

Motiva Flora[®]

Tissue Expander

ELEVATING TWO-STAGE
BREAST RECONSTRUCTION



Motiva Flora[®] Tissue Expander

The Motiva Flora[®] 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 reconstruction following mastectomy, to aid in the treatment of underdeveloped breasts and to aid treatment of soft tissue deformities.¹

Motiva Flora[®] Tissue Expander

- An innovative device with a passive radiofrequency identification port²
- MR Conditional integrated port allowing MRI scanning with 1.5 and 3 Tesla MR systems³
- Reduced potential clinical toxicity when post-mastectomy radiation therapy is indicated⁴
- A 4-micron biocompatible surface that results in reduced pro-fibrotic-related complications⁵
 - Higher surgeon satisfaction with the lower pole expansion and footprint created⁶
 - Increased patient aesthetic and comfort outcomes⁶

Motiva Flora[®] Tissue Expander



TRUEFIXATION[®] SYSTEM

MR-CONDITIONAL
MAGNET-FREE PORT

RADIOPAQUE LINES

SMOOTHSILK[®] SURFACE

ANATOMICAL SHAPE

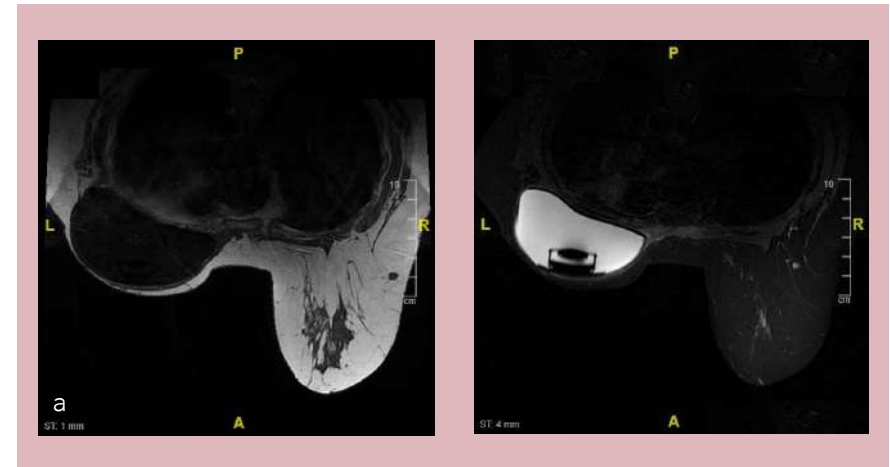


MR Conditional Magnet-free Injection Port

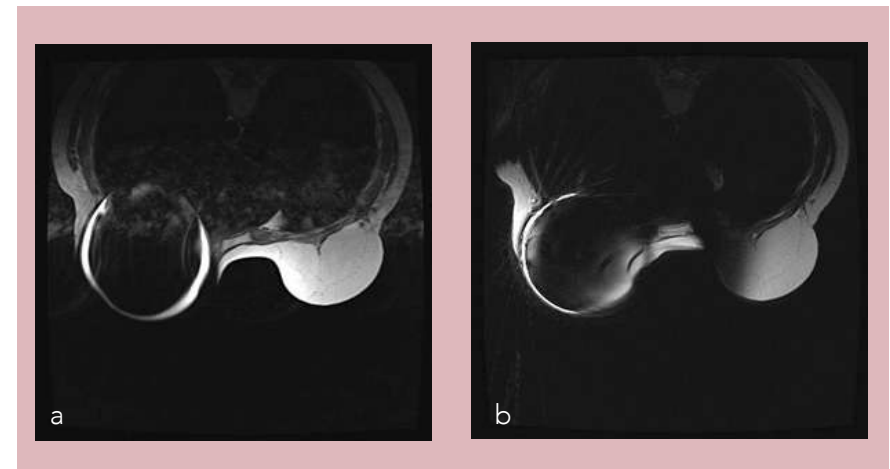
The Motiva Flora[®] Tissue Expander is an innovative device with a passive radiofrequency identification (RFID) port.²

The air-wound coil with RFID technology is embedded in the needle stop and is activated externally for precise location of the injection site through LED indicators on the port locator.²

The RFID port is magnet free, allowing MRI scanning to safely take place under specific conditions.³ Traditional tissue expanders with magnetic ports are labeled "MR Unsafe" and may be associated with safety issues such as valve dislodgment, and burning sensation, and produce a substantial distortion on MR images.⁷



Motiva Flora[®] Tissue Expanders with the RFID port do not generate distortion of T1 (a) or T2 (b) in weighted axial MRI images*.



