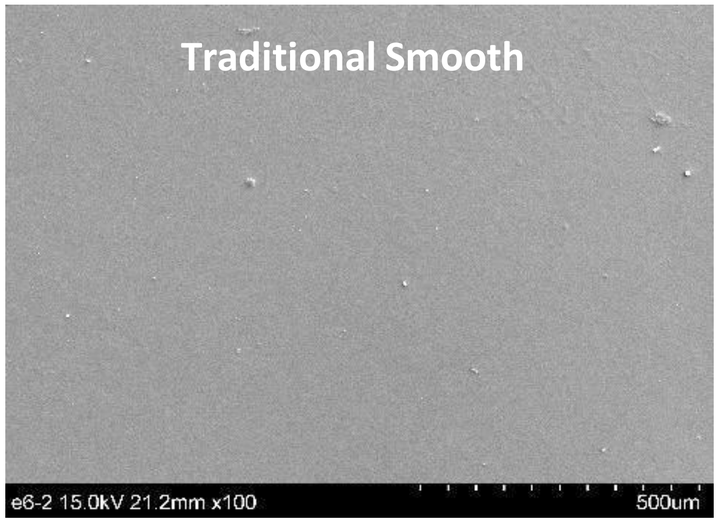
The Science of Breast Tissue Management

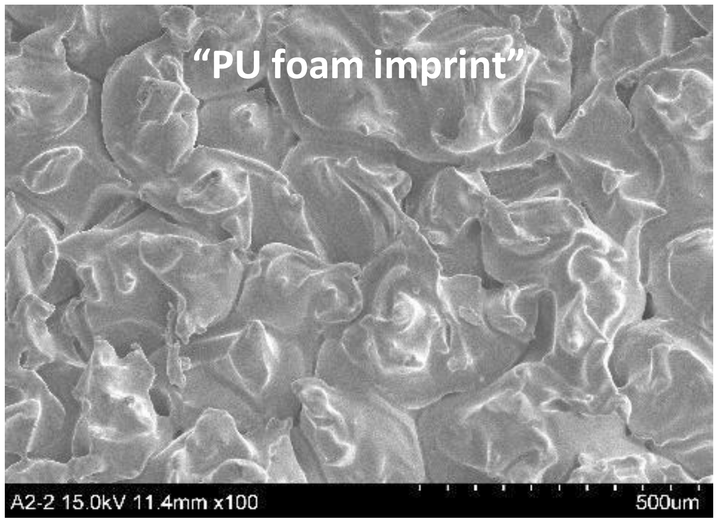
Breast Implants Surfaces and Immunology

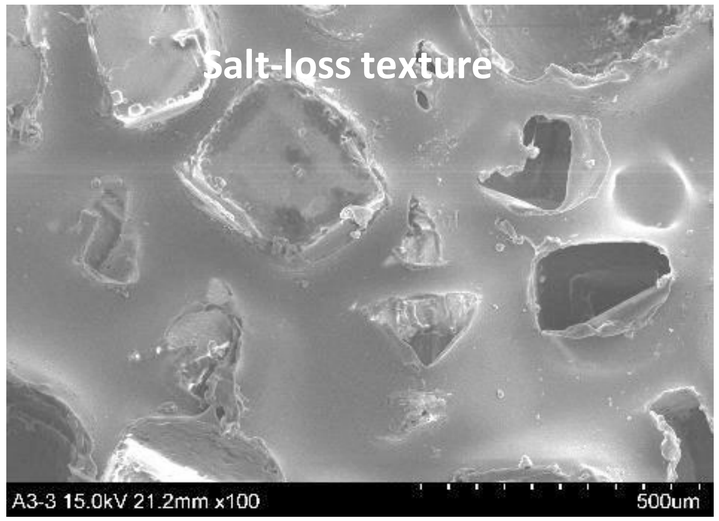
MotivaEDGE

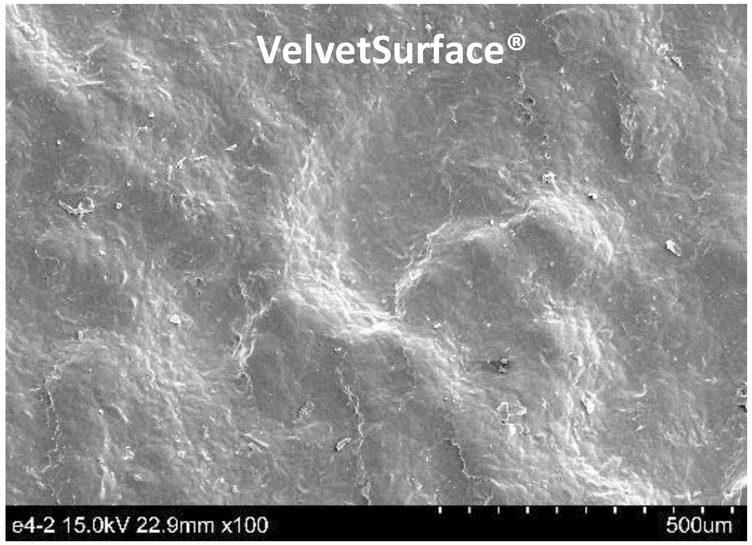
Breast Implants Surfaces and Immunology

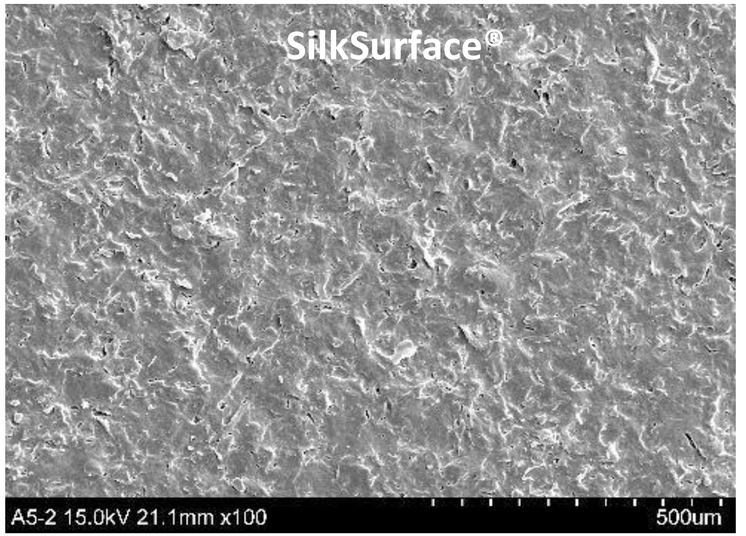
Available Breast Implants Surfaces in the Market











SEM images of different textures available in the market, at a scale of 500 µm and 100X magnification.

Traditional Breast Implants Manufacturing Processes

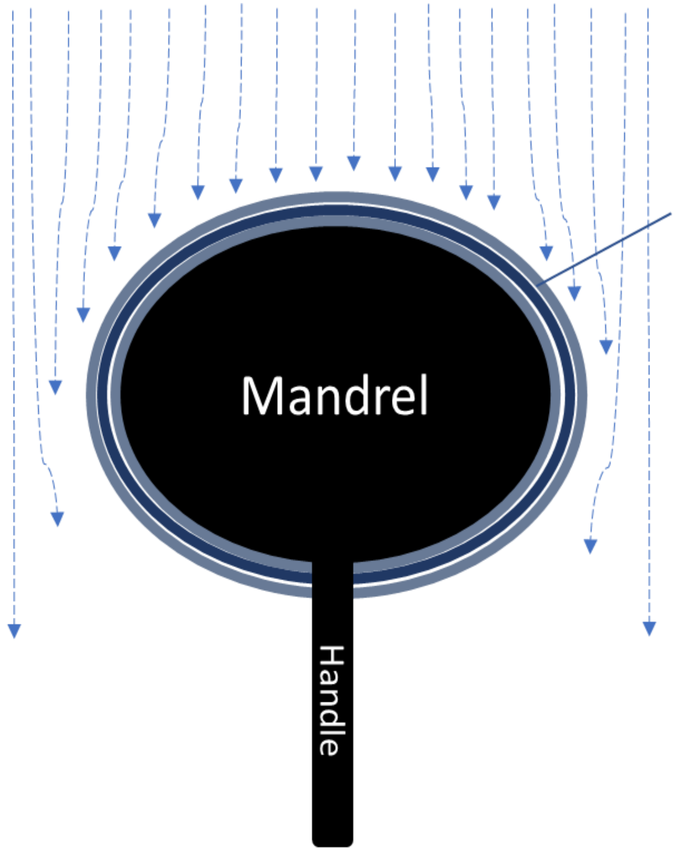
Primary Process

- Achieved in a single step process

Secondary Processes

- Require a second special treatment process after the shell has been manufactured
- Involve the use of some additional material

Traditional “Smooth” Surfaces are difficult to control



Illustrative image by Establishment Labs

Difficult to control, Silicone flow and air drying creates waves and irregularities

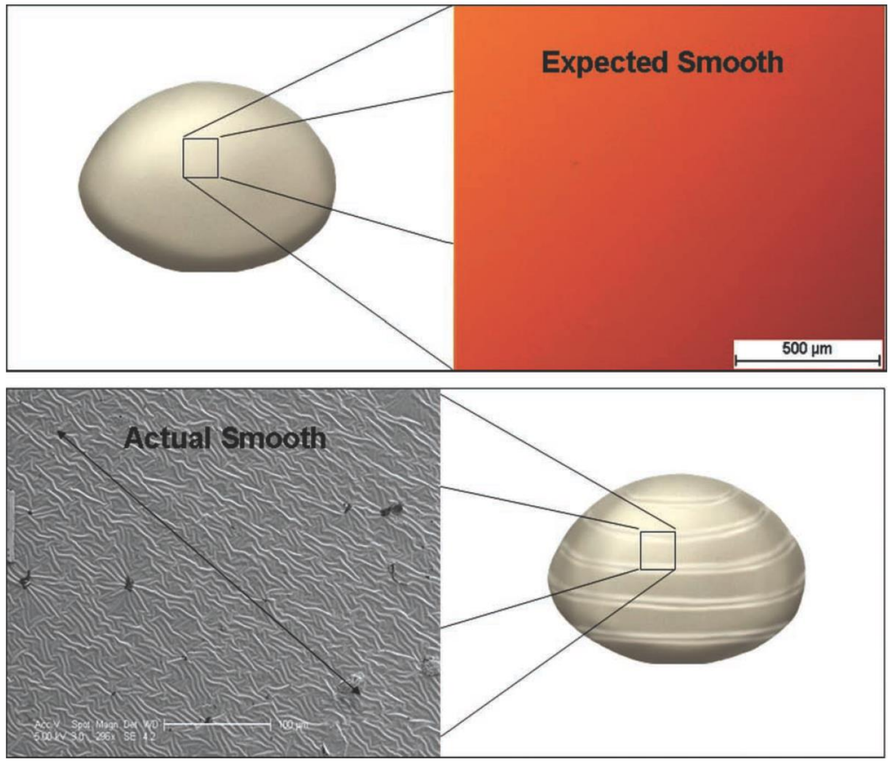


Figure 3. The actual resulting texture of smooth implants is shown. During manufacture, silicone creeps down the surface of the mandrel during curing, resulting in a regularly-ridged topography, rather than one that is strictly smooth.

Source: Breast Implants Surface Development: Perspective on Development and Manufacture, Simon Barr and Ardeshir Bayat, *Aesthetic Surgery Journal* 2011 31:56.

Traditional “Smooth” surface is not really smooth

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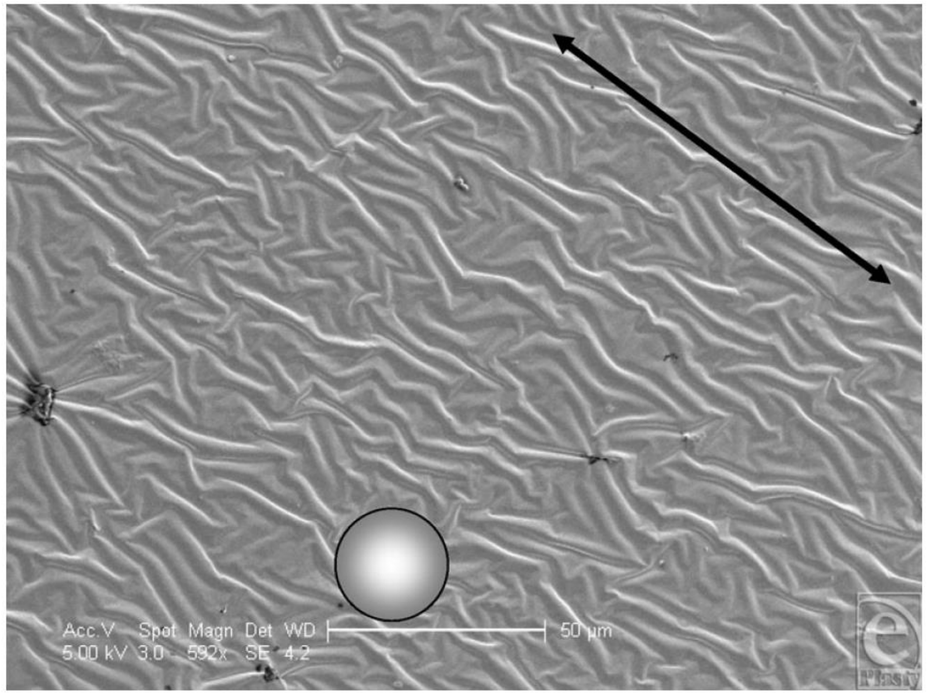
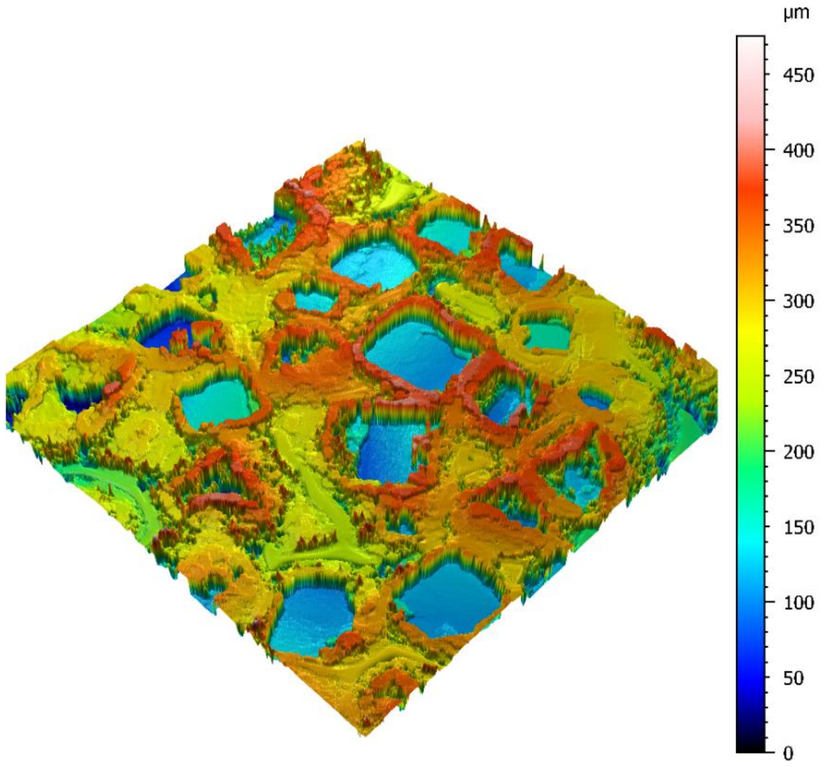


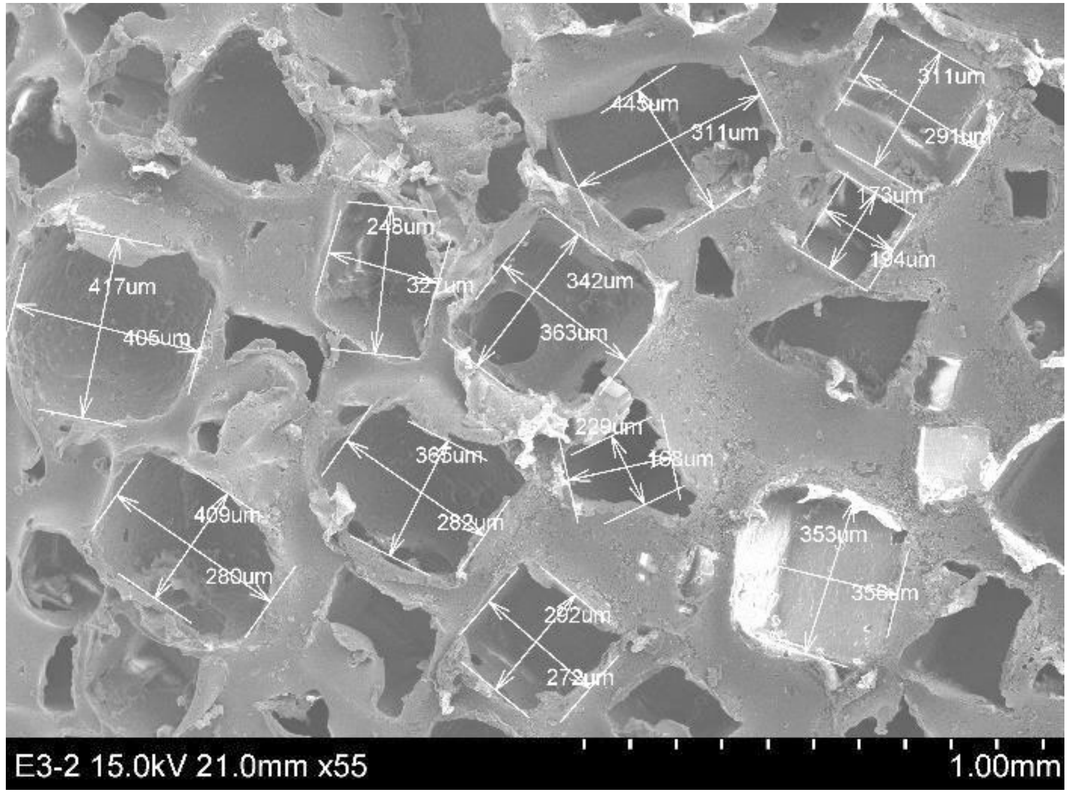
Figure 4. Allergan smooth surface implant in scanning electron microscopy at 592× magnification with a 50-μm scale bar, 25-μm fibroblast representation, and an arrow to illustrate the direction of the ridged surface texture. This scanning electron microscopy image illustrates the directional quality that the ridges on the surface of this implant have, which may be attributed to the drying stage of its manufacture. This image also better illustrates the dimensions of these ridges, especially with respect to an average-sized fibroblast.

Source: Barr, S. Hill, E., and Bayat, A. Current Implant Surface Technology: An Examination of Their Nanosurface and their influence on Fibroblast Alignment and Biocompatibility, Eplasty. 2009; 9: e22.

Traditional Salt-loss Texture (Secondary Manufacturing Process)



"Salt-loss" texture 3D topography view taken with uSurf Mobile Profilometer. Images Property of Establishment Labs (2017).

