informed consent:

INFORMATION FOR PATIENTS CONSIDERING TISSUE EXPANDERS WITH REMOTE INJECTION PORT (DERMASPAN™ AND SOFTSPAN™ REMOTE PORT)

INDICATIONS FOR USE: Silicone Tissue Expanders are intended for temporary subcutaneous implantation to develop surgical flaps and additional tissue coverage required in a wide variety of applications, particularly to aid in reconstruction following mastectomy, to aid in the treatment of underdeveloped breasts, and to aid in the treatment of soft tissue deformities.

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.

DEFLATION: The Expander and injection port may leak requiring replacement surgery. Deflation occurs when saline leaks through a damaged injection port, disconnected or damaged remote injection port or connection tube, or a damaged expander shell.

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 and/or remote injection port 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 also been reported with the use of 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 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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