

130

YEARS OF HEALTHCARE INNOVATION AT JOHNSON & JOHNSON

PROVEN WITH

MENTOR®

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

#1

GLOBAL BRAND

MENTOR® Breast Implants have



THE SAFETY AND PERFORMANCE of our implants.¹

MENTOR® MemoryGel™ Breast Implants are the

LEADING CHOICE OF

MILLIONS OF WOMEN

Worldwide²



Photo courtesy of Dr. Steven Teitelbaum, Santa Monica, CA, USA

This Breast Augmentation was achieved using a MENTOR® CPG™ and can be seen over an 8 year period.

Taking a closer look at CPG™ Breast Implants in Primary Breast Augmentation Patients:

LOWEST ROTATION RATE³ @ 10 years³

PROVEN PERFORMANCE

LOWEST REPORTED INCIDENCE OF IMPLANT RUPTURE⁵ @ 10 years⁵

The lowest reported risk of key complications in primary breast augmentation at 10 years^{3*}

† Not a head to head study. Based on the comparison of key complication rates reported in the 10 year Core Studies for MemoryShape®/CPG™ Gel Breast Implants, NATRELLE™ 410 TruForm™ 3 Gel Breast Implants, NATRELLE™ Round TruForm™ 1 Gel Breast Implants, and MemoryGel™ Breast Implants.

Primary Augmentation For 10 Years	MENTOR® CPG™ Breast Implant Core Study, Long Term 10 years ⁴	Allergan® Natrelle® 410 Breast Implant Core Study, Long Term 10 years ⁵	MOTIVA® Implant Matrix® Silicone Breast Implant Summary of Clinical Data, 5 years follow up ⁶	Review the Clinical Use Follow-Up of SEBBIN® Silicone Gel Breast Implants, 10-Year Final Report ⁷
Capsular Contracture (Baker III/IV)	3.6%	9.2%	N/A	4.2%
No. of Patients	572	492	145 patients at 5 years	163

Kaplan-Meier estimated risk of first occurrence, %

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, NATRELLE™ 410 TruForm™ 3 Gel Implants, Motiva Implant Matrix® Silicone Breast Implant Summary of Clinical Data, 5 Year follow up and Review the Clinical Use Follow-Up of SEBBIN® Silicone Gel Breast Implants, 10-Year Final Report.

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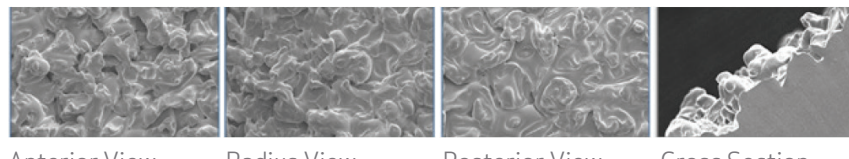
PROVEN TEXTURE YOU CAN TRUST

Reliable implants continuously delivering world class clinical results.



A closer look at MENTOR's proprietary SILTEX™ Texture¹⁰

SEM images of SILTEX™ Texture



All Texture is NOT the Same

MENTOR®: SILTEX™ Texture^{10*}

Allergan®: Biocell Texturing¹⁰

Surface Description	Gentle patterned surface	Aggressive, open-pored surface with cuboid-shape depressions and a stilted edge
Manufacturing Technique	Negative contact imprint off polyurethane texturing foam	Shell is pressed onto bed of finely granular salt: lost salt technique
Pore Size Width (µm)	70-150	600-800
Pore Size Depth/Height (µm)	40-100 (height)	150-200 (depth)
Edge (µm)	0	100-150
Distribution	Regular	Irregular
Depression or Nodules	Nodules	Depressions