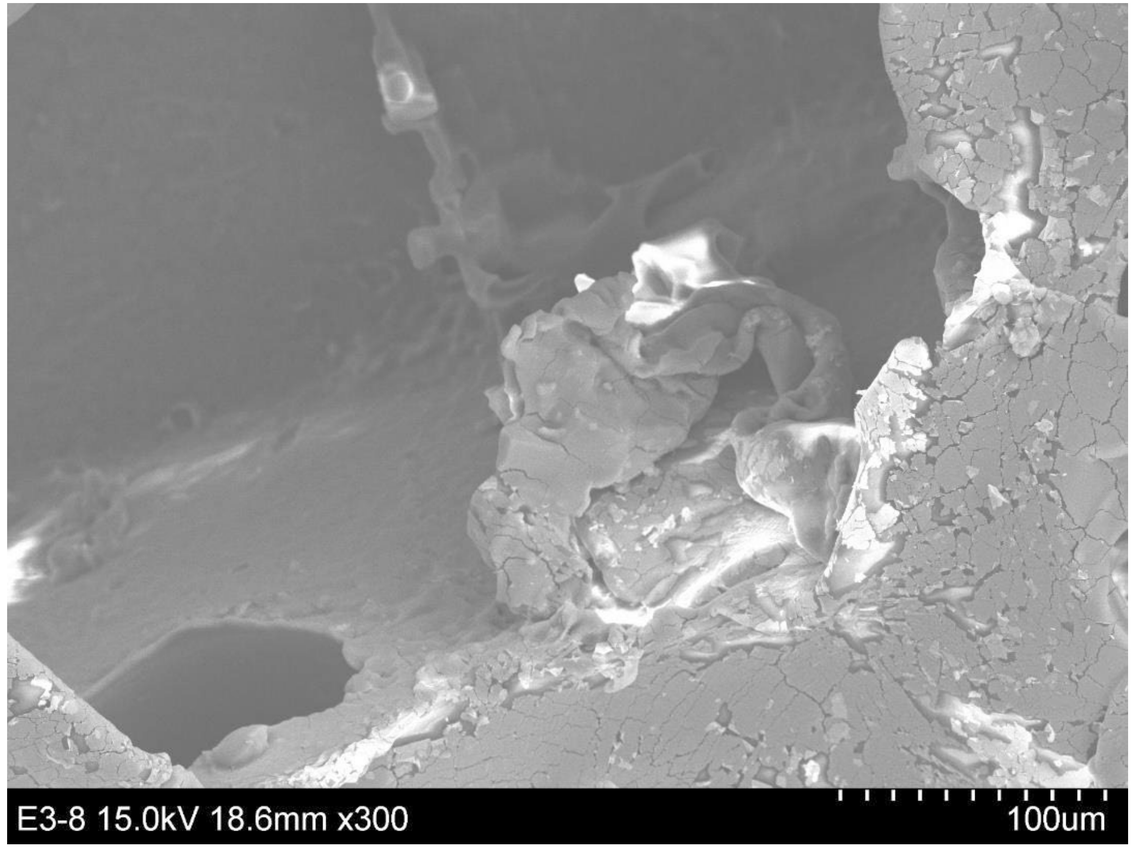


Cavities dimensions' measurements of the "salt-loss" macro-texture, at a scale of 1,00 mm and 55x magnification, taken from equator section. Images Property of Establishment Labs (2017).

Hall-Findlay EJ. Breast implant complication review: double capsules and late seromas. Plast Reconstr Surg. 2011 Jan;127(1):56-66. doi: 10.1097/PRS.0b013e3181fad34d. PubMed PMID: 21200201.

Traditional Salt-loss Texture (Secondary Manufacturing Process)

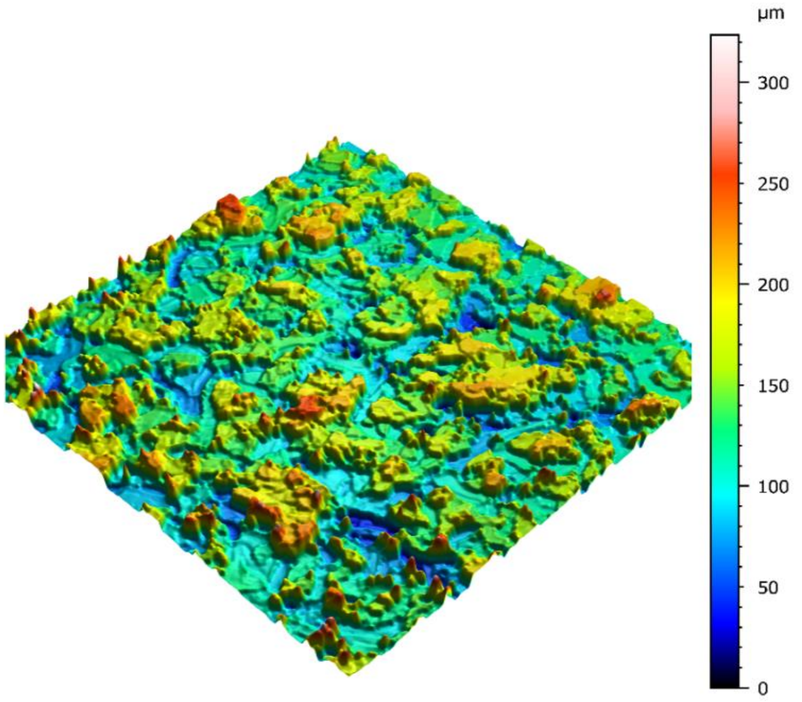
- “Pitted with cuboid shaped wells” with many irregularities (Barr, Hill and Bayat, 2009).
- Silicon debris.
- Structures outside cellular dimensions.
- Promote Tissue Ingrowth.



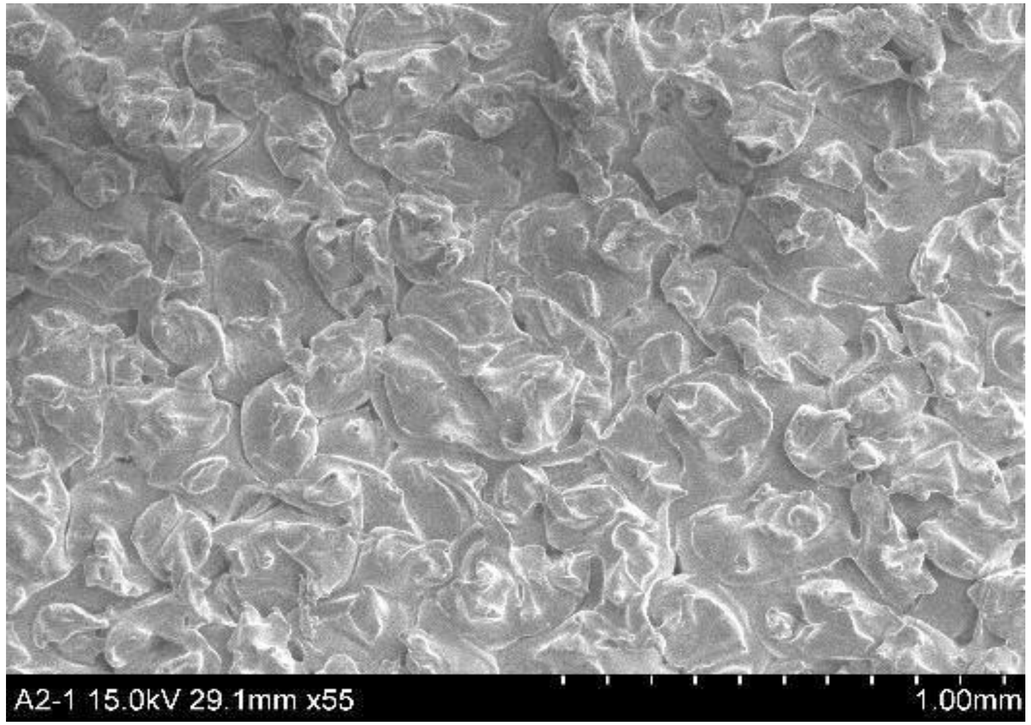
Silicone Debris in a cavity of the “salt-loss” macro-texture, at a scale of 100 um and 300x magnification, taken from equator section. Images Property of Establishment Labs (2017).

Barr, S., Hill, E., Bayat, A. (2009). Current implant surface technology: an examination of their nanostructure and their influence on fibroblast alignment and biocompatibility. Eplasty., 16, 9:e22.

Traditional Polyurethane Foam Imprint Texture (Secondary Manufacturing Process)



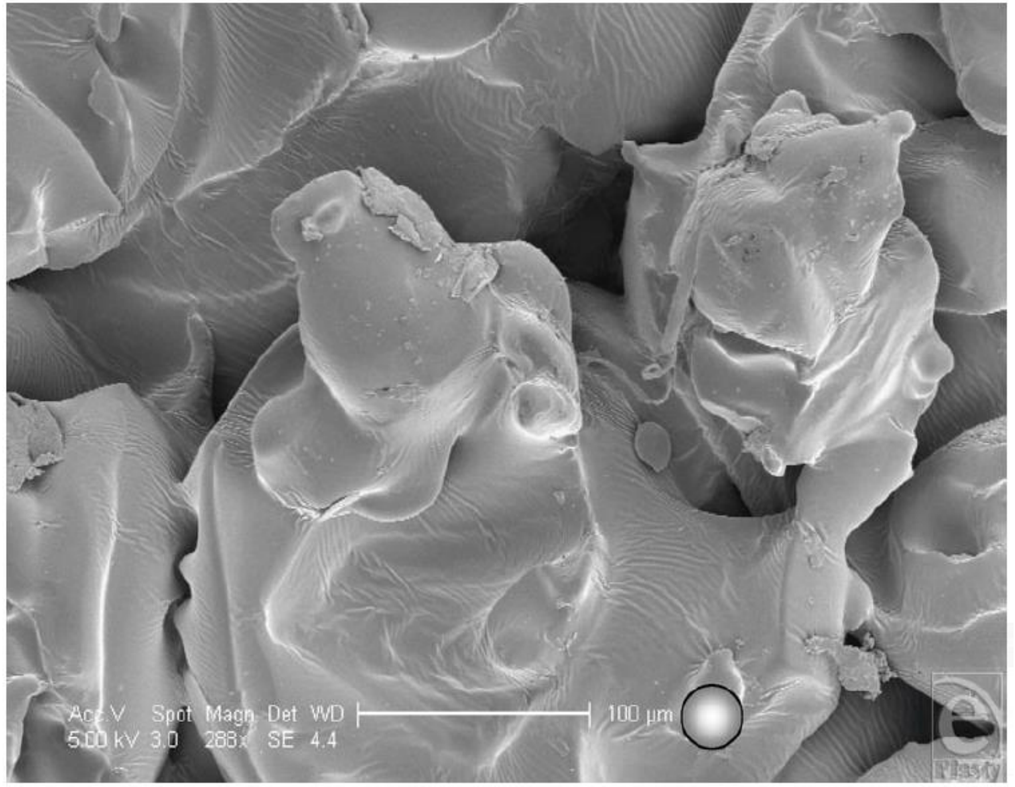
“PU foam imprint” texture 3D topography view taken with uSurf Mobile Profilometer.



“Negative imprint with foam” texture, at a scale of 1 mm and 55X magnification, taken from apex section.

Traditional Polyurethane Foam Imprint Texture (Secondary Manufacturing Process)

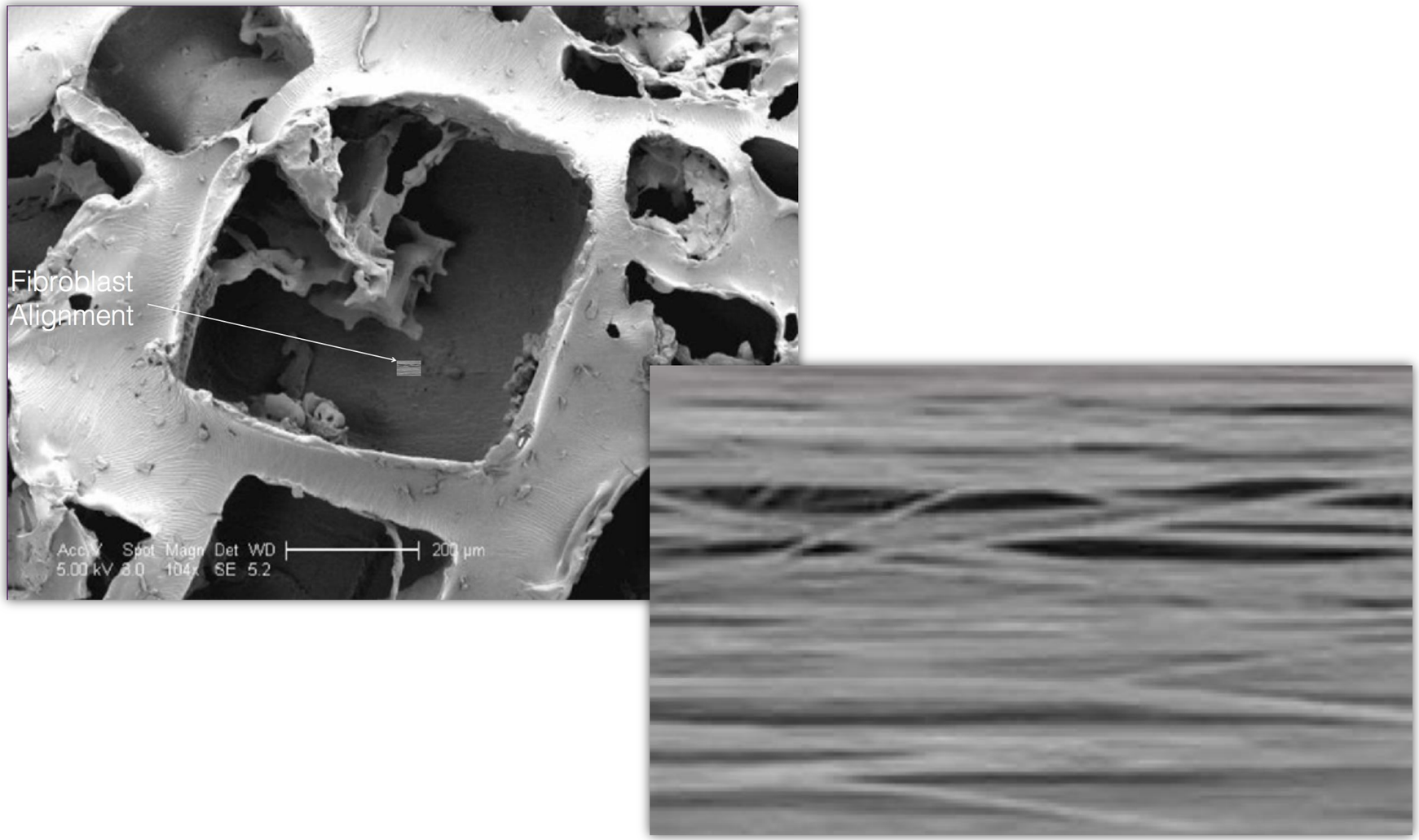
- This surface exhibits uneven nodules approximately 40 - 100 µm high and 50–150 µm in diameter, with high, flat-topped peaks and deep plunging crevasses” (Barr, Bayat and Hill, 2009).
- Silicon debris.
- Structures outside cellular dimensions.
- Potential Tissue Ingrowth.



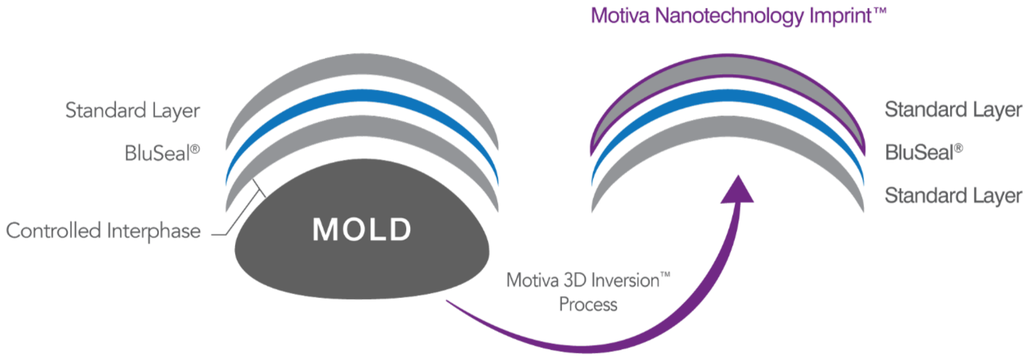
SEM image of “negative imprint with foam” texture with some silicone debris on its nodular structure. (Barr, Bayat and Hill, 2009).

Barr, S., Hill, E., Bayat, A. (2009). Current implant surface technology: an examination of their nanostructure and their influence on fibroblast alignment and biocompatibility. Eplasty., 16, 9:e22.

Fibroblast Alignment Macro Surfaces

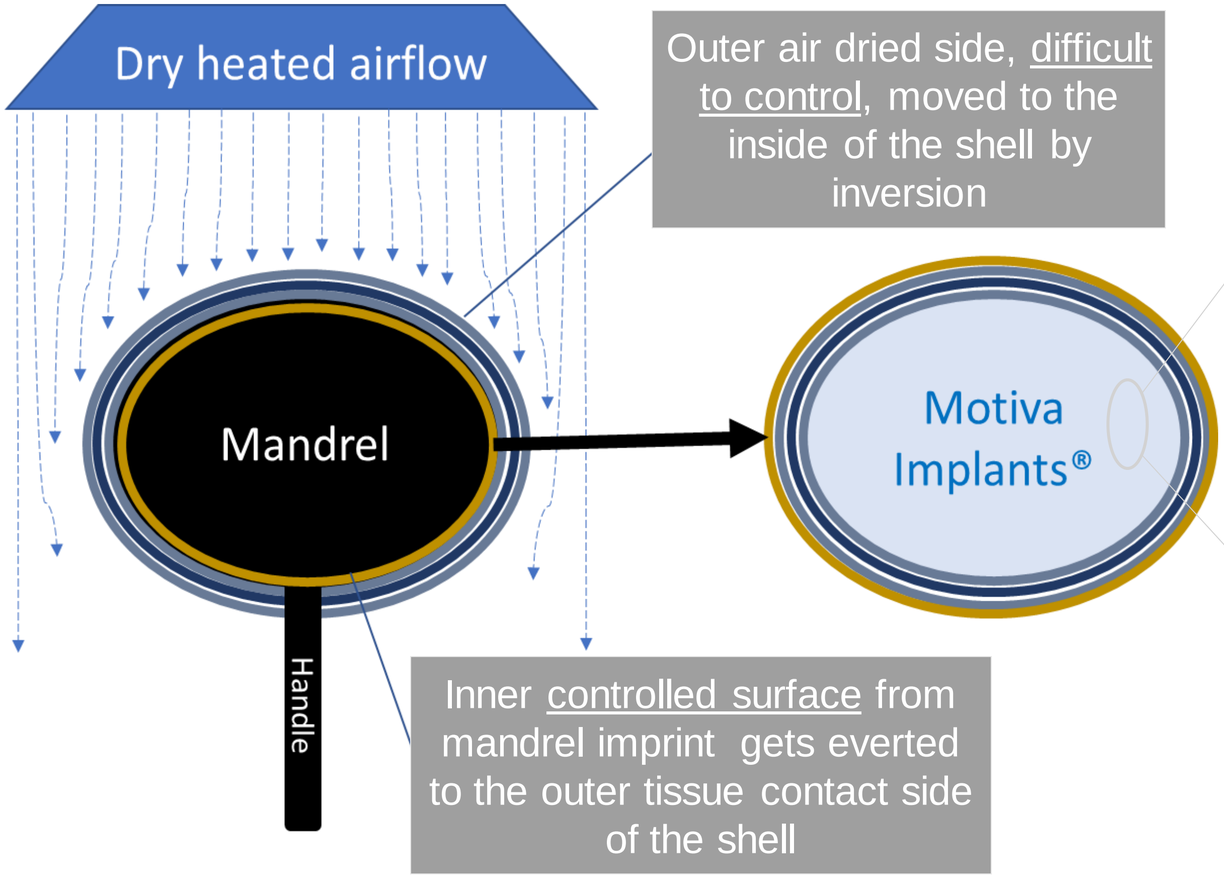


Motiva Implants® Surfaces (Primary Manufacturing Process)

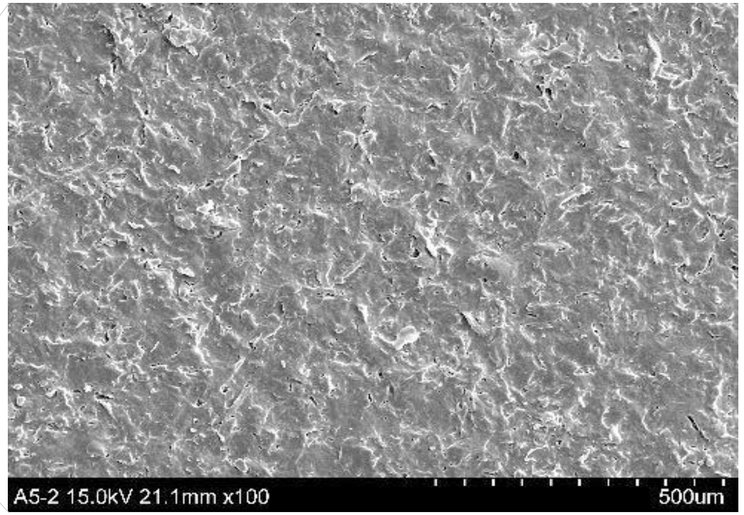


Motiva 3D Inversion™ Manufacturing Process.

