

DIRECTIONS FOR USE

Directions for Use

***NATRELLE® 133S and
NATRELLE® 133 Plus***
Tissue Expanders

WITH MAGNA-SITE®
INJECTION SITES

MAGNA-FINDER® XACT
& 21G NEEDLE INFUSION SET



CAUTION: U.S. Federal law restricts this device to sale by or on the order of a licensed physician.

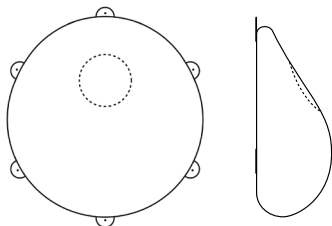
TABLE OF CONTENTS

Section	Page
<u>NATRELLE® 133S Tissue Expanders</u>	2
<u>NATRELLE® 133 Plus Tissue Expanders</u>	4
<u>Description</u>	6
<u>Tissue Expander Shapes</u>	6
<u>Shell Characteristics</u>	7
<u>Injection Sites</u>	7
<u>Indications</u>	8
<u>Contraindications</u>	8
<u>Warnings</u>	9
<u>Precautions</u>	11
<u>Information That Should Be Provided to the Patient</u>	13
<u>Warnings, Precautions, Adverse Reactions</u>	13
<u>Informed Consent: Information for Patients Form</u>	13
<u>Possible Adverse Events</u>	14
<u>Breast Implant Surgery Possible Adverse Events</u>	17
<u>Instructions for Use</u>	18
<u>Surgical Procedure</u>	18
<u>Single Use</u>	19
<u>Product Identification</u>	19
<u>Sterile Product</u>	19
<u>Product Accessories</u>	19
<u>How to Open Product Package</u>	20
<u>Preliminary Product Examination</u>	20
<u>Techniques for Using Tissue Expanders</u>	20
<u>Reporting and Return of Explanted Devices</u>	25
<u>Returned Goods Policy</u>	25
<u>Limited Warranty, Limitation of Liability and Disclaimer of Other Warranties</u>	26
<u>Product Ordering</u>	26

NATRELLE® 133S TISSUE EXPANDERS

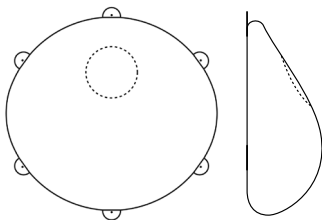
NATRELLE® 133S FV

Shaped Tissue Expander
with 6 Optional Suture Tabs
Full Height, Variable Projection
Saline-Filled
Smooth Surface
MAGNA-SITE® Injection Site



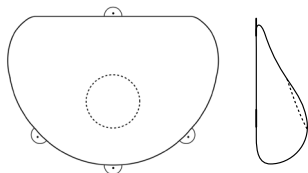
NATRELLE® 133S MV

Shaped Tissue Expander
with 6 Optional Suture Tabs
Moderate Height, Variable Projection
Saline-Filled
Smooth Surface
MAGNA-SITE® Injection Site



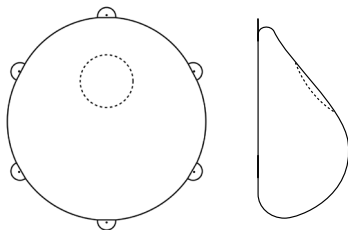
NATRELLE® 133S SV

Shaped Tissue Expander
with 4 Optional Suture Tabs
Short Height, Variable Projection
Saline-Filled
Smooth Surface
MAGNA-SITE® Injection Site

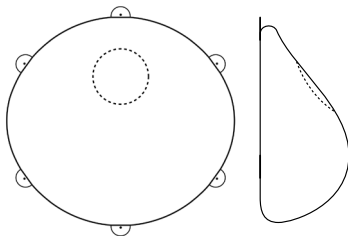


NATRELLE® 133S FX

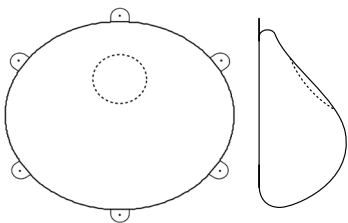
Shaped Tissue Expander
with 6 Optional Suture Tabs
Full Height, Extra Projection
Saline-Filled
Smooth Surface
MAGNA-SITE® Injection Site

**NATRELLE® 133S MX**

Shaped Tissue Expander
with 6 Optional Suture Tabs
Moderate Height, Extra Projection
Saline-Filled
Smooth Surface
MAGNA-SITE® Injection Site

**NATRELLE® 133S SX**

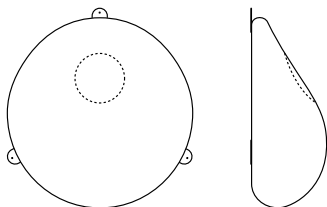
Shaped Tissue Expander
with 6 Optional Suture Tabs
Full Height, Extra Projection
Saline-Filled
Smooth Surface
MAGNA-SITE® Injection Site



NATRELLE® 133 PLUS TISSUE EXPANDERS

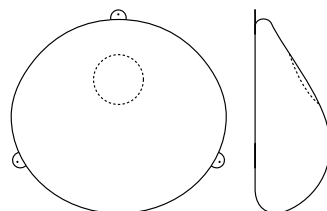
NATRELLE® 133 Plus FV

Shaped Tissue Expander
with Optional Suture Tabs
Full Height, Variable Projection
Saline-Filled
MICROCELL™ or BIOCELL® Textured
MAGNA-SITE® Injection Site