‡ Specification for MemoryGel™ Round Gel Implants

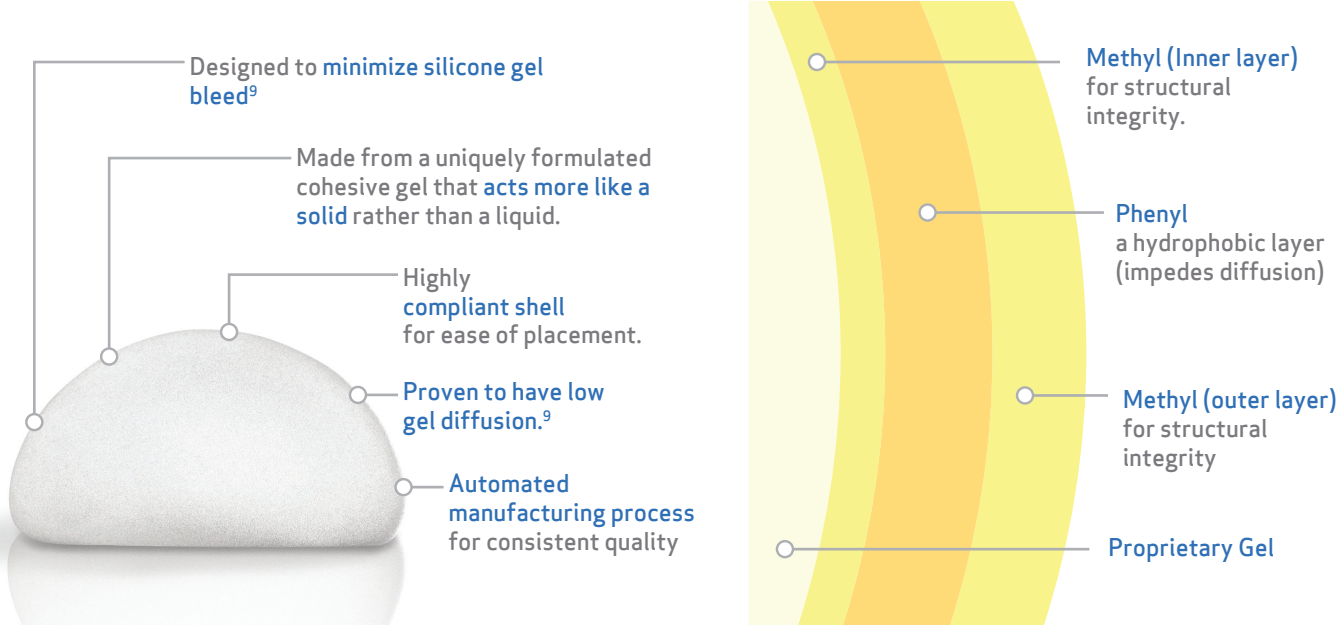
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● No Reported Cases of Double Capsule*

* Based on the MENTOR® MemoryShape® Breast Implants Core study report of (955 patients) reference: Mentor Worldwide, LLC. MemoryShape® Post-Approval Cohort Study (formerly Contour Profile Gel Core Study) Final Clinical Study Report. 02 June 2015.

PROVEN QUALITY

MENTOR® Breast Implants go through a series of controlled tests to ensure that only products that meet or exceed applicable standards leave our facility.⁸



PROVEN PEACE OF MIND

MENTOR® Breast Implants come with the most comprehensive plan in the industry

MENTOR Promise

MENTOR Promise Protection Plan Overview

- FREE AND AUTOMATIC ENROLLMENT
- FREE LIFETIME PRODUCTION REPLACEMENT FOR RUPTURE**
- UPTO €1000 FINANCIAL ASSISTANCE COVERAGE FOR RUPTURE*
- FREE PRODUCT REPLACEMENT IN THE EVENTS OF CAPSULAR CONTRACTURE (Baker III/IV), DOUBLE CAPSULE AND LATE STAGE SEROMA*
- FREE CONTRALATERAL IMPLANT at your surgeon's request

#1

Global Brand for Breast Implants



First Breast Implant company to receive FDA Approval



At MENTOR® we put patient safety as our number one priority



97% Patient Satisfaction at 10 years^{11***}

** In the event of a confirmed rupture or deflation (leaking) of any MENTOR® Breast Implant due to wear or delamination requiring surgical intervention, regardless of the age of the implant, Mentor will provide a free replacement of a MENTOR® Breast Implant of any size in the same or similar style as the originally implanted product.

*** Based on patient survey at 10 years in the MENTOR® MemoryGel™ Breast Implants Core Study final report, April 2013 and MENTOR® MemoryShape® Breast Implants Core Study report of 955 patients) reference: Mentor Worldwide, LLC.

MemoryShape® Post-Approval Cohort Study (formerly Contour Profile Gel Core Study) Final Clinical Study Report. 02 June 2015.

† When a replacement surgery of a MENTOR® Gel-Filled Breast Implant due to confirmed rupture occurs within ten (10) years from the date of implantation, provided that eligibility is proven and confirmed by Mentor based on its assessment and evaluation, Mentor will pay uninsured, out-of-pocket costs for operating room, anesthesia and/or surgical expenses directly related to revision surgery up to a maximum aggregate amount of €1000. Operating room and anesthesia charges shall be given payment priority. In such cases, the request for financial assistance under the Mentor Promise Protection Plan must be made to your surgeon. Financial assistance does not imply a loan to you.

‡ In the events of capsular contracture (Baker III/IV), double capsule or late-stage seroma in augmentation surgery of a MENTOR® Gel-Filled Breast Implant, Mentor will provide a replacement of a MENTOR® Gel-Filled Breast Implant, free of charge for the period of ten (10) years from the date of implantation, provided that eligibility is proven and confirmed by Mentor based on its evaluation of explanted product and assessment of all required documentation. Mentor will provide a replacement MENTOR® Product of any size in the same or similar style as the originally implanted product.