Traditional magnetic ports create large distortions that impede correct assessment of T1 (a) and T2 (b) in weighted axial MRI images, even in the contralateral breast*.

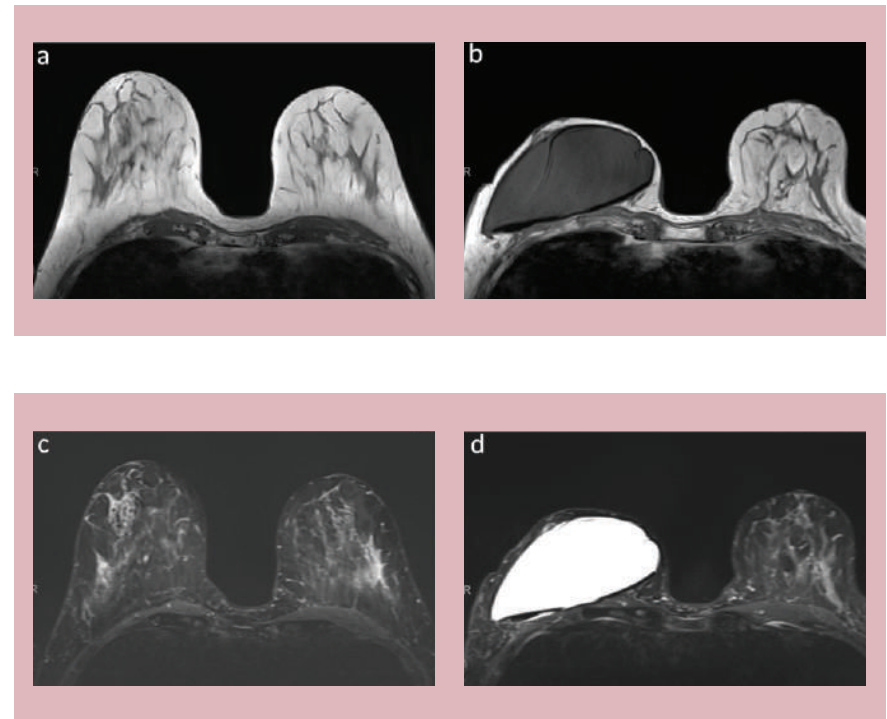
*Reprinted with authorization: Roller R, Chetlen A, Kasales C.
J Am Osteopath Coll Radiol. 2014;3(1):2-9. AOCR

Demonstrated MR Conditional Use

Clinical studies have shown that the Motiva Flora[®] has no known hazards in specific MR environments with conditions of use (1.5, and 3 Tesla MR systems).^{3,8}

The Motiva Flora[®] Tissue Expander images at high field (3T), did not impact T1-weighted fat suppressed (Dixon) sequences, or T2-weighted inversion recovery (TIRM) sequences.⁹

Under the specific MR conditions per labeling, the Motiva Flora[®] Tissue Expander demonstrated no MR-related complications such as discomfort related due to expander displacement, overheating reported, or MR damage to the expander port.^{3,9}



Figures of a patient that underwent skin-sparing mastectomy with prepectoral implantation of Motiva Flora[®] Tissue Expander. Extracted by Schiaffiano et al. 2023.

(a,c); Preoperative MR images, (b,d); Images prior to planned exchange surgery to permanent implant demonstrating no effects on image quality with the Motiva Flora[®] Tissue Expander. T1 weighed panels (a,b); T2 weighed panels (c,d).

MRI Usability During the Tissue Expansion Process

The Motiva Flora® Tissue Expander is designed to provide diagnostic MRI images in clinical scenarios such as:⁷



**Full analysis of high-risk
lesions on the
contralateral breast**

**Evaluation of the
integrity of the
tissue expander**

**Assessment of
preexisting augmented
contralateral breasts**

**Management of
absorption during the
fat-grafting process**

Advanced Magnet-free Integrated Port

Motiva Flora® Port Locator uses a radio frequency identification (RFID) wireless system to locate the injection dome of the Motiva Flora® Tissue Expander.¹⁰

The RFID injection port present in the Motiva Flora® can be successfully located after undergoing an MRI and under specific conditions with an MR system of a field strength of 1.5, and 3 Tesla, demonstrating no post-procedural damage of the port.^{2,9}



