

**MOTIVATED BY
FEMTECH INNOVATION IN
BREAST HEALTH AND AESTHETICS**

MOTIVATED BY WOMEN'S HEALTH.

Motiva® by Establishment Labs® is a first-of-its-kind medical technology company focused on breast aesthetics and reconstruction, bringing Femtech innovations for women's health and wellbeing.

DRIVEN BY FEMTECH

Two decades ago, Motiva® by Establishment Labs® changed the industry paradigm by putting women's health first. With innovation, safety, and technology, we started a revolution in the Femtech sphere by creating a new space for women's unmet needs within breast aesthetics and reconstruction. The main goal: to create Femtech solutions that heal, normalize and democratize breast health and aesthetics.

MOTIVA® BY ESTABLISHMENT LABS®

14+ YEARS OF GLOBAL INNOVATION¹

~4M DEVICES

Motiva® devices* in market worldwide since 2010

86+ COUNTRIES

Establishment Labs® devices* have been approved

210+ PATENTS

Applications approved/pending in 21 jurisdictions

140+ PUBLICATIONS

Support science-based research

Actual Motiva® Patient



* Nearly 4 million devices in market. This includes breast implants and breast tissue expanders worldwide.

MOTIVATED BY NEXT-LEVEL INNOVATION

SmoothSilk®

A 4-micron surface,² shown to promote low inflammation,² low friction,³ and low bacterial attachment.^{4,5}

TrueMonobloc®

Unifies the shell, patch, and gel into one single structure.⁶

BluSeal®

A visual indicator of the barrier layer that confirms the integrity of the implant for quality assurance and patient safety.^{7,8}

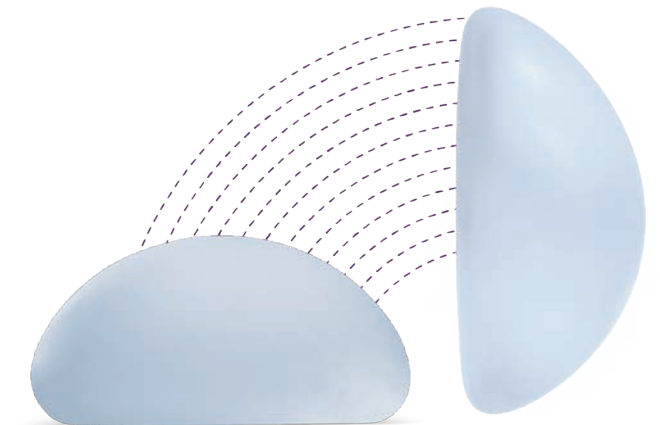
Highly Viscoelastic ProgressiveGel®

100% filled implants consisting of a 6th generation viscoelastic and highly cohesive silicone-gel.⁹⁻¹¹

MOTIVA SMOOTHSILK® IMPLANTS

Motiva SmoothSilk® Round

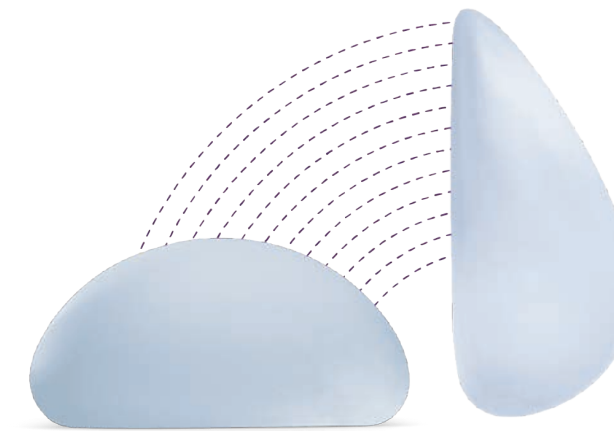
Combines the SmoothSilk® 4-micron surface, TrueMonobloc®, BluSeal® and is filled 100% with ProgressiveGel® PLUS for increased upper pole fullness and softness.¹⁰



Motiva SmoothSilk Ergonomix®

Combines the SmoothSilk® 4-micron surface, TrueMonobloc®, BluSeal® and is 100% filled with ProgressiveGel® ULTIMA®. The Motiva SmoothSilk Ergonomix® device is designed to mimic the look, feel, and movement of a natural breast.^{9,11}

The unique composition of this implant allows insertion through smaller* incisions.¹²

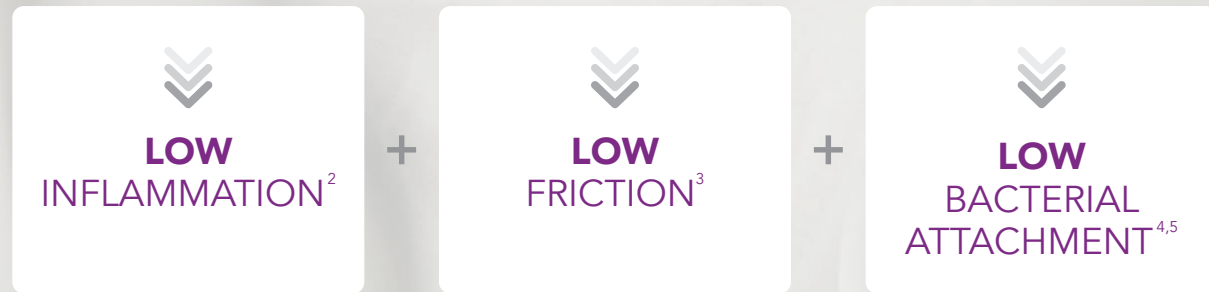


*As compared to SmoothSilk® Round Implant.

MOTIVATED BY BREAKTHROUGH SCIENCE THAT STARTS AT THE SURFACE

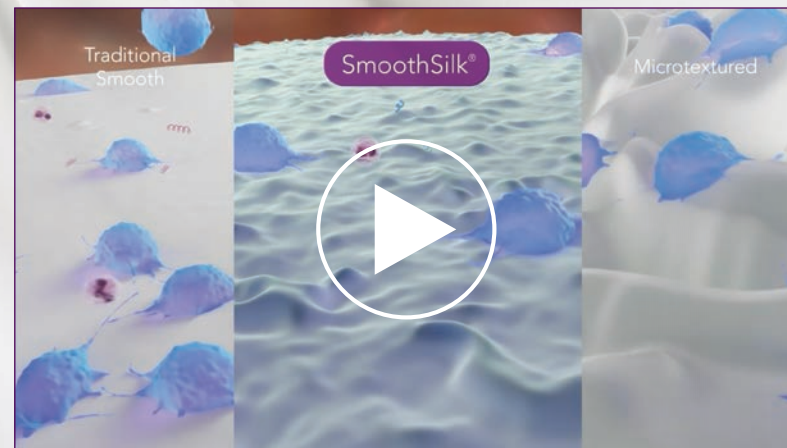
SmoothSilk® is a biocompatible 4-micron surface² designed to optimize the body's immune response.

