

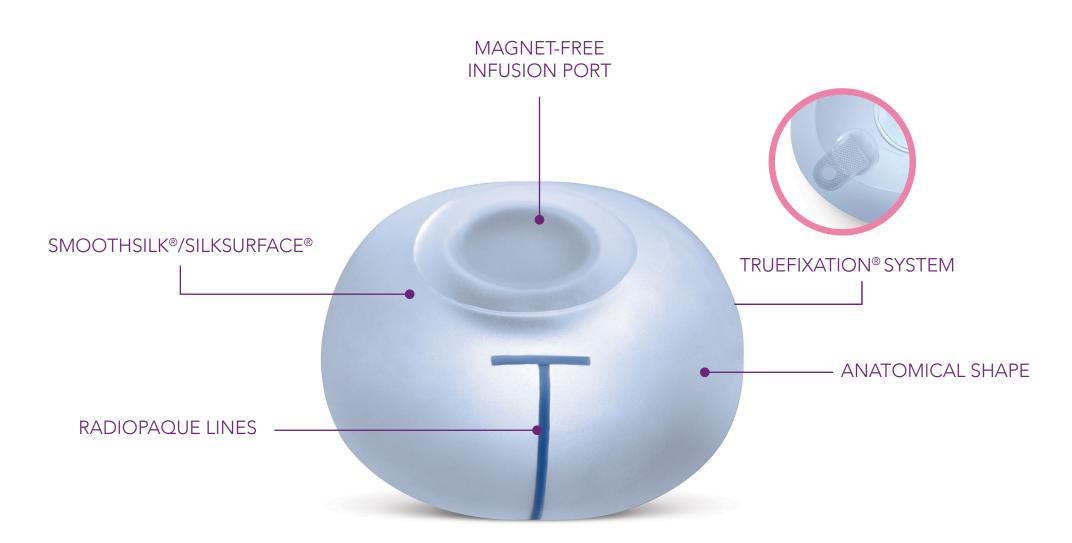
MOTIVA FLORRA® Tissue Expander

Enhancing the standard of care for women undergoing two-stage breast reconstruction



MOTIVA FLORA®

Tissue Expander



State-of-the-Art Technology

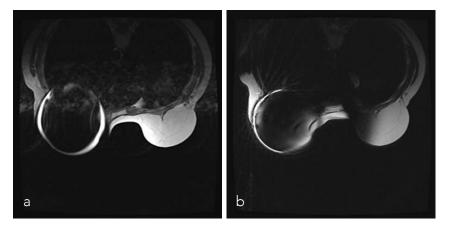
MRI compatible magnet-free port

The Motiva Flora[®] Tissue Expander is a first in class device equipped with an integrated Radiofrequency Identification (RFID) port.

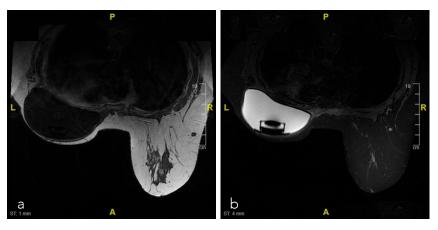
The air wound coil with RFID technology is embedded in the needle stop, and is activated externally to determine the precise location of the injection site through LED indicators on the Port Locator.

The RFID port has no magnets, allowing for MRI scanning during the expansion process.

Traditional tissue expanders have magnetic ports that create significant safety issues (valve dislodgement, burning sensation)¹, substantial signal loss, and distortion on MR images, and are thus labeled "MR Unsafe."



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



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

An Advanced Smooth Surface

Reduced inflammatory response



SmoothSilk[®] is a controlled, uniform, smooth breast implant surface with cellular-level dimensional features in its topography, and is manufactured with a one-step negative-imprint technology with no secondary process, such as salt-loss.

Textured surfaces are facing challenges due to rising safety concerns associated with their pro-inflammatory profile.

The safety and performance of smooth tissue expanders may reduce early post-operative complications^{2,3}.

The SmoothSilk[®] smooth surface (as classified per ISO 14607:2018) induces a lower degree of fibrosis compared to other surfaces⁴, including smooth, microtextured and macrotextured, creating a thin capsule around the device⁵; it does not promote tissue ingrowth⁶ and it minimizes silicone debris⁷.

