

Motiva Flora Tissue Expander

Category:

Best Medical Technology

Company Name:

Establishment Labs Holdings Inc.

Product/Solution Name:

Motiva Flora Tissue Expander

Compound/Tech Name:

Silicone tissue expander

Trade Name:

Motiva Flora® SmoothSilk® Tissue Expander

Corporate Name:

Establishment Labs S.A.

Date of Approval:

2023-10-13

Indications:

The Motiva Flora® SmoothSilk® Tissue Expander is intended for temporary subcutaneous or submuscular implantation to develop surgical flaps and additional tissue coverage required in a wide variety of applications, particularly to aid in breast reconstruction following a mastectomy. It can also be used in the treatment of underdeveloped breasts and soft tissue deformities (refer to attachments 1 and 2).

Motiva Flora SmoothSilk Tissue Expanders require periodic, incremental inflation, injected with sterile saline until the desired tissue volume is achieved. After reaching the desired volume, the expander is surgically removed and replaced with a breast implant in the same space as the previous tissue expander. This process usually takes no more than 6 months.

Therapeutic Areas:

Tissue expanders are crucial in breast reconstruction, particularly for breast cancer treatment and recovery. They are primarily used in:

1. Breast Reconstruction After Mastectomy:

Tissue expanders are used to stretch the skin and create a pocket where a long-term breast implant will eventually take its place. Patients can either undergo immediate or delayed reconstruction following a mastectomy, either during or after recovery and cancer treatments. The Motiva Flora® SmoothSilk® Tissue Expander is specifically engineered to support this approach.

2. Radiation Therapy:

Radiation can lead to skin tightening, fibrosis, and capsular contracture, which may impact the aesthetic and functional outcomes of implant-based reconstruction. These effects tend to be more pronounced when radiation follows implant placement. Staged reconstruction using tissue expanders is a common approach for patients undergoing postmastectomy radiation therapy (PMRT). Tissue expanders serve as placeholders, preserving the breast mound and skin integrity during radiation, allowing for improved cosmetic and functional outcomes in the second stage. Staged reconstruction with tissue expanders provides an advantage in addressing both oncologic safety and aesthetic restoration in breast cancer patients requiring PMRT. While it carries certain risks, this approach enables tailored reconstruction plans that meet individual patient needs and treatment schedules.

Motiva Flora® SmoothSilk® Tissue Expander, unlike traditional expanders with metallic ports, uses an RFID port that reduces radiation dose attenuation to 1.29% for 6 MV and 0.99% for 10 MV X-rays. This ensures accurate and uniform radiation delivery, reducing the risk of underdosing tumors or overdosing adjacent organs like the heart and lungs. The RFID port also minimizes imaging artifacts, improving CT and MRI clarity for precise radiation planning. Motiva Flora® SmoothSilk® Tissue Expander maintains material integrity under radiation exposure (up to 50 Gy) without losing mechanical or functional properties, supporting the surgical pocket throughout treatment. With its durability, imaging compatibility, and dosimetric performance, making it ideal for patients undergoing radiation-inclusive breast reconstruction, offering clinicians a reliable and patient-centered solution.

3. DIEP Flap Surgery:

The Motiva Flora® Tissue Expander supports delayed-immediate reconstruction protocols using DIEP flaps. It preserves the breast skin envelope and chest wall contour during radiation therapy, facilitating optimal conditions for final reconstruction and minimizing complications. Its SmoothSilk® surface and anatomical design maintain natural breast contours, while the RFID-based port system reduces imaging artifacts and improves CT and MRI compatibility.

General Information File Document upload:

Establishment Labs 1 FDA 510k Clearance K211676.pdf

Establishment Labs 2 Directions for Use Motiva Flora SmoothSilk Tissue Expander.pdf

Background information and need for drug / device:

Breast reconstruction is a medical procedure designed to restore breast tissue that has been lost due to cancer, cystic disease, congenital conditions, or trauma. This process often facilitates emotional recovery for many women by restoring and providing a natural appearance closest to their pre-cancer breast, compared to not having reconstruction or using a prosthesis.