This proprietary SmoothSilk® surface is scientifically shown to promote:



Resulting in soft breasts, low capsular contracture rates,^{8,13} and no reported primary device-related proliferative diseases (BIA-ALCL, BIA-SCC and B-cell lymphomas).¹

All commercially available breast implants are biocompatible by industry and regulatory standards*. Motiva®'s 4-micron SmoothSilk® surface was specifically engineered to enhance biocompatibility and scientifically shown to promote the least amount** of inflammation and foreign body response.²

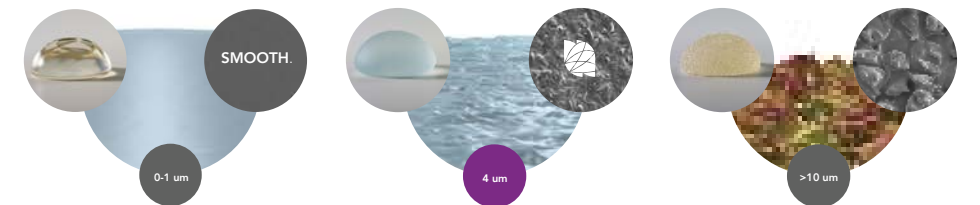
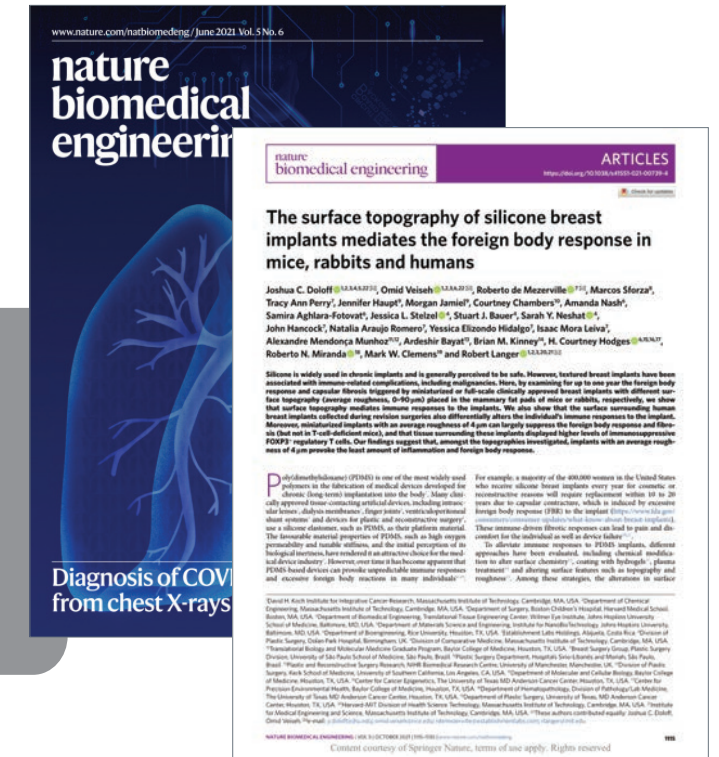


Scan to understand the SmoothSilk® surface architecture.

The surface topography of silicone breast implants mediates the foreign body response in mice, rabbits and humans

Our findings suggest that implants with an average roughness of 4 microns provoke the least amount of inflammation and foreign body response among the surfaces studied²

– Doloff et al. 2021 –



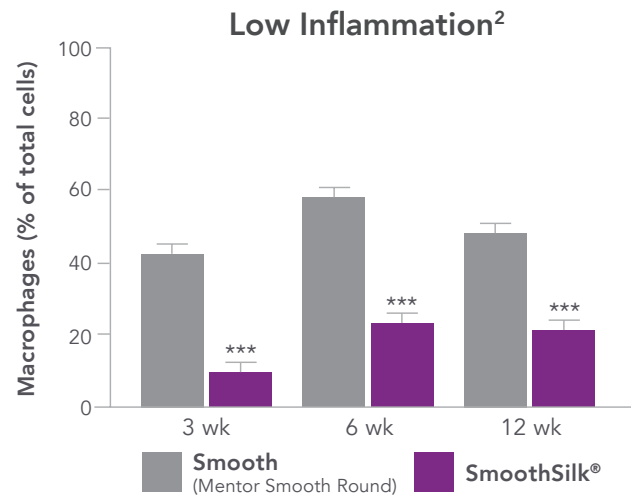
Variable	Traditional Smooth	SmoothSilk®	Textured
Sa (average roughness) ^{2,14}	<1 µm	4 µm	> 10 µm
Surface Area ¹⁵	80-100mm ²	80-100mm ²	> 100mm ²
Inflammatory ²	+++	+	+++
Frictional Shear Stresses ³	+	+	++/+++
Particulate Shedding ¹⁶	+	+	++/+++
Bacterial Attachment and Biofilm Formation ^{4,5}	+	+	++/+++
Tissue Ingrowth ²	No	No	Yes

+: Low, ++: Moderate, +++: High

* According to the International Standard ISO 10993-1:2018 and to the Saline, Silicone Gel, and Alternative Breast Implants Guidance for Industry and Food and Drug Administration Staff, September 29, 2020

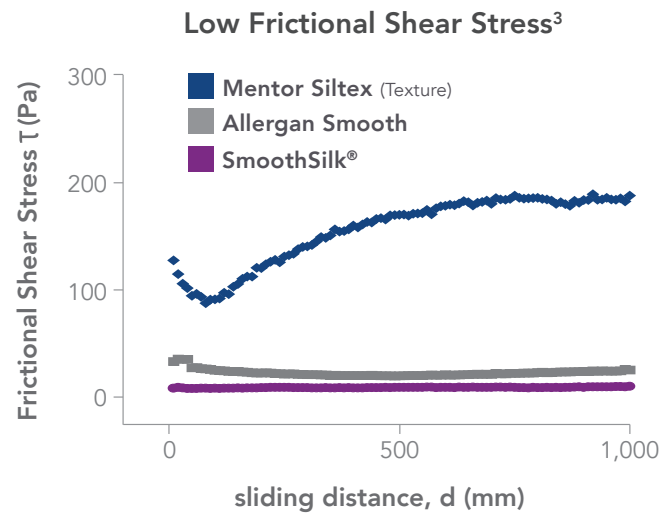
** Surfaces studied included the following competitors implants: Mentor Smooth Round, Mentor MemoryGel, Allergan Microcell and Allergan Biocell

KEY CHARACTERISTICS OF THE SMOOTHSILK® SURFACE

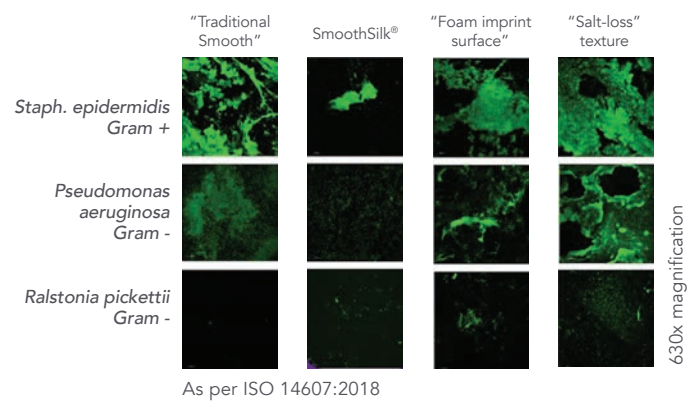


- Optimal early immune response*
- Lower shift in fibroblast cell response*
- Reduced RNA expression of inflammatory cytokines, with higher expression of anti-inflammatory cytokines and immunoinhibitory regulatory T-cells.**

SmoothSilk® and traditional smooth silicone breast implants result in low frictional shear stresses, resulting in no visible damage to breast epithelial cells, potentially reducing the risk of implant-related proliferative diseases.***



Low Bacterial Attachment^{4,5}



As a 4-micron surface, SmoothSilk® implants belong to a "Surface Type 1" group characterized by having minimal surface area, minimal roughness, and lower bacterial load, as compared to traditional smooth and textured surfaces.***

Clinically reduces the risk of chronic complications.^{4,5}

MOTIVATED BY UNMATCHED GEL-SHELL INTEGRATION

A SHELL FOR EVERY GEL.

