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

Natrelle® 133S SMOOTH TISSUE EXPANDERS

<table>
<thead>
<tr>
<th>Patient name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bra size Age Ht Wt</td>
</tr>
</tbody>
</table>

**BREAST PARAMETERS**

<table>
<thead>
<tr>
<th>RIGHT BREAST</th>
<th>LEFT BREAST</th>
</tr>
</thead>
<tbody>
<tr>
<td>Base width</td>
<td>cm cm</td>
</tr>
<tr>
<td>Nipple to inframammary fold distance</td>
<td>cm cm</td>
</tr>
<tr>
<td>Nipple to new inframammary fold distance</td>
<td>cm cm</td>
</tr>
<tr>
<td>Intermammary distance</td>
<td>cm</td>
</tr>
<tr>
<td>Sternal notch to nipple distance</td>
<td>cm cm</td>
</tr>
<tr>
<td>Internipple distance</td>
<td>cm</td>
</tr>
<tr>
<td>Nipple to midline distance</td>
<td>cm cm</td>
</tr>
<tr>
<td>Areolar diameter</td>
<td>cm cm</td>
</tr>
<tr>
<td>Removed tissue weight</td>
<td>g g</td>
</tr>
</tbody>
</table>

**SURGICAL PLAN**

Pocket location

- [ ] Prepectoral
- [ ] Subpectoral

**LEFT SIDE**

Tissue expander style

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

Serial No.

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

**RIGHT 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.
# Second Stage Worksheet: Natrelle INSPIRA® Breast Implants

## FIRST STAGE MEASUREMENTS (FROM PAGE 1)

<table>
<thead>
<tr>
<th></th>
<th>RIGHT BREAST</th>
<th>LEFT BREAST</th>
</tr>
</thead>
<tbody>
<tr>
<td>Original base width</td>
<td>_____ cm</td>
<td>_____ cm</td>
</tr>
<tr>
<td>Expander style</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Volume</td>
<td>_____ cc</td>
<td>_____ cc</td>
</tr>
<tr>
<td>Width/Diameter</td>
<td>_____ cm</td>
<td>_____ cm</td>
</tr>
<tr>
<td>Height</td>
<td>_____ cm</td>
<td>_____ cm</td>
</tr>
<tr>
<td>Projection</td>
<td>_____ cm</td>
<td>_____ cm</td>
</tr>
<tr>
<td>Final tissue expander fill volume</td>
<td>_____ cc</td>
<td>_____ cc</td>
</tr>
<tr>
<td>Removed tissue weight</td>
<td>_____ g</td>
<td>_____ g</td>
</tr>
</tbody>
</table>

## CURRENT BREAST MEASUREMENTS

<table>
<thead>
<tr>
<th></th>
<th>RIGHT BREAST</th>
<th>LEFT BREAST</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current base width</td>
<td>_____ cm</td>
<td>_____ cm</td>
</tr>
</tbody>
</table>

## DESIRED IMPLANT CHARACTERISTICS

<table>
<thead>
<tr>
<th></th>
<th>RIGHT BREAST</th>
<th>LEFT BREAST</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume</td>
<td>_____ min_____ max</td>
<td>_____ min_____ max</td>
</tr>
<tr>
<td>Width/Diameter</td>
<td>_____ min_____ max</td>
<td>_____ min_____ max</td>
</tr>
<tr>
<td>Projection</td>
<td>_____ min_____ max</td>
<td>_____ min_____ max</td>
</tr>
</tbody>
</table>

## SURGICAL PLAN

<table>
<thead>
<tr>
<th></th>
<th>Prepectoral</th>
<th>Subpectoral</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pocket location</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## NOTES

- 
- 
- 
- 

# DESIRED OUTCOME

- Minimal
- Moderate
- Enhanced
- Maximum

## 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.
Natrelle® 133S Smooth Tissue Expanders

**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 (e.g., 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 adjunct radiation therapy.
- Whose physiological condition (e.g., 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 undue 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.

**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.

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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 (e.g., lupus and scleroderma)
- A compromised immune system (e.g., 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®.