MENTOR®

MemoryGel® Breast Implants Are Safe and Effective[1]

#1
Global Brand[3]

7 MILLION+
Women with MENTOR® Breast Implants[3]

MemoryGel® Core Study Highlights

Highest Patient Satisfaction[§5]

98% Patients indicated that they would make the same decision to have breast implant surgery at 10 years

Low Reported Kaplan-Meier estimated cumulative incidence of key complications at 10 years for round gel implants among the primary augmentation cohort[6]

<1% - Malposition[7]
Wrinkling - 1.3%[7]

5.2% Capsular Contracture rate at 10 years in 614 Smooth submuscular Primary Breast Augmentation Patients[5]

* MemoryShape Post- Approval Cohort Study (formerly Contour Profile Gel Core Study) Final Clinical Study Report. Mentor Worldwide, LLC; 02 June 2015. MemoryGel Core Cel Clinical Study Final Report. Mentor Worldwide, LLC; April 2013. Mentor MemoryShape Post-Approval Continued Access Study (formerly Contour Profile Gel Continued Access Study), Final Report. October 2014. Mentor MemoryGel Breast Implant Large Post Approval Study Re-Op Phase Annual Report. 17 June 2016. Adjunct Study Final Report for Mentor's MemoryGel Silicone Gel-filled Breast Implants. 02 November 2012. Mentor MemoryShape 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, Final Clinical Study Report. 20 October 2015.
§ Based on patient survey at 10 years in the Mentor® MemoryGel™ Breast Implant 10-Year Core Gel Clinical Study Final Report

MENTOR®

You can Trust Mentor's evidence, can you Trust other's?

10 CLINICAL STUDIES

200,000 WOMEN PARTICIPATED[4]

High level of Evidence for Breast Implants[14]

MemoryGel® 10-year Core Study 2000-2013

GLOW 10-year Post-Approval Study 2016-Ongoing

- **Large-scale (1000+ patients enrolled)** to better represent diverse patient profiles
- **Multi-center (48 sites)** to avoid facility biases*
- **Longer term follow-up (up to 10 years follow-up)** allows for assessment of complications over time*[9,10]

Remember: Not all Clinical Evidence is the Same

MemoryGel® 10-year Core Study

9.8% Kaplan-Meier estimated rate of confirmed rupture by patients in Primary Augmentation MemoryGel® 10-year Core Study¶[8]

Post-market surveillance of MemoryGel® Breast Implants complaints related to rupture show a **0.6% global rupture complaint rate** based on MENTOR® MemoryGel® Breast Implants sales during Nov. 2006-Dec. 2019 in US and Jan. 2011-Dec. 2019 in EMEA, LATAM, Canada, and APAC.¥[11]

* Rupture rates tend to increase notably around 6-8 years post-implantation, BIA-ALCL typically takes 8-10 years to develop.
¶ 11 confirmed ruptures by patient out of 202 total patients in the MRI cohort for Primary Augmentation study subgroup.[13] Confirmed ruptures are confirmed by examining the implant for those patients that underwent implant removal. Cumulative incidence rate of confirmed rupture in the primary augmentation cohort of MRI Cohorts A and B (Table 5 in manuscript).
¥ Complaint data is passively collected through an internal system and cannot be determined from this reporting system alone due to potential under-reporting, duplicate reporting of events, and the lack of information. MENTOR® MemoryGel® Breast Implants are backed by a free lifetime product replacement policy that requires the patient to report incidence of rupture in order to benefit from the policy.[12]

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2. Mentor Worldwide LCC. GBI through Q1 2018 for implants, Expanders and sizers. Mentor Worldwide LCC. Mentor Worldwide Historical Implants Data 1985- May 2018
3. Mentor WW Historical Implant Data 2020.
4. 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. MemoryGel® Post Approval Study Seventh Annual Report, November 5, 2013. Adjunct Study Final Report for Mentor's MemoryGel® Silicone Gel-Filled Breast Implants, 02 November 2012. Mentor Worldwide, LLC. MemoryShape™ Post-Approval Cohort Study (formerly Contour Profile Gel Core Study) Final Clinical Study Report. 02 June 2015. Mentor Becker Expander/Breast Implant Clinical Trial 2013 Annual Report. Adjunct Study Annual Report for Mentor's Becker Adjustable Breast Implants: Year 18 (September 1992-November 2010) October 3, 2011. 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. MemoryShape™ Post-Approval Continued Access Study (formerly Contour Profile Gel Continued Access Study). 2014. Athena Study annual report (Sept 2018): Revision Reconstruction. Memory Gel and Shape Combined Cohort Post Approval Study, Glow Study Annual Report (Feb 2018).
5. Mentor Worldwide LLC. MemoryGel® Breast Implants Mentor Worldwide LLC. 10-Year Core Gel Clinical Study Final Report. April 2013.
6. Spear, Scott, et all. Natrelle Round Silicone Breast Implants: Core Study Results at 10 Years. Plas Reconstr Surg. 2014;133(6):1354-1361 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 NatrelleTM Silicone Filled Breast Implants - Textured Shell with Barrier Layer Application No. 61865 and 60524 License No License No 72264 and 72263. Date Issued: 2012/09/25. MENTOR Worldwide LLC. MemoryGel® Core Gel Clinical Study Final Report, April 2013 FDA: Sientra, Inc. Summary of Safety and Effectiveness Data (SSED). Santa Barbara, Calif: Sientra; 2012.
7. Summary of the Safety and Effectiveness of Mentor's Memory Gel Silicone Gel-Filled Implants in patients who are undergoing Primary Breast Augmentation, Primary Breast Reconstruction, or Revision Reconstruction.2012. Memory Gel and Shape Combined Cohort Post Approval Study, Glow Study Annual Report (Feb 2018).
8. Memory Gel Breast implants: Final Safety and Effcacy Results after 10 years follow up. p.14. Cumulative Incidence rate of confirmed rupture in the primary augmentation cohort of MRI Cohorts A and B.
9. Hillard, C., et al., Silicone breast implant rupture: a review. Gland Surg, 2017. 6(2): p. 163-168.
10. Clemens, M.W., et al., How to Diagnose and Treat Breast Implant-Associated Anaplastic Large Cell Lymphoma. Plastic and Reconstructive Surgery, 2018. 141(4): p. 586e-599e.
11. Mentor MemoryGel Complaint Data stats: US from 11/2006 through 12/2019, EMEA/ LATAM/ Canada/ APAC from 01/2011 through 12/2019.
12. MentorPromise Protection Plan Terms & Conditions 2017.
13. Mentor MemoryGel Rupture Stats Confirmed and Iatrogenic, Reported January 2020.
14. Burns P, Rohrich RJ, Chung K. The Levels of Evidence and Their Role in Evidence-Based Medicine. American Society of Plastic Surgeons. 2011; DOI: 10.1097/PRS.0b013e318219c171. Sinno H. et la Level of Evidenced in Plastic Surgery Research, ASPS, PRSJournal, 2010.

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. Breast implants are also associated with the risk of breast implant anaplastic large cell lymphoma (BIA-ALCL), an uncommon type of lymphoma and an individual's risk of developing BIA-ALCL with MENTOR® Breast Implants is considered to be low. 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.mentorwwllc.eu.

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