TrueMonobloc® is the next-generation technology that unifies the shell, patch, and gel into one single structure.⁶

Each Motiva Implant® is specifically designed with a unique shell that perfectly matches each gel for maximum gel-shell integration, adaptability, and dynamics.

TrueMonobloc® allows small incisions¹², implant softness¹⁷, and promotes low device-related complications such as capsular contracture^{8,13}, and rippling.⁸

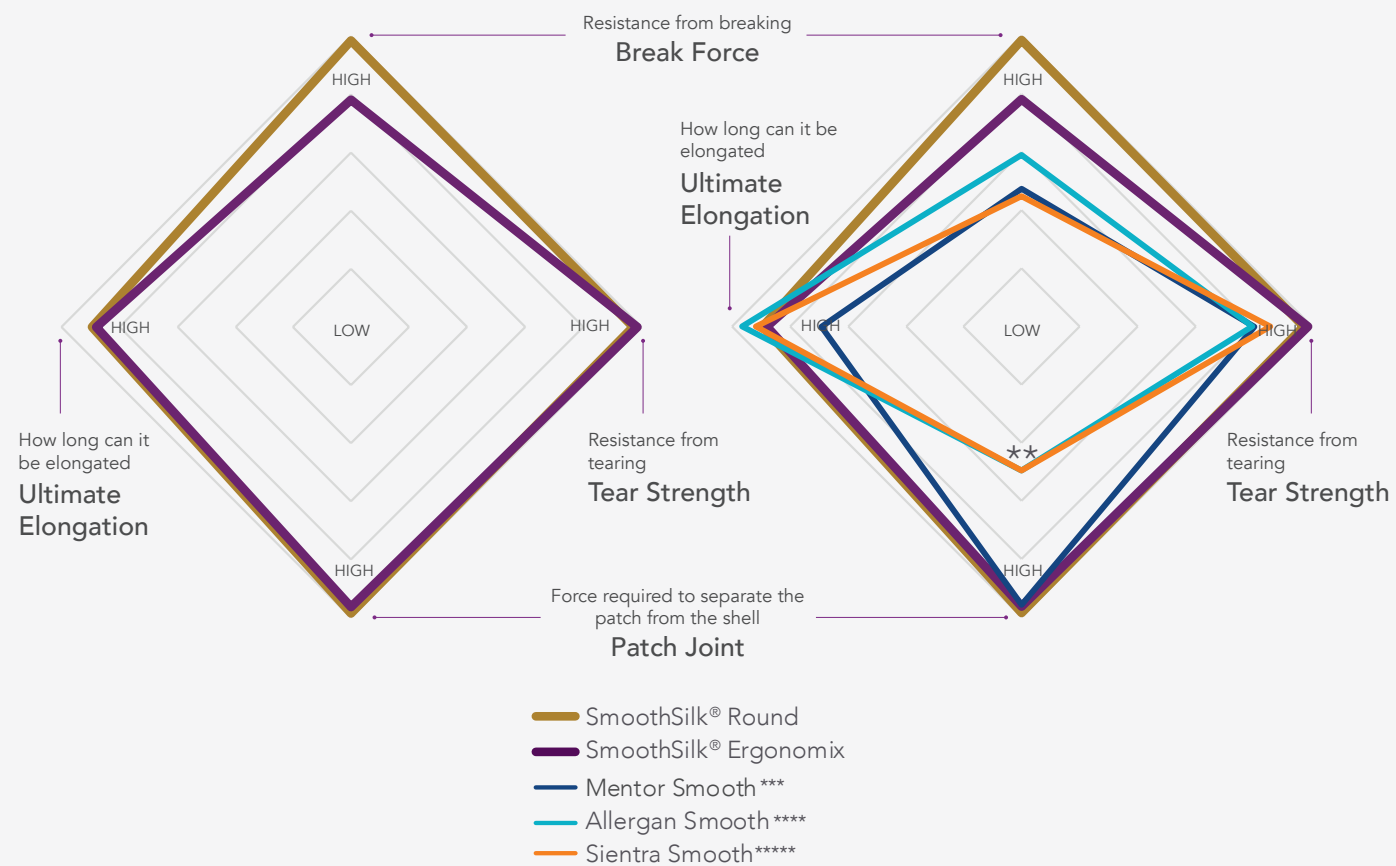


The Motiva Ergonomix® device was designed to adapt, react, feel, and behave like native breast tissue embodying the science of ergonomics.

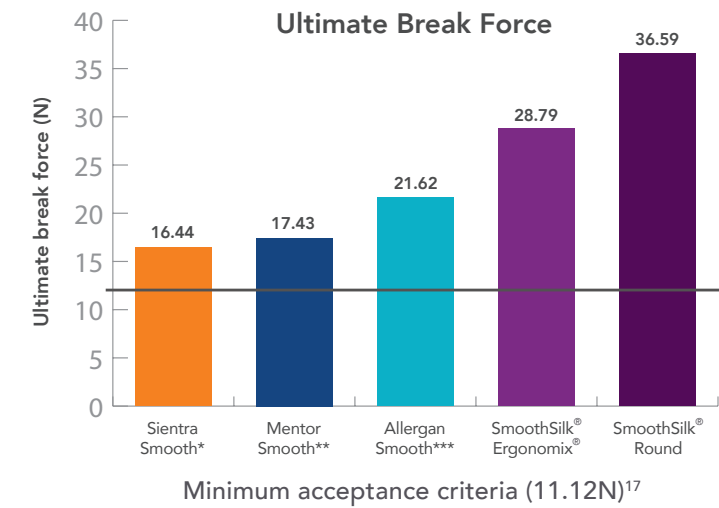
These unique characteristics are made possible by the rheological properties TrueMonobloc® and the ProgressiveGel ULTIMA® provide, allowing the implant to resemble the anatomy and dynamics of native breast tissue. Motiva Ergonomix® has a round base and is able to adapt based on gravitational shifts without the need to underfill the device.

TRUEMONOBLOC® ALLOWS MOTIVA IMPLANT® SHELLS TO EXCEED STANDARDS* IN DEVICE INTEGRITY BY OPTIMIZING IMPLANT DYNAMICS, WITHOUT COMPROMISING SHAPE.

Break force, elongation, tear strength, and patch joint are mechanical properties that secure implant integrity and are designed to allow for smaller incisions and to improve patient safety.¹⁷

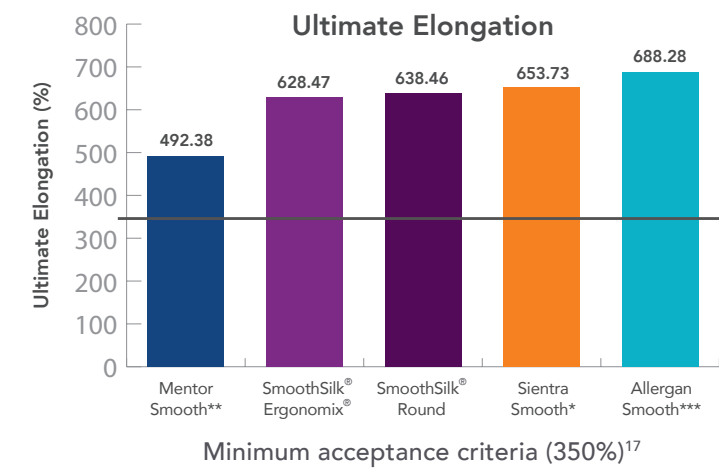


The shell of SmoothSilk® Round and Ergonomix® implants exhibit improved mechanical properties like resistance from breakage and tearing while maintaining appropriate elongation.¹⁷



