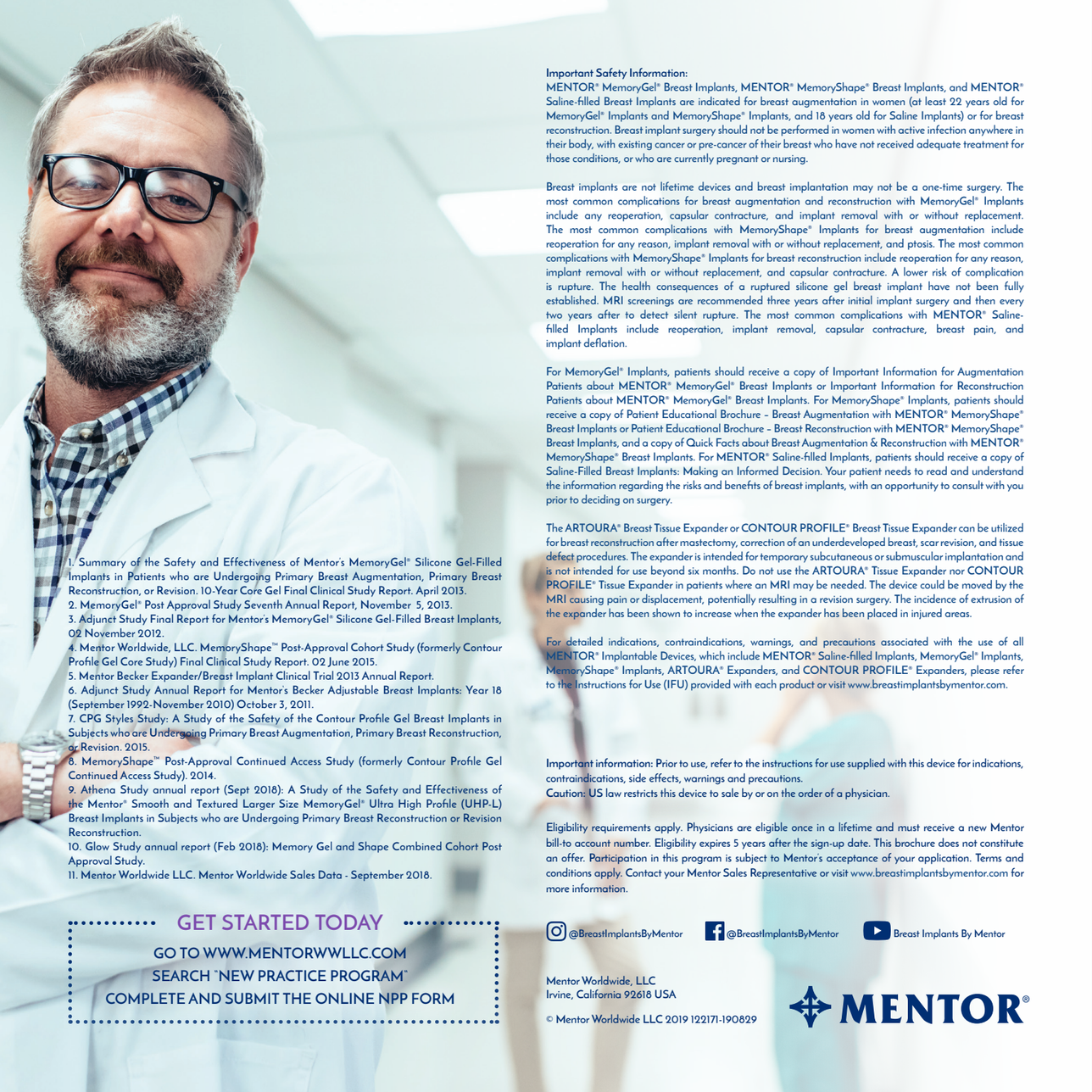

1. Summary of the Safety and Effectiveness of Mentor's MemoryGel® Silicone Gel-Filled Implants in Patients who are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction, or Revision. 10-Year Core Gel Final Clinical Study Report. April 2013.
2. MemoryGel® Post Approval Study Seventh Annual 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. Adjunct Study Annual Report for Mentor's Becker Adjustable Breast Implants: Year 18 (September 1992-November 2010) October 3, 2011.
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 Continued Access Study). 2014.
9. Athena Study annual report (Sept 2018): A Study of the Safety and Effectiveness of the Mentor® Smooth and Textured Larger Size MemoryGel® Ultra High Profile (UHP-L) Breast Implants in Subjects who are Undergoing Primary Breast Reconstruction or Revision Reconstruction.
10. Glow Study annual report (Feb 2018): Memory Gel and Shape Combined Cohort Post Approval Study.
11. Mentor Worldwide LLC. Mentor Worldwide Sales Data - September 2018.

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Important Safety Information:
MENTOR® MemoryGel® Breast Implants, MENTOR® MemoryShape® Breast Implants, and MENTOR® Saline-filled Breast Implants are indicated for breast augmentation in women (at least 22 years old for MemoryGel® Implants and MemoryShape® Implants, and 18 years old for Saline Implants) or for breast reconstruction. Breast implant surgery should not be performed in women with active infection anywhere in their body, 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.

Breast implants are not lifetime devices and breast implantation may not be a one-time surgery. The most common complications for breast augmentation and reconstruction with MemoryGel® Implants include any reoperation, capsular contracture, and implant removal with or without replacement. The most common complications with MemoryShape® Implants for breast augmentation include reoperation for any reason, implant removal with or without replacement, and ptosis. The most common complications with MemoryShape® Implants for breast reconstruction include reoperation for any reason, implant removal with or without replacement, and capsular contracture. 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. The most common complications with MENTOR® Saline-filled Implants include reoperation, implant removal, capsular contracture, breast pain, and implant deflation.