With a low average roughness (~ 4 μ m) that is characterized by a predominance of peaks over valleys (positive skewness), this "nanosurface" possesses increased focal points that provide optimal adhesion for fibroblasts⁸. The SmoothSilk[®] advanced smooth surface has also been linked to lower bacterial attachment and biofilm formation than micro- and macrotextured surfaces^{9,10}.

This low inflammatory and fibrotic profile has translated into clinical benefits such as low capsular contracture rates and the absence of chronic inflammatory complications such as double capsules or late seromas¹¹⁻¹⁶.

Contrarily, tissue expanders with macrotextured surfaces promote severe capsular contracture development after replacement with a permanent implant¹⁷.

Low short-term complications associated with SmoothSilk[®] surface reported in peer-reviewed articles¹¹⁻¹⁶ and post-market surveillance¹⁸.

REPORTED COMPLICATION	RANGE
SEROMA	0 – 0.33 %
INFECTION	0-0.28 %
HEMATOMA	0 – 1 %

Shedding of particulate debris can be triggered by mild to moderate adhesion¹⁹. Silicone droplets were observed in the capsules of textured tissue expanders but not smooth tissue expanders²⁰.

Increased implant debris could result in increased pathogenic inflammation over time²¹.

Tabbed Tissue Expander

Designed for top results

TrueFixation[®] system

This system includes fixation tabs made from reinforced silicone that are sutured to the adjacent tissue, thereby improving breast symmetry²² and preventing possible displacement after surgery.

A reinforced silicone base

The base provides extra support and rigidness to the back of the tissue expander, promoting preferential lower pole expansion while maintaining base width throughout the expansion process.



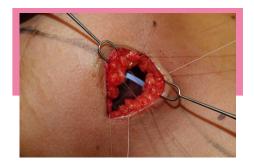
TrueMonobloc® Technology

The bonding of the patch to the shell is engineered to maintain the elasticity and integrity of the shell. Plan and Verify

Your treatment outcomes with peace of mind

Radiopaque lines for correct positioning verification

The Motiva Flora[®] Tissue Expander has orientation lines made from a radiopaque blue material that identify potential rotation after implantation during an X-ray procedure and aid in correct positioning of the device during implantation.



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

A MR Conditional* Device

Follow-up with full functional imaging capabilities is a critical component in the management of post-mastectomy cases.

Surgeons can now monitor possible complications using imaging tools with high sensitivity and specificity.

The Motiva Flora[®] Tissue Expander offers potential diagnostic advantages for patients undergoing MRI^{2,3}.

*A device that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use.



Expect Optimal Interaction

Integration with other systems

Tissue expanders with traditional magnetic ports generate distortion in Computerized Tomography (CT) images, leading to further difficulties in treatment planning^{24,25}.

The Motiva Flora[®] Tissue Expander minimizes artifacts in CT scans and is not affected by exposure to radiation doses up to 50 Gy²⁶.



Comparison of artifacts in a CT scan of a phantom with (left) Motiva Flora® Tissue Expander and (right) a tissue expander with ferromagnetic components.

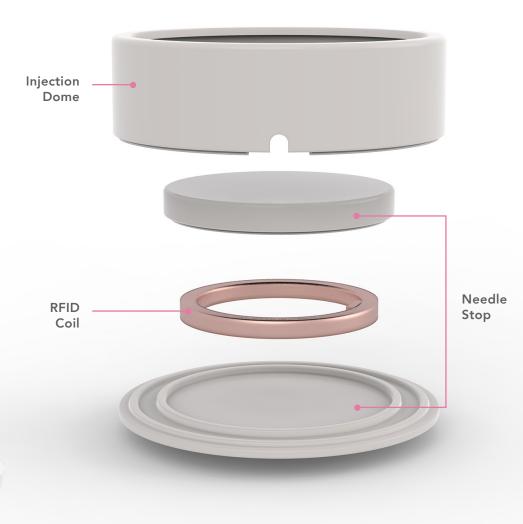
Extracted from Establishment Labs[®]. TS-18-039.R

Components

of the magnet-free integrated port

The Motiva Flora[®] Port Locator uses a radiofrequency identification (RFID) wireless system. It emits radio waves and receives signals back from the RFID coil located inside the needle stop to communicate its location.