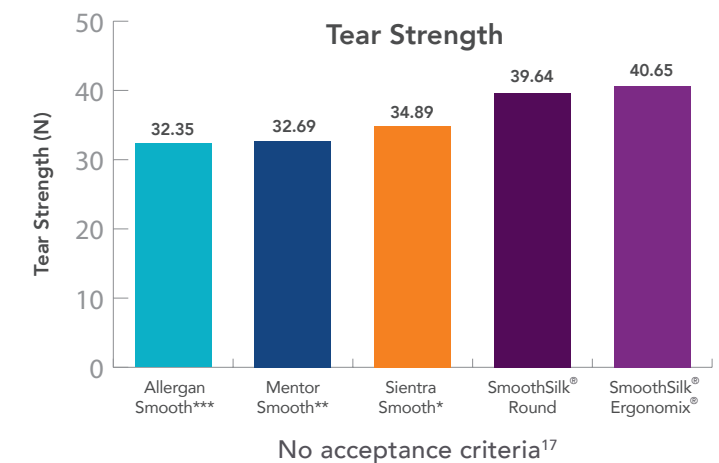
Ultimate Break Force: the ability to sustain large forces or impacts, resistance of the shell from breaking apart¹⁷

- Designed to improve patient safety by resisting internal and external damage from sustained forces.



Ultimate Elongation: shell elasticity measured by elongation length¹⁷

- Allowing for small incisions.



Tear Strength: the amount of force needed to extend a pre-existing tear¹⁷

- Providing shell integrity in the event of iatrogenic occurrence.

* ASTM F703
 ** At least one unit of Allergan and Sientra failed to meet the acceptance criteria for Patch Joint test. The sample failed to elongate to 300%. Bench-testing study conducted by Establishment Labs®.
 *** Mentor MemoryGel and Mentor Memory Gel Xtra
 **** Natrelle Inspira Cohesive®, Natrelle Inspira®, and Natrelle Inspira® SoftTouch
 ***** Sientra HSC and HSC+.

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 ** Mentor MemoryGel and Mentor Memory Gel Xtra
 *** Natrelle Inspira Cohesive®, Natrelle Inspira®, and Natrelle Inspira® SoftTouch

MOTIVATED BY UNCOMPROMISED SOFTNESS, SHAPE AND DYNAMICS

Motiva Implants® are 100% filled with the latest, 6th generation gel that is both highly cohesive and viscoelastic.

THIS GEL COMPOSITION IS DESIGNED FOR¹⁸

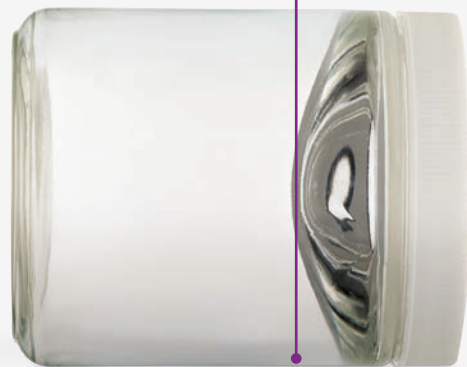
LESS FOLDS

LESS FRICTION

LOWER RISK OF RUPTURE

Motiva Implants® come in 2 different gel rheologies creating a distinct TrueMonobloc® for each implant type

Retains shape regardless of movement.



**ProgressiveGel PLUS®
SmoothSilk® Round**

A gel with balanced rheological properties that allow higher firmness while maintaining an equivalent volume distribution throughout the implant.^{8,9,19}

Viscoelasticity

LOW MEDIUM HIGH

Cohesiveness

LOW MEDIUM HIGH

Follows ergonomic principles by adapting to gravitational changes in movement.



**ProgressiveGel ULTIMA®
SmoothSilk Ergonomix®**

With unique rheological properties - low viscosity and high elasticity. This enables enhanced adaptability and responsiveness, resulting in soft consistency and gravitational shifting.^{8,9,19}

Viscoelasticity

LOW MEDIUM HIGH

Cohesiveness

LOW MEDIUM HIGH

EACH MOTIVA IMPLANT® PROVIDES DISTINCT AESTHETIC OUTCOMES^{10,11}, WHILE MAINTAINING SOFTNESS AND ADAPTABILITY

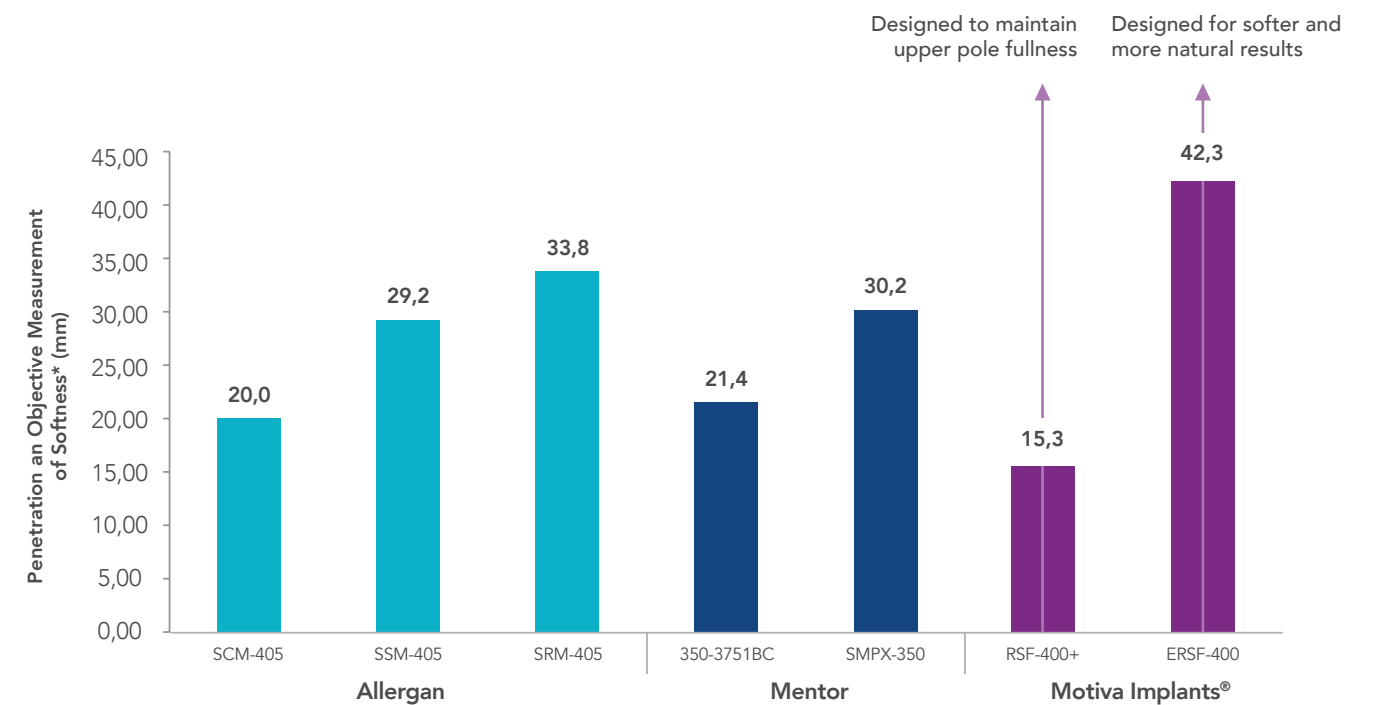
TrueMonobloc® - SmoothSilk® Round

Designed to optimize upper pole fullness¹⁰, the TrueMonobloc® used for SmoothSilk® Round allows for a firm shell and gel interaction, which is needed to maintain its shape.^{17,19}

