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

**Natrelle® 133 SERIES TISSUE EXPANDERS**

<table>
<thead>
<tr>
<th>Patient name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bra size</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</td>
</tr>
<tr>
<td>Nipple to inframammary fold distance</td>
<td>_____ cm</td>
</tr>
<tr>
<td>Nipple to new inframammary fold distance</td>
<td>_____ cm</td>
</tr>
<tr>
<td>Intermammary distance</td>
<td>_____ cm</td>
</tr>
<tr>
<td>Sternal notch to nipple distance</td>
<td>_____ cm</td>
</tr>
<tr>
<td>Internipple distance</td>
<td>_____ cm</td>
</tr>
<tr>
<td>Nipple to midline distance</td>
<td>_____ cm</td>
</tr>
<tr>
<td>Areolar diameter</td>
<td>_____ cm</td>
</tr>
<tr>
<td>Removed tissue weight</td>
<td>_____ g</td>
</tr>
</tbody>
</table>

**SURGICAL PLAN**

Pocket location

- [ ] Prepectoral
- [ ] Subpectoral

**NOTES**

<table>
<thead>
<tr>
<th>First Stage Worksheet: Natrelle® 133 Series Tissue Expanders</th>
</tr>
</thead>
</table>

Please see Indications and Important Safety Information on pages 3 and 4.
STAGE ONE 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</td>
<td>_____ max</td>
</tr>
<tr>
<td>Width/Diameter</td>
<td>_____ min</td>
<td>_____ max</td>
</tr>
<tr>
<td>Height</td>
<td>_____ min</td>
<td>_____ max</td>
</tr>
<tr>
<td>Projection</td>
<td>_____ min</td>
<td>_____ max</td>
</tr>
</tbody>
</table>

SURGICAL PLAN

Pocket location

- [ ] Prepectoral
- [ ] Subpectoral

NOTES

_________________________________________________________________
_________________________________________________________________
_________________________________________________________________
_________________________________________________________________

DESIRED OUTCOME

IMPLANT STYLE

- [ ] Natrelle INSPIRA® Cohesive
- [ ] Natrelle INSPIRA® SoftTouch
- [ ] Natrelle® 410
- [ ] Other

RIGHT IMPLANT SELECTED

Size (volume, width/diameter, height, projection) __________
Serial No. __________________________
Sizer style __________________________

LEFT IMPLANT SELECTED

Size (volume, width/diameter, height, projection) __________
Serial No. __________________________
Sizer style __________________________

Please see Indications and Important Safety Information on pages 3 and 4.
Natrelle® Breast Implants Important Information

INDICATIONS

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

• **Breast reconstruction.** Breast reconstruction 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.

IMPORTANT SAFETY INFORMATION

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.

WARNINGS

• Breast implants are not lifetime devices or necessarily a one-time surgery.
• Avoid damage during surgery: Care should be taken to avoid the use of excessive force and to minimize handling of the implant. Use care when using surgical instruments in proximity with the breast implant. For more information, please see the full Directions for Use.

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 following breast implant placement.
• Planned radiation therapy to the breast 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

Key adverse events are reoperation, implant removal with or without replacement, implant rupture with silicone-filled implants, implant deflation with saline-filled implants, and capsular contracture Baker Grade III/IV.

Other potential adverse events that may occur with breast implant surgery include: asymmetry, breast pain, breast/skin sensation changes, capsular calcification, delayed wound healing, hematoma, hypertrophic scarring/scarring, implant extrusion, implant malposition, implant palpability/visibility, infection, nipple complications, redness, seroma, swelling, tissue/skin necrosis, wrinkling/rippling.

For more information see the full Directions for Use at www.allergan.com/labeling/usa.htm. To report a problem with Natrelle® Breast Implants, please call Allergan at 1-800-433-8871.

Natrelle® Breast Implants are available by prescription only.
**Natrelle® 133 Tissue Expanders With/Without Suture Tabs and With MAGNA-SITE® Injection Sites Important Information**

**INDICATIONS**

Natrelle® 133 Tissue Expanders are indicated for:

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

**IMPORTANT SAFETY INFORMATION**

**CONTRAINDICATIONS**

Natrelle® 133 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® 133 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® 133 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.
- **Active infection anywhere may increase risk of periprosthetic infection.** Postoperative infections should be treated aggressively. Unresponsive or necrotizing infection may require premature removal.
- **Natrelle® 133 Tissue Expanders are temporary, single-use only 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 months.
- 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/labeling/usa.htm. To report a problem with Natrelle®, please call Allergan at 1-800-433-8871.

Natrelle® 133 Tissue Expanders are available by prescription only.

**Intraoperative Breast Implant Sizers Important Information**

**INDICATIONS**

The Natrelle® Silicone Sizer and the Allergan Saline Sizer are indicated for single use only for temporary intra-operative insertion in the surgical pocket to evaluate and assist in determining the final breast implant size/volume. The Natrelle® Re-sterilizable (410 and Round) Silicone Breast Implant Sizer is used during breast augmentation or reconstruction procedures to assist the surgeon in determining the appropriate size of a breast implant to use.

**IMPORTANT SAFETY INFORMATION**

**CONTRAINDICATIONS**

All sizers are contraindicated for use as long-term breast implants or tissue expanders. The Natrelle® Silicone Sizer and the Allergan Saline Sizer are contraindicated for multiple patient use or multiple sterilizations.

**WARNINGS**

Sizers are designed for temporary intra-operative use only and are NOT long-term implants. **DO NOT** alter, insert or attempt to repair a damaged sizer. **DO NOT** reuse the Natrelle® Silicone Sizer or the Allergan Saline Sizer, which are for single use only. The Silicone Sizers may rupture and release silicone gel. Infection, necrosis, hematoma/seroma and pain may occur following any type of surgery. Minute quantities of silicone gel may diffuse through the elastomer envelope.

**PRECAUTIONS**

The surgeon must carefully evaluate patient suitability and be knowledgeable about the use of this device. **DO NOT** expose the sizer to contaminants. Avoid damaging the sizer with surgical instruments (eg, sharp, blunt or cautery devices). **DO NOT** attempt to repair damaged products. **DO NOT** damage the sizer by overhandling, manipulation, or excessive force. Maintain a sterile back-up sizer during surgery.

**ADVERSE EVENTS**

Adverse events and/or complications may include sepsis, hemorrhage, thrombosis, bleeding, and/or infection.

For more information, please visit www.allergan.com/labeling/usa.htm. To report a problem, please call Allergan at 1-800-433-8871.

Intraoperative Breast Implant Sizers are available by prescription only.