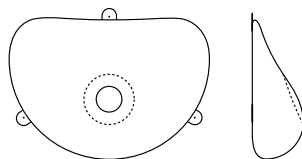
NATRELLE® 133 Plus MV

Shaped Tissue Expander
with Optional Suture Tabs
Moderate Height, Variable Projection
Saline-Filled
MICROCELL™ or BIOCELL® Textured
MAGNA-SITE® Injection Site



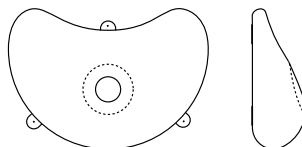
NATRELLE® 133 Plus SV

Shaped Tissue Expander
with Optional Suture Tabs
Short Height, Variable Projection
Saline-Filled
MICROCELL™ or BIOCELL® Textured
MAGNA-SITE® Injection Site



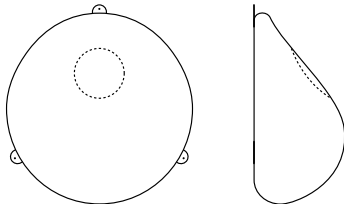
NATRELLE® 133 Plus LV

Shaped Tissue Expander
with Optional Suture Tabs
Low Height, Variable Projection
Saline-Filled
MICROCELL™ or BIOCELL® Textured
MAGNA-SITE® Injection Site



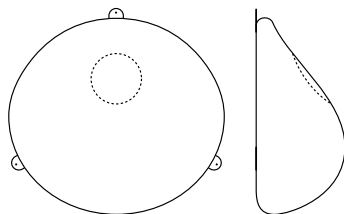
NATRELLE® 133 Plus FX

Shaped Tissue Expander
with Optional Suture Tabs
Full Height, Extra Projection
Saline-Filled
MICROCELL™ or BIOCELL® Textured
MAGNA-SITE® Injection Site



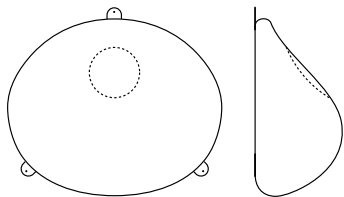
NATRELLE® 133 Plus MX

Shaped Tissue Expander
with Optional Suture Tabs
Moderate Height, Extra Projection
Saline-Filled
MICROCELL™ or BIOCELL® Textured
MAGNA-SITE® Injection Site



NATRELLE® 133 Plus SX

Shaped Tissue Expander
with Optional Suture Tabs
Full Height, Extra Projection
Saline-Filled
MICROCELL™ or BIOCELL® Textured
MAGNA-SITE® Injection Site



DESCRIPTION

NATRELLE® 133S and **NATRELLE® 133 Plus** Tissue Expanders are intended for temporary subcutaneous or submuscular implantation and require periodic, incremental inflation with sterile saline for injection until the desired amount of tissue is developed.

NATRELLE® 133S and **NATRELLE® 133 Plus** Tissue Expanders are constructed from silicone elastomer and consist of an expansion envelope, an orientation line, and a MAGNA-SITE® integrated injection site. The expanders are available in a wide range of styles and sizes to meet diverse surgical needs.

NATRELLE® 133S Tissue Expanders are available with a smooth surface expansion envelope and feature a clear orientation line and suture tabs that contain the colorant cobalt aluminate blue spinel at a concentration of 1%.

NATRELLE® 133 Plus Tissue Expanders contain an expansion envelope that is available in 2 types of implant shell surfaces: MICROCELL™ texture and BIOCELL® texture. **NATRELLE® 133 Plus** MICROCELL Tissue Expanders have a MICROCELL™ textured surface and are available exclusively with suture tabs.

NATRELLE® 133 Plus Tissue Expanders have a BIOCELL® textured surface are available both with and without suture tabs. The orientation line and suture tabs contain the colorant cobalt aluminate blue spinel at concentrations of 0.1% and 1%, respectively.

All **NATRELLE® 133S** and **NATRELLE® 133 Plus** Tissue Expanders with the MAGNA-SITE® integrated injection port are supplied with a sterile MAGNA-FINDER® Xact external locating device and a 21G Needle Infusion Set. In addition, Tissue Expander Fill Kits, Delivery Assistance Sleeves and other product accessories are available separately.

For more information on specific styles and accessories, please contact your Hospital or Surgical Sales Representative, or the Customer Care Department at 1.800.766.0171.

Tissue Expander Shapes

NATRELLE® 133S and **NATRELLE® 133 Plus** Tissue Expanders are designed as part of a system for breast reconstruction to create a pocket for placement of a **NATRELLE®** breast implant.

Shell Characteristics

Allergan's smooth surface has a lower surface area than Allergan's MICROCELL™ surface texture, which has a lower surface area than Allergan's BIOCELL® surface texture.

MICROCELL™ and BIOCELL® textured surfaces are designed to promote mild tissue adherence and tissue expander immobility.

Stable bases for greater control over expansion direction are included on all **NATRELLE® 133S** and **NATRELLE® 133 Plus** Tissue Expanders.

An orientation line is located on the lower pole of the device to aid in properly orienting the device intraoperatively.

Optional suture tabs can be utilized to anchor the device to pocket tissue, allowing for more secure placement.