Breast cancer is the most common cancer among women globally, with 2.3 million diagnoses and over 685,000 deaths in 2020. In the United States (US), 12.5% of women are diagnosed annually, with 35.5% undergoing mastectomies. There were nearly 140,000 breast reconstruction surgeries in 2020, underscoring their importance. Reconstruction methods include Tissue Expander/Implant, direct-to-implant, and autologous tissue grafts (DIEP Flap Surgery) (attachment 1).

Tissue expanders are used after mastectomies to stretch the remaining tissue, creating a pocket for the long-term breast implants. This method is associated with less operative time, faster recovery, and fewer functional limitations.

A small percentage of tissue expander reconstructions are performed to correct underdeveloped breasts and soft tissue deformities in the breast area. For this small group of patients, the tissue expanders' psychological benefits are the same as cancer patients.

Most commercially available tissue expanders in the market incorporate a magnetic injection port to allow the surgeon to detect the position where saline must be injected. This practice brings two main drawbacks when exposing a patient to an MRI (magnetic resonance imaging) environment. First, those devices are labeled MR Unsafe, and therefore MRIs are contraindicated, preventing patients from having a full analysis of high-risk lesions on the contralateral breast or malignancy progression, assessing procedure-related complications, or even evaluating a preexisting augmented contralateral breast for aesthetic reconstruction. Second, if the radiologist/technician proceeds with the scan, the presence of severe artifacts obscuring high-risk breast areas will be obscured, providing unsatisfactory images (attachment 2). A common practice for patients with traditional tissue expanders who require an MRI is to explant the device prior to imaging. This is due to the presence of metallic components-typically magnetic ports-that can interfere with MRI safety and image

quality. The need to remove the expander not only delays diagnostic procedures but also disrupts the breast reconstruction timeline, potentially compromising the surgical pocket and skin envelope that the expander was intended to preserve.

Consequently, advancements in tissue expander design became necessary, particularly for breast-related conditions, to improve the overall experience for patients.

Background File Document upload:

**Establishment Labs 1 Summary SOTA LTR Flora 2024 clean.pdf
ESTABL2.PDF**

ESTABL2.PDF

Establishment Labs 2 Benefits of Using MRI during Breast Tissue Expansion Literature Review and case series.pdf

History of the development of the solution/product:

While there are a few breast reconstruction options, surgical best practices often recommend a two-staged approach, involving the use of a tissue expander for progressive skin expansion and preparing the tissue for the subsequent long-term implant or autologous reconstruction. This approach has demonstrated a positive contribution to overall patient health and satisfaction by improving quality of life.

Establishment Labs takes a patient-centric approach to innovation, ensuring that new technology adds value to both the patient's experience and their health. Based on the limitations of current tissue expanders, the conceptualization of the Motiva Flora SmoothSilk Tissue Expander was focused around an enhanced surface topography, a non-magnetic RFID injection port, and an improved anatomical shape to foster patients' comfort, safety, and aesthetic outcome (attachment 1). The company studied RFID-enabled technologies to substitute the conventional magnet port, ensuring MRI compatibility and providing more options for radiologists and surgeons.

The decision to incorporate RFID was initially met with skepticism by some experts who thought the unique features of the Flora Tissue Expander were \"over-engineered\" and \"nice to have\". Regardless of feedback, we remained true to our goal of focusing on patient comfort and safety and backed up our technologies with science. Scientific evidence has demonstrated that a device's topography plays a significant role in clinical performance and patient outcomes. The surface of the expander can influence the body's response, the formation of scar tissue and overall biocompatibility. The Flora's SmoothSilk 4-micron surface elicits a milder immune response compared to other surfaces, as identified in a Nature Biomedical Engineering publication (attachment 2), potentially leading to better long-term outcomes. Thus, Establishment Labs decided to include their proprietary SmoothSilk surface in the Flora Tissue

Expander. During preclinical stages, Establishment Labs assessed the safety and effectiveness of the device using standard methods. The surface was evaluated per ISO 14607:2018 and tested in vitro, in animal models, and in humans for immune response, bacterial attachment, biofilm formation, and particle shedding. Its biocompatibility met EN ISO 10993-1 standards. Performance studies confirmed its function and technological enhancements, including a non-ferromagnetic port and RFID coil.

