OUR PLEDGE TO YOU

As a leading global manufacturer of the highest quality breast implants we, Mentor and our worldwide employee associates, strive to provide high-quality products and services to health care professionals and patients and to support the communities in which we work and live.

To Our Mentor Customers and Patients around the world, ***we pledge to you*** our commitment to excellence. We abide by the following guiding principles:

- Our primary concern is always for the health and safety of our patients.
- Our product innovation reflects patient and marketplace needs around the world.
- Our gel-filled breast implant products are manufactured with medical grade silicone, in regulated facilities and are designed to meet all relevant quality, safety and manufacturing standards while undergoing rigorous testing.
- As one of only three manufacturers with U.S. Food & Drug Administration (USFDA) approved breast implants, sold in the United States, we are committed to maintaining vigilance reporting procedures to continuously monitor the safe and effective use of our products and working in active partnership with USFDA and global Regulatory Authorities.
- We offer professional education to physicians on the safe and effective use of our products.

At Mentor, we are committed to making safe products that offer high quality, reliability and state-of-the-art design to enhance aesthetic and reconstructive procedures.

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 MENTOR® MemoryShape® Implants for breast augmentation include reoperation for any reason, implant removal with or without replacement, and ptosis. The most common complications with MENTOR® 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 CONTOUR PROFILE® 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 CONTOUR PROFILE® 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, and CONTOUR PROFILE® Expanders, please refer to the Product Insert Data Sheet provided with each product or visit www.mentorwwllc.com.

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