

# Reduce the Risk with Mentor<sup>®</sup> Micro Textured Siltex<sup>™</sup> 1,2



**PROVEN**

WITH

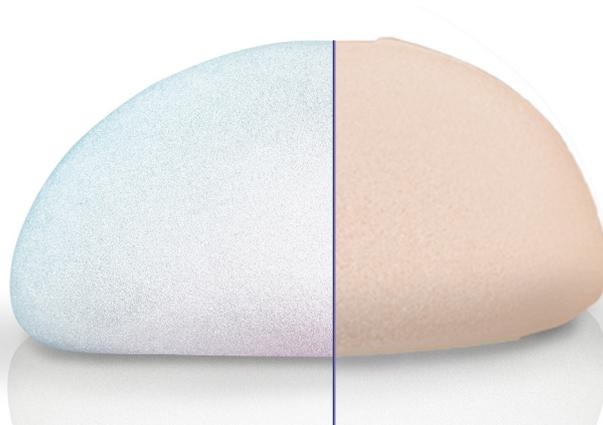
 **MENTOR<sup>®</sup>**

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

# Why Texture a Breast Implant? Not all Clinical Evidence is the Same

**PROVEN**  
WITH  
**MENTOR**  
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

## Reduce Capsular Contracture<sup>¥</sup>



MemoryGel™ Xtra, Siltex™ Breast Implant

Sebbin Silicone Breast Implant

**3.6%**  
CAPSULAR  
CONTRACTURE<sup>1</sup>

**10** *Year*  
FOLLOW UP

**5** *Year*  
FOLLOW UP

**3.8%**  
CAPSULAR  
CONTRACTURE<sup>3</sup>

### MULTI-CENTER CORE STUDY



**955**  
SUBJECTS

**43**  
SITES

### MULTI-CENTER CORE STUDY



**205**  
SUBJECTS

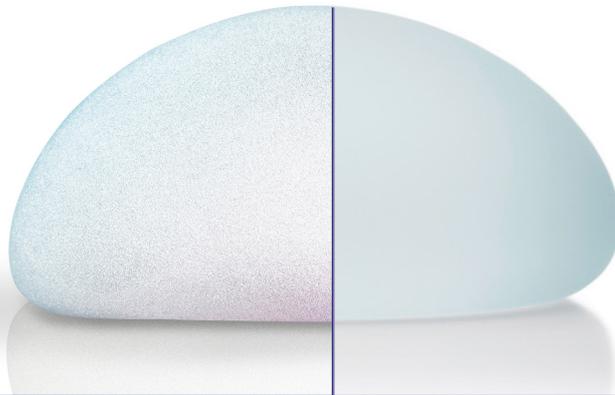
**4**  
SITES

<sup>¥</sup>. Kaplan-Meier estimated risk of first occurrence. MemoryGel™ Core Studies  
Kaplan-Meier estimated risk of first occurrence. MemoryShape®/CPG™ Core Studies.  
Not a head to head study. Based on the comparison of key complication rates reported in the 10 year Core Studies for CPG™ Gel Breast Implants, Follow-Up of SEBBIN® Silicone Gel Breast Implants, 10-Year Final Report. The third-party trademarks used herein are trademarks of their respective owners.