Innovative RFID Port Locator

Localizing the integrated magnetic ports in traditional tissue expanders has been reported in literature to pose challenges to the surgeon.¹¹

The Motiva Flora[®] Port Locator is a noninvasive electronic medical device that interacts exclusively with the Motiva Flora[®] Tissue Expander to easily locate the expander's integrated port and enable accurate injection filling.¹⁰

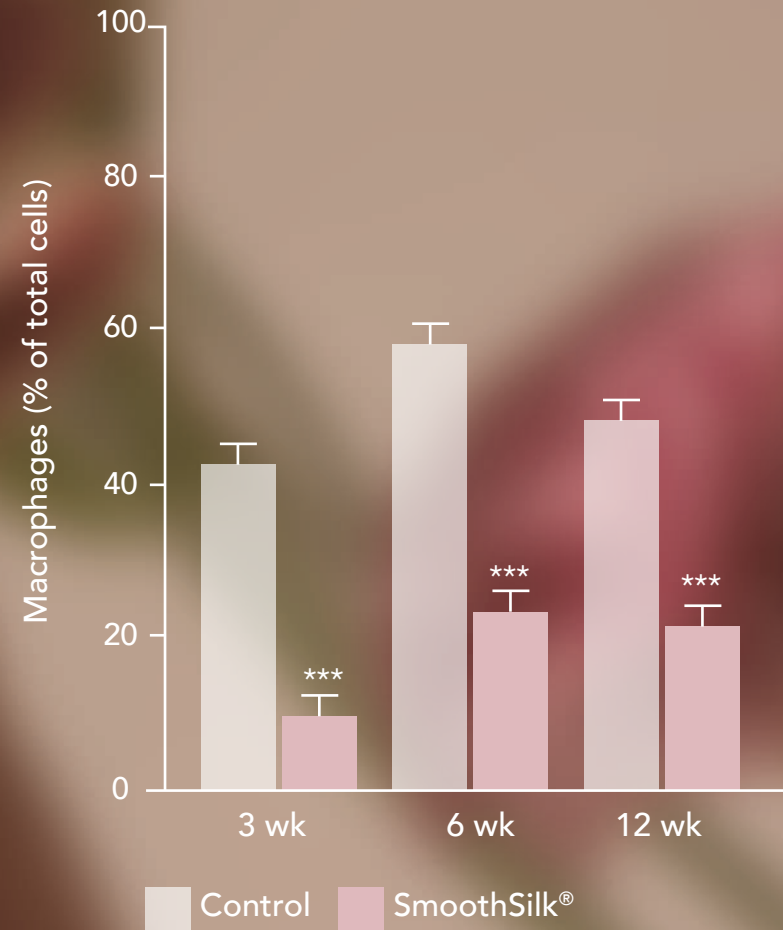
The Motiva Flora[®] Port Locator comes with a light indicator in the form of two rings, which will change color depending on the device's status. The internal ring will turn green upon identifying the correct location on the breast of the filling port.¹⁰



SmoothSilk[®] Surface

The Motiva Flora[®] Tissue Expander has a controlled surface architecture produced by the mandrel imprinting technique with an average roughness of 4 microns.

SmoothSilk[®] is a biocompatible implant surface scientifically proven to generate low inflammatory and cell-friendly response, resulting in reduced profibrotic-related complications.⁵⁻⁶



Composition of immune infiltrate in capsules surrounding breast implants with SmoothSilk[®] surface and a control group. ***P<0.001. Adapted from Doloff et al. 2020.

SmoothSilk[®] Surface

Landmark studies demonstrate surface advantages:^{5,6}



1.

Significantly lower
capsular thickness*

Reduced fibrotic markers in ultrasound
and histological analysis.

2.

A unique immune infiltrate
in the capsule

The lowest level of immune activators and
a balanced presence of regulatory cells.*

3.

Reduced expression of inflammatory
cytokines and higher presence of
anti-inflammatory cytokines.*

Significant decrease of pro-inflammatory cells,
compared with textured surface devices.

4.

Significantly reduced periprosthetic
fluid around the Motiva Flora[®]
Tissue Expander.**

*Among those breast devices tested, smooth and textured.
** When compared to textured surfaced breast devices.