The dataset indicates suitability for subcutaneous or submuscular implantation. Sterilization met BS EN ISO 20857:2013 standards, and mechanical testing adhered to ASTM F1441-03. MRI safety, Electromagnetic Compatibility, Electrical Safety Testing, and interactions with ultrasound, X-rays, and CT scans were evaluated based on ASTM standards.

Thanks to a collaborative effort, we ultimately secured FDA Clearance and successfully introduced our expander to the U.S. market in 2023. Since then, surgeons across the United States have gone above and beyond to ensure that their hospitals and clinics can offer this groundbreaking technology to their patients, sometimes even obtaining special authorization due to its distinctive features and related advantages.

Following its clearance, numerous U.S. surgeons have adopted the device and consistently reported superior results and improved patient outcomes. These findings are supported by the publication (attachment 3) of MD Anderson Cancer Center in Houston; one of the first and most prestigious institutions to adopt the Motiva Flora Tissue Expander.

Development File Document upload:

[Establishment Labs 1 Summary of Device Description Motiva Flora SmoothSilk Tissue Expander.pdf](#)

[Establishment Labs 2 The surface topography of silicone breast implants mediates foreign body response in mice rabbits and humans.pdf](#)

[Establishment Labs 3 MRIConditional Tissue Expanders in Breast Reconstruction Clinical Outcomes and Radiation Therapy Implications.pdf](#)

Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition:

The Motiva Flora SmoothSilk Tissue Expander represents a significant advancement in reconstructive breast surgery, with broad implications for future research and improving patient outcomes. As the first RFID-enabled MR Conditional tissue expander, this technology represents an advancement that allows for non-invasive port detection with MRI compatibility. This technology could pave the way for future research of other \"smart\" technology that may lead to personalized treatment protocols and safer ways

to enhance the expansion process. We're further expanding our RFID platform to include biosensing capabilities that would allow surgeons to track patients' temperature, vital signs and potentially implant integrity, all for the benefit of the patient.

Clinically, Flora enhances patient safety, comfort, and access to care-particularly in underserved settings-while reducing the burden of follow-up procedures. By streamlining reconstruction and improving the patient experience, it contributes meaningfully to both physical and emotional recovery after mastectomy.

Flora's technological features include:

- A non-magnetic passive radiofrequency identification (RFID) port with Integrated Port Needle Stop Assembly. The RFID port is a non-battery and non-emitting device part made from non-ferromagnetic materials, conversely it incorporates polyetheretherketone (PEEK), and a copper coil, which allows for MRI compatibility. Non-ferromagnetic devices can be imaged using X-ray and computed tomography (CT) without significant artifacts caused by ferromagnetic materials (attachment 2). This feature adds benefit in patients who require post-mastectomy radiation therapy, in which the CT images of the Treatment Planning System present negligible streaking artifacts, thus avoiding the need for contouring and adjusting. Studies have been able to demonstrate this advantage clinically, confirming a more precise radiation dose delivery with a reduction of up to 75% of dose uncertainty when compared to competitors. This contributes to a reduction of underdosing the target area and overdosing the adjacent healthy tissues, such as the heart and lungs (attachment 5). This feature also enables healthcare professionals undergoing expansion to safely continue their work around MRI machines, reducing the disease burden and enhancing their overall quality of life.

- The Motiva Flora Port Locator: A non-invasive electronic device that interacts exclusively with the Flora Tissue Expander to locate the integrated port and enable accurate injection filling. The air-wound coil with RFID technology is embedded within the needle stop and is activated externally for precise location of the injection site through LED indicators in the form of two rings, which will change color depending on its proximity to the port (attachment 3).

- SmoothSilk surface topography: A controlled architecture produced by reverse mandrel imprinting, with an average roughness of 4-micron (attachment 1). This proprietary surface reduces the foreign body response and has demonstrated to minimize the implant risks of bacterial contamination, silicone particle shedding, and debris. Statistically significant lower infection rates have been documented, when compared to traditional expanders.

The low roughness and low friction coefficient of this surface promote a favourable interaction between the expander's surface and surrounding tissues, with studies showing that this may result in less fibrotic tissue envelopes and lower periprosthetic fluid compared to other shell surfaces (attachment 4).