TrueMonobloc® - SmoothSilk Ergonomix®

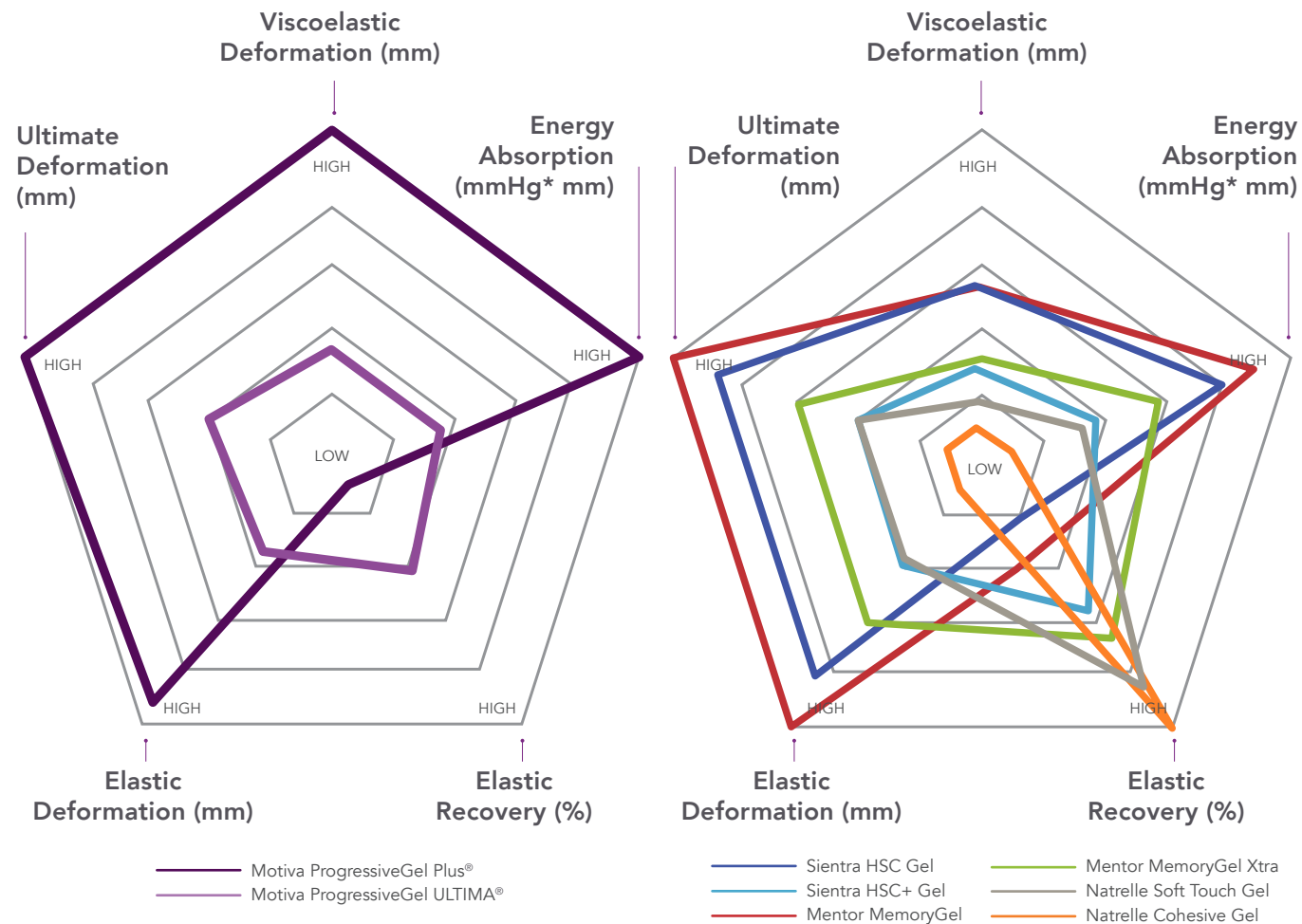
Designed to optimize softness¹¹ and movement, the TrueMonobloc® used for SmoothSilk Ergonomix® has a more flexible shell and gel interaction, therefore more adaptability and softness.^{17,19}

Penetration an Objective Measurement of Softness*



*Bench-testing study developed by Establishment Labs®.

PROGRESSIVEGEL PLUS® DESIGNED TO PROVIDE UPPER POLE FULLNESS AND PROGRESSIVEGEL ULTIMA® DESIGNED FOR A NATURAL LOOK AND FEEL.



Viscoelastic Deformation

LOW ↓	HIGH ↑
A lower elastic and viscoelastic deformation exhibit of a maintained upper pole fullness despite movement or postural changes. ^{9*}	A higher elastic and viscoelastic deformation exhibit of a steady response to movement or postural changes. ^{9*}

Energy Absorption

LOW ↓	HIGH ↑
Implant shape changes occur slower due to a low energy absorption. ^{9*}	Changes occur easily due to a greater energy absorption. ^{9*}

Elastic Recovery

LOW ↓	HIGH ↑
Balanced elastic recovery correlates with gel rigidity. ^{9*}	Lower elastic recovery correlates with lower gel rigidity. ^{9*}

MOTIVATED BY SAFETY^{7,8} YOU CAN SEE

Barrier layers are crucial in breast implant shells and are designed to reduce the risk of patient exposure to low-weight molecular siloxanes.⁷ BluSeal® provides a visual indicator of the barrier layer that confirms the integrity of the external and internal components of the implant for quality assurance and patient safety.^{7,8}



All Motiva Implants® are 100% covered with a biocompatible blue visual indicator.^{10,11}

MOTIVATED BY UNMATCHED SAFETY AND SATISFACTION

Motiva® 4-year Key Complication Rates (Kaplan-Meier, KM) Including MRI Cohort**

PRIMARY AUGMENTATION	2-YEAR (N=451) 95% CI ²⁰	3-YEAR (N=451) 95% CI ²¹	4-YEAR (N=451) 95% CI ¹³
Capsular contracture (Baker Grade III/IV)	0.5%	0.5%	0.5%
Rupture, suspected or confirmed (MRI Cohort) ¹	0.6%	0.6%	0.6%
Breast pain	0.5%	0.7%	0.9%
Infection	0.9%	0.9%	0.9%
Implant removal, with or without replacement	1.6%	1.6%	1.8%
Any reoperation ²	5.7%	6.1%	6.8%
Any complication ³	7.5%	8.4%	9.6%

1. MRI cohort, N=176
 2. Any surgery on the breast or chest area, device or non-device related, including size change
 3. Any device or non-device related event, including reoperation

