First Stage Worksheet: *Natrelle*® 133S Smooth Tissue Expanders

A full line of gel breast implants and matching tissue expanders for your BREAST RECONSTRUCTION patients

Natrelle® 133S SMOOTH TISSUE EXPANDERS

Patient name _____

Bra size _____ Age _____ Ht _____ Wt _____

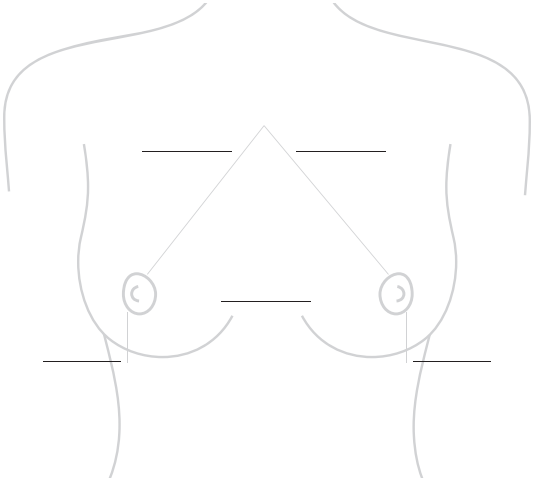
BREAST PARAMETERS

	RIGHT BREAST	LEFT BREAST
Base width	_____ cm	_____ cm
Nipple to inframammary fold distance	_____ cm	_____ cm
Nipple to new inframammary fold distance	_____ cm	_____ cm
Intermammary distance	_____ cm	
Sternal notch to nipple distance	_____ cm	_____ cm
Internipple distance	_____ cm	
Nipple to midline distance	_____ cm	_____ cm
Areolar diameter	_____ cm	_____ cm
Removed tissue weight	_____ g	_____ g

SURGICAL PLAN

Pocket location ☐ Prepectoral ☐ Subpectoral

NOTES



RIGHT SIDE

Tissue expander style _____

Size (volume, width/diameter, height, projection) _____

Serial No. _____

Date	Fill Volume (cc)	Cumulative Fill Volume (cc)	Comments

LEFT SIDE

Tissue expander style _____

Size (volume, width/diameter, height, projection) _____

Serial No. _____

Date	Fill Volume (cc)	Cumulative Fill Volume (cc)	Comments

Please see additional Important Safety Information on pages 3 and 4, including Boxed Warning.

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Second Stage Worksheet: *Natrelle* INSPIRA® Breast Implants

FIRST STAGE MEASUREMENTS (FROM PAGE 1)

	RIGHT BREAST	LEFT BREAST
Original base width	_____ cm	_____ cm
Expander style	_____	_____
Volume	_____ cc	_____ cc
Width/Diameter	_____ cm	_____ cm
Height	_____ cm	_____ cm
Projection	_____ cm	_____ cm
Final tissue expander fill volume	_____ cc	_____ cc
Removed tissue weight	_____ g	_____ g

CURRENT BREAST MEASUREMENTS

	RIGHT BREAST	LEFT BREAST
Current base width	_____ cm	_____ cm

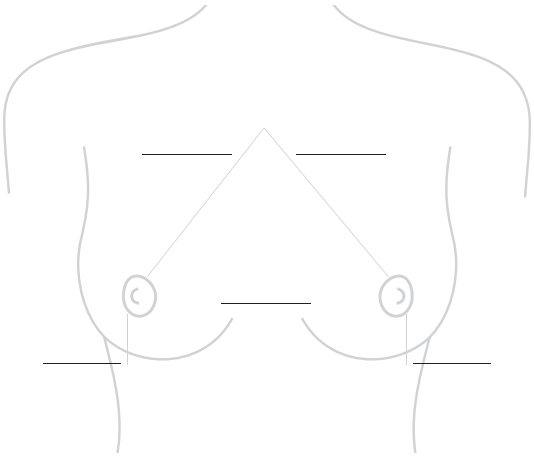
DESIRED IMPLANT CHARACTERISTICS

	RIGHT BREAST	LEFT BREAST
Volume	_____ min _____ max	_____ min _____ max
Width/Diameter	_____ min _____ max	_____ min _____ max
Projection	_____ min _____ max	_____ min _____ max

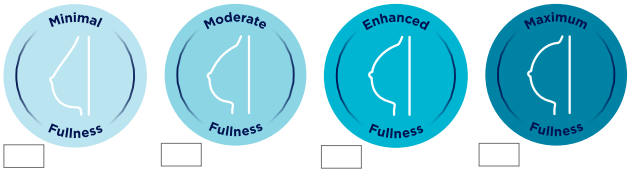
SURGICAL PLAN

Pocket location ☐ Prepectoral ☐ Subpectoral

NOTES



DESIRED OUTCOME



☐ ☐ ☐ ☐

IMPLANT STYLE

☐ *Natrelle* INSPIRA® **Cohesive**

☐ *Natrelle* INSPIRA® **SoftTouch**

☐ *Natrelle* INSPIRA® **Responsive**

☐ Other

RIGHT IMPLANT SELECTED

Size (volume, width/diameter, projection)

_____

Serial No. _____

Sizer style _____

LEFT IMPLANT SELECTED

Size (volume, width/diameter, projection)

_____

Serial No. _____

Sizer style _____

Please see additional Important Safety Information on pages 3 and 4, including Boxed Warning.

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Natrelle® 133S Smooth Tissue Expanders With MAGNA-SITE® Injection Sites Important 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, 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.
- 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 months to 6 month.

PRECAUTIONS

Active infections may need to be treated and resolved before surgery. Allergan relies on the surgeon to know and 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

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 visit www.allergan.com/products. To report a problem with *Natrelle*®, please call Allergan at 1-800-433-8871.

Natrelle® 133S Smooth Tissue Expanders are available by prescription only.

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

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

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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®.

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