No additional treatments or process to manufacture Motiva Implants® SmoothSilk®/SilkSurface® or VelvetSurface®

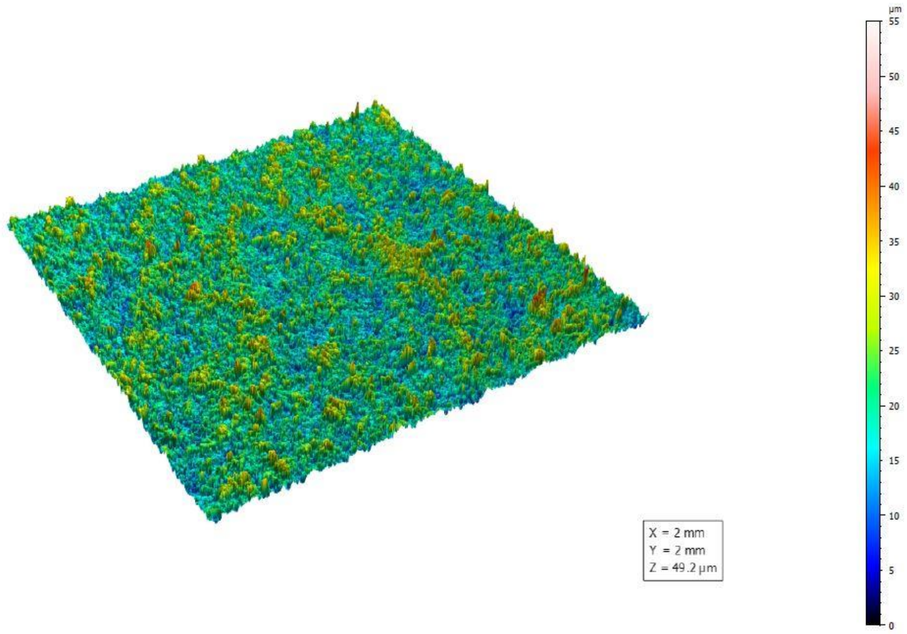


Illustrative image by Establishment Labs

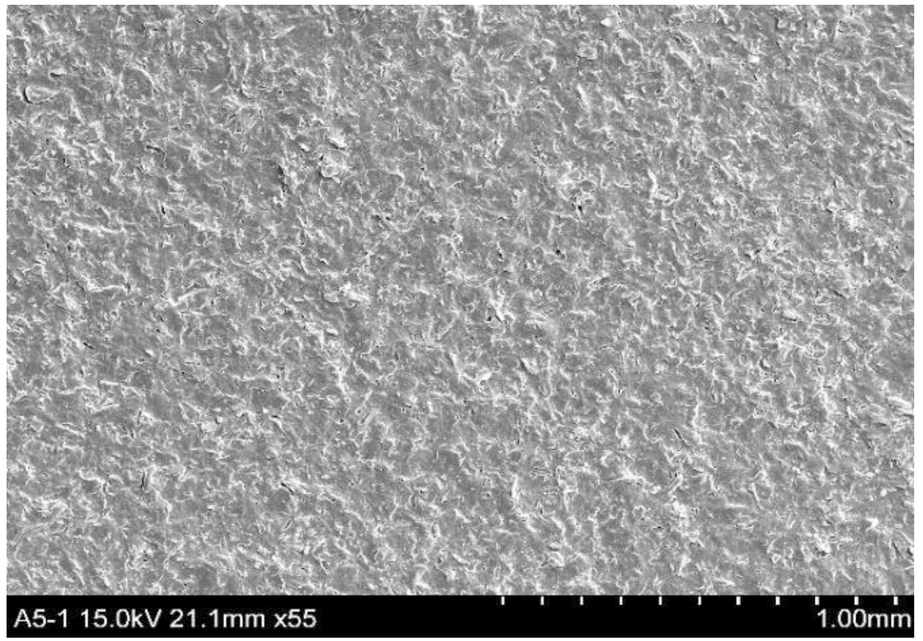


Microscopic image by Establishment Labs

Motiva Implants® SmoothSilk®/SilkSurface®

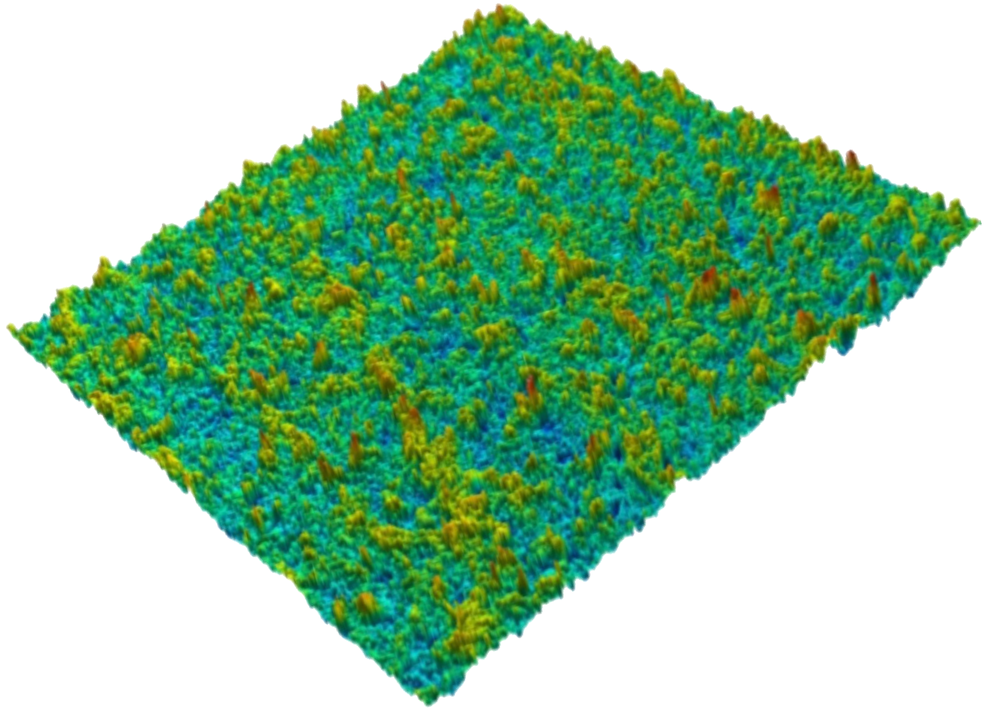


SmoothSilk®/SilkSurface® 3D topography view taken with uSurf Mobile Profilometer per ISO 25178-2:2012

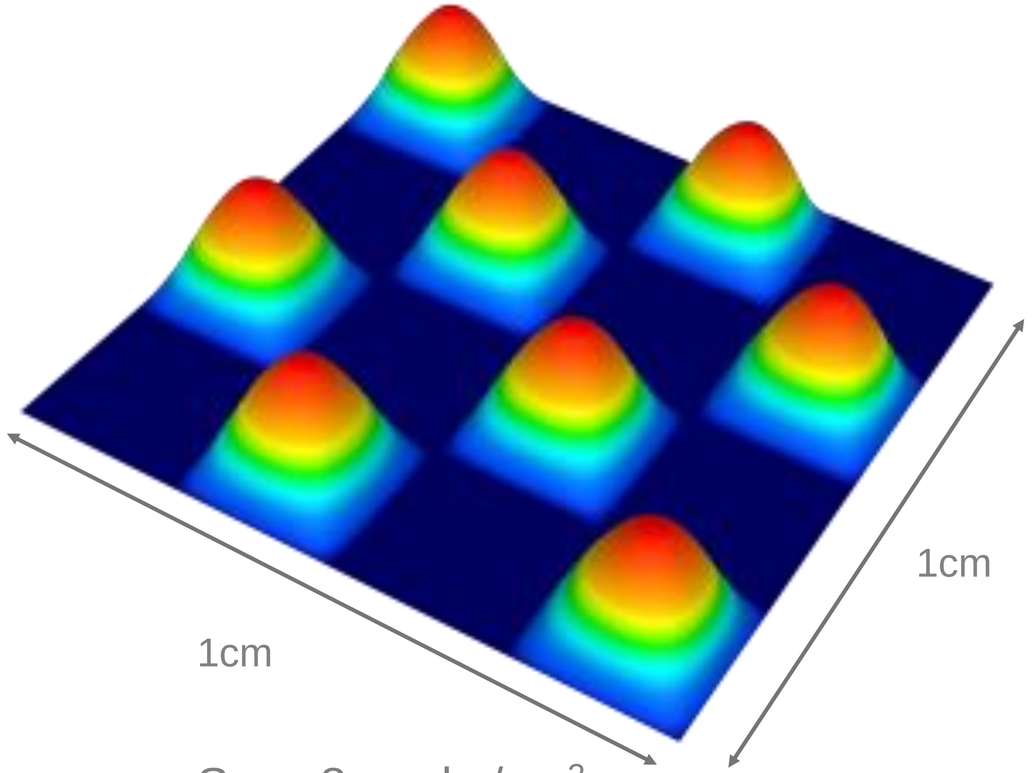


SmoothSilk®/SilkSurface® SEM image at a scale of 1 mm and 55X magnification

High Density of Peaks



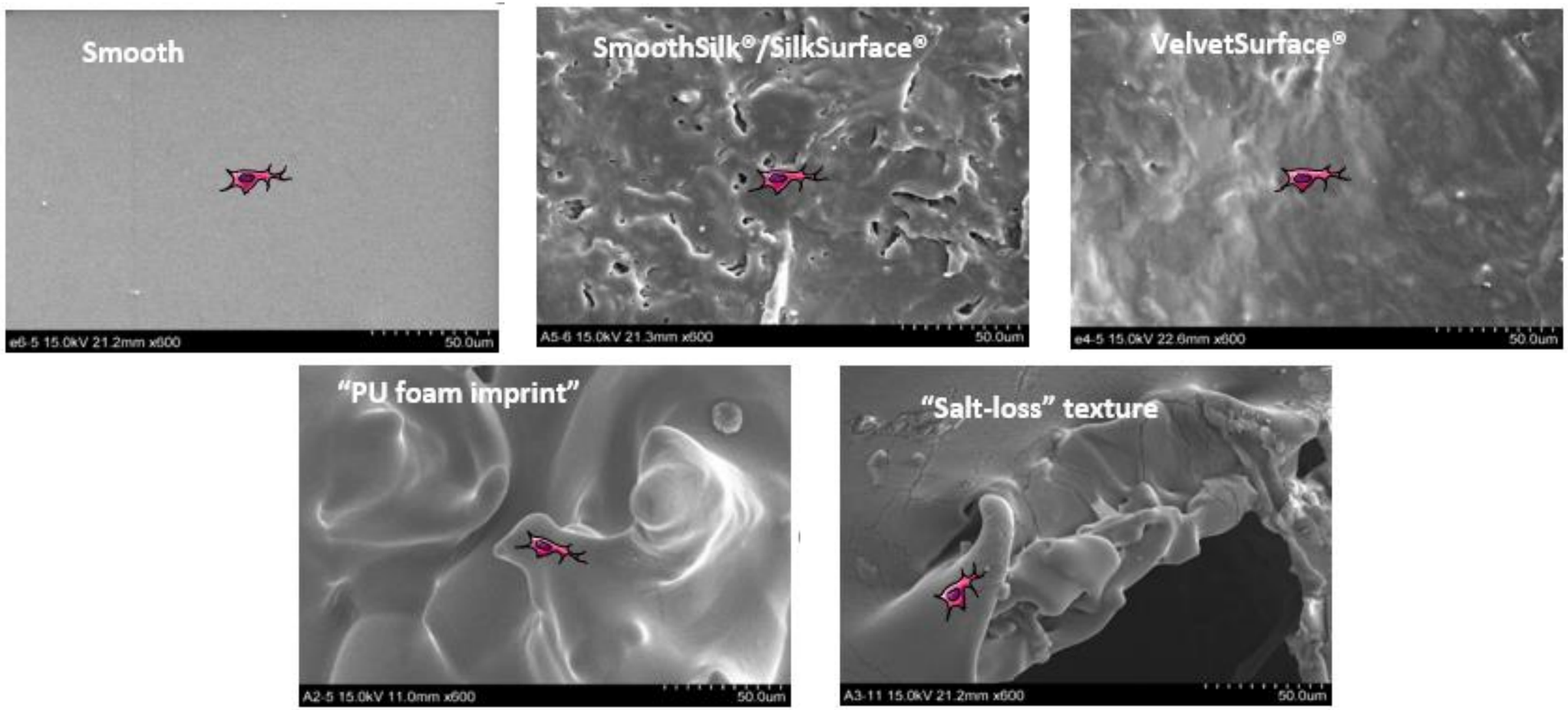
SmoothSilk®/SilkSurface®
Density of Peaks (S_{pd}):
49000 (Peaks/cm^2)



S_{pd} = 8 peaks/cm^2

Illustrative Image

Size comparison of a fibroblast on the surfaces



Representation of how a fibroblast may look on a breast implant surface at the same magnification, considering the standardized fibroblast size of 25 µm used by Dalby et al. (2004).

Dalby MJ, Riehle MO, Johnstone H, Affrossman S, Curtis ASG. Investigating the limits of filopodial sensing: a brief report using SEM to image the interaction between 10 nm high nano-topography and fibroblast filopodia. Cell Biol Int. 2004;28(3):229–36.

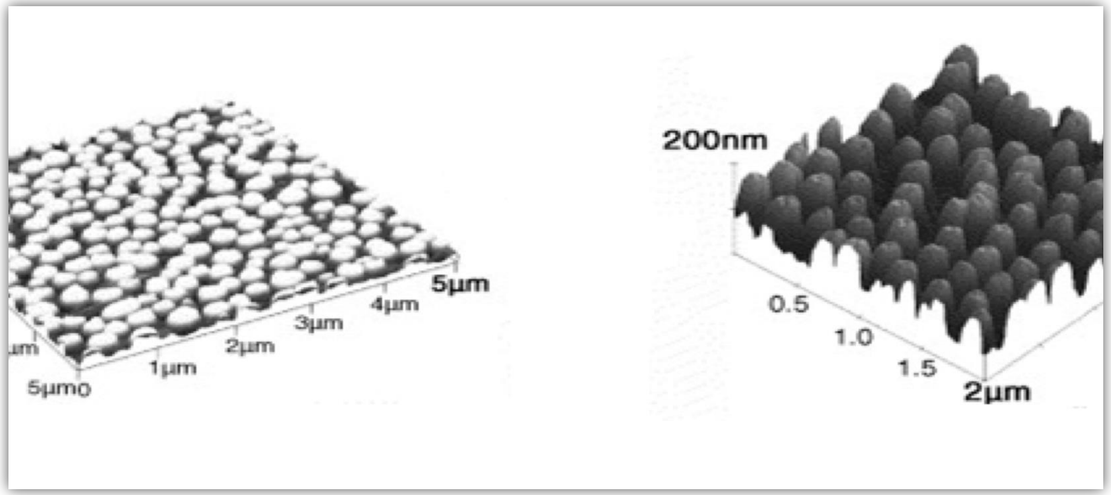
Fibroblast Alignment

A fibroblast is a cell in connective tissue which produces collagen and other fibres.

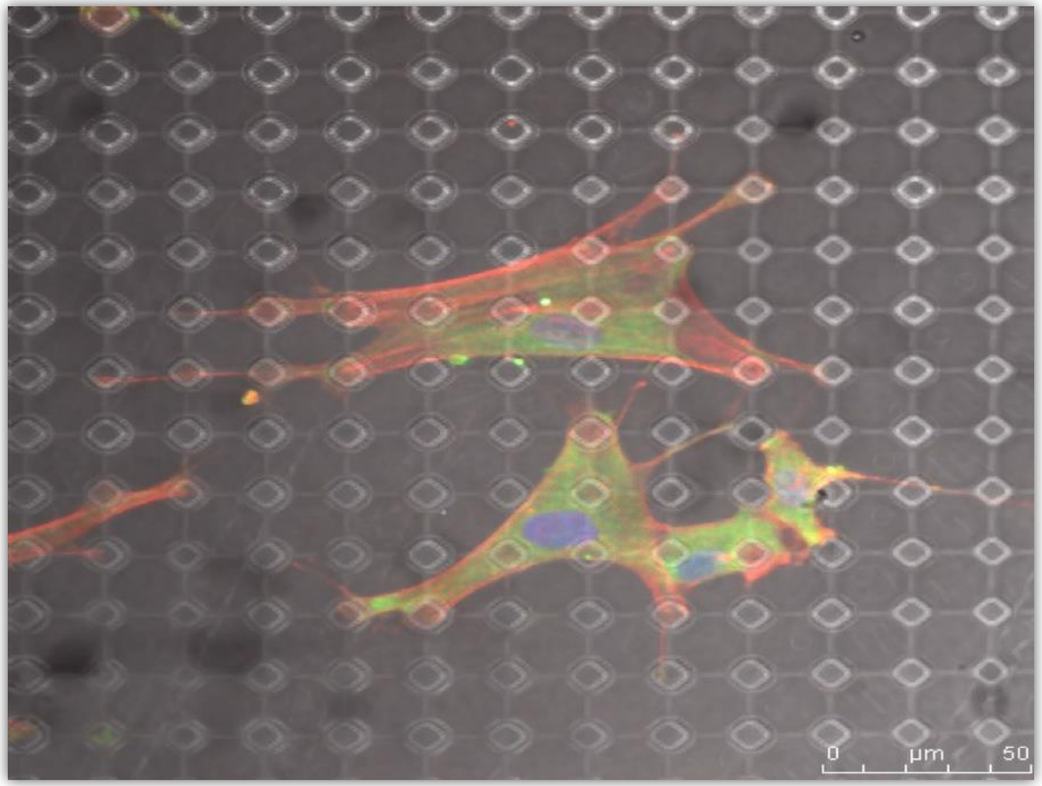
At a cellular level these fibroblasts adhere to very small substrates – They anchor to very small points.

Human fibroblasts are 20-25 microns in size and are affected by nano-topography

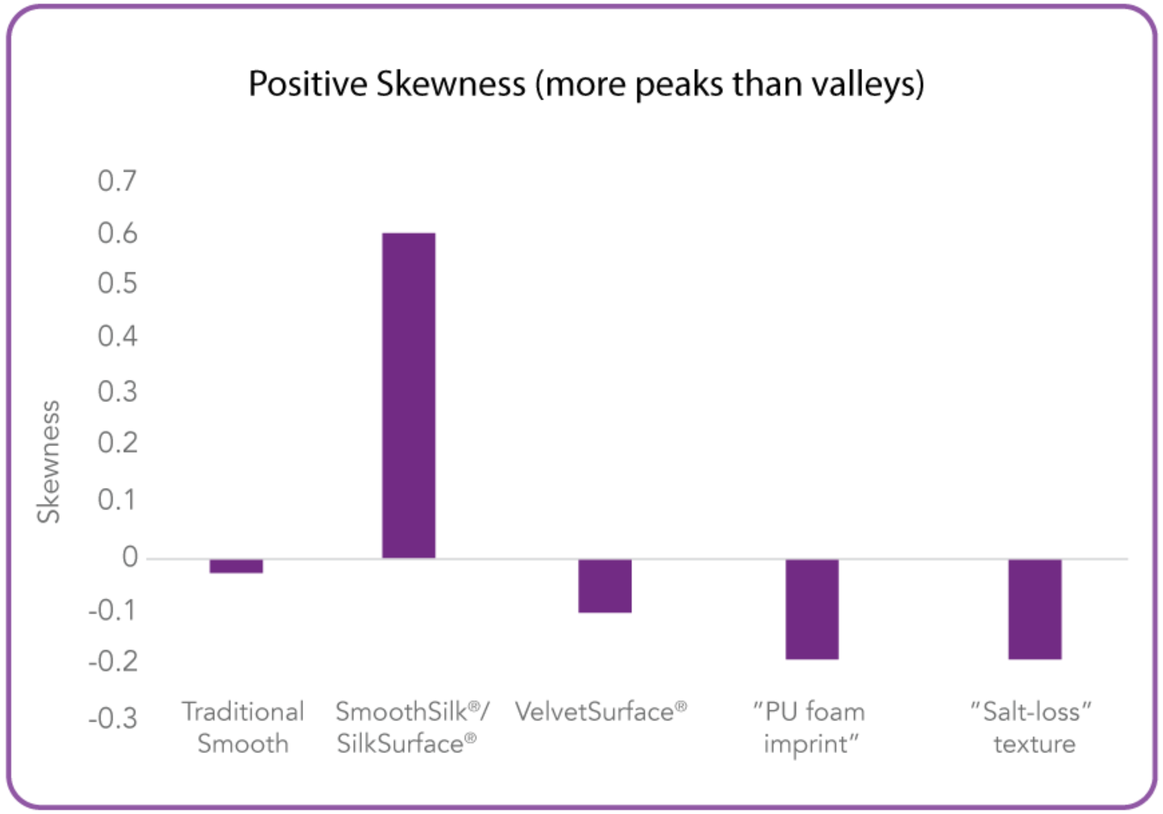
Cells prefer to adhere to very small substrates



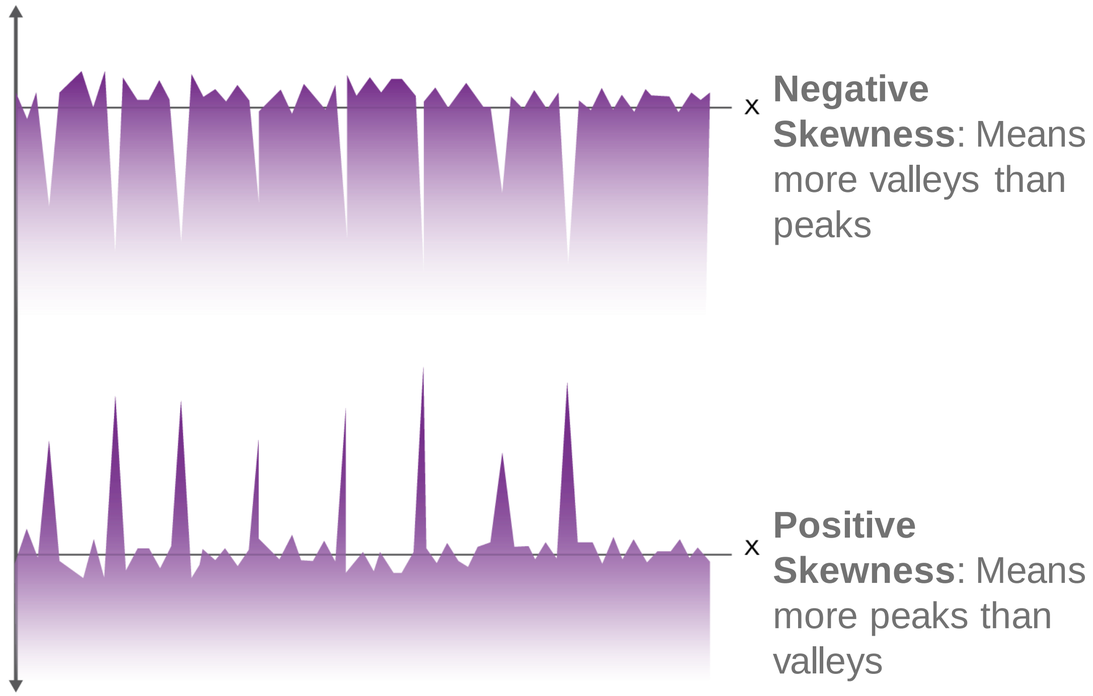
Fibroblast Alignment Nano Surfaces



SilkSurface® has more peaks than valleys : Skewness Comparison



Skewness parameter comparison of different breast implants available in the market, measured with uSurf Mobile non-contact profilometer. Results Property of Establishment Labs (2017).