MENTOR® 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. Patients may require additional unplanned surgeries on the breast(s) because of complications or unacceptable cosmetic outcomes. Many of the changes to the breast(s) following implantation are irreversible (cannot be undone) and breast implants may affect the ability to breastfeed, either by reducing or eliminating milk production. 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 (meaning neither you nor your doctor will know you have a rupture). 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. The most common complications with MENTOR® Saline-Filled Breast Implants include re-operation, implant removal, capsular contracture, wrinkling, deflation, asymmetry, and breast pain. Patients are reminded to discuss the indications, contraindications, warnings, precautions and the risks and benefits associated with MENTOR® Breast Implants with their surgeon and review the Important Safety Information provided at www.mentorwllc.com. It is important that patients understand the risks associated with breast implant surgery when considering MENTOR® Breast Implants. Safety and effectiveness have not been established in patients with autoimmune diseases (for example lupus and scleroderma), a weakened immune system, conditions that interfere with wound healing and blood clotting, or reduced blood supply to breast tissue. Patients with a diagnosis of depression, or other mental health disorders, should wait until resolution or stabilization of these conditions prior to undergoing breast implantation surgery. The information contained in this material is for educational purposes only and is not a substitute for medical advice. You should talk to your doctor about what to expect and follow your surgeon's advice regarding activities after surgery. Individual patient results may vary and this patient's experience is not indicative of all outcomes. Patients should consult their physicians to find out if this procedure is appropriate for their condition. See Product Information Data Sheet for Full Product Information.

1. Summary of the Safety and Effectiveness of Mentor's 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.
2. MemoryGel® Post-Approval Study Seventh Annual Report, November 5, 2013.
3. Adjunct Study Final Report for Mentor's MemoryGel® Silicone Gel-Filled Breast Implants, 02 November 2012.
4. Mentor Worldwide, LLC. MemoryShape® Post-Approval Cohort Study (formerly Contour Profile Gel Core Study) Final Clinical Study Report. 02 June 2015
5. Mentor Becker Expander/Breast Implant Clinical Trial 2013 Annual Report.
6. MemoryShape® Post-Approval Cohort Study (formerly Contour Profile Gel Core Study) 2013
7. CPG Styles Study: A Study of the Safety of the Contour Profile Gel Breast Implants in Subjects who are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction, or Revision. 2015
8. MemoryShape® Post-Approval Continued Access Study (formerly Contour Profile Gel Core Study) 2014
9. Mentor Worldwide, LLC. Mentor Worldwide Sales Data as of 2016.
10. Mentor Worldwide, LLC. MemoryShape® Post-Approval Cohort Study (formerly Contour Profile Gel Core Study) Final Clinical Study Report. 02 June 2015
11. "Ten-Year Results From the Natrelle 410 Anatomical Form-Stable Silicone Breast Implant Core Study" (2015). Public Health Resources. Health Canada: Summary Basis of Decision (SBD) for Natrelle™ Highly Cohesive Silicone-Filled Breast Implants - Application No. 88573. License No. 72262. Date Issued: 2014/01/17. Health Canada: Summary Basis of Decision (SBD) for Natrelle™ Silicone-Filled Breast Implants - Smooth Shell With Barrier and Nanelle(TM) Silicone Filled Breast Implants - Textured Shell with Barrier Layer. Application No. 61865 and 60524 License No. 72264 and 72263. Date Issued: 2012/09/25
12. "Ten-Year Results From the Natrelle 410 Anatomical Form-Stable Silicone Breast Implant Core Study" (2015). Public Health Resources. Health Canada: Summary Basis of Decision (SBD) for Natrelle™ Highly Cohesive Silicone-Filled Breast Implants. Application No. 88573. License No. 72262. Date Issued: 2014/01/17. Health Canada: Summary Basis of Decision (SBD) for Natrelle™ Silicone-Filled Breast Implants - Smooth Shell With Barrier and Nanelle(TM) Silicone Filled Breast Implants - Textured Shell with Barrier Layer. Application No. 61865 and 60524 License No. 72264 and 72263. Date Issued: 2012/09/25
13. Motiva Implant Matrix® Silicone Breast Implant Summary of Clinical Data, 5 year follow up, 12 February 2016
14. SEBBIN® Silicone Gel Breast Implants, 10-year Final Report
15. ISO: Non-active surgical implants — Particular requirements. 14607. Second edition. 2007-02-15
16. FDA: Summary of Safety and Effectiveness Data: Mentor MemoryGel® Silicone Gel-Filled Breast Implants. P030053. Recommended April 13, 2005. 2007-02-15. <http://www.accessdata.fda.gov/scripts/cdrh/cdrtocs/c/pma/pma.cfm?fd=0300053>. Accessed 9/1/2016
17. Danino, A. M., Basnacioglu, P., Saito, S., Rocher, F., Blanchet-Bardon, C., Revil, 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.
18. Based on MENTOR® MemoryGel® Core Gel Clinical Study Report, April 2013 and MENTOR® MemoryShape® Breast Implants Core study report of 955 patients) reference: Mentor Worldwide, LLC. MemoryShape® Post-Approval Cohort Study (formerly Contour Profile Gel Core Study) Final Clinical Study Report. 02 June 2015.



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Mentor Medical Systems B.V.
Zemkedreef 2, 2333 CL Leiden
The Netherlands
Email: contact@medgjb.jnj.com

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