Injection Sites

The MAGNA-SITE® injection site and MAGNA-FINDER® Xact external locating device contain rare-earth, permanent magnets for an accurate injection system. When the MAGNA-FINDER® Xact external locating device is passed over the surface of the tissue being expanded as described in INSTRUCTIONS FOR USE, its rare-earth, permanent magnet indicates the location of the MAGNA-SITE® injection site.

All injection sites contain a self-sealing port and a titanium needle guard (see **Figure 1**) to prevent inadvertent puncture through the base of the injection site.

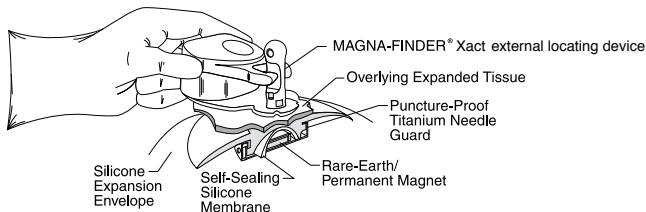


FIGURE 1:
MAGNA-SITE® & MAGNA-FINDER® Xact Locating System

NOTE: In vitro tests show that the MAGNA-SITE® injection site is detectable through 60 mm of phantom tissue.

CAUTION: DO NOT use **NATRELLE® 133S** and **NATRELLE® 133 Plus** Tissue Expanders in patients who already have implanted devices that would be affected by a magnetic field (e.g., pacemakers, drug infusion devices, artificial sensing devices).

DO NOT perform diagnostic testing with Magnetic Resonance Imaging (MRI) in patients with **NATRELLE® 133S** or **NATRELLE® 133 Plus** Tissue Expanders in place.

*See **Magnetic Field** under **WARNINGS** for more information.*

The indications and contraindications in the sections that follow are generalized. Each patient must be individually evaluated for tissue expansion based on the medical judgment of a qualified surgeon.

INDICATIONS

NATRELLE® 133S and **NATRELLE® 133 Plus** Tissue Expanders can be utilized for breast reconstruction after mastectomy, correction of an underdeveloped breast, scar revision and tissue defect procedures. The expander is intended for temporary subcutaneous or submuscular implantation and is not intended for use beyond six months.

CONTRAINDICATIONS

NATRELLE® 133S and **NATRELLE® 133 Plus** 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).
- Patients whose tissue at the intended expansion site is determined as unsuitable by the surgeon. To a varying degree, radiation damage, ulceration, compromised vascularity, history of compromised wound healing, or scar deformity may affect tissue suitability.
- Patients who have an active infection at the expansion site.
- Patients who have a residual gross tumor at the intended expansion site that may significantly complicate the expansion process and local tumor treatment.

- Patients undergoing adjuvant radiation therapy, which is a relative contraindication and may make use of the tissue expander more difficult and increase the risk of complications.
- Patients whose physiological condition is determined by the surgeon to pose unduly high risk of surgical and/or postoperative complications. To a varying degree, sensitive over or underlying anatomy, obesity, smoking, diabetes, autoimmune disease, hypertension, chronic lung or severe cardiovascular disease, or osteogenesis imperfecta may affect patient suitability for tissue expander surgery.
- Patients whose use of drugs might result in high surgical risk and/or significant postoperative complications, including any drug that would interfere with blood clotting or affect tissue viability.
- Psychologically unsuitable patients.

WARNINGS

1. Magnetic Field

DO NOT use **NATRELLE**® 133S or **NATRELLE**® 133 *Plus* Tissue Expanders in patients who already have implanted devices that would be affected by a magnetic field (e.g., pacemakers, drug infusion devices, artificial sensing devices), 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 or **NATRELLE**® 133 *Plus* Tissue Expanders in place. The MRI equipment could cause movement of the tissue expander, and result in not only patient discomfort, but also expander displacement, requiring revision surgery. In addition, the MAGNA-SITE® magnet could interfere with MRI detection capabilities.

Allergan has not tested the in vivo effects of radiation therapy with **NATRELLE**® 133S or **NATRELLE**® 133 *Plus* Tissue Expanders and cannot warrant the safety of such use. The decision regarding the use of **NATRELLE**® 133S or **NATRELLE**® 133 *Plus* Tissue Expanders in patients about to undergo radiation therapy should be made by the surgeon and the radiation oncologist.

See also Contraindications.

2. Alteration

DO NOT alter the tissue expander. Alteration to the original design and fabrication voids all warranties, express or implied.

3. Adulterated Fill

DO NOT use adulterated fill. Expanders are to be filled only with sterile saline for injection, and only as described in INSTRUCTIONS FOR USE. Allergan can neither predict, nor warrant, the safety of intraluminal introduction of any adulterated fill, including, but not limited to, anesthetic, steroid, and antibiotic solutions.

4. Reuse

DO NOT reuse explanted products. **NATRELLE® 133S** and **NATRELLE® 133 Plus** Tissue Expanders are intended for single use only.

5. Tissue Damage

DO NOT expand if the pressure will compromise wound healing. DO NOT expand beyond patient or tissue tolerance.

Excessively rapid tissue expansion may compromise the vasculature of the overlying tissue. Stop filling immediately if any signs of tissue damage, wound dehiscence, abnormal skin pallor (e.g., blanching), erythema, edema, pain, or tenderness are observed. In the absence of other signs, some temporary erythema may occur as a recognized normal tissue response to expansion.

Tissue viability may be adversely affected by radiotherapy, steroid use in the surgical pocket, excessive heat or cold therapy, and smoking.