The Motiva Flora[®] Tissue Expander contains a passive RFID transponder that provides an Electronic Serial Number (ESN) that is unique to each device. This ESN can be matched to a database of internal records for traceability of relevant information (serial and lot numbers, reference number, volume, size, projection, model, surface type, manufacturing date).



Motiva Flora® Tissue Expanders

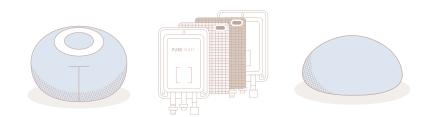
Various bases, heights, projections, and volumes for your specific needs



	Catalogue	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		995

Have You Thought of Hybrid Ergonomic Breast Reconstruction?

Motiva Flora[®] Tissue Expander + MotivaHybrid[®] + Ergonomix[®] implants



Innovative modern breast reconstruction technologies have greatly improved aesthetic satisfaction among surgeons and patients.

Fat grafting to the reconstructed breast can smoothen irregular contours of the transition areas in the native chest wall $^{\rm 27,28}$.

MotivaHybrid® surgery uses a closed-system design for a safer and sterile fat transfer processing.



Intraoperative breast silhouette with filled expander

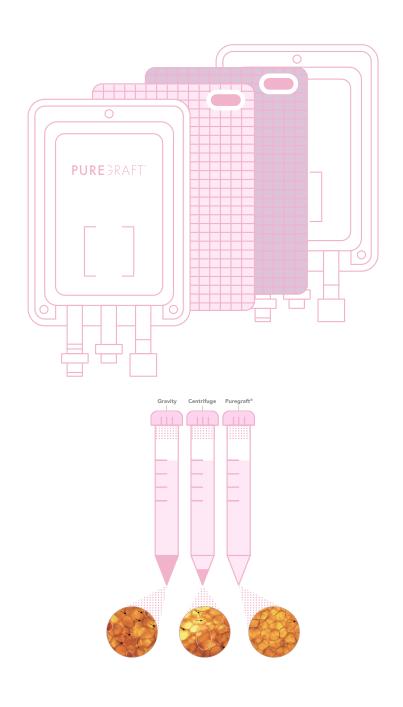
The MotivaHybrid[®] selective filtration technology was designed to dialyze fat tissue in a gentle and reproducible manner to preserve the regenerative properties of fat²⁹.

The reduction of contaminants such as blood, oil, and fluid during MotivaHybrid[®] fat grafting decreases inflammation, tissue damage, and safety risks³⁰, and increases accuracy, fat retention^{29,31}, and patient satisfaction^{30,32}.

A complete approach to reconstructing a natural-looking breast should include Ergonomix[®] implants.

Ergonomix[®] implants are widely used in the reconstructive field, offering a set of advantageous outcomes: attractive cleavage, dynamic lower pole fullness, and patients often claim a more genuine feeling²⁸.

Ergonomic implants adapt to the position and motion of the breast^{12, 28}, and are part of the discussion of future directions in the reconstructive field³³.



REFERENCES

1. Yitta S, Joe BN, Wisner DJ, Price ER, Hylton NM. Recognizing artifacts and optimizing breast MRI at 1.5 and 3 T. Am J Roentgenol. 2013;200(6):673-682. doi:10.2214/AJR.12.10013

2. Smooth Versus Textured Tissue Expanders in Breast Reconstruction Reduced Early Post-operative Complications Ruth Tevlin, MB BAO BCh , MRCS , MD , Nazerali , MD Socioeconomic Factors Affect The Treatment Of Mandibular Fractures Thomas Q . Xu, MD , Taylor. 2019:2019.