88.9%
 The office visit follow-up rate at 4-years was at 88.9%.¹³

97.1%
 of the patients were satisfied with their results.^{22*}

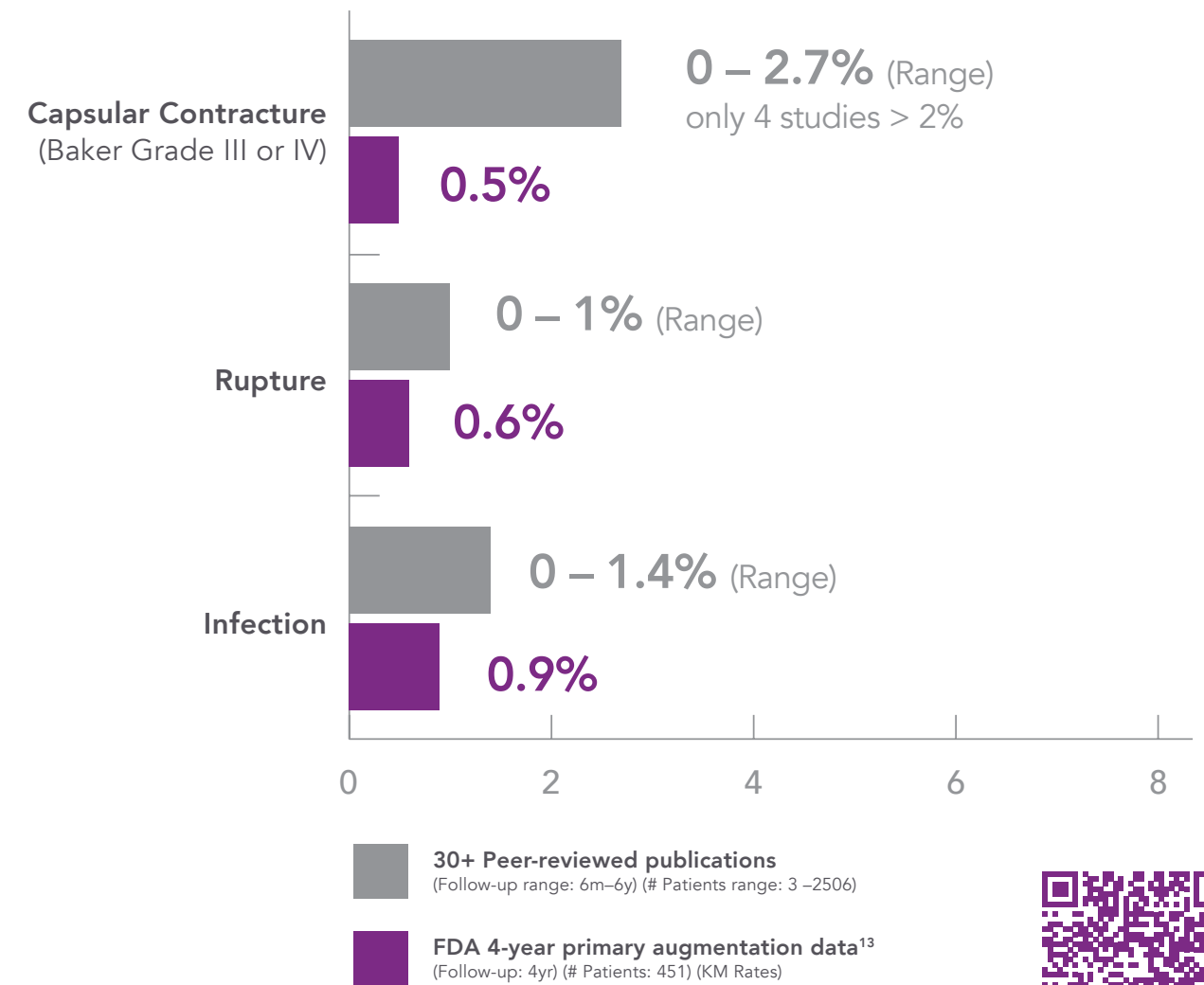
99.0%
 of the surgeons were satisfied with their results.^{22*}

3.2%
 malposition complication rate (KM) at 3-year follow-up²²

“
 The consistency in these clinical results at four years is notable. Since we released the two-year data, we have seen no increase in capsular contracture or in number of patients with suspected or confirmed rupture, including the MRI cohort. Relative to historic benchmarks, patient follow-up remains very high and the rates of complication remain very low.
 – Caroline Glicksman, MD, FACS –
 ”

14+ YEARS OF CONSISTENTLY LOW DEVICE-RELATED COMPLICATION RATES GLOBALLY

- Low complication rates have been demonstrated over the last 14+ years worldwide, as shown in post market surveillance and national implant registries.¹
- The low complication rates shown worldwide are backed by 140 publications. Evidence-based outcomes⁸ are consistent with the low complication rates reported in the Motiva Implants® ongoing FDA IDE study.^{13,20,21}



Scan this QR code to access the 30+ peer-reviewed publications list.

* Based on the 5-point Likert Scale. The office-visit follow-up rate at 3-years follow-up was of 92.7%.
 ** All data presented is preliminary 2, 3, and 4 year follow-up data and does not reflect the final study results nor establish the ultimate safety or effectiveness of the device.

A HEALTH PROGRAM EXCEEDING INDUSTRY NORMS

Because your safety and peace of mind are always our priority, the Motiva® Health Program isn't just a warranty, it's a program designed to complement your breast health journey.



Scan QR code to learn more about our breast health program options

Motiva® Health Program – Complimentary*

LIFETIME

- FREE implant replacement for rupture & \$3,500 financial assistance (10 yr)
- FREE implant replacement BIA-ALCL & \$7,500 financial assistance

10 YEAR

- FREE implant replacement for complications of capsular contracture (Baker Grade III/IV) & \$2,000 financial assistance
- FREE implant replacement for late forming seroma and double capsule

Motiva® Health Program Plus – \$250**

LIFETIME

- FREE implant replacement for late forming seroma and double capsule & \$3,500 financial assistance (2 yr)
- FREE implant replacement for rupture & \$5,000 financial assistance (10 yr)
- FREE implant replacement BIA-ALCL & \$15,000 financial assistance*** (10 yr)

10 YEAR

- FREE implant replacement for complications of capsular contracture (Baker Grade III/IV) & \$2,500 (5 yr)

FEMTECH FREEDOM

We are excited for you to experience the benefits of your Motiva Implants® and are confident you'll love them. Your satisfaction is important to us, so as part of the Motiva® Health Program Plus, if you find that implants aren't the perfect fit for you, we are proud to offer an additional program credit of up to \$2,500 for up to 2 years towards your explant procedure.

MOTIVATED BY A COMMITMENT TO WOMEN'S HEALTH.

