informed consent:

INFORMATION FOR PATIENTS CONSIDERING TISSUE EXPANDERS WITH INTEGRATED INJECTION PORT AND/OR MAGNETIC DRAIN PORT (ALLOX2®, DERMASPAN™ AND SOFTSPAN™)

INDICATIONS FOR USE: The Sientra Dermaspan, Softspan and AlloX2 Tissue Expanders are intended for temporary (less than six months) subcutaneous or submuscular implantation to develop surgical flaps and additional tissue coverage required in a wide variety of applications, particularly to aid in reconstructions following mastectomy, to aid in the treatment of underdeveloped breasts and to aid in treatment of soft tissue deformities. Additionally, the AlloX2 Tissue Expanders contain a silicone drain component which allows access to and drainage of latent fluids from the periprosthetic space. This drain component does not replace short-term, immediate, intraoperatively placed drains.

ALLOX2, DERMASPAN AND SOFTSPAN INTEGRATED PORT TISSUE EXPANDERS WITH MAGNETIC INJECTION PORT.
The AlloX2, Dermaspan and Softspan Tissue Expanders have integral injection ports containing a strong rare-earth, permanent magnet, and the AlloX2 Tissue Expander has two integral ports containing a strong rare-earth, permanent magnet; one port for injecting streile saline into the expander and one port for draining fluids during the expansion process if necessary.

Sientra tissue expanders are intended for temporary implantation. All Sientra tissue expanders require periodic, incremental inflation with sterile saline solution. Tissue expansion can be a beneficial surgical alternative for many patients. Nevertheless, tissue expansion is not appropriate for every patient, because it is a time and labor intensive process that may cause temporary discomfort and distortion. Before beginning the expansion process you should fully understand the elective nature of the procedure and discuss with your surgeon other alternatives for treatment. You should be willing to comply with all expansion process requirements to minimize the risk of complications.

The following summary of known and unknown risks is discussed more specifically in the Sientra tissue expander package insert.

MAGNETIC FIELD: Tissue Expanders with the Magnetic Injection Port contain a strong rare-earth permanent magnet. You must not have a Magnetic Injection Port Tissue Expander implanted if you have any implanted device that would be affected by a magnetic field, such as, drug infusion device, pacemaker, artificial sensing device. Additionally, it is recommended that patients with Magnetic Injection Ports not undergo diagnostic testing with Magnetic Resonance Imaging (MRI). The MRI equipment could cause movement of the injection port, resulting in discomfort or misplacement of the expander, or the injection port magnet could interfere with the MRI detection process. You must advise any future attending physician or healthcare provider that you have an implanted expander with a permanent magnet prior to any treatment.

DEFLATION: Deflation can occur when the saline (salt water) leaks through a damaged injection port, the port becomes disconnected or there is damage to the expander shell as a result of surgical instrument damage or trauma. Deflation may require surgery to replace the expander in order to continue with the expansion process.

TISSUE DAMAGE: Tissue damage may occur if expansion occurs more rapidly than the overlying tissue can tolerate, resulting in inadequate blood circulation, or if the overlying and/or surrounding tissue or wound is unstable. Tissue damage may compromise tissue covering and/or wound healing, result in the expander extruding through the tissue, and require early expander removal.

INFECTION: Infection is an inherent risk following any type of invasive surgery, and may occur during the tissue expansion process. Infections must be treated and may ultimately result in early expander removal.

TOXIC SHOCK: Toxic Shock Syndrome has been reported as a complication associated with reconstructive surgery.

CAPSULAR CONTRACTURE: Scar tissue generally forms around any implanted device including tissue expanders. This scar tissue may tighten and cause a range of symptoms including firmness, discomfort, pain, distortion, palpability, and/or displacement of the expander. Capsular contracture may make expansion difficult and painful, causing an interruption in the expansion process or ultimately requiring early expander removal.

PREMATURE EXPLANTATION: Adverse reactions may require early expander removal.

DISPLACEMENT: The expander may become displaced making the injection port difficult or impossible to locate without surgical correction.

EFFECTS ON BONE: Chest wall compression has been reported in association with the use of tissue expanders for breast reconstruction. Bone resorption following forehead and scalp tissue expansion has been reported with extremity tissue expanders. In most cases, any bone defect caused by the pressure of expansion is reversed following expander removal.

PAIN/SENSATION: Pain of varying intensity and duration may occur following any invasive surgical procedure, including expander placement and expansion.

UNKNOWN RISKS: In addition to the above known risks, questions have been raised about whether silicone implants could cause cancer or connective tissue disorders, such as ALCL (Anaplastic Large Cell Lymphoma), BIA-ALCL (Breast Implant Associated Anaplastic Large Cell Lymphoma) or rheumatoid arthritis. Although these questions have been focused on silicone breast implants, to the extent that such research applies to the safety of silicone in general for implantation, it is relevant to tissue expanders.

ADDITIONAL INFORMATION: Additional information, including a more thorough discussion of the above is available in the package insert provided to your surgeon with each Sientra tissue expander.

LIMITED WARRANTY: Sientra warrants that reasonable care is used in the manufacture and production of all its products. Sientra does not warrant either a good effect or against an ill effect following the use of this product. Sientra shall not be responsible for any incidental or consequential loss, damage, or expenses, directly or indirectly arising from use of this product.

PATIENT CONSENT: I have read and understand the above information. My surgeon has satisfactorily addressed any unclear statement(s) above. 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 I 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 silicone tissue expanders.

Patient (or Patient's guardian) Signature: _____ Date: _____

Print or Type Patient Name: _____ Witness Signature: _____ Date: _____

Original: Surgeon Copy: Patient

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