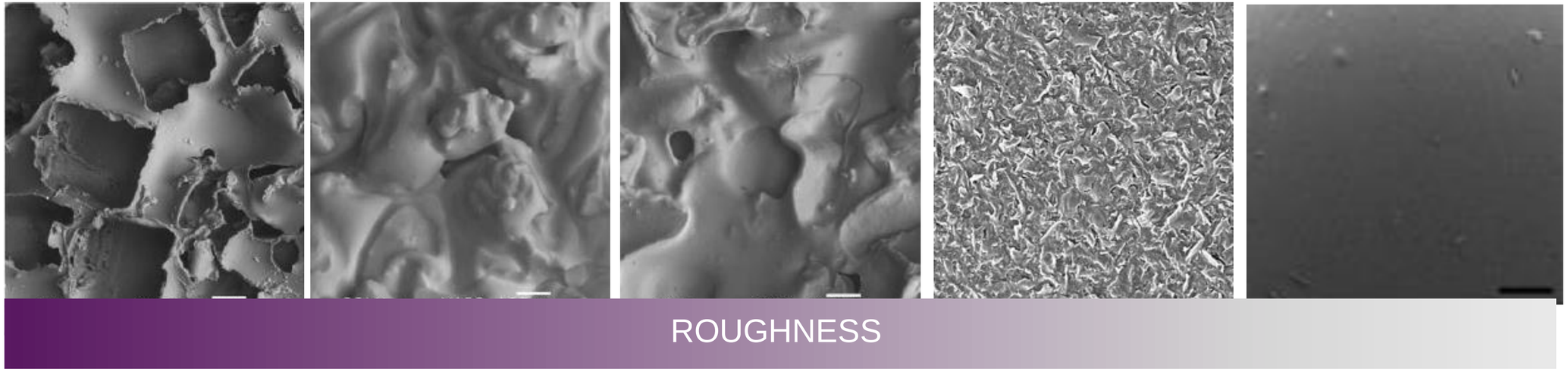
Negative Skewness: Means more valleys than peaks

Positive Skewness: Means more peaks than valleys

Roughness trace

Motiva Nanotechnology Imprint™ is Designed to Reduce Damage to the Human Body Caused by Friction and Wear

SILKSURFACE™ IS DESIGNED TO REDUCE FRICTION AND INFLAMMATION



	Allergan Biocell	Mentor Siltex	Sientra True	SilkSurface®	Mentor Smooth
Roughness S_a	80 ± 12 µm	44 ± 12 µm	34.4 ± 8 µm	4 ± 1 µm	0.022 ± 0.0096 µm

Macro Textures | Nano/Smooth

1. Motiva® Introduction to Motiva Implants: Safety Through Innovation. Las Vegas Slide Deck, 2016. 2. Derby BM, Codner MA. Textured Silicone Breast Implant Use in Primary Augmentation: Core Data Update and Review. *Plast. Reconstr. Surg.* 2015;135(1): 113-124. 3. Data on file. Establishment Labs®. 4. Kyle DJT et al. *Biomaterials*. 52:88-102.

BREAST IMPLANT SURFACE CATEGORIES

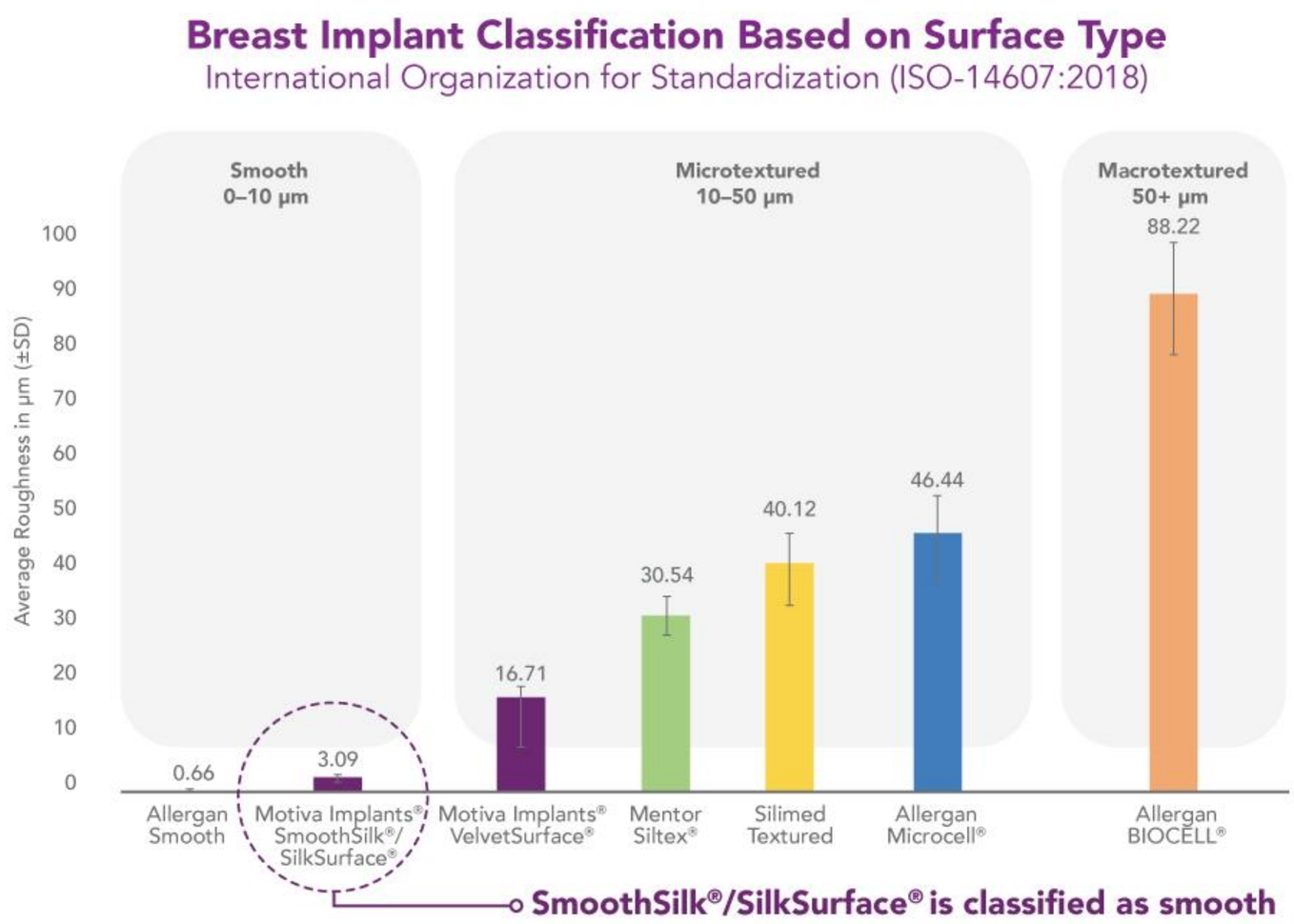
There have been different methodologies used to measure surface roughness and surface area. **In 2018, the ISO (the International Organization for Standardization) test for surface characteristics was released and it classifies SmoothSilk®/SilkSurface® within the same category as traditional smooth implants.**

SUMMARY OF SMOOTH & TEXTURED IMPLANT CLASSIFICATIONS[1]

ISO Average roughness by SEM		ANSM Average roughness by SEM		Atlan 2018 Surface area by X - ray and CT		Jones/Deva 2018 Surface area/roughness by SEM and CT		James/Kinney 2018 Surface area/roughness by profilometry	
Smooth <10 µm	All smooth, **Motiva Silk**	Smooth	All smooth	Smooth/ nanotexture 80-100 mm^2	All smooth, **Motiva Silk and Velvet**	**1** Minimal	All smooth, **Motiva Silk/Velvet**	Smooth	All smooth, **Motiva Silk/Velvet**
Microtextured 10 to 50 µm	**Motiva Velvet**, B-Lite, Allergan Microcell/BRST, Sientra True	Microtextured	Arion Micro, Sebbin Micro, **Motiva Silk/Velvet**	Microtextured 100-200 mm^2	Mentor Siltex, Allergan Microcell /BRST	**2** Low	Mentor Siltex, Nagor		
Macrotextured over 50 µm	Allergan Biocell, Mentor Siltex, Silimed PU, Polytech PU	Macrotextured	Allergan Microcell/Biocell, Mentor Siltex, Eurosilicone Micro, Nagor, Polytech, Silimed	Macrotextured 200-300 mm^2	Allergan Biocell, Sientra True, Eurosilicone	**3** Intermediate	Allergan Biocell, Eurosilicone	Rough	Allergan Biocell, Mentor Siltex
				Macrotexture-Plus > 300 mm^2	Nagor, Polytech	**4** High	Polytech PU Surgitek PU Silimed PU		
Establishment Labs data generated internally per ISO-14607:2018		Data generated by ANSM per ISO-14607:2007		Peer reviewed scientific publications					

Abbreviations: mm2: millimeters squared, SEM: scanning electron microscopy, ISO: the international Organization for Standardization., CT: Computed Tomography.
Surface area is a measure of the total area that the outer surface topography of an implant occupies and that interfaces with the patient.
Surface roughness is a measure of the average height of the peaks and valleys of an implant surface.

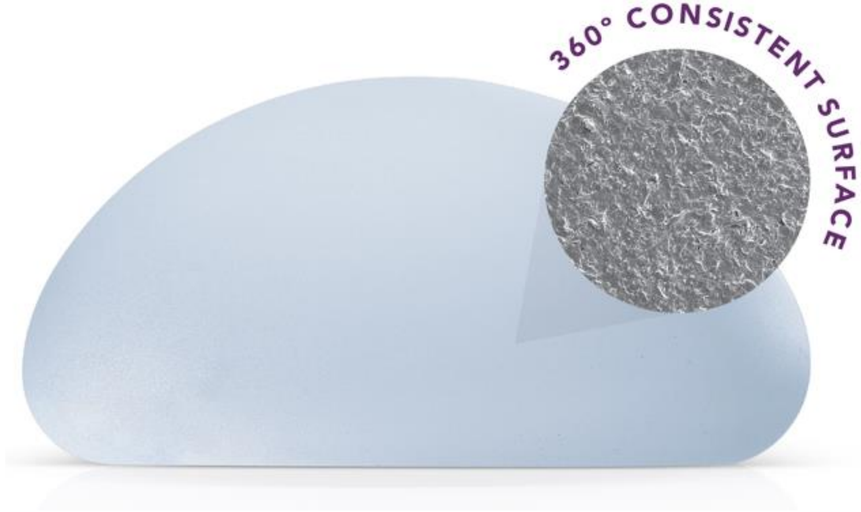
Roughness Comparison



Establishment Labs data generated internally per ISO-14607:2018
Surface Characterization Report of different breast implants available in the market. TS-001019 Rev. 1, June 2019.

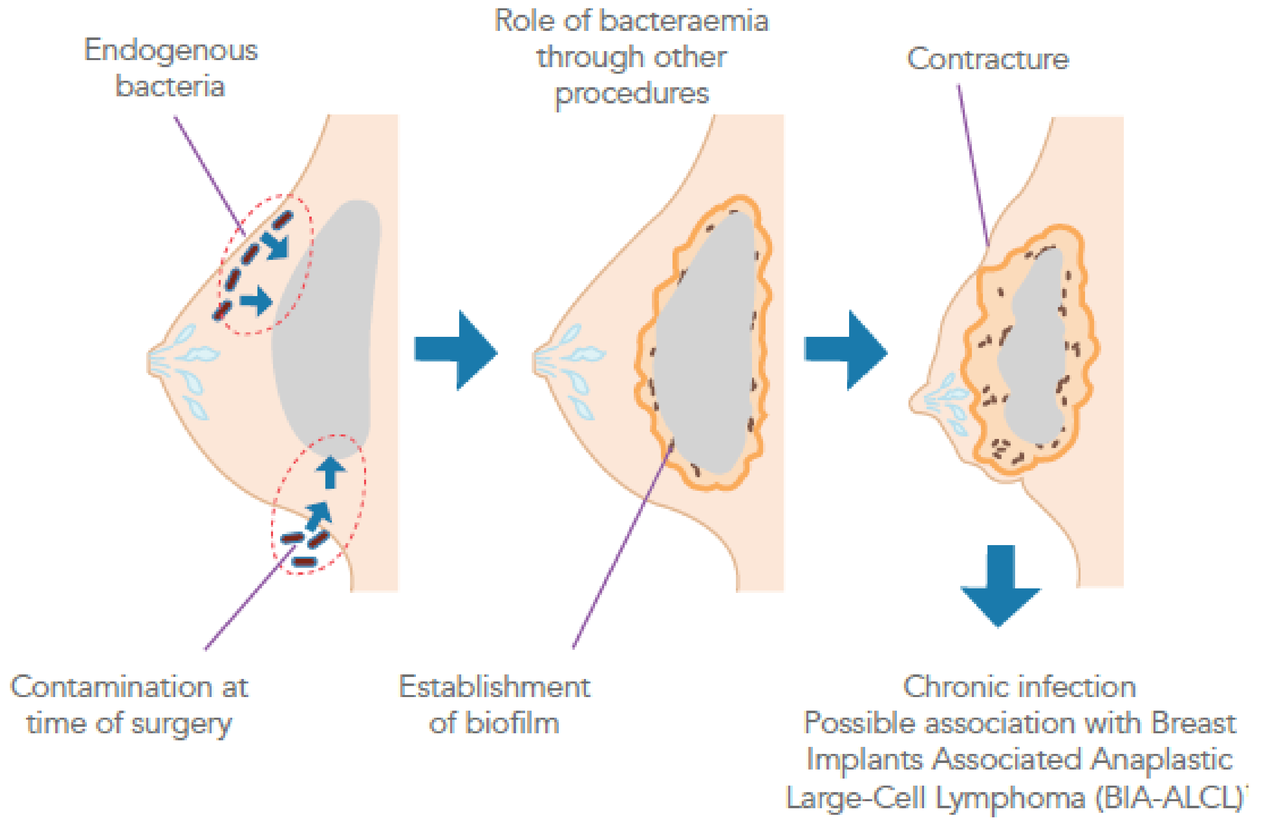
SmoothSilk®/SilkSurface®
Bio-Engineered Cell Friendly Surface

Three-dimensional (3D) surface imprinting for 360° controlled surface topography and optimal cellular response



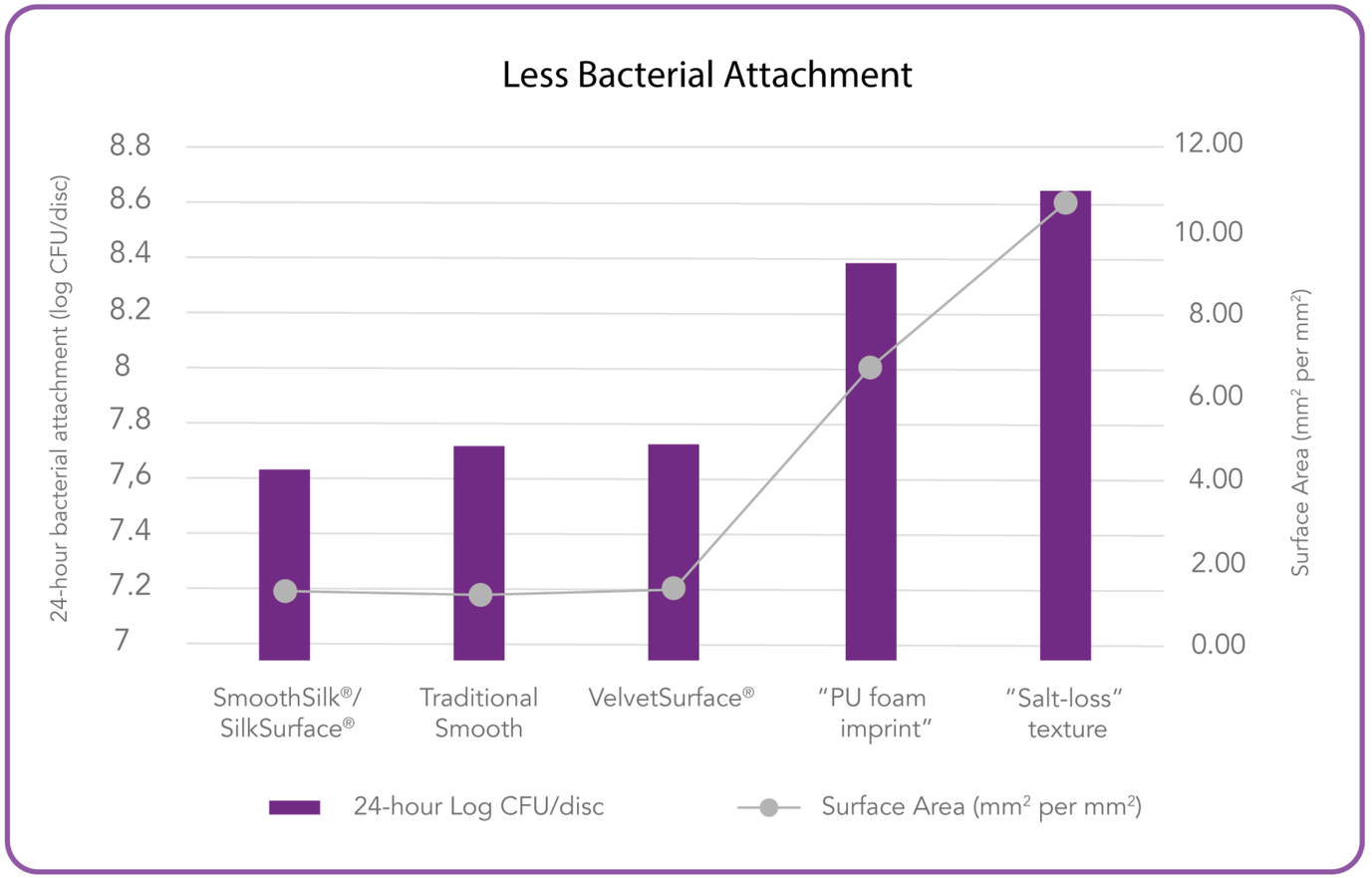
Complications associated with Biofilm Formation

Biofilm is a significant contributor to capsular contracture, potential trigger of ALCL



Ajdic, D., Zoghbi, Y., Gerth, D., Panthaki, Z., & Thaller, S. (2016). *Aesthetic Surgery Journal,* 36(3), 297–309. Deva, A. K., Adams, W. P. & Vickery, K. 2013. *Plast Reconstr Surg*, in press. Hu H, Jacombs A, Vickery K, Merten SL, Pennington DG, Deva AK. (2015). Plast Reconstr Surg., 135, 319–329. Rieger, U. M., Mesina, J., Kalbermatten, D. F., Haug, M., Frey, H. P., Pico, R., Frei, R., Pierer, G., Luscher, N. J. & Trampuz, A. (2013). Br J Surg, 100, 768-74. Tamboto, H., Vickery, K. & Deva, A. K. (2010). Plast Reconstr Surg, 126, 835-842.