	MOTIVA® HEALTH PROGRAM ^{1*}	MOTIVA® HEALTH PROGRAM PLUS ^{1**}	Allergan ConfidencePlus ²	MENTOR Promise ³	MENTOR Promise ³ Enhanced ³	Sientra Platinum 20 ⁴
Surgery Date As of	9/26/2024	9/26/2024	5/1/2020	1/1/2021	1/1/2021	5/1/2018
Cost	Free	\$250 for Round and Ergonomix ⁵	Free	Free	\$300	Free
RUPTURE						
Implant Replacement	Lifetime	Lifetime	Lifetime	Lifetime	Lifetime	Lifetime
Contralateral Implant Replacement	✓	✓	✓	✓	✓	✓
Financial Assistance	\$3,500 – 10 YR	\$5,000 – 10 YR	\$3,500 – 10 YR	\$3,500 – 10 YR	\$3,500 – 10 YR	\$5,000 – 20 YR
CAPSULAR CONTRACTURE (BAKER GRADE III OR IV)						
Implant Replacement	10 Years	10 Years	10 Years	10 Years	10 Years	20 Years
Contralateral Implant Replacement	✓	✓	✓	✓	✓	✓
Financial Assistance	\$2,000 – 2 YR	\$2,500 – 5 YR	\$2,000 – 2 YR	\$2,000 – 2 YR	\$3,500 – 10 YR	\$2,000 – 2 YR
Primary Augmentation	✓	✓	✓	✓	✓	✓
Revision Augmentation	✓	\$2,500 – 2 YR	✓	✓	✓	✓
LATE FORMING SEROMA						
Implant Replacement	10 Years	Lifetime	20 Years	10 Years	10 Years	20 Years
Contralateral Implant Replacement	✓	✓	✓	✓	✓	✓
Financial Assistance	\$0	\$2,000 – 2 YR	\$0	\$0	\$3,500 – 10 YR	\$2,000 – 2 YR
Primary Augmentation	✓	✓	✓	✓	✓	✓
Revision Augmentation	✓	✓	✓	✓	✓	✓
DOUBLE CAPSULE						
Implant Replacement	10 Years	Lifetime		10 Years	10 Years	20 Years
Contralateral Implant Replacement	✓	✓		✓	✓	✓
Financial Assistance	\$0	\$3,500 – 2 YR		\$0	\$3,500 – 10 YR	\$2,000 – 2 YR
Primary Augmentation	✓	✓		✓	✓	✓
Revision Augmentation	✓	✓		✓	✓	✓
BIA-ALCL						
CD30 Panel Testing/ Late Seroma	✓	✓	✓			✓
Implant Replacement	Lifetime	Lifetime	✓	✓	✓	20 Years
Financial Assistance ⁵	\$7,500	Up to \$15,000 – 10 YR ^{***}	\$7,500	\$7,500	\$7,500	\$7,500 – 20 YR
Contralateral Replacement	✓	✓	✓	✓	✓	✓
FEMTECH FREEDOM^{****}						
Implant Explant	\$0	\$2,500 – 2 YR	\$0	\$0	\$0	\$0

* It is recommended that all patients should register within 90 days of surgery. Subject to the full program Ts & Cs at www.motivausa.com

** Registration and payment will be required to be eligible for the Motiva® Health Program Plus. Subject to the full program Ts & Cs at www.motivausa.com

*** Coverage will be \$7,500 after 10 years

**** Subject to the full program Ts & Cs at www.motivausa.com




1. Motiva® USA LLC. Motiva® Health Program and Motiva® Health Program Plus Warranty Program. 2024 2. Allergan, Inc. The natrelle confidenceplus warranty program. Allergan; May 2020. 3. Mentor Worldwide LLC. Mentorpromise and mentorpromise enhanced protection plan for memorygel breast implants and memoryshape breast implants terms and conditions. Mentor Corporation; 2021. 4. Sientra, Inc. Sientra Platinum20 warranty program. Sientra; May 2018. 5. For financial assistance of uninsured patients, please see the BIA-ALCL Patient Assistance Fund Application at <https://www.aserf.org/images/documents/bia-alcl-patient-fund-grant-request-form.pdf>.




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MOTIVATED BY THE PERFECT SET

Motiva SmoothSilk® Round									
	MINI 			DEMI 			FULL 		
$\overset{\circ}{\sim}A\sim$ (cm)	Catalog #	$\overset{\circ}{\sim}B\sim$ (cm)	V (cc)	Catalog #	$\overset{\circ}{\sim}B\sim$ (cm)	V (cc)	Catalog #	$\overset{\circ}{\sim}B\sim$ (cm)	V (cc)
10.0				RSD-205	3.5	205			
10.25				RSD-215	3.5	215	RSF-255	4.2	255
10.5				RSD-230	3.6	230	RSF-275	4.3	275
10.75				RSD-245	3.7	245	RSF-295	4.4	295
11.0				RSD-265	3.8	265	RSF-315	4.5	315
11.25				RSD-285	3.8	285	RSF-335	4.6	335
11.5	RSM-245	2.8	245	RSD-300	3.9	300	RSF-355	4.7	355
11.75	RSM-260	2.8	260	RSD-320	3.9	320	RSF-375	4.8	375
12.0	RSM-275	2.9	275	RSD-340	4.0	340	RSF-400	4.9	400
12.25	RSM-290	2.9	290	RSD-360	4.0	360	RSF-425	5.0	425
12.5	RSM-310	3.0	310	RSD-380	4.1	380	RSF-450	5.1	450
13.0	RSM-360	3.1	360	RSD-425	4.3	425	RSF-500	5.3	500
13.5	RSM-400	3.2	400	RSD-475	4.4	475	RSF-550	5.5	550
14.0				RSD-525	4.5	525	RSF-625	5.7	625

Motiva SmoothSilk Ergonomix®									
	MINI 			DEMI 			FULL 		
$\overset{\circ}{\sim}A\sim$ (cm)	Catalog #	$\overset{\circ}{\sim}B\sim$ (cm)	V (cc)	Catalog #	$\overset{\circ}{\sim}B\sim$ (cm)	V (cc)	Catalog #	$\overset{\circ}{\sim}B\sim$ (cm)	V (cc)
9.0				ERSD-155	3.3	155			
9.5				ERSD-180	3.4	180			
9.75	ERSM-150	2.4	150	ERSD-190	3.4	190			
10.0	ERSM-160	2.5	160	ERSD-205	3.5	205			
10.25	ERSM-170	2.5	170	ERSD-215	3.5	215	ERSF-255	4.2	255
10.5	ERSM-185	2.6	185	ERSD-230	3.6	230	ERSF-275	4.3	275
10.75	ERSM-205	2.6	205	ERSD-245	3.7	245	ERSF-295	4.4	295
11.0	ERSM-220	2.7	220	ERSD-265	3.8	265	ERSF-315	4.5	315
11.25	ERSM-230	2.7	230	ERSD-285	3.8	285	ERSF-335	4.6	335
11.5	ERSM-245	2.8	245	ERSD-300	3.9	300	ERSF-355	4.7	355
11.75	ERSM-260	2.8	260	ERSD-320	3.9	320	ERSF-375	4.8	375
12.0	ERSM-275	2.9	275	ERSD-340	4.0	340	ERSF-400	4.9	400
12.25	ERSM-290	2.9	290	ERSD-360	4.0	360	ERSF-425	5.0	425
12.5	ERSM-310	3.0	310	ERSD-380	4.1	380	ERSF-450	5.1	450
13.0	ERSM-360	3.1	360	ERSD-425	4.3	425	ERSF-500	5.3	500
13.5	ERSM-400	3.2	400	ERSD-475	4.4	475	ERSF-550	5.5	550
14.0	ERSM-430	3.3	430	ERSD-525	4.5	525	ERSF-625	5.7	625
14.5	ERSM-475	3.4	475	ERSD-575	4.6	575			

A=Base B=Projection V=Volume




IMPLANT MATRIX HOW TO OPTIMIZE?