3. Fairchild B, Ellsworth W, Selber JC, et al. Safety and Efficacy of Smooth Surface Tissue Expander Breast Reconstruction. Aesthetic Surg J. 2018;(August). doi:10.1093/asj/sjy199

4. Cappellano G, Ploner C, Lobenwein S, et al. Immunophenotypic characterization of human T cells after in vitro exposure to different silicone breast implant surfaces. PLoS One. 2018;13(2):1-14. doi:10.1371/journal.pone.0192108

5. Nam S, Lee M, Shin BH, Elfeky B, Lee YU, Moon DH. Characterization of BellaGel SmoothFine ® Implant Surfaces and Correlation with Capsular Contracture. 2019:196-211.

doi:10.4236/jbnb.2019.104012

6. Atlan M, Nuti G, Wang H, Decker S, Perry TA. Breast implant surface texture impacts host tissue response. J Mech Behav Biomed Mater. 2018. doi:10.1016/j.jmbbm.2018.08.035

7. Hallab NJ, Samelko L, Hammond D. Particulate Debris Released From Breast Implant Surfaces Are Highly Dependent on Implant Type. Aesthetic Surg J. February 2021. doi:10.1093/asj/sjab051

8. Kyle DJT, Oikonomou A, Hill E, Bayat A. Development and functional evaluation of biomimetic silicone surfaces with hierarchical micro/nano-topographical features demonstrates favourable invitro foreign body response of breast-derived fibroblasts. Biomaterials. 2015;52(1):88-102.

doi:10.1016/j.biomaterials.2015.02.003

9. James GA, Boegli L, Hancock J, Bowersock L, Parker A, Kinney BM. Bacterial Adhesion and Biofilm Formation on Textured Breast Implant Shell Materials. Aesthetic Plast Surg. 2019;43(2):490-497. doi:10.1007/s00266-018-1234-7

10. Jones P, Mempin M, Hu H, et al. The Functional Influence of Breast Implant Outer Shell Morphology on Bacterial Attachment and Growth. Plast Reconstr Surg. 2018;142(4):837-849. doi:10.1097/PRS.000000000004801

11. Sforza M, Zaccheddu R, Alleruzzo A, et al. Preliminary 3-Year Evaluation of Experience with SilkSurface and VelvetSurface Motiva Silicone Breast Implants: A Single-Center Experience with 5813 Consecutive Breast Augmentation Cases. Aesthetic Surg J. 2018;38:S62-S73. doi:10.1093/asj/sjx150

12. Huemer GM, Wenny R, Aitzetmüller MM, Duscher D. Motiva ergonomix round silksurface silicone breast implants: Outcome analysis of 100 primary breast augmentations over 3 years and technical considerations. Plast Reconstr Surg. 2018;141(6):831e-842e. doi:10.1097/PRS.00000000004367

13. Quirós MC, Bolaños MC, Fassero JJ. Six-year prospective outcomes of primary breast augmentation with nano surface implants. Aesthetic Surg J. 2019;39(5):495-508. doi:10.1093/asj/sjy196 14. Sim HB. Revisiting Prepectoral Breast Augmentation: Indications and Refinements. Aesthetic Surg J. 2019;39(5):NP113-NP122. doi:10.1093/asj/sjy294

15. D'Onofrio C. Subfascial Breast Augmentation with Crossed Fascial Sling, Under Tumescent Anaesthesia With or Without Sedation and Lower Periareolar Access. Aesthetic Plast Surg. 2020. doi:10.1007/s00266-020-01723-0

16. Rigo MH, Piccinini PS, Sartori LDP, de Carvalho LAR, Uebel CO. SMS—Split Muscle Support: A Reproducible Approach for Breast Implant Stabilization. Aesthetic Plast Surg. 2020;44(3):698-705. doi:10.1007/s00266-019-01565-5 17. Lee K-T, Park HY, Jeon B-J, Mun G-H, Bang SI, Pyon JK. Does the Textured-type Tissue Expander Affect the Outcomes of Two-stage Prosthetic Breast Reconstruction? A Propensity Score Matching Analysis between Macro- and Microtextured Expanders. Plast Reconstr Surg. 9000;PRS Online First. https://journals.lww.com/plasreconsurg/Fulltext/9000

Does_the_Textured_type_Tissue_Expander_Affect_the.96606.aspx.