TrueFixation[®] system

Designed to promote breast symmetry and prevent displacement.²

TRUEFIXATION[®] SYSTEM

The Motiva Flora[®] fixation tabs are made from reinforced silicone and are sutured to the adjacent tissue. The two tabs provide additional stabilization, aiding in the prevention of displacement, improving breast symmetry,^{12,13} and a controlled expansion during inflation.²

A REINFORCED SILICONE BASE

The reinforced base provides extra support to the back of the tissue expander, promoting preferential lower pole expansion, while maintaining breast-width during the expansion process.²

TRUEMONOBLOC[®] TECHNOLOGY

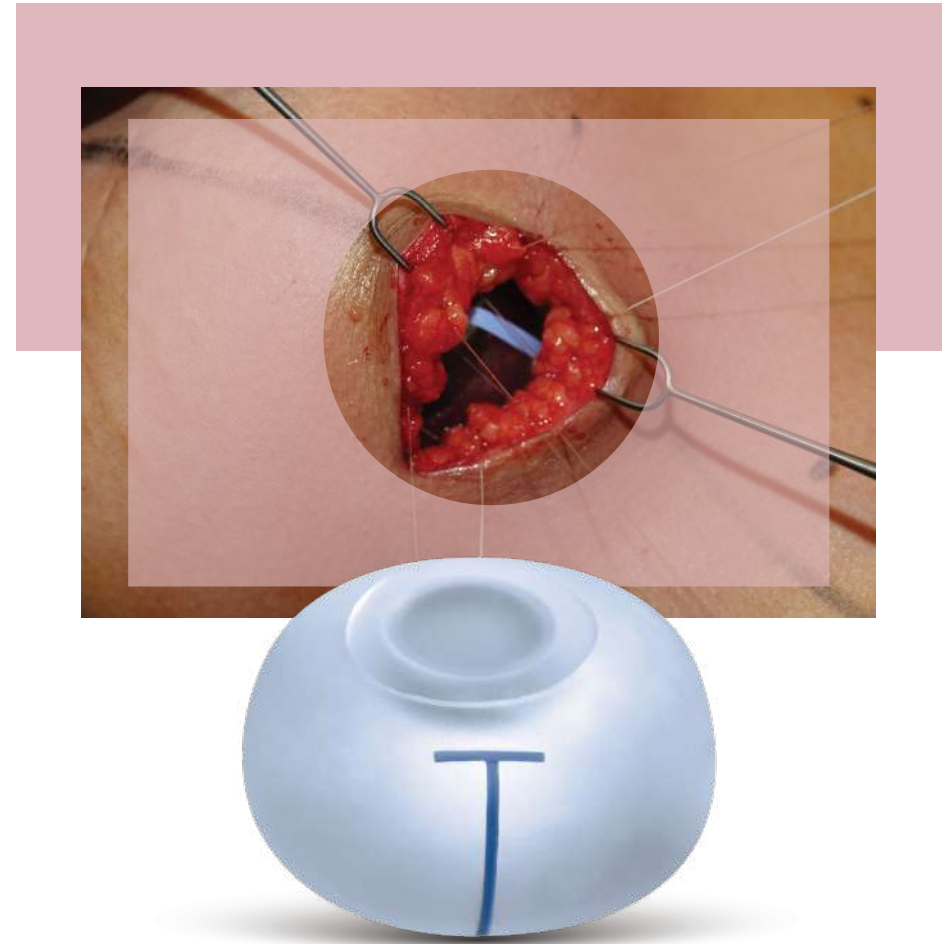
The patch is bonded to the shell to maintain the elasticity and integrity of the device.²



Radiopaque lines

The Motiva® Flora Tissue Expander has orientation lines made from a radiopaque blue material that allows healthcare professionals to identify a potential rotation after implantation during an X-ray procedure, and additionally, aids the surgeon in the correct positioning of the device during implantation.²

Follow-up with functional imaging modalities is a critical component in the management of post-mastectomy cases. The radiopaque lines featured in Motiva Flora® Tissue Expander can be easily and precisely recognized by imaging techniques.²



Immediate verification of the expander's aligned position aided by the radiopaque line.

