

Informed Consent: Information for Patients Considering Breast Tissue Expanders with MAGNA-SITE® Injection Sites

NATRELLE® Style 133V Series Tissue Expanders are intended for temporary implantation. As a patient already determined eligible for tissue expander surgery, you should receive the following information about the risks involved before surgical placement is scheduled, so that you have time to review and discuss the information, including any unfamiliar medical terms, with your doctor. You must decide whether you are willing to accept the risks along with the benefits of tissue expansion. The risks and benefits may vary, depending on the patient and the specific procedure(s) performed. The summary of known and unknown risks provided below is based on information in the NATRELLE® Style 133V Series Tissue Expander Matrix Directions for Use.

GENERAL KNOWN RISKS

Any invasive surgical procedure has risks such as infection, hematoma, dysesthesia (changes in sensation), postoperative pain, and delayed wound healing. Smoking may significantly increase your risk of delayed wound healing.

SPECIFIC KNOWN RISKS

In addition to posing general surgical risks the use of tissue expanders poses certain specific risks, including:

- **Magnetic field.** The MAGNA-SITE® integral injection site contains a strong rare-earth, permanent magnet. If you already have an implanted device that would be affected by a magnetic field (e.g., pacemaker, drug infusion device, artificial sensing device) you must not have a MAGNA-SITE® tissue expander implanted. In addition, patients with MAGNA-SITE® expanders in place should not undergo diagnostic testing with Magnetic Resonance Imaging (MRI). The MRI equipment could cause movement of the MAGNA-SITE® expander (resulting in discomfort and/or displacement requiring revision surgery), and the MAGNA-SITE® magnet could interfere with MRI detection capabilities. Before any medical treatment, you should advise all attending physicians and health care professionals that you have an implanted expander containing a permanent magnet.
- **Deflation.** The expander and injection site may leak as a result of damage from surgical instruments or trauma. Deflation releases the saline (salt water) filling and will require surgery to replace the expander to continue with the expansion process.
- **Tissue damage.** Tissue damage may occur if the overlying skin is too weak to tolerate the pressure of expansion. Tissue damage is most likely to occur with expansion against an unstable wound or tissue area, or expansion that occurs too rapidly, causing ischemia (lack of blood circulation).
- **Extrusion.** Extrusion of the expander may occur as a result of tissue damage. Extrusion may require removal of the expander.
- **Capsular contracture.** The scar tissue that normally forms around any implanted device, including tissue expanders, may tighten and become firm around the expander. Capsular contracture may make expansion difficult and painful, and necessitate surgical intervention.
- **Premature explantation.** Adverse reactions may require premature explantation.
- **Displacement.** Shifting and rotation of the expander/injection site may occur. Displacement may make the injection site difficult to locate and require surgical intervention.
- **Effects on bone.** Chest wall compression has been reported in association with the use of tissue expanders for breast reconstruction. In most cases, any bone defect caused by the pressure of expansion is reversed following expander removal.
- **Changes in sensation.** The expansion process may affect sensation. Sensation may increase or decrease, temporarily or permanently.
- **Discomfort/distortion.** Tissue expansion is an intensive process that causes temporary discomfort and distortion.

RESEARCH RELATING TO UNKNOWN RISKS

In addition to the above known risks, questions have been raised about whether silicone implants could cause cancer or connective tissue disorders. These questions have focused on silicone breast implants. However, these questions may also apply to the safety of silicone in general for implantation. Leading physicians, including plastic surgeons, rheumatological specialists, and the American Medical Association, have concluded that there is no scientific evidence linking silicone breast implants to connective tissue disorders or cancer. Definitive long-term studies to evaluate the risk potential are still underway. A few controlled studies have provided preliminary safety data showing no connection between silicone breast implants and cancer or connective tissue disorders.

ADDITIONAL INFORMATION AVAILABLE

In addition to the above information, you may wish to discuss aspects of the following information with your surgeon before surgery:

- Alternatives to using a tissue expander;
- The detailed product information provided in the NATRELLE® Style 133V Series Tissue Expander Matrix Directions for Use;
- The risks and benefits of the specific surgical procedure(s) to be performed in your case.

LIMITED WARRANTY

Allergan warrants that reasonable care is used in the manufacture and production of its products. Allergan shall not be responsible for any subsequent losses, damages, or expenses directly or indirectly arising from use of this product.

PATIENT CONSENT

I have read and I understand the above information. I realize that the surgical and post-surgical risks associated with tissue expanders cannot be completely predicted, even with the best medical manufacturing, technology and surgical care, and I accept these conditions and limitations. I have also fully informed my physician of my medical history, including any and all conditions that would contraindicate tissue expansion, and realize that my failure to do so could result in significant surgical and post-surgical complications. I remain convinced that the expected benefits of tissue expansion with the expander(s) I have chosen outweigh the said risks. Having reached this conclusion, I take full responsibility for my choice to proceed with surgical placement, inflation and subsequent removal of one or more tissue expanders.

SIGNED BY: _____

Print or type patient name:

DATE

SIGNED BY: _____

Print or type witness name:

DATE

Original: Surgeon

Copy: Patient

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