*See also **Contraindications** for initial patient exclusion criteria.*

6. Infection

Active infection anywhere in the body may increase risk of periprosthetic infection. DO NOT expose the tissue expander or injection needles to contaminants, which increase the risk of infection. Patients who present wound dehiscence, tissue erosion, ischemia or necrosis run an increased risk of periprosthetic infection. Measures to protect such areas from infection should be taken.

Signs of acute infection reported in association with tissue expanders include, tenderness, fluid accumulation, pain and fever. Infection may compromise the

expansion process. Postoperative infections should be treated aggressively according to standard medical practices to avoid more serious complications. Infection that is unresponsive to treatment or necrotizing infection may require premature tissue expander removal.

See also Infection, under ADVERSE REACTIONS.

7. Temporary Device

NATRELLE® 133S and **NATRELLE® 133 Plus** Tissue Expanders are temporary devices, and are not to be used for permanent implantation or beyond 6 months. Tissue expanders should be removed once adequate tissue has developed. Tissue expansion in breast reconstruction typically requires four to six months. The total expansion period will vary depending on patient tolerance, tissue tolerance, and desired tissue expansion.

8. Premature Explantation

Adverse reactions may require premature explantation.

9. Suturing

When using expanders with suture tabs, be careful to avoid piercing the shell when suturing the tabs. Discard the device and use a new one if damage occurs.

PRECAUTIONS

1. Pre-existing Infection

Patients who present with any active infection may need to be treated and the infection resolved before placement of the tissue expander.

See also Infection, under WARNINGS and ADVERSE REACTIONS.

2. Surgical Planning

Allergan relies on the surgeon to know and follow proper surgical procedures specific to the type of expansion performed to minimize the occurrence of adverse reactions. The surgeon must carefully evaluate patient suitability for expansion and desired physical outcome, tissue expander surface, tissue expander dimensions, incision placement, pocket dissection, use of optional suture tabs, expander filling, and any other relevant dimensions, using current, accepted techniques and individual experience. Templates are available through Allergan to assist the surgeon with tissue expander selection.

3. Avoiding Contamination at Surgery

To avoid contamination, aseptic technique is essential. DO NOT expose the tissue expander to lint, talc, sponge, towel, and other contaminants. Contamination at the time of surgery increases the risk of periprosthetic infection, which could require premature explantation of the tissue expander.

To minimize the risk of contamination, follow recommended procedures in INSTRUCTIONS FOR USE.

4. Avoiding Damage During Surgery

Extreme care should be taken to avoid damage to the tissue expander during surgery. Possible sources of damage include sharp surgical instruments such as scalpels and needles used during the initial surgery, subsequent filling, or hematoma/fluid evacuation.

A sterile back-up tissue expander must be readily available at the time of surgery in the event that damage occurs. Products must be carefully inspected for leaks or nicks prior to use. DO NOT attempt to repair damaged products.

To minimize the risk of damage, follow recommended procedures in INSTRUCTIONS FOR USE for breast tissue expander handling, examination, placement, and filling.

5. Maintaining Hemostasis/Avoiding Fluid Accumulation

Postoperative hematoma and seroma may be minimized by meticulous attention to hemostasis during surgery, and possibly by postoperative use of closed drains. Persistent, excessive bleeding must be controlled before the tissue expander is placed. If the wound is stable the tissue expander may be filled to tissue tolerance at the time of surgery to help minimize serous fluid accumulation in the surrounding pocket. If wound stability is a concern, inflate only slightly to fill the pocket space, without applying tension to the tissue.

Any postoperative evacuation of hematoma or other fluid accumulation must be conducted with care to avoid introduction of contaminants or damage to the tissue expander from needles or other sharp instruments.

6. Avoiding Tissue Damage During Expansion

Avoiding tissue damage during expansion requires careful attention to tissue tolerance, including:

- If the wound is stable, the tissue expander may be filled to tissue tolerance at the time of surgery;

- Expansion should proceed in moderate increments, never beyond patient or tissue tolerance;
- If tissue damage, abnormal skin pallor (e.g., blanching), erythema, edema, pain, or tenderness are observed, filling should immediately stop until the problem is resolved.

See also *Tissue Damage* under **WARNINGS** and **ADVERSE REACTIONS**.

7. Avoiding Tissue Expander Damage During Expansion

Extreme care should be taken to avoid needle puncture or other damage to the tissue expander or the injection site during the expansion process.

To minimize the risk of tissue expander damage during expansion, fill the expander only with sterile saline for injection and use the appropriate location methods and instruments, as described in **INSTRUCTIONS FOR USE**.

INFORMATION THAT SHOULD BE PROVIDED TO THE PATIENT

While tissue expansion may be a beneficial surgical alternative for many patients, it may not be appropriate for every patient, because it is a time and labor-intensive process that may cause temporary discomfort and distortion. The surgeon is responsible for selecting appropriate candidates, and counseling those patients on the risk/benefit relationship. Before tissue expander placement, patients should fully understand the elective nature of the procedure, and be willing to comply with expansion process requirements to minimize the risk of complications.

Warnings, Precautions, Possible Adverse Events

Allergan relies on the surgeon to advise the patient of all warnings, precautions, and possible adverse events before the decision to proceed with tissue expander placement and inflation. The surgeon should advise the patient that adverse reactions may interfere with the original surgical plan and that medical management may include premature explantation.