Surface Area & Biofilm

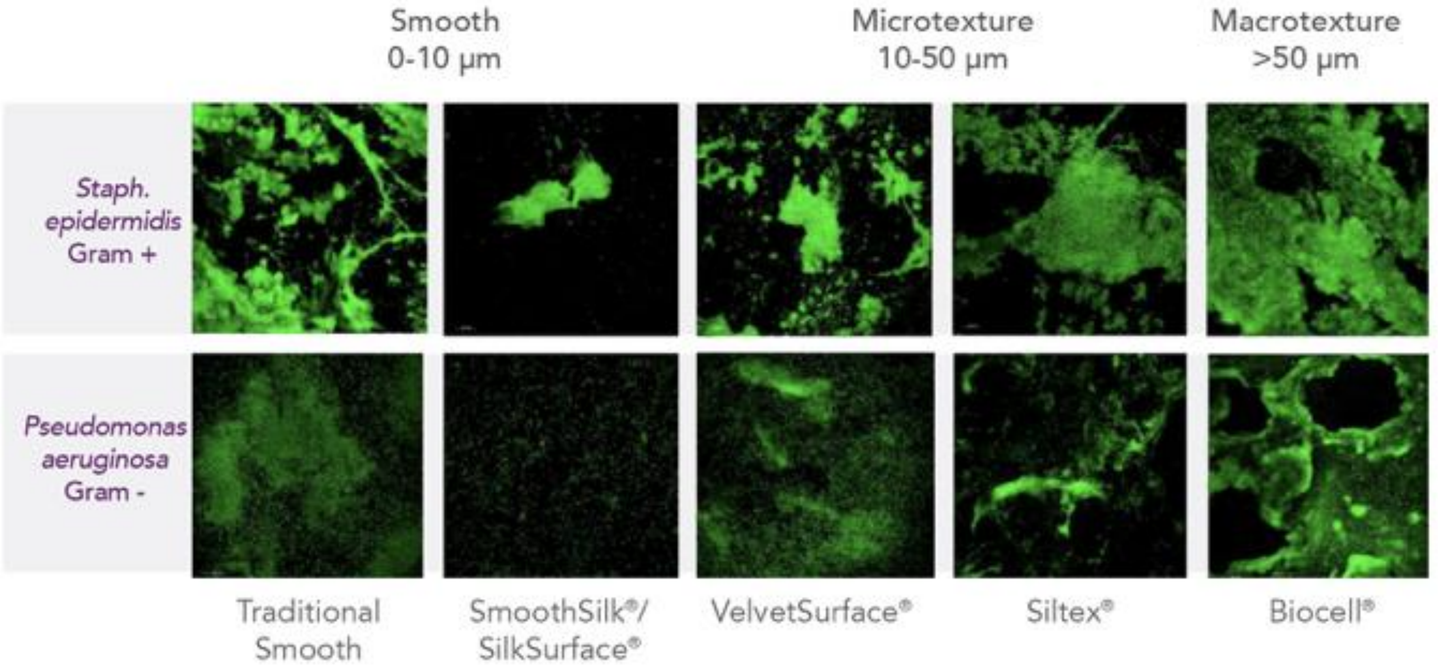


Surface area measured for different breast implants and 24- hour average log(10) CFU/disc (*Staphylococcus epidermidis* bacteria attachment) to them, based on The Center of Biofilm Engineering Testing at Montana State University.

Loch-Wilkinson, A., Beath, K., Knight, R., Wessels, W., Magnusson, M., Papadopoulos, T., Connell, T., Lofts, J., Locke, M., Hopper, I., Cooter, R., Vickery, K., Joshi, P., Prince, M., Deva, A. Breast implant associated Anaplastic Large Cell Lymphoma in Australia and New Zealand – high surface area textured implants are associated with increased risk. Plastic and Reconstructive Surgery Advance Online Article.

Less Bacterial Adhesion & Biofilm[7,8]

Surfaces with rougher texture and greater surface area promote a higher growth of bacteria compared to smoother surfaces.[7,8]



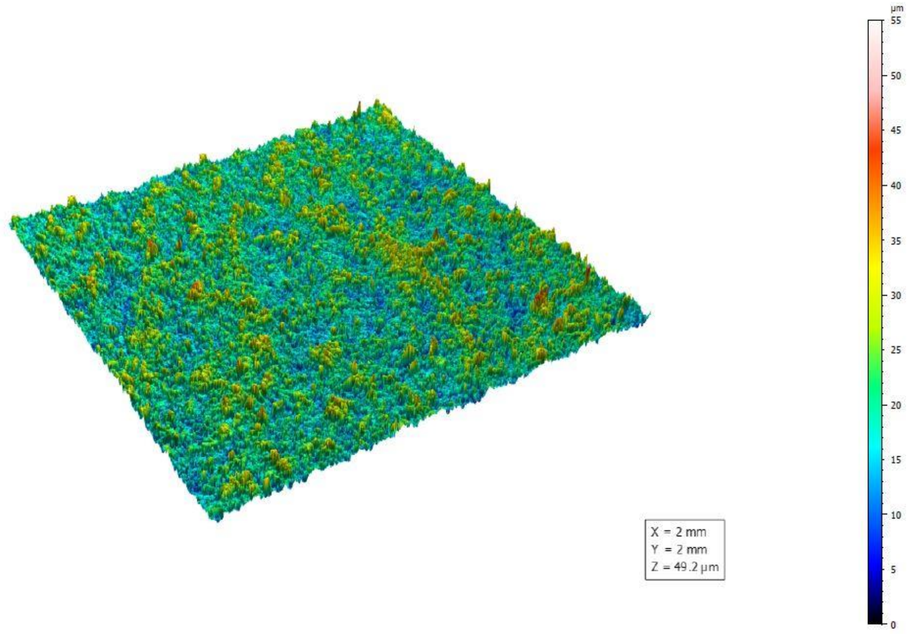
Confocal microscopy images of *S. epidermidis* and *P. aeruginosa* biofilms after 24 h of growth on breast implant surfaces. More biofilm was observed on the Biocell® and Siltex® textures than the SmoothSilk®/SilkSurface® and VelvetSurface® textures.

Independent testing performed by the Center for Biofilm Engineering, Montana State University, USA.

Loch-Wilkinson, A., Beath, K., Knight, R., Wessels, W., Magnusson, M., Papadopoulos, T., Connell, T., Lofts, J., Locke, M., Hopper, I., Cooter, R., Vickery, K., Joshi, P., Prince, M., Deva, A. Breast implant associated Anaplastic Large Cell Lymphoma in Australia and New Zealand – high surface area textured implants are associated with increased risk. Plastic and Reconstructive Surgery Advance Online Article.

SmoothSilk®/SilkSurface®

- Topography made of small dimensions
- More peaks than valleys
- High density of peaks
- Low inflammation
- Low roughness
- Low surface area
- Low bacteria attachment
- Less friction

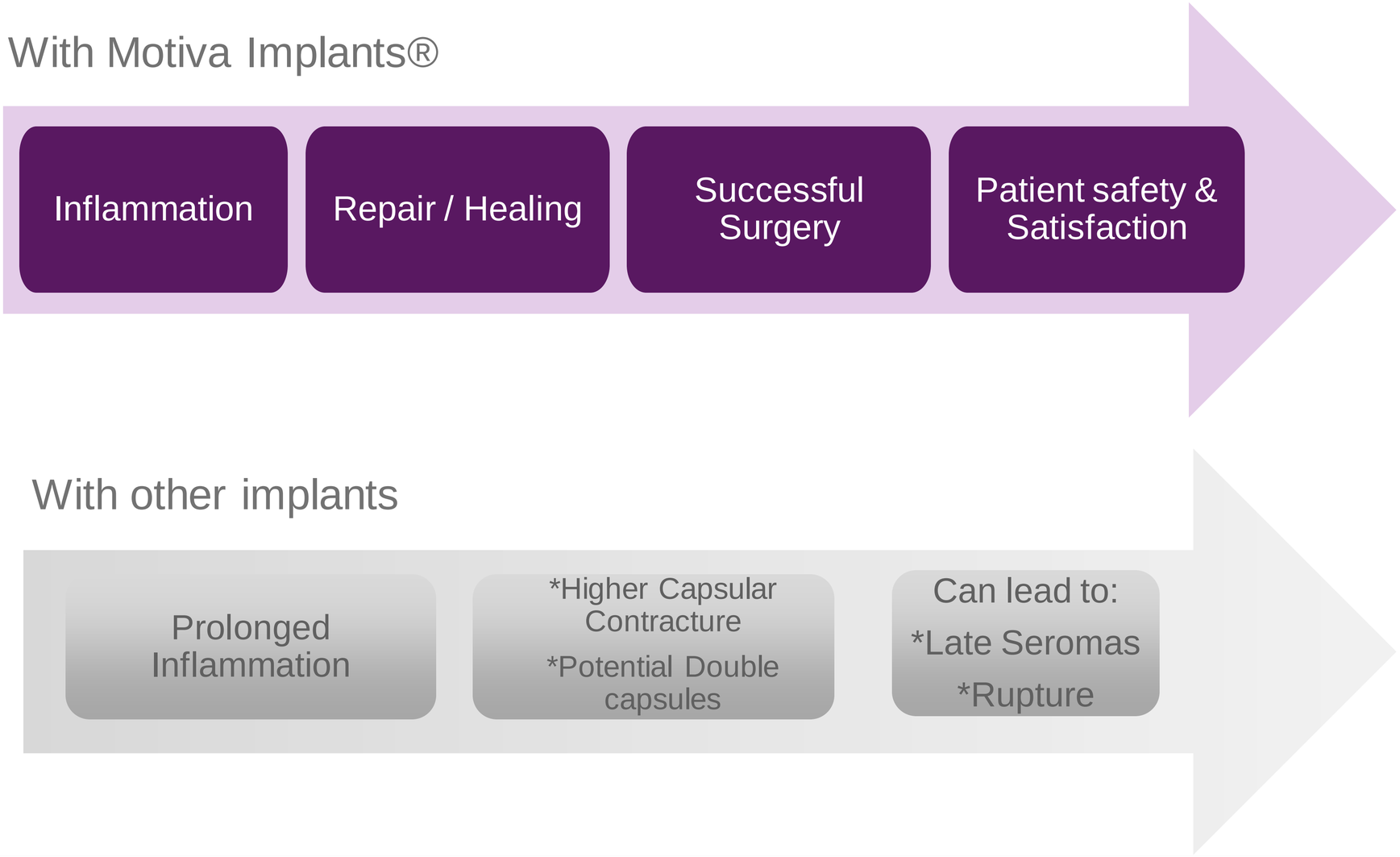


SmoothSilk®/SilkSurface® 3D topography view taken with uSurf Mobile Profilometer

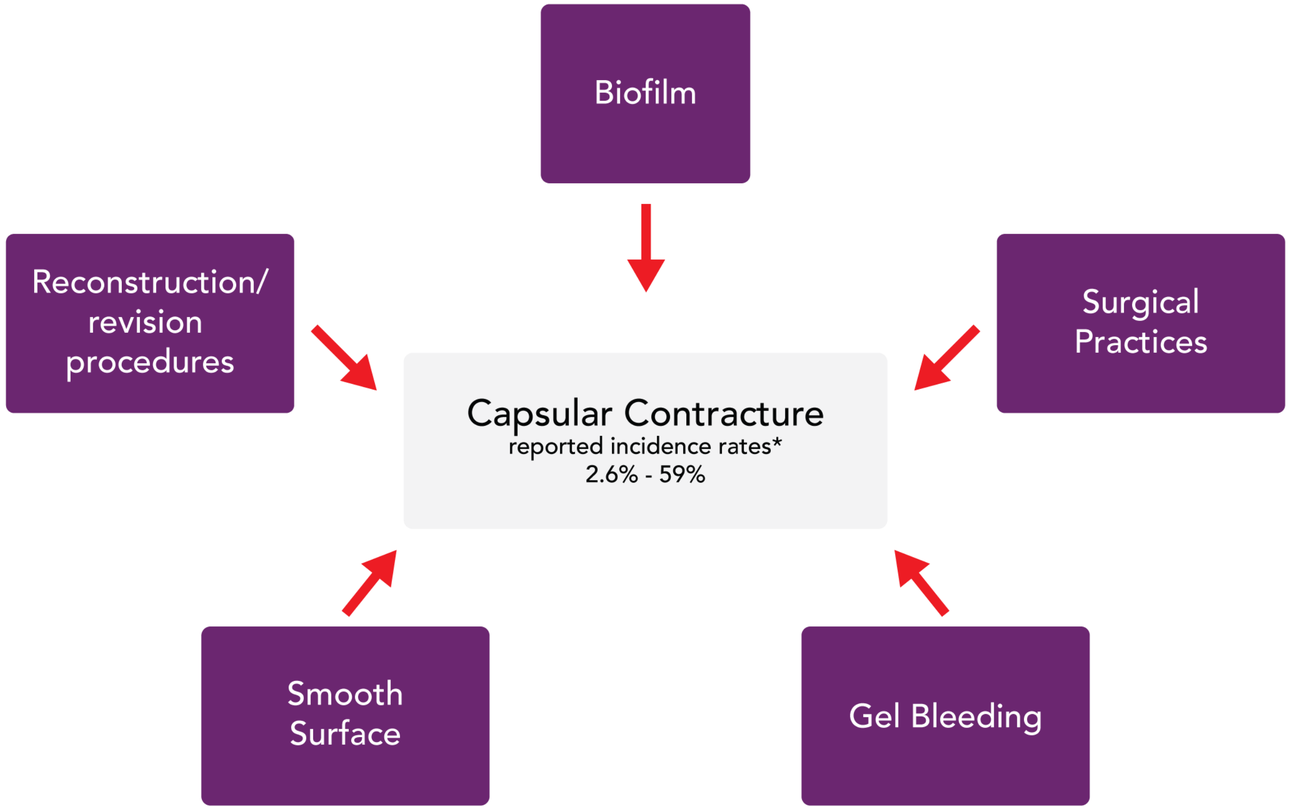
Biocompatibility

Compatibility with living tissue or a living system by not being toxic, injurious or physiologically reactive and not causing immunological rejection

Foreign Body Response



Drivers that Increase the Risk of Capsular Contracture



*Lower value corresponding to textured implant rate from Sientra·s 5-Year Study (Stevens, et al., 2013) and higher value corresponding to smooth surface rate from a three year follow-up (Malata et al. 1997).1. Barnsley, et al. 2006. 2. Barr, et al. 2009. 3. Stevens, et al. 2008. 4. FDA, 2011. 5. Rebello, et al. 2011. 6. Barr, Hill, Bayat, 2009.7. Harvey, Hill & Bayat, 2013. 8.Dalby et al. 2004. 9. Jacombs, et al. 2014. 10. Tamboto, Vickery & Deva, 2010. 11.Deva, Adams, Vickery, 2013. 12. Wong, et al. 2006. 13. Liv et al. 2015. 14. Caterson & Orgill, 2014. 15.Spear, et al. 2007. 16. Spear&Murphy, 2014.

Prevention

- Less Biofilm
- Less Friction
- Less Silicon debris
- Less Gel Bleed
- Optimized surface topography

Surface Optimization in Literature

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Current Implant Surface Technology: An Examination of Their Nanostructure and Their Influence on Fibroblast Alignment and Biocompatibility

S. Barr, BSc,[a] E. Hill, PhD,[b] and A. Bayat PhD, MBBS, MRCS[a]

[a]Plastic & Reconstructive Surgery Research, Manchester Interdisciplinary Biocentre, The University of Manchester, Manchester, United Kingdom; and [b]Manchester Centre for Mesoscience & Nanotechnology, Information Technology Building, The University of Manchester, Manchester, United Kingdom

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Biomaterials

journal homepage: www.elsevier.com/locate/biomaterials

Development and functional evaluation of biomimetic silicone surfaces with hierarchical micro/nano-topographical features demonstrates favourable *in vitro* foreign body response of breast-derived fibroblasts

CrossMark

Daniel J.T. Kyle [a, b], Antonios Oikonomou [b], Ernie Hill [b], Ardeshir Bayat [a, *]

[a] *Plastic and Reconstructive Surgery Research, Manchester Institute of Biotechnology, University of Manchester, Manchester, UK*
[b] *School of Computer Science, Centre for Mesoscience and Nanotechnology, The University of Manchester, Manchester, UK*

EXPERT REVIEWS

Designing implant surface topography for improved biocompatibility

Expert Rev. Med. Devices 10(2), 257–267 (2013)

Alison G Harvey[1], Ernie W Hill[2] and Ardeshir Bayat*[1,3]

[1]*Plastic and Reconstructive Surgery Research, Manchester Institute of Biotechnology, The University of Manchester, Manchester, UK*
[2]*The Manchester Centre for Mesoscience and Nanotechnology, The University of Manchester, Manchester, UK*
[3]*Manchester Academic Health Science Centre, Institute of Inflammation*

Modern approaches to biomaterials aim to instigate a specific tissue response to create truly biocompatible materials. With this in mind, the responses of cells to biomimetic surface topographies have been studied. This review compares the findings and links the results to the processes which occur when cells contact a surface. Topographical features such as grooves and ridges or pits and pillars can have a dramatic effect on the composition of protein layers affecting protein orientation and conformation. It has been demonstrated that these surface properties along with others, such as surface compliance, can significantly impact on specific cell–surface interactions. Design strategies to minimize foreign body reactions should consider the shape, size, spacing and curvature of topographical features. In doing this, it should be possible to control the signals that are relayed to the nucleus and thus gain a degree of control over the cell behavior and ultimately the tissue response.