Natural Shape

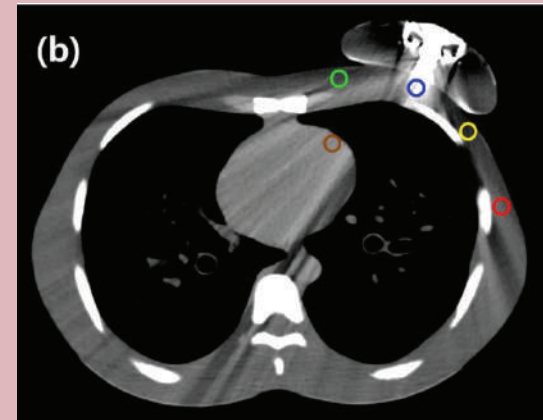
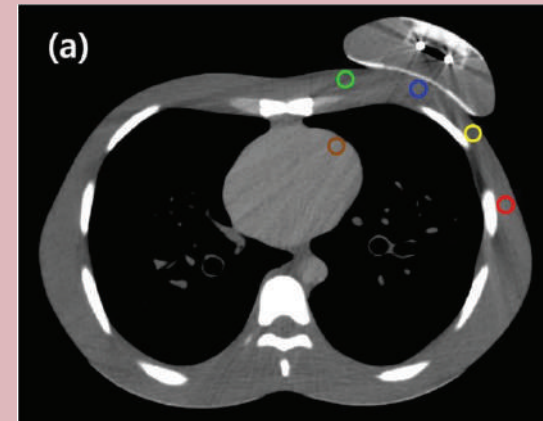
The Motiva Flora[®] Tissue Expander has an anatomically-shaped design that allows it to simulate the natural breast, with a tear-drop shape. The tear-drop shape progressively shifts the volume to the lower pole during the expansion process.¹²



Superior Dosimetric Results

The RFID port technology reduces the artifact on CT imaging due to a lower radio density in comparison to metals in conventional expander ports.^{3,4}

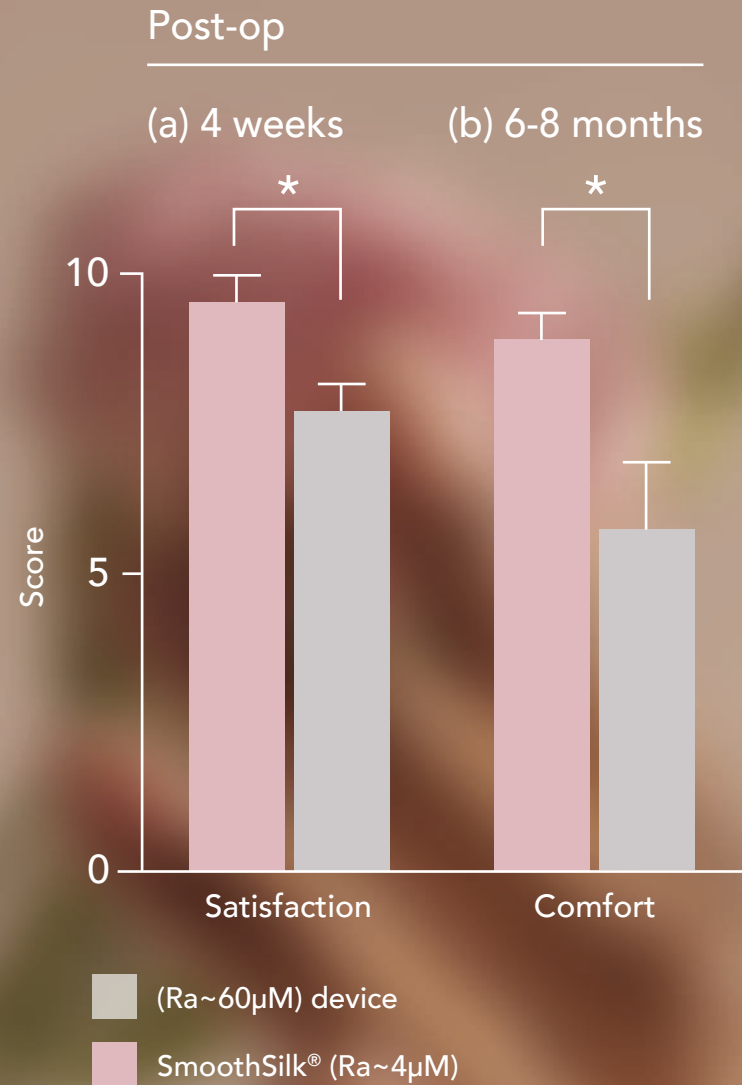
During radiotherapy treatment planning, the Motiva Flora[®] Tissue Expander has shown superior dosimetric results for doses to the heart and lungs in comparison to traditional metallic port expanders, reducing the potential clinical toxicity to these vital organs.⁴