Informed Consent: Information for Patients Form

NATRELLE® 133S and **NATRELLE® 133 Plus** Tissue Expanders Informed Consent: Information for Patients form may be used to facilitate patient awareness and acceptance of the risks associated with tissue expander surgery. The two-part form allows both the patient and the surgeon to retain copies for their records. Please contact your Hospital or Surgical Sales Representative or visit www.allerganlabeling.com for informed consent forms.

POSSIBLE ADVERSE EVENTS

1. Deflation

Patients should be advised that the tissue expanders may deflate, and require replacement surgery. Deflation occurs when saline leaks through a damaged injection site or a damaged tissue expander envelope.

See also Avoiding Damage During Surgery and Avoiding Tissue Expander Damage During Expansion, under PRECAUTIONS.

2. Tissue Damage

Improper patient selection, tissue expander selection, placement and inflation may result in tissue damage and require premature explantation of the tissue expander. Signs of tissue damage include abnormal skin pallor (e.g., blanching), erythema, edema, pain, or tenderness, and should be promptly investigated. In the absence of other signs, some temporary erythema may occur, and is a recognized normal tissue response to expansion.

The stresses of the expanding device may induce pressure ischemia and necrosis, especially in tight or thin-skinned areas. Folds in a partially filled tissue expander may also result in thinning and erosion of adjacent tissue. Excessively rapid tissue expansion may compromise the vascularity of the overlying tissue.

Tissue viability may be adversely affected by radiotherapy, steroid use or other drug therapy in the surgical pocket, excessive heat or cold therapy, and smoking.

See also Avoiding Tissue Damage During Expansion, under PRECAUTIONS.

3. Infection

Pre-existing infections not resolved before tissue expander placement may increase the risk of periprosthetic infection.

Infection is an inherent risk following any type of invasive surgery, and may occur during the tissue expansion process. Patients who present with wound dehiscence, tissue erosion, ischemia or necrosis, and patients undergoing immediate breast reconstruction run an increased risk of periprosthetic infection. Signs of acute infection reported in association with tissue expanders include erythema, tenderness, fluid accumulation, pain and fever.

Erythema may also occur as a normal response to expansion. Aspiration to differentiate between this type of erythema and erythema as a sign of early infection is a recognized precaution.

Research identifies *Staphylococcus* and *Pseudomonas* organisms in association with infection around tissue expanders. *Escherichia* and *Streptococcus* organisms have also been noted in association with tissue expanders in the lower extremities. Infection may occur at any time after surgery, and may compromise the expansion process. Capsular contracture may be related to infection in the area surrounding the implant. Postoperative infections should be treated aggressively according to standard medical practices to avoid more serious complications. Infection that is unresponsive to treatment or necrotizing infection may require premature tissue expander removal.

In rare instances, acute infection may occur in a breast with implants. The signs of acute infection include erythema, tenderness, fluid accumulation, pain, and fever. Very rarely, Toxic Shock Syndrome, a potentially life-threatening condition, has been reported in women after breast implant surgery. It is characterized by symptoms that occur suddenly and include high fever (102°F, 38.8°C or higher), vomiting, diarrhea, a sunburn-like rash, red eyes, dizziness, lightheadedness, muscle aches, and drops in blood pressure, which may cause fainting. Patients should be advised to contact a physician immediately for diagnosis and treatment for any of these symptoms.

See also Infections under WARNINGS.

4. Extrusion

Tissue damage may compromise tissue covering and/or wound healing, result in extrusion, and require premature tissue expander removal.

See also Tissue Damage under WARNINGS.

5. Hematoma/Seroma

Postoperative hematoma and seroma may contribute to infection. Postoperative hematoma and seroma may be minimized by meticulous attention to hemostasis during surgery, and possibly by postoperative use of closed drains. Persistent, excessive bleeding must be controlled before the device is implanted.

6. Capsular Contracture

Formation of a fibrous tissue capsule around an implanted device is a normal physiological response, although not all capsules contract. Contracture of the fibrous capsular tissue surrounding the tissue expander may cause a range of symptoms including firmness, discomfort, pain, distortion, palpability, and/or displacement. Contracture may make expansion difficult and painful.

7. Premature Explantation

Adverse reactions may require premature explantation, which may affect desired flap size.

8. Displacement

The tissue expander may become displaced, especially if the surgical pocket is too large. Tissue expander displacement may make the integrated valve location difficult or impossible without surgical correction.

9. Effects on Bone

Chest wall compression has been reported in association with the use of tissue expanders for breast reconstruction. The presence of a thick capsule, causing greater resistance to expansion, may be a contributing factor. The medical literature indicates that following tissue expander removal, effects on bone caused by the pressure of expansion are often completely reversed.

10. Pain

As expected following any invasive surgical procedure, pain of varying intensity and duration may occur following tissue expander placement. In addition, the expansion process may cause some discomfort, but should not cause excessive pain. Pain may indicate expansion beyond tissue tolerance, which could result in ischemia and necrosis. Pain may also accompany other adverse reactions. Unexplained pain must be promptly investigated. Further expansion should be discontinued until the pain is resolved.

11. Sensation

The possibility of temporary or permanent dysesthesia (abnormal sensation) exists following any invasive surgical procedure. Surgical technique and expansion must be performed carefully to avoid neurological impairment. Nerve traction and compression have been reported in rare cases in

association with tissue expansion. Immediate partial deflation should be a standard precaution if nerve impingement is suspected, and filling should not resume until the problem is resolved.

