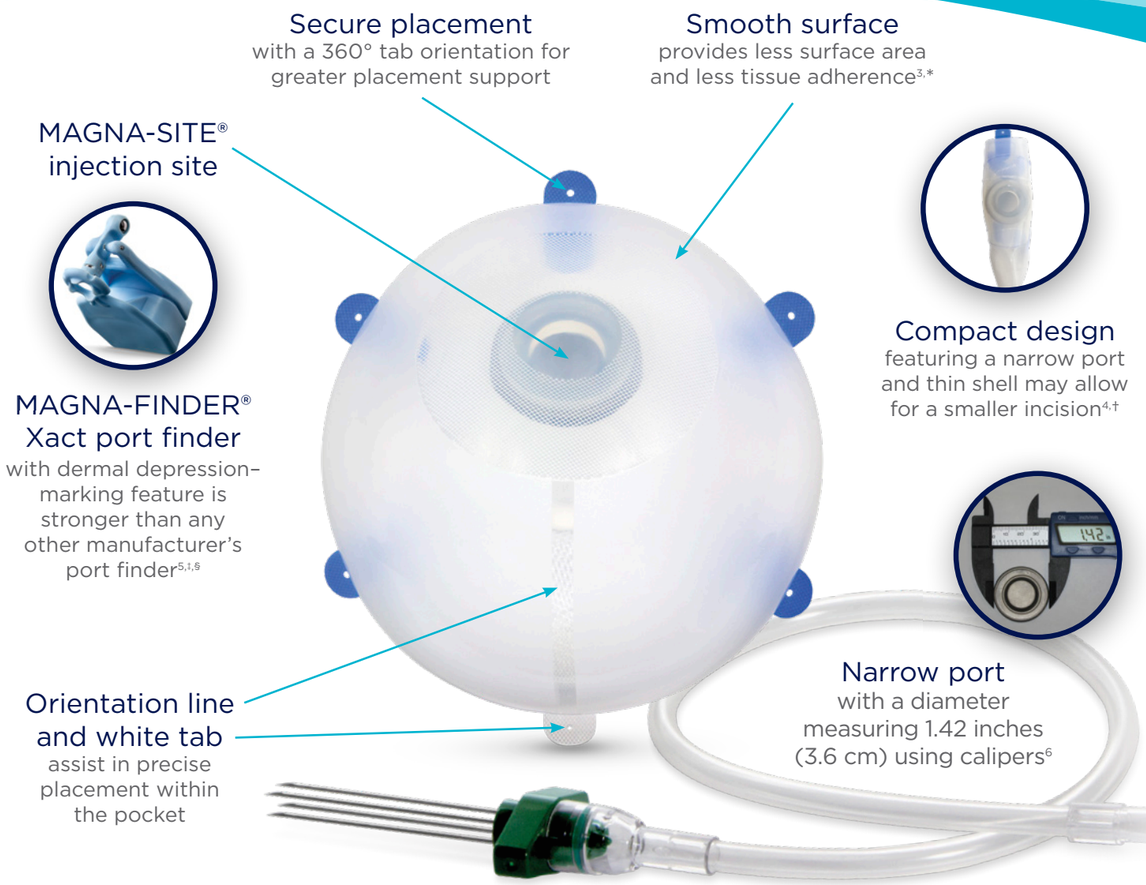
	Variable Projection	Extra Projection
Full height	FV 	FX 
Moderate height	MV 	MX 
Short height	SV 	SX 

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

Unique FEATURES for your unique patients



Features the FOURTÉ® Expander Fill System for 4X faster fill[7,*,‖]

*Clinical significance has not been established.
†Based on tissue expanders comparable in size: *Natrelle*® Style 133MX, 500 cc and *Mentor*® *Artoura*® High Profile, 500 cc.
‡**Methodology** Results from a study comparing the magnetic performances of the MAGNA-FINDER® Xact system and similar competitive devices including the *Mentor*® *Centerscope*® magnetic detection device. Six units each of 7 different tissue expanders (2 each *Natrelle*® 133, 1 *Mentor*® *CPX*®4, 1 *Mentor*® *CPX3*®, and 3 *Sientra*® *ACX*®) were all tested for magnetic force using their respective ports and magnetic locators at distances of 0.25, 0.5, 0.75, 1.0, 1.25, and 1.5 inches. The average values of magnetic force were measured against the distance of separation.
§When used with *Natrelle*® 133S Tissue Expanders.
‖**Methodology** The FOURTÉ® 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.

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

Please see additional _Natrelle_® 133S Smooth Tissue Expanders Important Safety Information on following pages.

Paired for PRECISION®

Giving you the **MOST MATCHES** with smooth round implants.[8,*]

with *Natrelle* INSPIRA® round implants

(in base width *and* projection).[8,*]

*__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.

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

WARNINGS (continued)

- **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

Efficient tissue expansion with FOURTÉ® technology. 4 NEEDLES. 4X FASTER FILL.[7,*]

Seeing is believing—experience the FOURTÉ® Expander Fill System with a live demonstration.

Less physical force for injection than a standard 21-gauge needle. › **4X faster** than a standard 21-gauge needle.[7,*,†] › **May save up to 9 minutes** of expander fill time.[7,*,†]

*Clinical significance has not been established.

†**Methodology** The FOURTÉ® 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. Total time saved based on extrapolation of multiple fills (using a 60-cc syringe) to fill an 850 cc tissue expander.

Natrelle® 133S smooth tissue expander

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

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.

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.

The precise expansion you want in a SMOOTH SURFACE

Natrelle® 133S Tissue Expander—available from Allergan Aesthetics

- Smooth surface options for diverse patient needs
- Compact design and precise matching system[4,8]
- Smooth surface for less tissue adherence[3,*]
- Features the FOURTÉ® Expander Fill System for efficient tissue expansion[7,*,†]

For more information, learn more at **NatrelleSurgeon.com**

*Clinical significance has not been established.

†**Methodology** The FOURTÉ® 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. Total time saved based on extrapolation of multiple fills (using a 60-cc syringe) to fill an 850 cc tissue expander.

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

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.

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, July 14, 1986; FDA Section 510(k) marketing approval letter. **2.** Data on file, Allergan, August 2019; Allergan Plastic Surgery Order Form. **3.** O'Shaughnessy K. Evolution and update on current devices for prosthetic breast reconstruction. *Gland Surgery*. 2015;4(2):97-110. **4.** Data on file, Allergan, June 2016; Study Report MD15017-DV. **5.** Data on file, Allergan, September 2014; Technical Report TR-1121. **6.** Data on file, Allergan, July 2010. **7.** Data on file, Allergan, January 4, 2016; Protocol MM-1225-FR. **8.** Data on file, Allergan, January 6, 2017; Study Report MD16076-DV.

Allergan Aesthetics
an AbbVie company

Natrelle.com NAT118122-v4 05/22 016848

Natrelle® 133S smooth tissue expander