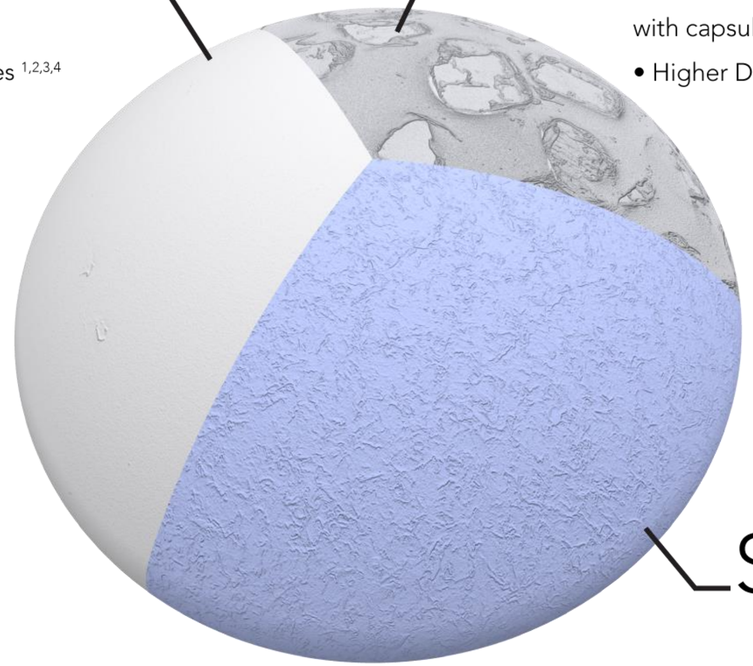
Surface & Medical Complications Linkage

Smooth Surface

- Higher Inflammation [1,2,3,4]
- Higher Fibrosis [1,2,3,4]
- Higher capsular contracture rates [1,2,3,4]
- Lower Biofilm development [3,4]

Macro Texture

- Associated with BI-ALCL [6,9]
- Capsular contracture rates still high.[1,2,3,4]
- Higher Biofilm development [1,4,5,7,8] associated with capsular contracture [1,2,3,4]
- Higher Double Capsule [16,17,18]and late Seroma rates [3,16,17]

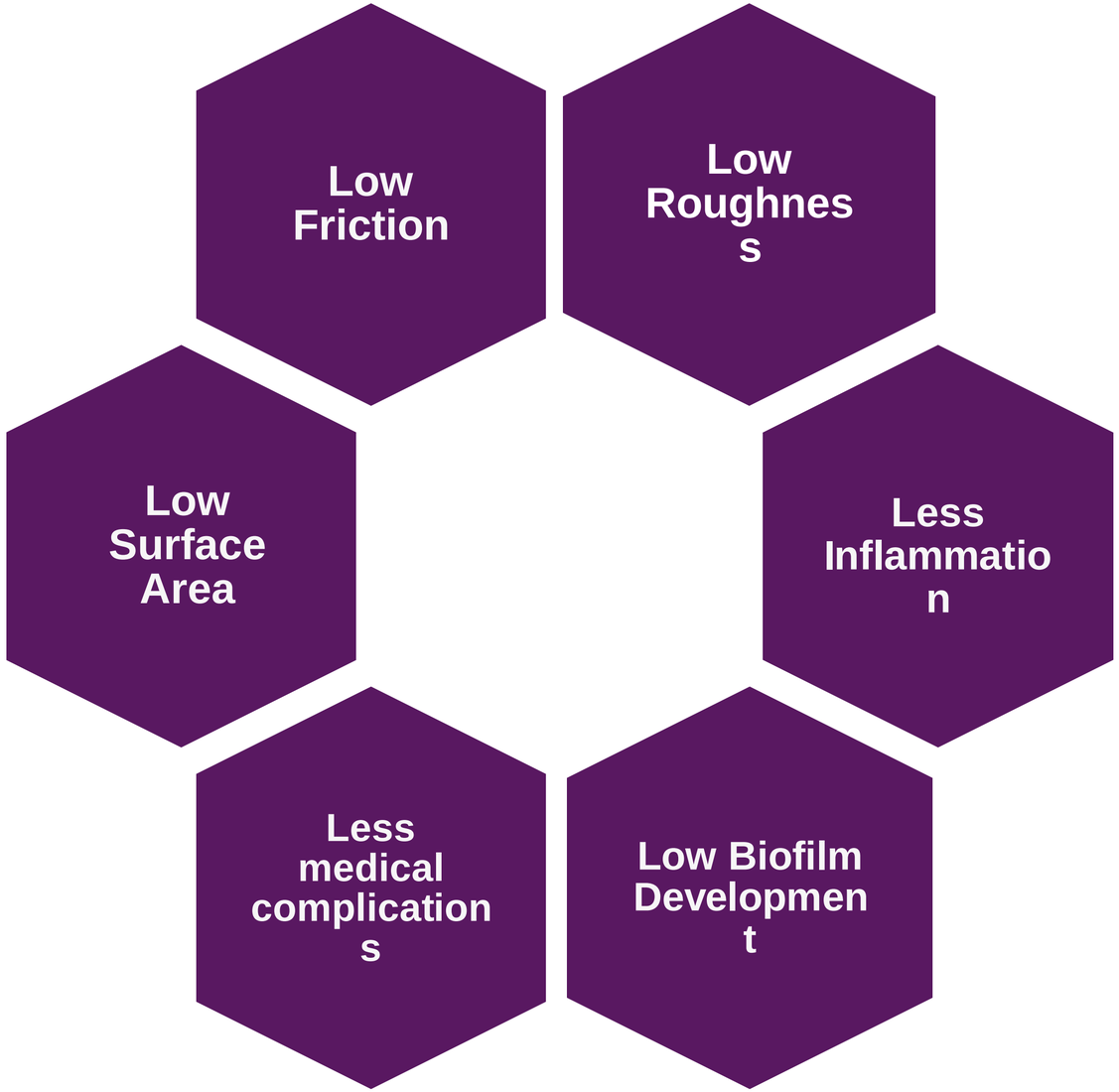


SilkSurface®

- Lower Inflammation [13,14]
- Less Fibrosis [13,14]
- Less CC rates [10,11,12,13,14,19]
- No ALCL reported cases [3,10,11,12]
- Less Biofilm development [15]

1.*Barnsley, et al. 2006.* **2.** *Stevens, et al., 2010.* **3.** *FDA, 2011.* **4.** *Jacombs, et al., 2014.* **5.***Hu, et al. 2014.* **6.** *FDA, (BIA-ALCL), 2017.* **7.** *Tamboto, Vickery & Deva, 2010.* **8.** *Deva, Adams & Vickery, 2013.* **9.** *Loch-Wilkinson, et al., 2107*
10. *Summary of Clinical Data 6-Year Follow-up. Establishment Labs. February 2016.* **11.** *Preliminary Assessment of the Motiva Implants 3 years Follow-up report, 2016.* **12.** *Dolan Park Hospital Report, 2016. 13. Barr, Hill, Bayat, 2009.*
14. *Doloff, J. C & Veiseh, 2017.* **15.** *Garth-James, K. A. 2017.* **16.** *Hall-Findlay, 2011.* **17.** *Maxwell, et al. 2014.* **18.** *Danino, 2015.* **19.** *Motiva Implants® Post Market Surveillance Report (2017)*

SmoothSilk®/ SilkSurface®



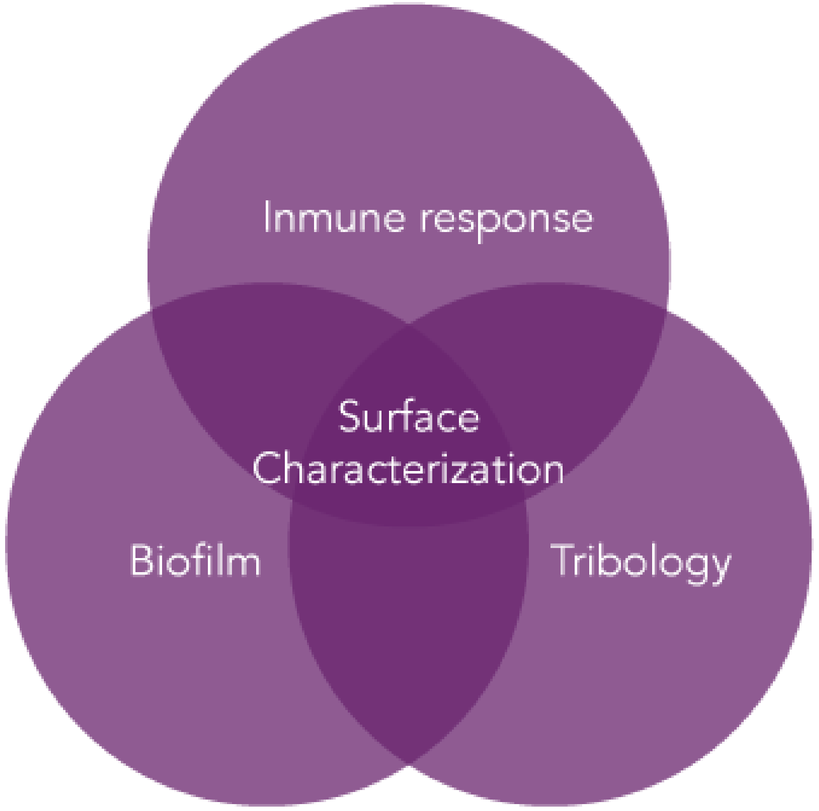
1. Motiva Implants® Silicone Breast Implants: Summary of Clinical Data- 6-Year Follow Up. February 2017. Establishments Labs Alajuela, Costa Rica. 2. Sforza, MD., Zaccheddu, MD, MSc., Alleruzzo, MD., Seno, MD., Mileto, MD., Paganelli, MD., Sulaiman, MD., Payne, MD., Maurovich-Horvat, PhD Preliminar. 3-year Evaluation of Experience With SilkSurface® and Velvet Surface® Motiva® Silicone Breast Implants: a Single Center Experience with 5813 Consecutive Breast Augmentation Cases. Aesthetic Surgery Journal 2017, 1–12. 3. Motiva Implants® Complaint Data Report October 2010 - December 2017.

The Science of Breast Tissue Management

The Research Approach of Motiva Implants®

Research Fields:

Surface Characterization and Biocompatibility



Research External Collaboration Efforts

The University of Manchester

RUSH UNIVERSITY
MINISTRARE PER SCIENTIAM
CHICAGO 1972

Tribology

Massachusetts Institute of Technology

MEDIZINISCHE UNIVERSITÄT
INNSBRUCK

UNIVERSIDAD DE COSTA RICA

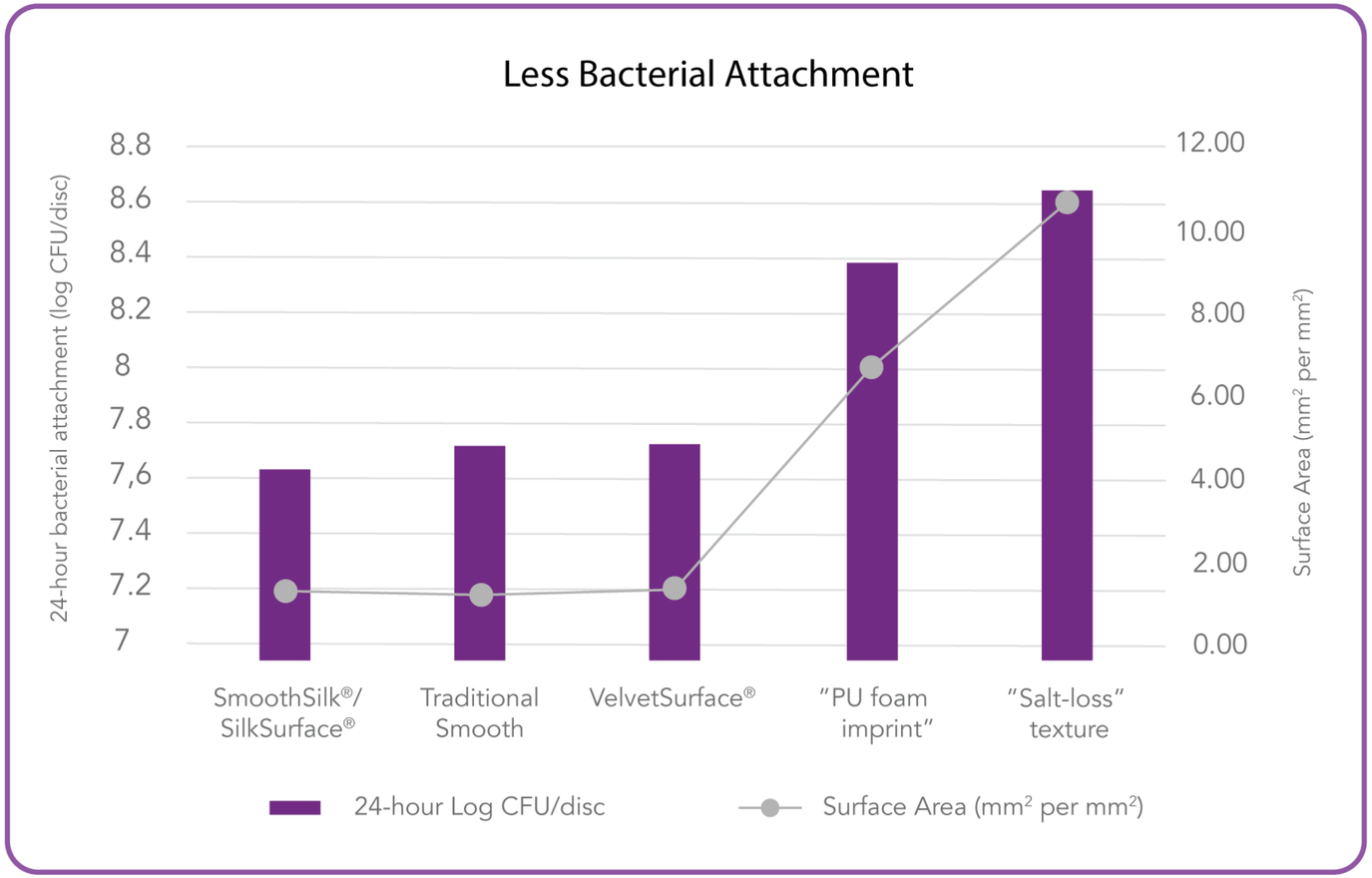
Inmune Response

MACQUARIE University

MONTANA STATE UNIVERSITY

Biofilm

Surface Area & Biofilm



Surface area measured for different breast implants and 24- hour average log (10) CFU/disc (*Staphylococcus epidermidis* bacteria attachment) to them, based on The Center of Biofilm Engineering Testing at Montana State University.

Garth James, PhD[1], Laura Boegli, BS.[1], John Hancock, BSME[2], Brian M. Kinney, MD[3]. In-vitro Testing of Bacterial Attachment and Biofilm Formation on Different Breast Implant Outer Shell Surfaces
[1]Montana State University, Bozeman, MT, USA, [2]Establishment Labs, Santa Barbara, CA, USA, [3]University of Southern California, Beverly Hills, CA, USA. http://meeting.aaps1921.org/abstracts/2018/P8.cgi

Evaluation of the effect of SilkSurface® on fibrosis in vivo animal models

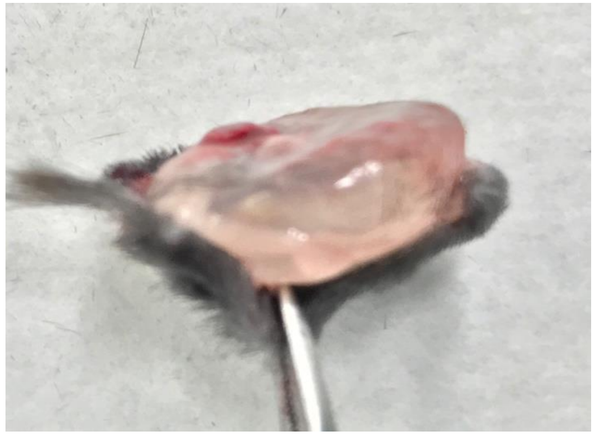
Smooth Implants

SilkSurface® Implants

In Vivo animal model
(B6 Mouse & Rabbit)

Research performed at the Robert Langer Laboratory at MIT, Boston , USA

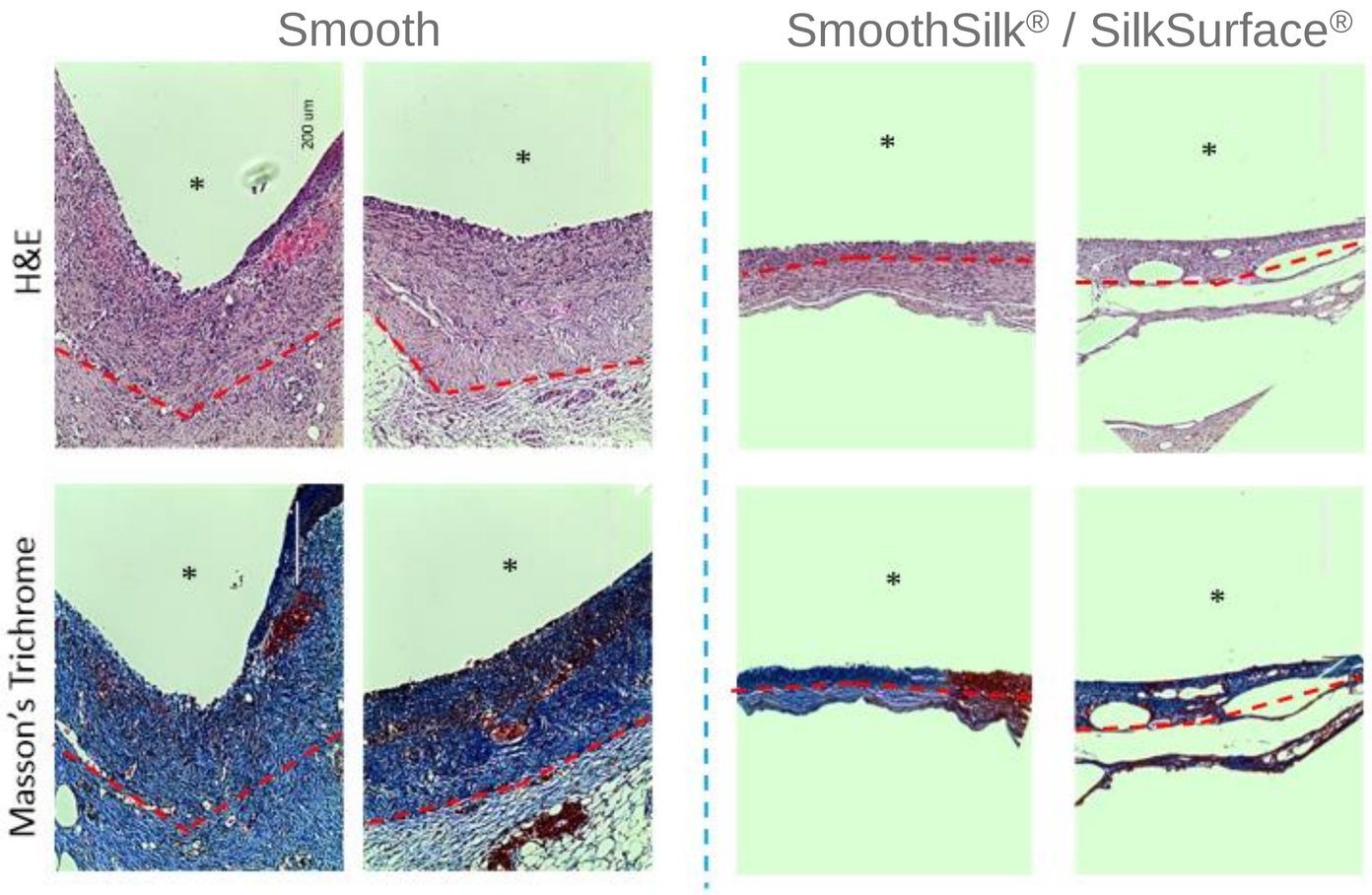
Gross examination of explanted Mini Control vs. SilkSurface® implant with tissue overgrowth

	Traditional Smooth (Control)	SmoothSilk®/SilkSurface®
3 weeks		
12 weeks		

Research performed at the Robert Langer Laboratory at MIT, Boston , USA

Low Inflammatory Response Research

SmoothSilk® / SilkSurface® ameliorates fibrosis in B6 mice

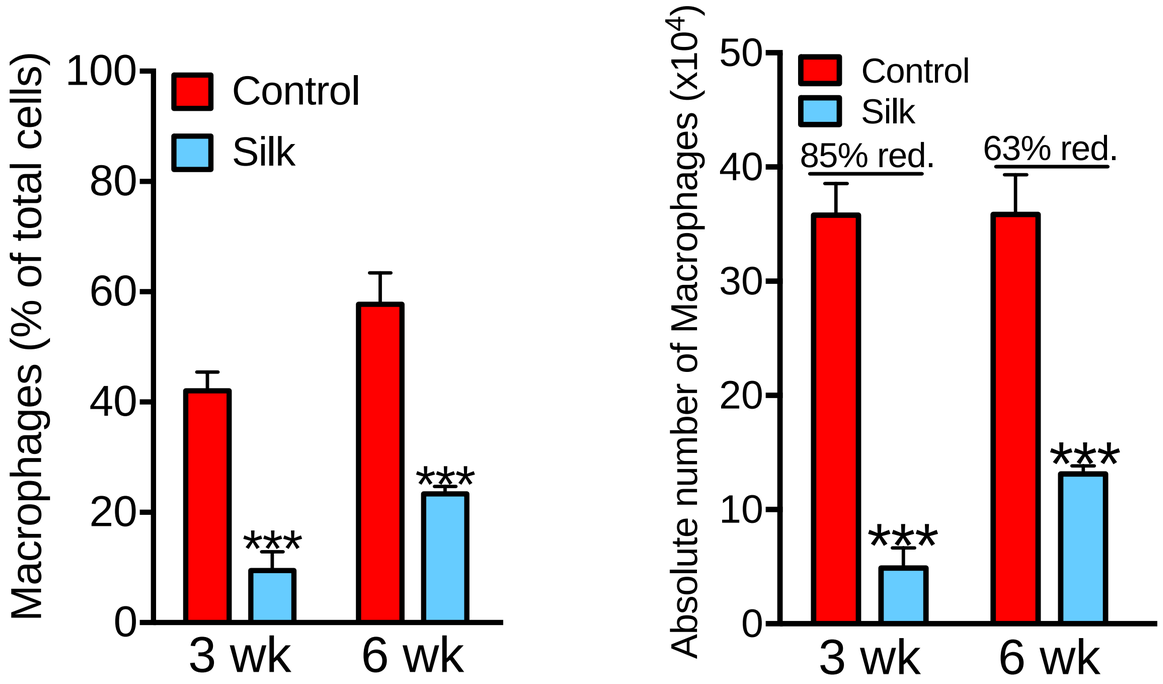


Histological analysis of the tissue capsule surrounding the Smooth and SmoothSilk® / SilkSurface® tiny implants with two different staining techniques.