12. Distortion

Tissue expansion is a time and labor intensive process that may cause temporary discomfort and distortion. Patients should be psychologically suitable, well-informed, and motivated to complete the expansion process. Patient response to the distortion of body image may vary. Negative reactions may include depression and withdrawal.

13. Inadequate Tissue Flap

Inadequate tissue flap following expansion may occur and may require additional surgery and expansion. In cases with limited viable donor site tissue, such sequential expansion may be included as part of the original surgical plan.

See also Surgical Planning, under PRECAUTIONS.

14. Inflammatory Reaction

Studies evaluating the capsules around textured expanders have reported what were possibly silicone particles within giant cells, indicative of a local (and non-specific) foreign body reaction, and silicone granuloma formation. Another study suggests that certain types of capsule cells, including some perceived as giant cells, may actually be secretory cells that form in response to the frictional forces of the tissue expander, providing lubrication at the capsule-expander interface.

BREAST IMPLANT SURGERY POSSIBLE ADVERSE EVENTS

Research continues to address the various hypothetical long-term effects of silicone implants, primarily silicone-filled breast implants. To the extent that such research applies to the safety of silicone in general for implantation, it is relevant to tissue expanders. However, given the intended temporary use of tissue expanders, and the fact that tissue expanders consist primarily of a silicone elastomer shell filled with sterile saline for injection, the research has not been directly concerned with tissue expander use.

The following is a list of potential adverse events that may occur with breast implant surgery. The risks include: implant deflation/leakage, additional surgery, capsular contracture, infection, Toxic Shock Syndrome, necrosis, hematoma, seroma,

extrusion, breast pain, changes in nipple sensation, changes in breast sensation, dissatisfaction with cosmetic results (wrinkling, folding, displacement, asymmetry, palpability, visibility, ptosis, sloshing), calcific deposits, irritation/inflammation, delayed wound healing, hypertrophic scarring, breast tissue atrophy/chest wall deformity, difficulty/inability in breast feeding, and inability to adequately visualize breast lesions with mammography. In addition to these potential adverse events, there have been concerns with certain systemic diseases.

1. Connective Tissue Disease

Concern over the association of breast implants to the development of autoimmune or connective tissue diseases, such as lupus, scleroderma, or rheumatoid arthritis, was raised because of cases reported in the literature with small numbers of women with implants. A review of several large epidemiological studies of women with and without implants indicates that these diseases are no more common in women with implants than those in women without implants.

2. Cancer

Published studies indicate that breast cancer is no more common in women with implants than those without implants.

3. Second Generation Effects

There have been concerns raised regarding potential damaging effects on children born of mothers with implants. A review of the published literature on this issue suggests that the information is insufficient to draw definitive conclusions.

INSTRUCTIONS FOR USE

Surgical Procedure

Allergan relies on the surgeon to know and follow the appropriate surgical procedures for the type of expansion performed. The surgeon must carefully evaluate patient suitability for expansion and desired physical outcome, tissue expander surface, tissue expander dimensions, use of optional suture tabs, incision placement, pocket dissection, expander filling and any other relevant dimensions, using current, accepted techniques and individual experience.

Tissue expander templates and educational materials are available from Allergan separately to assist the surgeon with tissue expander use. These materials introduce the dimensional techniques intended for use with **NATRELLE® 133S** or **NATRELLE® 133 Plus** Tissue Expanders and **NATRELLE®** breast implants.

A sterile back-up tissue expander must be readily available at the time of surgery.

Single Use

DO NOT reuse explanted devices. This product is intended for single use only.

Product Identification

A patient record label accompanies each device within the internal product packaging. The patient record label provides product-specific information. The patient record label may be attached to the patient's chart for identification purposes.

Sterile Product

Each sterile tissue expander is supplied in a sealed, double primary package. **NATRELLE® 133S** and **NATRELLE® 133 Plus** Tissue Expanders sterile product accessories are also supplied within the product packaging. Sterility of the tissue expander is maintained only if the thermoform packages, including the package seals, are intact.

DO NOT use the product if the thermoform packages or seals have been damaged.

DO NOT resterilize **NATRELLE® 133S**, **NATRELLE® 133 Plus** Tissue Expanders, or **MAGNA-FINDER® Xact** and 21G Needle accessories.

NEVER, under any circumstances, attempt to resterilize using ethylene oxide, which is known to cause adverse tissue reaction, if not completely removed from the device.

Product Accessories

NATRELLE® 133S and **NATRELLE® 133 Plus** Tissue Expanders with **MAGNA-SITE®** integrated injection sites are supplied with a **MAGNA-FINDER® Xact** external locating device and a 21G Needle Infusion Set.

Fill Kits, Delivery Assistance Sleeves, and other product accessories are available separately.

How to Open Product Package

Remove the tissue expander and product accessories from their sterile packages in an aseptic environment and using talc-free gloved hands.

DO NOT expose the tissue expander to lint, talc, sponge, towel, and other contaminants.

1. Peel open the lid of the outer thermoform package.
2. Invert the outer thermoform over the sterile field, allowing the sealed inner thermoform to gently fall into the field.
3. Peel open the lid of the inner thermoform package using the pull tab.
4. Gently retrieve the tissue expander.

Prior to use, keep the tissue expander in the inner thermoform and covered to prevent contact with airborne and surgical field particulate contaminants.