# Not all Clinical Evidence is the Same



Reduce Risk of Rotation<sup>¥</sup>



MemoryGel™ Xtra, Siltex™ Breast Implant

Motiva Implants®, SilkSurface™

**1%**

MALPOSITION  
AT 10 YEARS<sup>2</sup>

**5.6%**

MALPOSITION  
OUT AT 1 YEAR<sup>4</sup>

MULTI-CENTER CORE STUDY



**1008**  
SUBJECTS

**48**  
SITES



**100**  
SUBJECTS

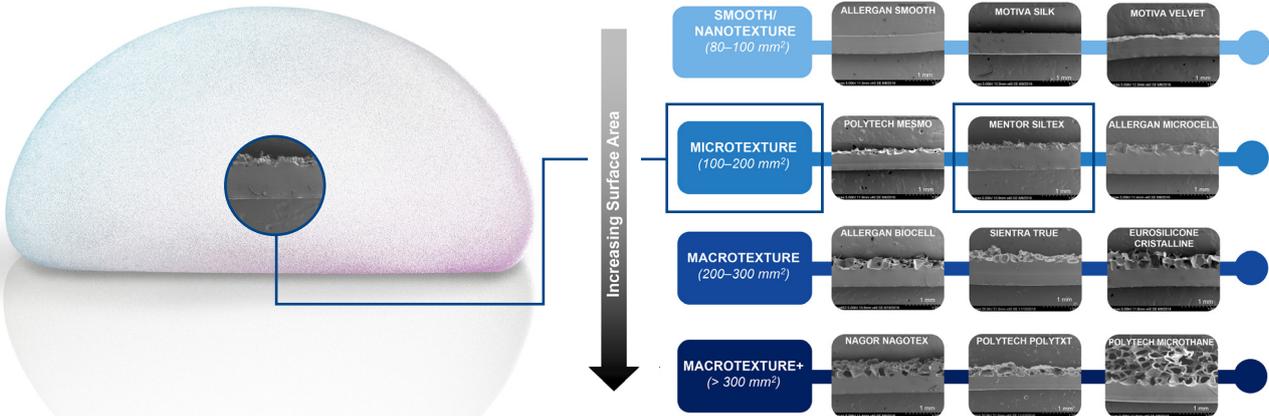
**1**  
SITES

<sup>¥</sup>. Kaplan-Meier estimated risk of first occurrence. MemoryGel™ Core Studies

Not a head to head study. Based on the comparison of key complication rates reported in the 10 year Core Studies for MemoryGel™ Gel Breast Implants, Motiva Ergonomix Round SilkSurface Silicone Breast Implants: Outcome Analysis of 100 Primary Breast Augmentations over 3 Years and Technical Considerations. The third-party trademarks used herein are trademarks of their respective owners.

# Mentor® Siltex™ has a low Surface Area as Proven in Peer Reviewed Published Studies<sup>5</sup>

Recent studies of breast implant surface area show that the use of micro-computed topography method has allowed a more accurate morphologic assessment of texture classification.<sup>5</sup>

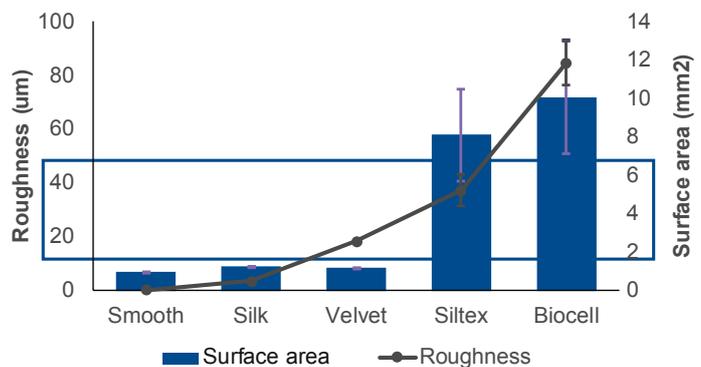


Flat surface = 79 mm<sup>2</sup> for a 10-mm diameter disk  
 Atlan et al, Breast Implant Surface Texture Impacts Host Tissue Response, 2018.

						
Process	Polyurethane foam	Salt Loss (Biocell/Eurosilicone)	Vulcanisation	Salt Loss (Nagotex)	Imprinting	Smooth/Nano
Surface Area	High	Intermediate	Intermediate	Low	Low	Minimal
Roughness	High	Intermediate	Low	Low	Low	Minimal
Surface Type	4	3	3	2	2	1

Jones et al, The Functional Impact of Breast Implant Outer Shell Morphology on Bacterial Attachment and Growth, PRS Nov 18.

ISO Standard for Micro:  
 Roughness between 10-50 micros  
 Shows Mentor® Siltex™ as having  
 a roughness of less than 50 microns



Bacterial Adhesion and Biofilm Formation on Textured Breast Implant Shell Materials.  
 James and Kinney et al. Aesthetic Plastic Surgery Journal, 2018.

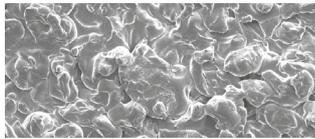
# Reduce the Risk with Mentor® Micro Textured Siltex™<sup>1,2</sup>



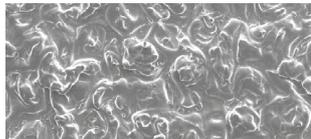
Not all Micro Surfaces have the same Long Term Outcomes.  
Siltex™ is Proven in Long Term Studies<sup>1,2</sup>

## A closer look at Mentor® patented Siltex™ Texture

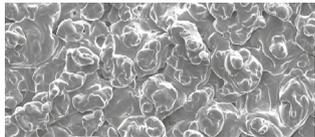
SEM images of Siltex™ texture



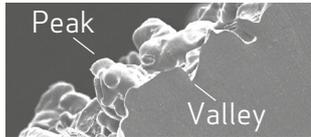
Anterior View



Radius View



Posterior View



Cross Section



- Automated Manufacturing Process to Ensure Consistency
- Mentor® CPG™ Breast Implants have the most consistent coefficient of friction regardless of implant size<sup>6</sup>
- Siltex™ imprinting method of texturing<sup>5</sup>
- **3.6%** Capsular Contracture at **10 years** with **572** Primary Augmentation Patients<sup>1</sup>
- **0.29** Coefficient of Friction<sup>6</sup>

LOWEST  
ROTATION  
RATE<sup>1</sup>



LOWEST  
REPORTED  
INCIDENCE OF  
IMPLANT RUPTURE

Not a head to head study. Based on the comparison of key complication rates reported in the 10 year Core Studies for CPG™ Gel Breast Implants, 10-Year Final Report. The third-party trademarks used herein are trademarks of their respective owners.