Research performed at the Robert Langer Laboratory at MIT, Boston , USA

FACS analysis was used to quantify macrophages in tissue capsules surrounding implants

Less macrophages presence with SmoothSilk®/SilkSurface®

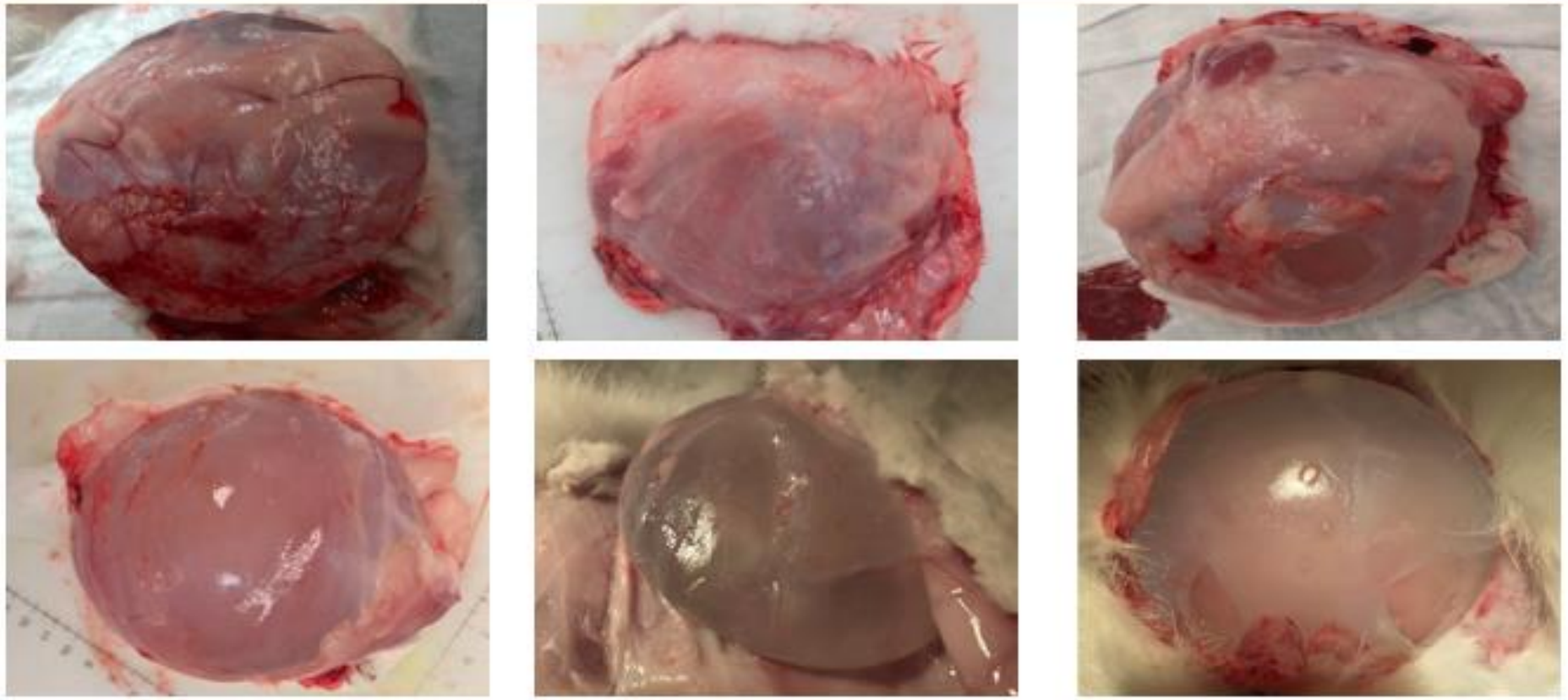


SilkSurface® **decreases fibrosis-dependent innate immune macrophages.**

Full-size Human-scale Implants testing in Higher Order Rabbit Model
3-week retrievals

Traditional Smooth (control)

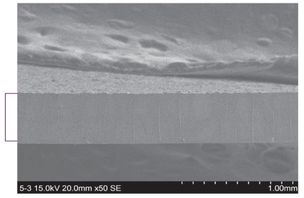
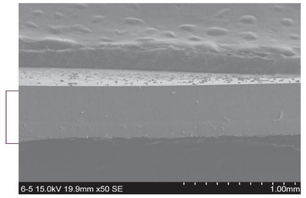
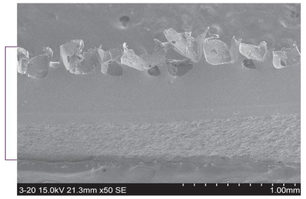
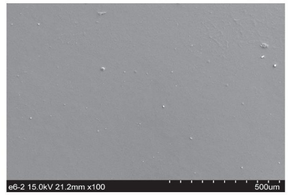
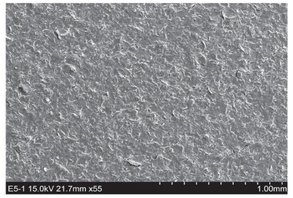
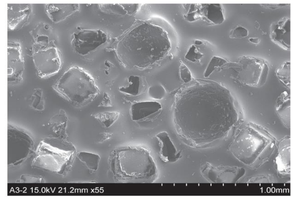
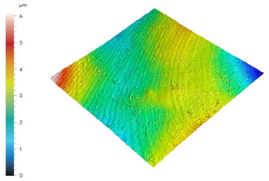
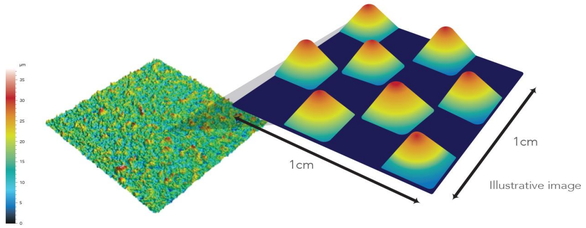
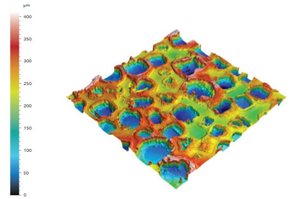
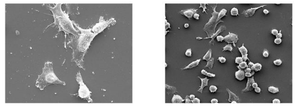
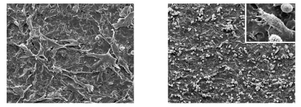
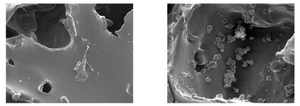
SmoothSilk®/ SilkSurface®



Research performed at the Robert Langer Laboratory at MIT, Boston , USA

WHAT MAKES SMOOTHSILK® /SILKSURFACE® UNIQUE?

1 Controlled surface topography designed for fibroblast and macrophage attachment

	Traditional Smooth	VS	SmoothSilk®/SilkSurface®	VS	Macrotexture (Salt Loss)
SEM side view					
SEM top view					
3D representation			 • **Thousands of contact points per cm²** • **Higher peaks than valleys**[5]		
Cellular Interaction	Promotes fibroblast alignment[4]  Fibroblasts Macrophages		**Promotes fibroblast attachment**[6]  Fibroblasts Macrophages		Promotes uneven fibroblast attachment and aggregation[4]  Fibroblasts Macrophages

SEM images of fibroblasts (obtained from breast tissue) and macrophages (from THP-1 monocytes cell line, ATCC) growing on different silicone surfaces.

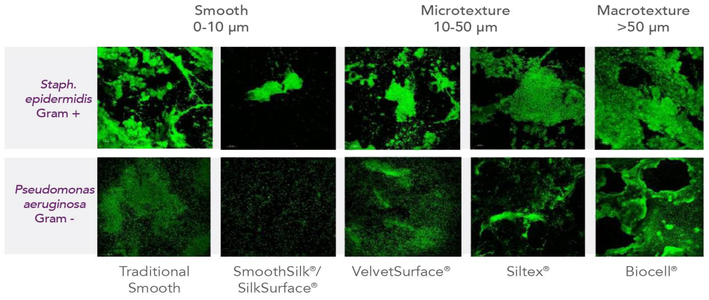
SEM & 3D Representation images courtesy of Establishment Labs
Fibroblast & macrophage images courtesy of Bayat A. University of Manchester

WHAT MAKES SMOOTHSILK® /SILKSURFACE® UNIQUE?

2 Optimal Immune System Response

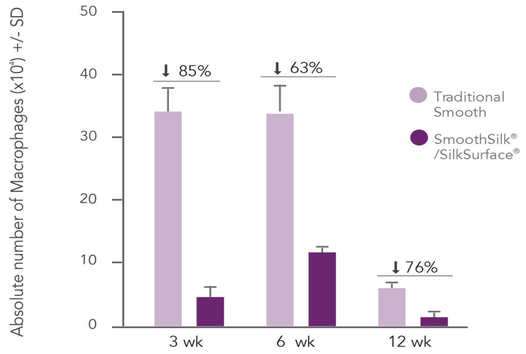
Less Bacterial Adhesion & Biofilm[7,8]

Surfaces with rougher texture and greater surface area promote a higher growth of bacteria compared to smoother surfaces.[7,8]



Confocal microscopy images of *S. epidermidis* and *P. aeruginosa* biofilms after 24 h of growth on breast implant surfaces. More biofilm was observed on the Biocell® and Siltex® textures than the SmoothSilk®/SilkSurface® and VelvetSurface® textures.

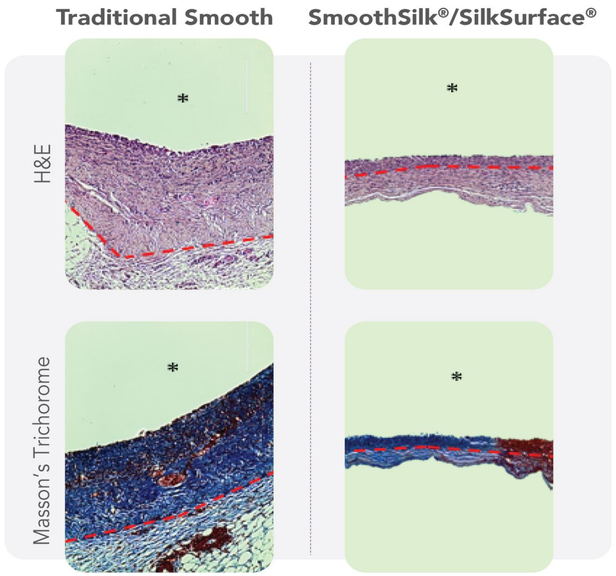
Low Inflammatory Response with Less Macrophages than Traditional Smooth[9]



SmoothSilk®/SilkSurface® decreases fibrosis-dependent innate immune macrophages in mouse capsule tissue.

Less Fibrotic Encapsulation than Traditional Smooth[9]

SmoothSilk®/SilkSurface® ameliorates fibrosis in C57Bl6 mice



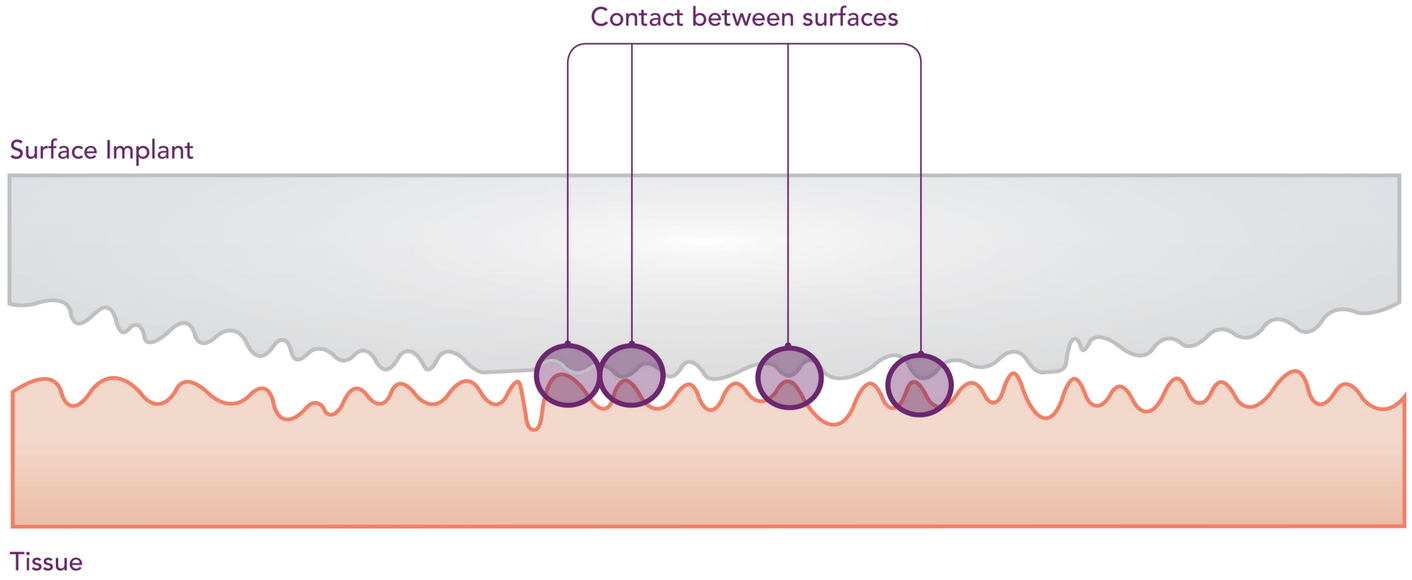
Asterisk shows where the implant was. Dotted red line delimits the capsule layers

Histological analysis of the tissue capsule surrounding traditional smooth implants on the left and SmoothSilk®/SilkSurface® tiny implants on the right with two different staining techniques.

Tribology Testing

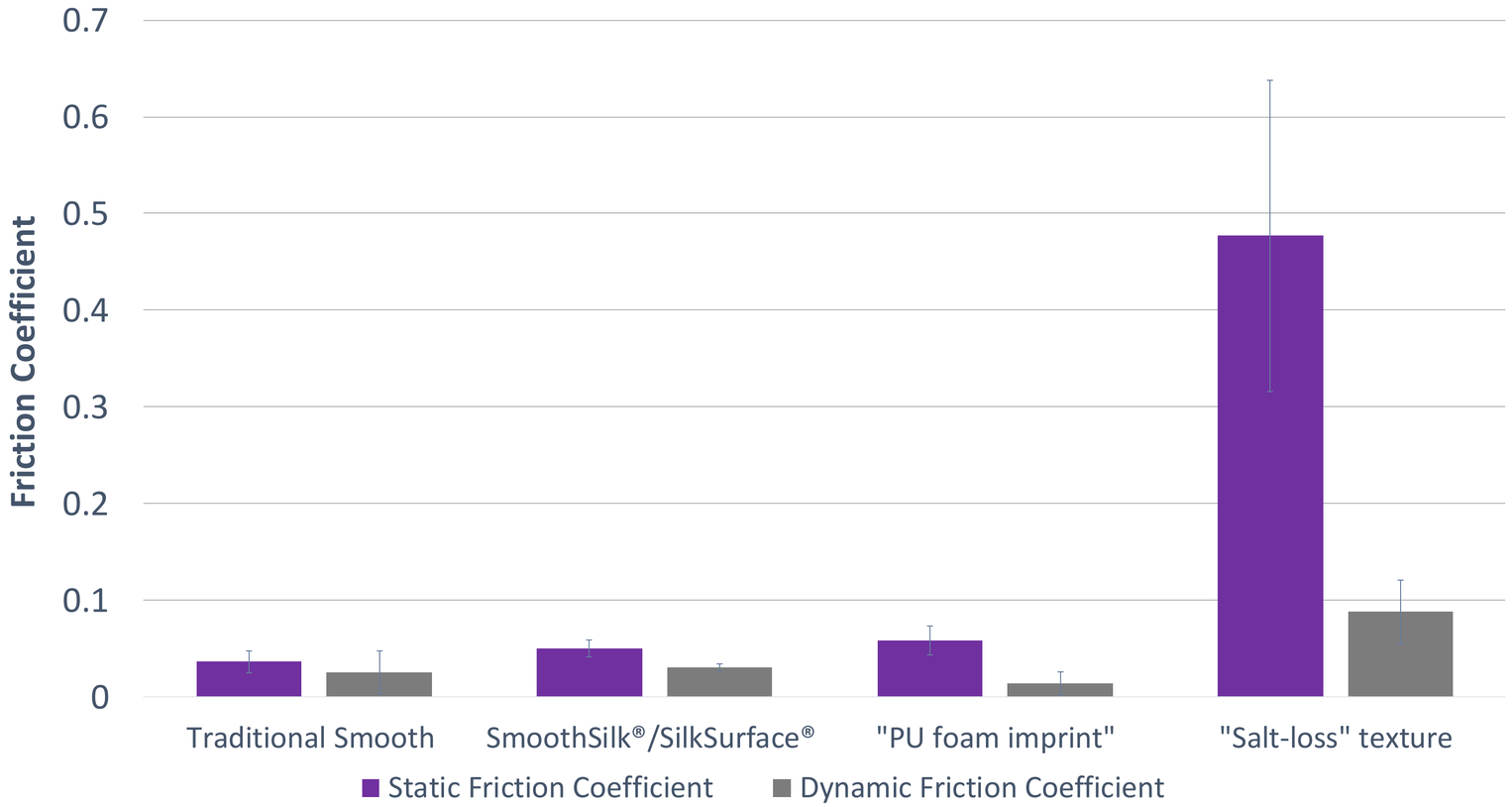
Tribology is the study of the surfaces moving relative to one another

- Wear particles
- Wear rate
- Friction coefficient



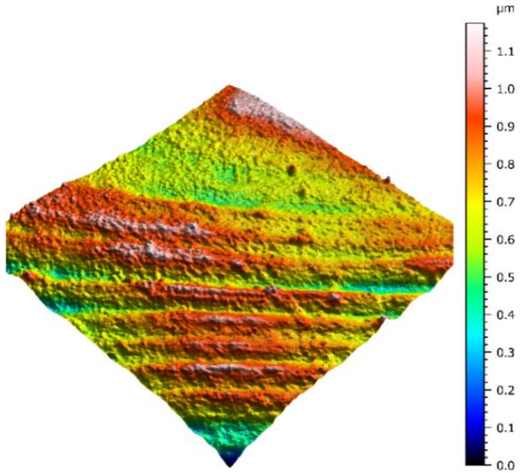
Tribology: Friction and Wear

- Static friction: is the force that must be overcome to start moving the object.
- Dynamic friction: relates to the force needed to keep a surface in motion at a constant velocity.

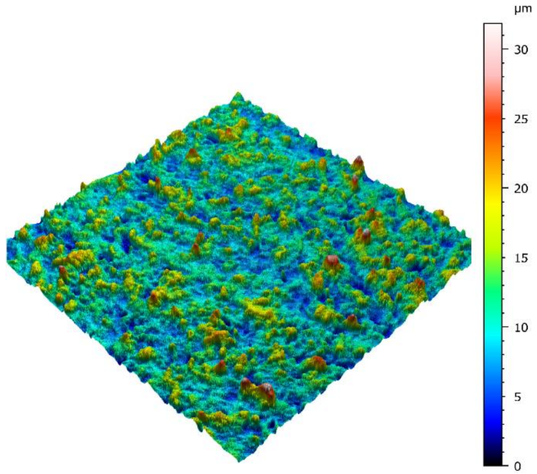


Comparative of static and dynamic average coefficients of different breast implants available in the market. Testing Performed on Akron Rubber Development Laboratory, Inc. Results Property of Establishment Labs (2017).