For MemoryGel® Implants, patients should receive a copy of Important Information for Augmentation Patients about MENTOR® MemoryGel® Breast Implants or Important Information for Reconstruction Patients about MENTOR® MemoryGel® Breast Implants. For MemoryShape® Implants, patients should receive a copy of Patient Educational Brochure – Breast Augmentation with MENTOR® MemoryShape® Breast Implants or Patient Educational Brochure – Breast Reconstruction with MENTOR® MemoryShape® Breast Implants, and a copy of Quick Facts about Breast Augmentation & Reconstruction with MENTOR® MemoryShape® Breast Implants. For MENTOR® Saline-filled Implants, patients should receive a copy of Saline-Filled Breast Implants: Making an Informed Decision. Your patient needs to read and understand the information regarding the risks and benefits of breast implants, with an opportunity to consult with you prior to deciding on surgery.

The ARTOURA® Breast Tissue Expander or CONTOUR PROFILE® Breast Tissue Expander can be utilized for breast reconstruction after mastectomy, correction of an underdeveloped breast, scar revision, and tissue defect procedures. The expander is intended for temporary subcutaneous or submuscular implantation and is not intended for use beyond six months. Do not use the ARTOURA® Tissue Expander nor CONTOUR PROFILE® Tissue Expander in patients where an MRI may be needed. The device could be moved by the MRI causing pain or displacement, potentially resulting in a revision surgery. The incidence of extrusion of the expander has been shown to increase when the expander has been placed in injured areas.

For detailed indications, contraindications, warnings, and precautions associated with the use of all MENTOR® Implantable Devices, which include MENTOR® Saline-filled Implants, MemoryGel® Implants, MemoryShape® Implants, ARTOURA® Expanders, and CONTOUR PROFILE® Expanders, please refer to the Instructions for Use (IFU) provided with each product or visit www.breastimplantsbymentor.com.

Important information: Prior to use, refer to the instructions for use supplied with this device for indications, contraindications, side effects, warnings and precautions.
Caution: US law restricts this device to sale by or on the order of a physician.

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