18. Establishment Labs. Post-Market Surveillance Report Q4. December 2020

19. Webb LH, Aime VL, Do A, Mossman K, Mahabir RC. Textured breast implants: A closer look at the surface debris under the microscope. Plast Surg. 2017;25(3):179-183. doi:10.1177/2292550317716127 20. Thuesen B, Siim E, Christensen L, Schrøder M. Capsular contracture after breast reconstruction with

the tissue expansion technique: A comparison of smooth and textured silicone breast prostheses. Scand J Plast Reconstr Surg Hand Surg. 1995;29(1):9-13. doi:10.3109/02844319509048417

21. Hallab NJ, Samelko L, Hammond D. The Inflammatory Effects of Breast Implant Particulate Shedding: Comparison with Orthopedic Implants. Aesthetic Surg J. 2019;39:S36-S48. doi:10.1093/asj/sjy335

22. 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

23. Bayasgalan M, Munhoz AM, Shellock FG. Breast Tissue Expander With Radiofrequency Identification Port: Assessment of MRI Issues. Am J Roentgenol. 2020;(July):1-6. doi:10.2214/a-jr.19.22492

24. Gee HE, Bignell F, Odgers D, et al. In vivo dosimetric impact of breast tissue expanders on post-mastectomy radiotherapy. J Med Imaging Radiat Oncol. 2016;60(1):138-145. doi:10.1111/1754-9485.12403

25. Damast S, Beal K, Ballangrud Å, et al. Do metallic ports in tissue expanders affect postmastectomy radiation delivery? Int J Radiat Oncol Biol Phys. 2006;66(1):305-310. doi:10.1016/j.ijrobp.2006.05.017

26. Establishment Labs. TS-18-042.R Effect of Radiation on Mechanical and Functional Properties of Motiva Flora Tissue Expander

27. Katzel EB, Bucky LP. Fat grafting to the breast: Clinical applications and outcomes for reconstructive surgery. Plast Reconstr Surg. 2017;140(5S):69S-76S. doi:10.1097/PRS.000000000003945 28. Stillaert FBJL. The Prepectoral , Hybrid Breast Reconstruction : The Synergy of Lipofilling and Breast Implants. :1-10. doi:10.1097/GOX.00000000002966

29. Zhu M, Cohen SR, Hicok KC, et al. Comparison of three different fat graft preparation methods: Gravity separation, centrifugation, and simultaneous washing with filtration in a closed system. Plast Reconstr Surg. 2013;131(4):873-880. doi:10.1097/PRS.0b013e31828276e9

30. Mestak O, Sukop A, Hsueh YS, et al. Centrifugation versus PureGraft for fatgrafting to the breast after breast-conserving therapy. World J Surg Oncol. 2014;12(1):1-8. doi:10.1186/1477-7819-12-178

31. Gerth DJ, King B, Rabach L, Glasgold RA, Glasgold MJ. Long-term volumetric retention of autologous fat grafting processed with closed-membrane filtration. Aesthet Surg J. 2014;34(7):985-994. doi:10.1177/1090820X14542649

32. Sforza M, Andjelkov K, Zaccheddu R, Husein R, Atkinson C. A preliminary assessment of the predictability of fat grafting to correct silicone breast implant-related complications. Aesthetic Surg J. 2016;36(8):886-894. doi:10.1093/asj/sjw060

33. Unger JG, Keller PR. Tradeoffs in Implant Selection for Reconstructive Surgery and Adjuncts Utilized to Maximize Aesthetic Outcomes. Plast Reconstr Surg. 2019;144(1S Utilizing a Spectrum of Cohesive Implants in Aesthetic and Reconstructive Breast Surgery):51S-59S. doi:10.1097/PRS.000000000005950

Intra-operative images courtesy of Dr Filip Stillaert. MRI images courtesy of Dr. Luis Picard-Ami

A Motiva® Partnership

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

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.



MotivaEDGE®

A global platform exclusively dedicated to educating plastic surgeons on the latest technological innovation and techniques in the field.



A digital platform designed to help

patients find top Motiva® surgeons in the

world and connect with them easily.

MotivaEDGE® Global Webinars

A webinar series created as part of our mandate to help 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 relevant channels.

Learn more here:



Center Locator

Motiva Flora Tissue Expander