An example of the CT image (a) RFID port, (b) metallic port analysis using five reference points; a: central chest wall (blue), b: medial chest wall (green), c: lateral chest wall (yellow), d: axilla (red) and e: left anterior descending artery (brown). Extracted from Hwang et al. 2021

Higher Patient and Surgeon Satisfaction

- **Surgeons reported:**
Higher satisfaction with the lower pole expansion and the footprint created.^{6*}
- **Patients reported:**
Significantly higher aesthetic and comfort scores.
Less breast pain, discomfort, and nipple sensitivity.^{6*}



Patient satisfaction and comfort rating of tissue expanders at 4 weeks (a) and 6-8 months (b).

*: Statistically significant difference ($p < 0.05$).
Adapted from Shoberleitner et al, 2021.

*Compared to a textured breast tissue expander.

Motiva Flora[®] Tissue Expander

Bases, heights, projections and volumes for desired outcomes

	Catalog	Base (cm)	Height (cm)	Projection (cm)	Volume (cc)
Low Height	XML-54	11.0	9.0	5.4	260
	XML-58	12.0	10.0	5.8	345
	XML-62	13.0	11.0	6.2	440
	XML-66	14.0	12.0	6.6	570
Medium Height	XMM-54	11.0	10.0	5.4	300
	XMM-58	12.0	11.0	5.8	375
	XMM-62	13.0	12.0	6.2	490
	XMM-66	14.0	13.0	6.6	605
	XMM-70	15.0	14.0	7.0	750
Full Height	XMF-54	11.0	11.5	5.4	345
	XMF-58	12.0	12.5	5.8	440
	XMF-62	13.0	13.5	6.2	545
	XMF-66	14.0	14.5	6.6	680
	XMF-70	15.0	15.5	7.0	825
	XMF-74	16.0	16.5	7.4	995

Motiva Flora[®] Tissue Expander to Motiva[®] Implants Conversion Guidelines

The Motiva Flora[®] conversion matrix is available to help aid in the process of converting this tissue expander to the final breast implant once the expansion process has been complete.

This conversion matrix aims to provide a potential implant size compatibility using Ergonomix[®], Ergonomix2[®], and Anatomical TrueFixation[®] (Full and Corsé) implants.

STEP BY STEP:

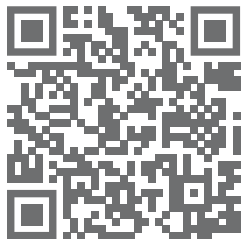
HOW TO USE MOTIVA FLORA[®]
TISSUE EXPANDER CONVERSION TABLES








Motiva® partnership

As your business partners, we care about growing together. This is why we continuously invest, not only in technological and safety innovation, but also in specialized tools and game-changing digital platforms that bring you closer to your patients.

Learn more here:



	Designed surgeries	A suite of consultation and surgical tools for designed surgeries: MotivaHybrid® and Motiva MinimalScar®, created to offer your patients tailored and unique results
	Medical Education	A global platform exclusively dedicated to peer-to-peer learning on the latest technological innovation and techniques in the field
	Global webinars	Educational series to facilitate surgeons network, exchange experiences, share tips and tricks, and receive quality content
	Resource center	Educational content on the latest surgical techniques and marketing materials to help you grow your practice through social media and other channels
	Center locator	A digital platform designed to help patients find top Motiva® surgeons in the world, and easily connect