Innovation File Document upload:

Establishment Labs 2 Flora Radiation One pager.pdf

Establishment Labs 1 Motiva Flora SmoothSilk Tissue Expander Innovation.pdf

Establishment Labs 3 Motiva Flora Port Locator Quick Reference Guide.pdf

ES65331.PDF

ES99061.PDF

Establishment Labs 4 Is it all about Surface Topography.pdf

Establishment Labs 5 Dosimetric effect of injection ports in tissue expander on post mastectomy.pdf

Please provide appropriate references (PubMed, Abstract, Website):

The complete list of all references can be found in the file attached, including the abstract and website of each publication.

Our main publications are:

1. Doloff JC, Veisheh O, de Mezerville R, et al. The surface topography of silicone breast implants mediates the foreign body response in mice, rabbits, and humans. Nat Biomed Eng.. 2021;5(10):1115-1130. doi:10.1038/s41551-021-00739-4
2. Schoberleitner I, Augustin A, Egle D, Brunner C, Amort B, Zelger B, Brunner A, Wolfram D. Is It All about Surface Topography? An Intra-Individual Clinical Outcome Analysis of Two Different Implant Surfaces in Breast Reconstruction. J Clin Med. 2023 Feb 7;12(4):1315. doi: 10.3390/jcm12041315. PMID: 36835850; PMCID: PMC9967160.
3. Clemens MW, Mitchell MP, Christensen JM, Olenczak JB, Shay PL, Hanwright P, Ha AY, Kapur S, Melancon A, Shuck JW. MRI-Conditional Tissue Expanders in Breast Reconstruction: Clinical Outcomes and Radiation Therapy Implications. Plast Reconstr Surg. 2025 Feb 11. doi: 10.1097/PRS.00000000000012029. Epub ahead of print. PMID: 39946673.
4. Westmore, Kristin E., \"Ensuring Safe MRI Examinations and Earlier Detection of Recurrent Cancer: A Scoping Review to Identify Breast Tissue Expanders That are Safe for High-Risk Breast Cancer Survivors\" (2024). Capstone Experience. 345. https://digitalcommons.unmc.edu/coph_slce/345
5. Bayasgalan M, Munhoz AM, Shellock FG. Breast Tissue Expander With Radiofrequency

Identification Port: Assessment of MRI Issues. American Journal of Roentgenology, 2020. 215(1), pp.159-164. doi:<https://doi.org/10.2214/ajr.19.22492>

6. Matsubayashi F, Takahashi T, Miyauchi H, Ito Y, Harada A, Yoshioka Y. Modeling of a tissue expander with a radiofrequency identification port in postmastectomy radiation therapy planning. J Radiat Res Imaging. 2024. doi:10.1093/jrr/rrae004

7. Hwang NH, Kim M, Lee NK, Lee S, Hwang J. Dosimetric Effect of Injection Ports in Tissue Expanders on Post-Mastectomy Volumetric Modulated Arc Therapy (VMAT) Planning for Left-Sided Breast Cancer. Applied Sciences (Switzerland). 2022;12(13). doi:10.3390/app12136461

8. Schiaffino S, Cozzi A, Pompei B, et al. MRI-Conditional Breast Tissue Expander: First In-Human Multi-Case Assessment of MRI-Related Complications and Image Quality. J Clin Med. 2023;12(13). doi:10.3390/jcm12134410

9. Clausen-Oreamuno C, Perez-Rodrigo S, Stillaert FBJL, Tejerina A, Tejerina A, Shellock FG. Benefits of Using Magnetic Resonance Imaging During Breast Tissue Expansion: Literature Review and Case Series. Aesthet Surg J. Published online August 14, 2023. doi:10.1093/asj/sjad264

10. Catic A, Weinzierl A, Heimer J, Pompei B, Harder Y. Smooth Operator: Nanotextured MRI-compatible breast tissue expanders are associated with lower rates of capsular contracture. Social Science Research Network. Published online 2024. <https://ssrn.com/abstract=4807881>

References File Document upload:

[Establishment Labs List of references to publications and links.pdf](#)