Best surgical practices with Motiva Implants® include a tight, precise pocket. For optimal results, when selecting an implant:

- 1 Measure the patient base width
- 2 Determine desired projection per profile (Mini/Demi/Full)
- 3 The matrix will provide the appropriate volume that aligns with the optimal aesthetic outcome

Assessing asymmetries:

- Projection asymmetry (Move right/left – Mini/Demi/Full)
- Width asymmetry (Move down/up – Base width "A")

Motiva SmoothSilk® Round									
	MINI 			DEMI 			FULL 		
$\overset{\circ}{\sim}A\sim$ (cm)	Catalog #	$\overset{\circ}{\sim}B\sim$ (cm)	V (cc)	Catalog #	$\overset{\circ}{\sim}B\sim$ (cm)	V (cc)	Catalog #	$\overset{\circ}{\sim}B\sim$ (cm)	V (cc)
10.0				RSD-205	3.5	205			
10.25				RSD-215	3.5	215	RSF-255	4.2	255
10.5				RSD-230	3.6	230	RSF-275	4.3	275
10.75				RSD-245	3.7	245	RSF-295	4.4	295
11.0				RSD-265	3.8	265	RSF-315	4.5	315
11.25				RSD-285	3.8	285	RSF-335	4.6	335
11.5	RSM-245	2.8	245	RSD-300	3.9	300	RSF-355	4.7	355
11.75	RSM-260	2.8	260	RSD-320	3.9	320	RSF-375	4.8	375
12.0	RSM-275	2.9	275	RSD-340	4.0	340	RSF-400	4.9	400
12.25	RSM-290	2.9	290	RSD-360	4.0	360	RSF-425	5.0	425
12.5	RSM-310	3.0	310	RSD-380	4.1	380	RSF-450	5.1	450
13.0	RSM-360	3.1	360	RSD-425	4.3	425	RSF-500	5.3	500
13.5	RSM-400	3.2	400	RSD-475	4.4	475	RSF-550	5.5	550
14.0				RSD-525	4.5	525	RSF-625	5.7	625

Increments of 0.25 for full customization for your patients

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REFERENCES:

1. Establishment Labs®, Post-Market Surveillance Preliminary Results Q1 2024. Internal Data on File.
2. 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. *Nature Biomedical Engineering*. 2021. doi:10.1038/s41551-021-00739-4
3. Rosas JM, Atkins DJ, Chau AL, et al. In vitro models of soft tissue damage by implant associated frictional shear stresses. *Proceedings of the Institution of Mechanical Engineers, Part J: Journal of Engineering Tribology*. 2022;0(0). doi:10.1177/13506501221132897
4. 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.0000000000004801
5. James G, Boegli L, Hancock J et al. Bacterial Adhesion and Biofilm Formation on Textured Breast Implant Shell Materials. *Aesth Plast Surg*. 2019 Apr; 43:490–497. doi: 10.1007/s00266-018-1234-7
6. Establishment Labs, TS-001196: Mechanical and peel testing study of Motiva Implants® to support the TrueMonobloc® technology. Data on File.
7. Establishment Labs, TSD-001019: Technical Summary Document Assessment of silicone diffusion/ gel bleed from Motiva Implants®, according to ISO 14607:2018 method. Data on File.
8. Aitzetmuller-Kleitz ML, Yang S, Wiebinghaus P, Wellenbrock S, Ozturk M, Kuckelhaus M et al. Complication rates after breast surgery with the Motiva Smooth SilkSurface silicone gel implants – A systematic review and meta-analysis. *Clin. Med*. 2023, 12,1881. doi: 10.3390/jcm12051881
9. Establishment Labs, TR-001038: Rheological analysis of silicone filling gels of Motiva Implants® and other brands' silicone filling gels using the BTC-2000. Data on File.
10. Establishment Labs, DDD-001: Device Description Document Sterile Silicone Breast Implants Motiva Implants® Round SmoothSilk®/SilkSurface® Plus. Data on File.
11. Establishment Labs, DDD-002: Device Description Document for Sterile Silicone Breast Implants Motiva Implants® Ergonomix® Round SmoothSilk®/SilkSurface®. Data on File.
12. Zeplin PH. Narbensparende Brustvergrößerung: Erfahrungen mit über 500 Implantaten. *Handchirurgie · Mikrochirurgie · Plastische Chirurgie*. 2021;53(02):144-148. doi:10.1055/a-1307-3917
13. Establishment Labs Holdings Corp. Establishment Labs Notes Presentation of 4-Year Results from Motiva U.S. IDE Study at The Aesthetic Meeting 2024. <https://investors.establishmentlabs.com/press-releases/pressreleasesdetails/2024/Establishment-Labs-Notes-Presentation-of-4-Year-Results-from-Motiva-U.S.-IDEStudy-at-The-Aesthetic-Meeting-2024/default.aspx>. Published May 2nd, 2024. Accessed May 28th, 2024.
14. Barr S, Hill EW, Bayat A. Functional biocompatibility testing of silicone breast implants and a novel classification system based on surface roughness. *J Mech Behav Biomed Mater*. 2017. Nov;75:75-81. doi:10.1016/j.jmbbm.2017.06.030
15. 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
16. Hallab NJ, Samelko L, Hammond D. Particulate Debris Released From Breast Implant Surfaces Are Highly Dependent on Implant Type. *Aesthet Surg J*. Published online February 10, 2021:1-18. doi:10.1093/asj/sjab051
17. Establishment Labs, LT-001309: Comprehensive characterization of Motiva Implants® and other breast implants available in the market (Mentor, Allergan, and Sientra).
18. Brandon HJ, Taylor ML, Powell TE, Walker PS. Morphology of Breast Implant Fold Flaw Failure. *J Long Term Eff Med Implants*. 2006. 16(6):441-450. doi: 10.1615/jlongtermeffmedimplants.v16vi6.40
19. Establishment Labs, REC-003677: Morphological Analysis for Silicone Gel Breast Implants Motiva Implant Matrix of Establishment Labs®. Data on File.
20. Establishment Labs Holdings Corp. Establishment Labs Notes Presentation of 2-Year Results from Motiva U.S. IDE Study at The Aesthetic Meeting 2022. Establishment Labs Holdings Corp. – Establishment Labs Notes Presentation of 2-Year Results from Motiva U.S. IDE Study at The Aesthetic Meeting 2022. Published April 21th, 2022. Accessed May 28th, 2024.
21. Establishment Labs Holdings Corp. Establishment Labs Notes Presentation of 3-Year Results from Motiva U.S. IDE Study at The Aesthetic Meeting 2023. Establishment Labs Holdings Corp. – Establishment Labs Notes Presentation of 3-Year Results from Motiva U.S. IDE Study at The Aesthetic Meeting 2023. April 20th, 2023. Accessed May 28th, 2024.
22. Summary of Safety and Effectiveness Data (SSED) Motiva Implants® Silicone Gel-Filled Breast Implants, SmoothSilk® Round, Motiva Implants® Silicone Gel-Filled Breast Implants, SmoothSilk Ergonomix®. (2024). U. S. Food and Drug Administration.





INDICATION

Motiva Round and Ergonomix® SmoothSilk® Silicone Gel Breast Implants are indicated for breast augmentation for women of at least 22 years old. Breast augmentation includes primary breast augmentation to increase the breast size, as well as revision surgery to correct or improve the result of an original primary breast augmentation surgery (i.e., revision-augmentation). Breast Implant surgery is contraindicated in women with active infection anywhere in their bodies, with existing cancer or pre-cancer of their breast, who have not received adequate treatment for those conditions, or who are currently pregnant or nursing. Plastic surgeons should review all risk information found in the Directions for Use, before utilization. Key complications associated with silicone gel breast implants include capsular contracture, implant removal, reoperation, and infection. For The Directions for Use and more detailed information regarding the risks and benefits of Motiva Round and Ergonomix® SmoothSilk® Breast Implants, please visit www.motivausa.com or call Motiva at 1-800-924-5072.

The sale and distribution of this device is restricted to users and/or user facilities that provide information to patients about the risks and benefits of this device in the form and manner specified in the approved labeling provided by Establishment Labs® and Motiva® USA. Federal (USA) Law restricts this device to sale by or on the order of a physician.

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