Establishment Labs[®] 13+ years of innovation worldwide¹⁰

**3,000,000+
Devices**

Establishment Labs[®] devices*
in worldwide market
since 2010

**85+
Countries**

Where Establishment
Labs[®] devices* have
been approved

**210+
Patents**

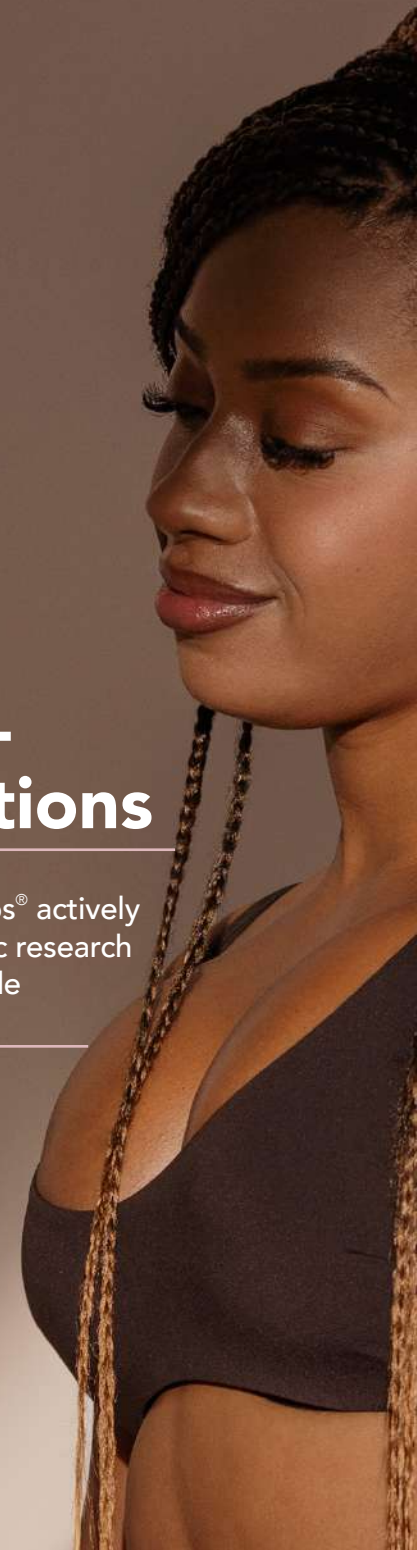
Applications
approved/pending
globally in 21 jurisdictions

**90+
Publications**

Establishment Labs[®] actively
supports scientific research
worldwide

The Motiva Flora[®] Tissue Expander is a Femtech solution that supports,
normalizes and democratizes breast reconstruction.

*This includes breast implants and breast tissue expanders.



REFERENCES

1. Establishment Labs®. DOC-037: Directions for Use for Motiva Flora Tissue Expander. March 2023.
2. Establishment Labs®. DDD-008* Device Description Document For Motiva Flora® Tissue Expander. September 2023.
3. 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>.
4. 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*. 2022, 12 (13), 6461. doi:10.3390/app12136461
5. Doloff JC, Veisoh 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
6. Schoberleitner I, Augustin A, Egle D, et al. Is It All about Surface Topography? An Intra-Individual Clinical Outcome Analysis of Two Different Implant Surfaces in Breast Reconstruction. *J. Clin. Med.* 2023, 12, 1315. <https://doi.org/10.3390/jcm12041315>
7. Clausen-Oreamuno C, Perez-Rodrigo S, Stillaert F, Tejerina A, Tejerina A, Shellock F. Benefits of Using Magnetic Resonance Imaging During Breast Tissue Expansion: Literature Review and Case Series, *Aesth Surg Jour*, 2023; sjad264, doi.org/10.1093/asj/sjad264
8. Establishment Labs®, Post-Market Surveillance Preliminary Results. Q1 2023.
9. Schiaffino S, Cozzi A, Pompei B, Scarano AL, Catanese C, Catic A, Rossi L, Del Grande F, Harder Y. MRI-Conditional Breast Tissue Expander: First In-Human Multi-Case Assessment of MRI-Related Complications and Image Quality. *J Clin Med*. 2023 Jun 30;12(13):4410. doi: 10.3390/jcm12134410.
10. Establishment Labs®. DOC-038: Directions for Use for Motiva Flora Port Locator. August 2023.
11. McCulloch I Rokosz J, Chambers J, McClellan T. PortFindr: A novel, more accurate, and precise device for locating tissue expander ports. *Plastic Surgery*. 2021, Vol 29 (2), 118-121. doi: 10.1177/2292550320963113
12. Bletsis P, Bouwer L, Ultee K, Cromheecke M, van der Lei B. Evaluation of anatomical and round breast implant aesthetics and preferences in Dutch young lay and plastic surgeon cohort. *J Plast Reconstr Aesthet Surg*. 2018. 71(8), 1116-1122. doi: 10.1016/j.bjps.2018.04.010
13. Khavanin N, Gust MJ, Grant DW, Nguyen KT, Kim JYS. Tabbed tissue expanders improve breast symmetry scores in breast reconstruction. *Arch Plast Surg*. 2014;41(1):57-62.doi:10.5999/aps.2014.41.1.57