Preliminary Product Examination

Prior to use, examine the tissue expander for leakage by partially filling with sterile saline for injection and gently compressing. To avoid missing any leaks due to hand position, reposition the tissue expander several times and repeat the inspection. If satisfactory, aspirate all sterile saline and air from the inspected tissue expander, return the expander to the inner thermoform tray and cover it with the lid until implanted to prevent contact with airborne contaminants.

DO NOT implant any device that appears to have particulate contamination, nicks or leaks. A sterile back-up tissue expander must be readily available at the time of surgery.

DO NOT attempt to repair damaged products.

Techniques for Using Tissue Expanders

DO NOT use force during any of the steps in the following procedure.

DO NOT damage the tissue expander with sharp surgical instruments such as needles and scalpels, blunt instruments such as clamps and forceps, and/or by excessive handling and manipulation during introduction into the surgical pocket.

1. Tissue Expander Placement

Plan and dissect the surgical pocket for placement of the tissue expander using current and accepted surgical techniques. If the pocket is too small, the expander may not have adequate room to unfold, increasing the risk of tissue erosion. If the pocket is too large, the expander may not remain in proper position for filling and expansion.

DO NOT use lubricants, which create the risk of pocket contamination. Lubricants may also affect tissue adherence.

To minimize friction during initial MICROCELL™ or BIOCELL® tissue expander insertion, a sterile Delivery Assistance Sleeve is available separately. Insert the tissue expander into one end of the sleeve. Insert the proximal end of the sleeve into the surgically-prepared pocket. With the tissue retracted, the sleeve can be twisted at its distal end to gently guide the tissue expander into the pocket. Once the tissue expander is inserted, gently remove the sleeve, and verify the correct orientation of the expander. The expander is oriented properly when the blue orientation line on the lower pole of the anterior of the device is vertically positioned in the surgical pocket.

DO NOT resterilize or reuse the Delivery Assistance Sleeve.

*NOTE: Place the tissue expander in the exact desired location, as MICROCELL™ and BIOCELL® textured surfaces promote mild tissue adherence to help immobilize the expander. **NATRELLE® 133S and NATRELLE® 133 Plus** Tissue Expanders can be further immobilized by suturing the tabs to the surrounding tissue. Sutures can be placed through the pre-cut needle hole on each tab. Suturing material and technique used are up to the judgment of the surgeon.*

2. MAGNA-SITE® Injection Site Placement

Place the tissue expander flat and correctly-oriented in the pocket. The MAGNA-SITE® injection site should be situated anteriorly, adjacent to the skin surface.

3. MAGNA-FINDER® Xact Locating Device

To assist with the MAGNA-SITE® injection site location, a MAGNA-FINDER® Xact locating device is included in a single, sterile package inside the secondary packaging of each product. The MAGNA-FINDER® Xact is supplied sterile for

single use only in a sterile field. After initial use it is not intended to be re-used in a sterile field. For re-use in a non-sterile field follow the MAGNA-FINDER® Xact locating device Cleaning Instructions, below.

MAGNA-FINDER® Xact Locating Device Cleaning:

Wash the MAGNA-FINDER® Xact locating device thoroughly with isopropyl alcohol. A mild, non-oily soap may also be used, if necessary, prior to the alcohol wash. DO NOT use synthetic-based detergents or oil-based soaps. Rinse copiously with clean, non-pyrogenic water to remove all wash residues and other particulate contamination.

4. MAGNA-SITE® Injection Site Location

While the injection site can be generally identified by palpation, always verify the location and orientation of the injection site with the MAGNA-FINDER® Xact locating device, as described below, before each filling.

Step 1: Be sure the magnet inside the MAGNA-FINDER® Xact locating device moves freely without obstruction.

Step 2: Place the MAGNA-FINDER® Xact locating device on the tissue overlaying the implanted MAGNA-SITE® injection site.

Step 3: Slowly move the base of the MAGNA-FINDER® Xact locating device in a circular motion (as shown in **Figure 2**) until the magnet of the locating device detects (points towards) the location of the injection site on one plane.

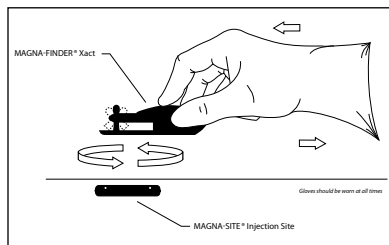


FIGURE 2

Step 4: When the magnet on the MAGNA-FINDER® Xact locating device is pointing straight towards the hole in the base of the MAGNA-FINDER® Xact locating device, then the MAGNA-SITE® injection site has been located.

Step 5: With the magnet of the MAGNA-FINDER® Xact centered in the MAGNA-SITE® injection site, gently press the MAGNA-FINDER® Xact into the skin covering the injection site. The protrusions on the underside of the MAGNA-FINDER® Xact will leave temporary indentations in the skin when the device is lifted. The injection site is located in the center of the circle created by the indentations (**Figure 3**).