# We take care of the science so you get the lowest key complications at 10 years<sup>1,2</sup>

## PATIENTS HIGHLY SATISFIED

# 97%

## AUGMENTATION

# 99%

## RECONSTRUCTION

Based on patient survey at 10 years in the MENTOR® MemoryGel™ Breast Implant 10-year Core Gel Clinical Study Final Report. Mentor Worldwide LLC. MemoryGel™ Core Gel Clinical Study Final Report, April 2013.

## BACKED BY THE *Most* COMPREHENSIVE WARRANTY<sup>8</sup>

### References

1. Mentor Worldwide, LLC. MemoryShape® Post-Approval Cohort Study (formerly Contour Profile Gel Core Study) Final Clinical Study Report. 02 June 2015
2. Summary of the Safety and Effectiveness of MENTOR® MemoryGel™ Silicone Gel-Filled Implants in Patients who are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction, or Revision. 10-Year Core Gel Final Clinical Study Report. April 2013
3. SEBBIN® Silicone Gel Breast Implants, 10-year Final Report
4. Huemer G, et al. Motiva Ergonomix Round SilkSurface Silicone Breast Implants: Outcome Analysis of 100 Primary Breast Augmentations over 3 Years and Technical Considerations. *Plast. Reconstr. Surg.* 141:831e, 2018
5. Jones P, et al. The Functional Influence of Breast Implant Outer Shell Morphology on Bacterial Attachment and Growth. *Plast. Reconstr. Surg.* 142: 837, 2018
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7. Danino, A. M., Basmacioglu, P., Saito, S., Rocher, F., Blanchet-Bardon, C., Revol, M., & Servant, J. M. (2001). Comparison of the capsular response to the Biocell RTV and Mentor 1600 Siltex breast implant surface texturing: a scanning electron microscopic study. *Plastic and reconstructive surgery*, 108(7), 2047-2052.
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9. Barnsley G. P. Textured Surface Breast Implants in the Prevention of Capsular Contracture among Breast Augmentation Patients: A Meta-Analysis of Randomized Controlled Trials. *Plast Reconstr Surg.* 2006; 117(7):2183-2190
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11. Maxwell, G. Patrick. Benefits and Limitations of Macro textured Breast Implants and Consensus Recommendations for Optimizing Their Effectiveness. *Aesthetic Surgery Journal*. 2014; Vol 34(6) : p 878
12. Health Canada: Summary Basis of Decision (SBD) for MENTOR® MemoryGel™ Silicone Gel Filled Breast Implants. Application No. 69312/69313, 111635 License No.72269. Date Issued 2016/05/09

**Important Safety Information:** MENTOR® MemoryGel™ Breast Implants are indicated for breast augmentation, in women who are at least 18 years old, or for breast reconstruction. Breast implant surgery should not be performed in those women with active infection anywhere in their body, those with existing cancer or pre-cancer of their breast(s), those who have not received adequate treatment for these conditions or those who are pregnant or nursing. There are risks associated with breast implant surgery. Breast implants are not lifetime devices and breast implantation is not necessarily a one-time surgery. The most common complications with MENTOR® MemoryGel™ Breast Implants include re-operation, implant removal, capsular contracture, asymmetry, and breast pain. A lower risk of complication is implant rupture, which is most often silent. The health consequences of a ruptured silicone gel-filled breast implant have not been fully established. Screenings such as mammography, MRI, or ultrasound are recommended after initial implant surgery to assist in detecting implant rupture. Your patient needs to be informed and understand the risks and benefits of breast implants, and she should be provided with an opportunity to consult with you prior to deciding on surgery. For detailed indications, contraindications, warnings and precautions associated with the use of all MENTOR® Implantable Devices, please refer to the Product Insert Data Sheet provided with each product, or review the Important Safety Information provided at [www.mentorwllc.eu](http://www.mentorwllc.eu). The most common complications for breast augmentation with MemoryGel™ Implants include any reoperation, capsular contracture, nipple sensation changes, and implant removal with or without replacement. The most common complications with CPG™ Implants for breast augmentation include reoperation for any reason, implant removal with or without replacement, and ptosis. A lower risk of complication is rupture. The health consequences of a ruptured silicone gel breast implant have not been fully established. MRI screenings are recommended three years after initial implant surgery and then every two years after to detect silent rupture.

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