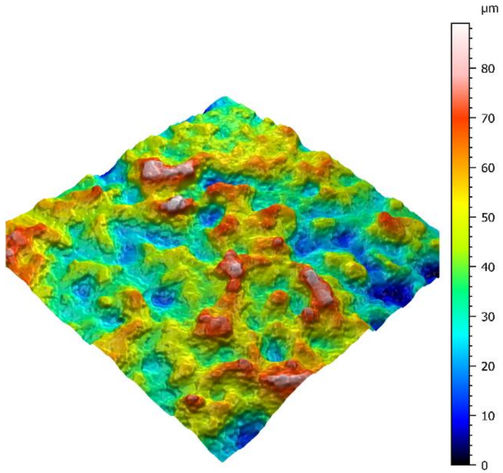
3D Topography views taken with uSurf Mobile Profilometer



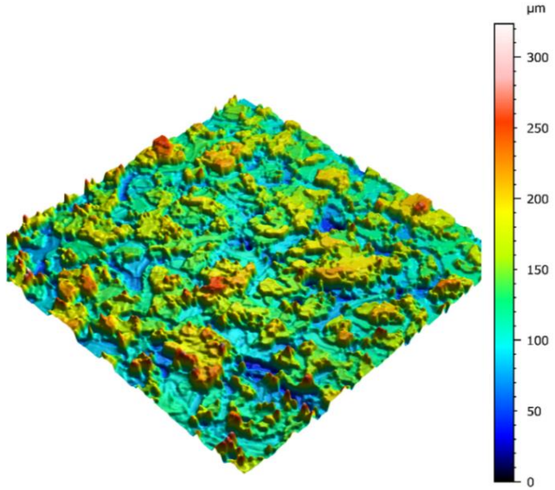
Traditional Smooth



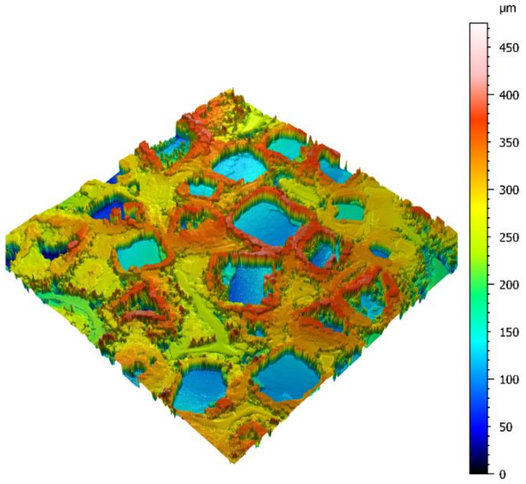
SmoothSilk®/SilkSurface®



VelvetSurface®



“PU foam imprint”



“Salt-loss” texture

This is an automatic zoom made by the equipment, note the color scale dimensions

Conclusions from these Research Projects

1. Less biofilm formed on the SilkSurface® and VelvetSurface® than the "PU foam imprint" and "Salt-loss" macro-textures, showing a link between surface area and biolfilm load.

2. SmoothSilk®/SilkSurface® ameliorates the development of fibrotic capsules in mice and rabbit models compared to traditional smooth, showing that a nano scale surface reduces the innate immune response, leading to less aggressive capsules.

3. SmoothSilk®/SilkSurface® have less inflammatory cellular presence than traditional smooth implants in mice and rabbit models, demonstrating the improved biocompatibility of this surface.

The Science of Breast Tissue Management

Motiva Implants® Clinical Evidence

2017 progress report at 6 years of a 10 year prospective study with MRI

Safety

No reported rupture, capsular contracture, double capsule or late seromas. No implant replacement due to clinical reasons.

100% of MRI cohort showed no evidence of implant rupture or capsular contracture

*MRI cohort 62% of the patients (N=20)

<1%

Complication	MRI cohort results 6-years follow-up (N=20)	6-years follow-up results (N=35)
Capsular contracture III/IV	0%	0%
Rupture after implantation	0%	0%
Late seroma	0%	0%
Double capsule	*N/A	0%
ALCL	*N/A	0%

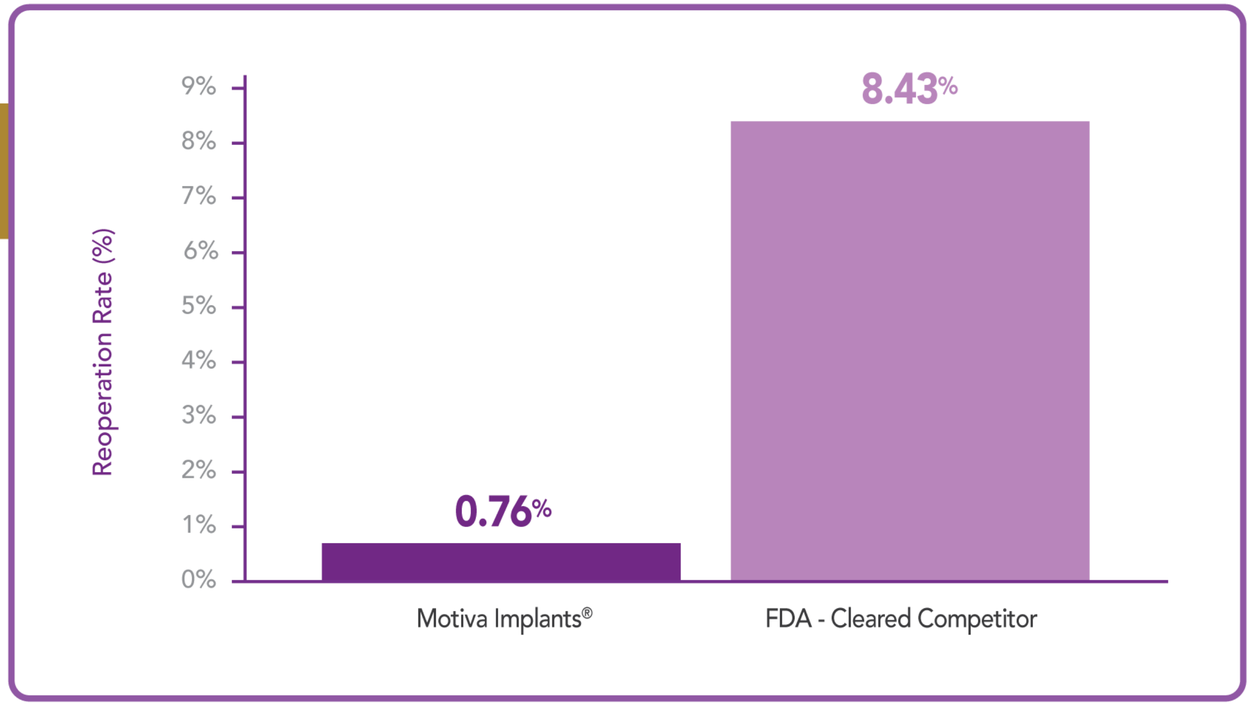
*Not applicable

<1% Low complication rates in comparison to those reported in published literature regarding silicone gel-filled breast implants.

Retrospective Study: 3-year follow-up of 5,813 consecutive causes with Motiva Implants® and competitor experience at Dolan Park Hospital in the United Kingdom performed by 16 Consultant Plastic Surgeons

Lower Reoperation Rate at 3 years

<1%



<1% Low complication rates in comparison to those reported in published literature regarding silicone gel-filled breast implants.

Article Contents

Preliminary 3-Year Evaluation of Experience With SilkSurface and VelvetSurface Motiva Silicone Breast Implants: A Single-Center Experience With 5813 Consecutive Breast Augmentation Cases

Marcos Sforza, MD ✉, Renato Zaccheddu, MD, MSc, Angelo Alleruzzo, MD, Adriano Seno, MD, Domenico Mileto, MD, Arnaldo Paganelli, MD, Hassan Sulaiman, MD, Michael Payne, MD, Lajos Maurovich-Horvat, PhD

Aesthetic Surgery Journal, sjx150, https://doi.org/10.1093/asj/sjx150

Published: 14 September 2017

Abstract

Background

Silicone breast implants have been in use for breast augmentation for more than 50 years, but technological innovation has been lacking in implant design until recently.

Study Design

- A Single-Center Experience, The Hospital Group, UK
- 16 Plastic Surgeons
- 5813 consecutive breast augmentation and revision cases
- SilkSurface® and VelvetSurface®

Published Paper Conclusions

- Excellent safety profile
- Very low rates of early complications
- No late-term complications
- No cases of device-related implant rupture
- No primary capsular contracture (Baker III/IV) cases
- No double capsules/No late seromas
- Very low re-operation rate
- 3 times more complications with VelvetSurface® than SilkSurface®

MOTIVA IMPLANTS® 3 YEARS RETROSPECTIVE ANALYSIS

Study published in Aesthetic Surgery Journal

5813 PATIENTS

2506 with Motiva Implants® SilkSurface®
(Representing more than 5000 implants)

100% OF ASSESSED PATIENTS

Mean of post-surgical follow-up interval: 23 months

16 PLASTIC SURGEONS

One Study Site: Dolan Park Hospital in UK

KAPLAN-MEYER ANALYSIS

SURGICAL TECHNIQUE

97% INFRAMAMMARY INCISION

79% DUAL PLANE

RESULTS

OVERALL COMPLICATION RATE WITH MOTIVA IMPLANTS® SILKSURFACE®

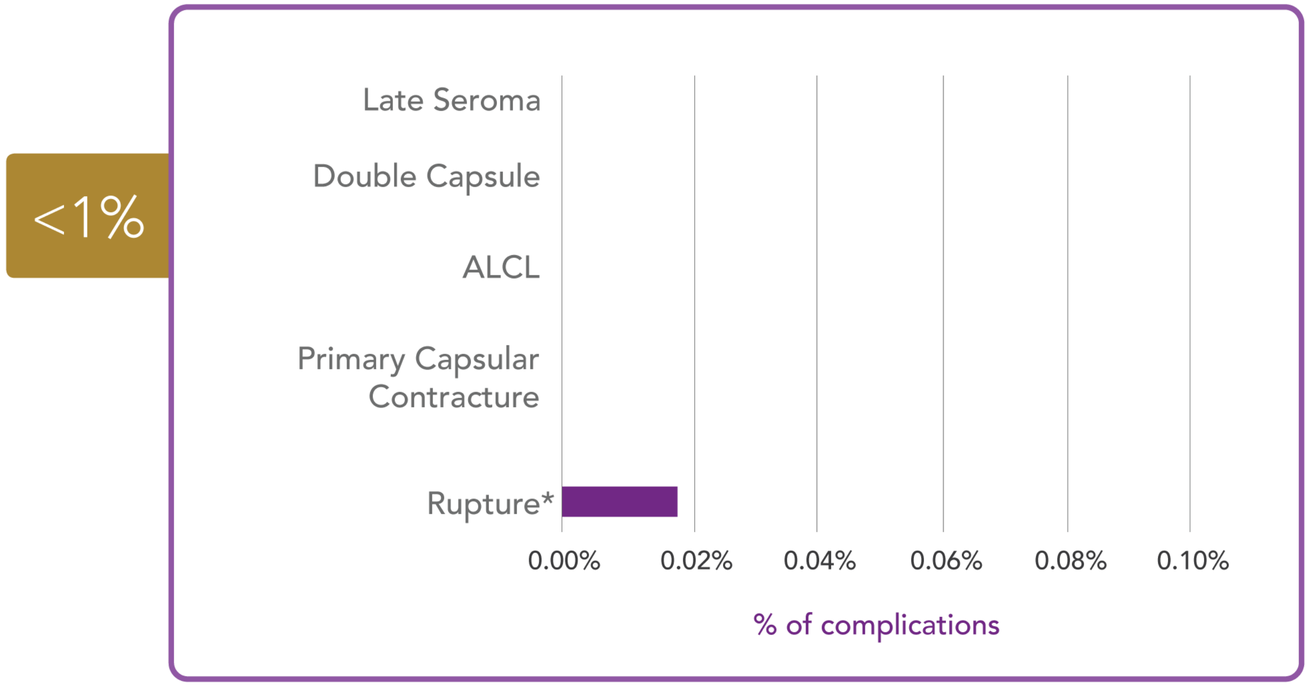
Complications were: Early Seroma, Infection, Dehiscence

NO CASES OF:

- **0% CAPSULAR CONTRACTURE**
- **0% RUPTURE DUE TO DEVICE FAILURE**
- **0% RIPPLING**
- **0% LATE SEROMA**

Retrospective Study: 3-year follow-up of 5,813 consecutive causes with Motiva Implants® and competitor experience at Dolan Park Hospital in the United Kingdom performed by 16 Consultant Plastic Surgeons

Complications Rates at 3 years



**Implant ruptures related to contact with metal instruments.*

No reports of implant rupture due to device failure.

Sforza, MD., Zaccheddu, MD, MSc., Alleruzzo, MD., Seno, MD., Mileto, MD., Paganelli, MD., Sulaiman, MD., Payne, MD., Maurovich-Horvat, PhD Preliminar. 3-year Evaluation of Experience With SilkSurface® and Velvet Surface® Motiva® Silicone Breast Implants: a Single Center Experience with 5813 Consecutive Breast Augmentation Cases. Aesthetic Surgery Journal 2017, 1–12.

Motiva Implants® Post Market Vigilance Report

In the first 7 years since the launch more than 300,000 Motiva Implants® have been placed with only 108 clinically related adverse events reported.

Complications Rates (N=386,284)

<1%

Complication	Number of cases	Risk rates %
Capsular contracture III/IV	56	<1%
Rupture after implantation*	13	<1%
Late seroma	0	0%
Double capsule	0	0%
ALCL	0	0%

**No cases of implant rupture due to device failure.*

Clinical related events

0.028%

Motiva Implants® Complaint Data Report October 2010 - December 2017.

Post-Market Surveillance – Motiva Implants®

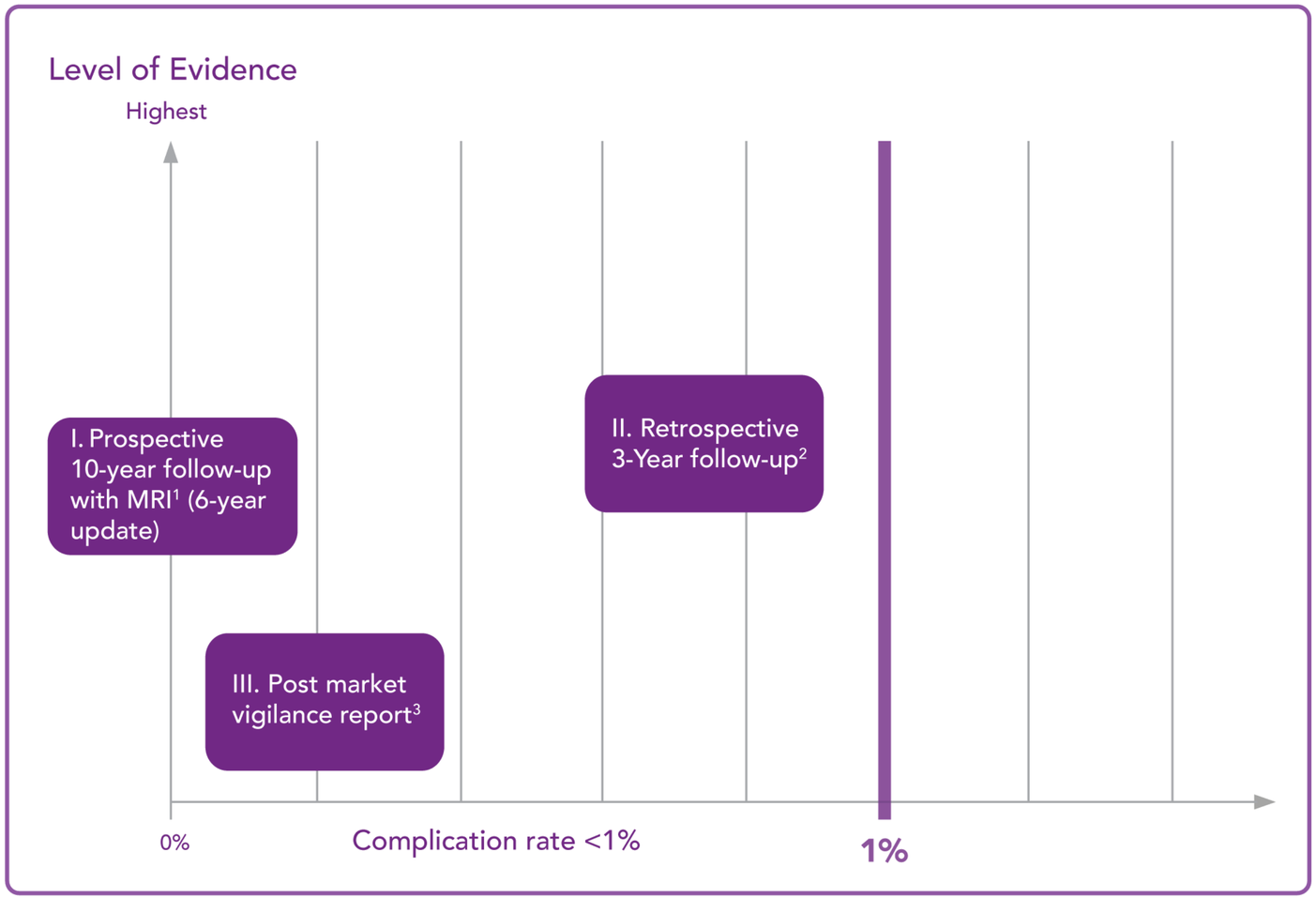
Positive outcomes indicated by thin capsules
CAPSULES FROM RE-OPERATIONS FOR SIZE CHANGE

6 months

26 months

5 years

Multiple Levels of Clinical Evidence Indicate Superior Safety



Motiva Implants® real world data suggests superior clinical results according to the level of evidence provided by each report.

1. Motiva Implants® Silicone Breast Implants: Summary of Clinical Data- 6-Year Follow Up. February 2017. Establishments Labs Alajuela, Costa Rica. 2. Sforza, MD., Zaccheddu, MD, MSc., Alleruzzo, MD., Seno, MD., Mileto, MD., Paganelli, MD., Sulaiman, MD., Payne, MD., Maurovich-Horvat, PhD Preliminar. 3-year Evaluation of Experience With SilkSurface® and Velvet Surface® Motiva® Silicone Breast Implants: a Single Center Experience with 5813 Consecutive Breast Augmentation Cases. Aesthetic Surgery Journal 2017, 1–12. 3. Motiva Implants® Complaint Data Report October 2010 - December 2017.

WHAT MAKES SMOOTHSILK® /SILKSURFACE® UNIQUE?

3 Positive Clinical Outcomes

<1%

Low rates of capsular contracture[10, 11, 12]

Low rates of rupture[10, 11, 12]

Overall complication rates of less than 1% reported through 8 years of Post-Market Surveillance of Motiva Implants®[12]

0.36%

Overall Complication Rate

with Motiva Implants® SmoothSilk®/SilkSurface®[10]

3 year retrospective clinical data in 5,813 patients with 16 plastic surgeons at 1 study site[10]

0%

Implant Related Events[11]

6 year report on prospective safety outcomes

No implant rupture, capsular contracture, double capsule or late seroma at 6 years following 35 patients in a 10 year follow-up study with MRI assessment[11]

CHOOSE WITH CONFIDENCE

Complication Incidence	Complication Severity: Low	Complication Severity: High
Uncommon	Cell-friendly advanced smooth — Motiva® implants	**Macrotexture** (chronic inflammation-related complications)
Common	**Traditional smooth** (capsular contracture)	

Although chronic inflammation-related complications with textured devices may be less common, smooth implants may be selected to minimize the risk. Traditional smooth implants have a high incidence of capsular contracture, whereas Motiva Implants® show a low risk of both capsular contracture and BIA-ALCL.[10,11,12]

SAFETY THROUGH **INNOVATION**

MotivaEDGE

MOTIVA IMPLANTS® OFFER
THE MOST COMPREHENSIVE SMOOTH* PORTFOLIO

IMPLANT FAMILY OPTIONS

Round

Ergonomix® Round

Anatomical TrueFixation®

Ergonomix® Oval

MotivaHybrid® with Puregraft®

FIRST-OF-ITS-KIND SAFETY FEATURES

Q Inside®
RFID technology

BluSeal®
Barrier layer

TrueMonobloc®
Shell-gel-patch configuration

*ISO-14607:2018 *Non-active surgical implants - Mammary implants - Particular requirements.*
Product availability may differ by country, please check regulations for locally approved products.

SAFETY THROUGH **INNOVATION**

Motiva® implants

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11. Chacón M, Chacón M & Fassero J. Six-Year prospective outcomes of primary breast augmentation with nano-surface Implants. Aesthet Surg J. Nov 2018. doi: 10.1093/asj/sjy196
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