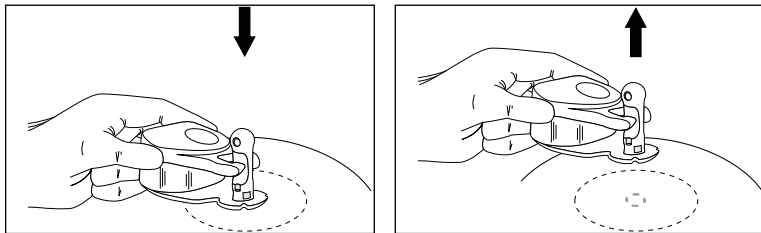


FIGURE 3

As an alternative to the procedure described above, a mark may be made with an ink pen in each of the four notches around the anterior perimeter of the base (Reference **Figure 4**). After all four marks have been made, lift the device away from the patient. Using the same pen, carefully connect the opposing dots with a line, creating an injection “crosshair”. Then make a clear mark at the point where the two perpendicular lines intersect. This point is the exact location of the MAGNA-SITE® injection site.

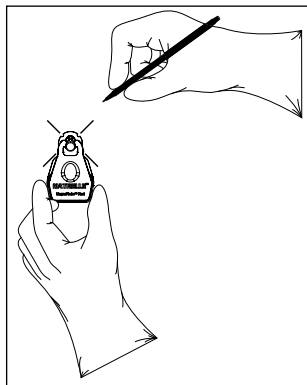


FIGURE 4

Step 6: Prepare the injection site for filling using an appropriate antiseptic swab.

DO NOT store or use the MAGNA-FINDER® Xact locating device near any loose metal particles as they may attach themselves to the magnet.

5. MAGNA-SITE® Injection Site Filling

If the wound is stable, the tissue expander may be filled to tissue tolerance at the time of surgery. This will help to maintain proper tissue expander placement and elevate the injection site, as well as help to minimize fluid accumulation, expander folds, and the formation of a thick, resistant capsule. Initial inflation is especially useful with MICROCELL™ or BIOCELL® textured expanders to encourage rapid tissue adherence and immobility.

If wound stability is a concern, inflate only slightly to fill the pocket space, without applying tension to the tissue.

DO NOT unnecessarily delay expansion after placement. The longer the delay, the more likely the formation of a resistant capsule, making expansion difficult.

NOTE: To avoid contamination and damage due to multiple needle punctures during each session, use a closed filling system, such as an Allergan Fill Kit, which are available separately.

Step 1: Insert a new, sterile 21-gauge (or smaller) standard bevel hypodermic needle into injection site (one 21G Needle Infusion Set is provided with the Tissue Expander for the first session). Ideally, the needle should enter perpendicular to the top of the injection site as shown in **Figure 5**.

Step 2: Penetrate the injection site until the needle is stopped by the needle guard.

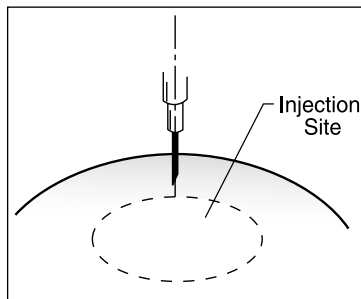


FIGURE 5

NOTE: The surgeon should feel the needle making gentle contact with the metal needle guard. Contact must be made with the needle guard to ensure flow into the expansion envelope.

DO NOT force the needle against the needle guard, which may bend or burr the needle, and result in injection site damage.

Step 3: Fill the tissue expander only with sterile saline for injection, and only through the injection site after precise location of the MAGNA-SITE® injection site with the MAGNA-FINDER® Xact locating device. Fill carefully and only to patient and tissue tolerance.

NEVER proceed with filling beyond patient or tissue tolerance.

Fill volumes during each session, intervals between filling sessions, and total expansion time may vary because they are highly patient and procedure dependent. Filling is typically performed at weekly intervals. A Patient Fill Volume Record card is provided with each tissue expander for recording fill volumes and monitoring the expansion process.

NOTE: The suggested fill volume is located on the patch of each tissue expander and is also listed on the product data sheet.

The patient should be carefully monitored during each session for any signs of adverse reactions. If any signs of tissue damage, abnormal skin pallor (e.g., blanching), erythema, edema, pain, or tenderness are observed, filling should immediately stop until the etiology is determined and the problem resolved.

REPORTING AND RETURN OF EXPLANTED DEVICES

The reason for explantation should be reported and the explanted device returned to Allergan. In the event of such an explantation, please contact *Product Support* at 1.800.624.4261 for an Explant Return Kit and explant return instructions.

RETURNED GOODS POLICY

Product returns should be handled through a Hospital or Surgical Sales Representative or the Allergan Customer Care Department at 1.800.766.0171. Return value is based on time limitations. All package seals must be intact to be eligible for return. Returned products may be subject to a restocking charge.

LIMITED WARRANTY, LIMITATION OF LIABILITY AND DISCLAIMER OF OTHER WARRANTIES

Allergan warrants that reasonable care was used in the manufacture and production of this product. Because Allergan has no control over the conditions of use, patient selection, surgical procedure, post-surgical stresses, or handling of the device after it leaves our possession, Allergan does not warrant either a good effect or against an ill effect following its use. Allergan shall not be responsible for any incidental or consequential loss, damage or expenses directly or indirectly arising from use of this product. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law, or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for use.

PRODUCT ORDERING

To order directly in the U.S.A or for product information, please contact your Hospital or Surgical Sales Representative or the Allergan Customer Care Department at 1.800.766.0171.



www.allergan.com

Allergan Sales, LLC
2525 DuPont Drive
Irvine, CA 92612 USA
Tel: 1.800.624.4261

© 2021 Allergan. All rights reserved.
All trademarks are the property of their respective owners
Patented. See: www.Allergan.com/Products/Patent_Notices

L3831rev03 01/2021