



## FDA Approves New Styles Of The MENTOR® MemoryShape® Silicone Breast Implant

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SANTA BARBARA, CALIF., September 15, 2014 - Mentor Worldwide LLC, the U.S. market leader in breast aesthetics, today announced the U.S. Food and Drug Administration (FDA) has approved four additional styles of the MENTOR® MemoryShape® Breast Implants, expanding its suite of silicone breast implant products. MemoryShape® Implants are supported by unsurpassed 10-year prospective clinical data. With the addition of these styles, the MemoryShape® Implant product line will better meet the wide spectrum of patient needs.

"This product line demonstrates our commitment to meet the needs of plastic surgeons and their patients with an expanded range of shaped styles and sizes of implants that have demonstrated excellent patient satisfaction and safety in our long-term study," said David J. Wilson, Worldwide President, Mentor Worldwide LLC. "Our growing portfolio can now more effectively meet the needs of patients undergoing either breast reconstruction or augmentation surgery by allowing a better match between the patient and the implant on height, width and desire for optimal projection."

"Breast reconstruction and breast augmentation patients have varying desires, specifically with regard to projection. These approved implants address those needs," said Dennis Hammond, M.D. of Partners in Plastic Surgery of West Michigan, and lead investigator of the MENTOR® MemoryShape® Breast Implant clinical trial. "Expansion of the product line, in combination with Mentor's unique imprint texturing, limits implant rotation allowing surgeons to achieve consistent, long-term, optimal outcomes for their patients."

The FDA approval is supported by clinical studies including a core study of 955 patients implanted with MemoryShape® Implant Style MM (FDA approved in 2013) and a study of all five MemoryShape® Implant styles consisting of 3,637 patients. In the core study, patients with MemoryShape® Implants expressed high satisfaction with their breast appearance and 97 percent reported they would make the same decision again to have breast implant surgery.

#### About MENTOR® MemoryShape® Breast Implants

MENTOR® MemoryShape® Breast Implants have a teardrop shape, much like the silhouette of a natural breast. They have been approved for more than a decade outside of the U.S. and are filled with a uniquely formulated cohesive gel that enables shape retention, while providing a natural silhouette and youthful firmness. MENTOR® MemoryShape® Breast Implants are indicated for breast augmentation in women at least 22 years old and for breast reconstruction.

MENTOR® MemoryShape® Breast Implants require careful pre-operative planning, measurements, and surgical technique. Mentor, as a leader in surgeon and patient education, has developed a comprehensive range of educational resources for surgeons to use in becoming familiar with MemoryShape® Breast Implants. For more information, surgeons can visit [www.MentorDirect.com/MemoryShape](http://www.MentorDirect.com/MemoryShape). Completion of the MENTOR® MemoryShape® Implant Device Training is required for all physicians in order to gain access to MENTOR® MemoryShape® Breast Implants. Physician online training can be accessed via [www.MentorDirect.com](http://www.MentorDirect.com).

Breast implants may not be suitable for everyone. Women should speak with a plastic surgeon to learn if implants are right for them. To learn more about MemoryShape® Breast Implants, visit [www.LoveYourLook.com](http://www.LoveYourLook.com) or [www.YourBreastOptions.com](http://www.YourBreastOptions.com). For detailed product and safety information, visit [www.mentorwwllc.com](http://www.mentorwwllc.com).

#### MENTOR® MemoryShape® Breast Implants Important Safety Information

MENTOR® MemoryShape® Breast Implants are indicated for breast augmentation in women at least 22 years old, 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 pregnant or nursing.

There are risks associated with breast implant surgery. Breast implants are not lifetime devices and breast implantation may not be a one-time surgery. You may need additional unplanned surgeries on your breasts because of complications or unacceptable cosmetic outcomes. Many of the changes to your breast following implantation are irreversible (cannot be undone) and breast implants may affect your ability to breastfeed, either by reducing or eliminating milk production. The most common complications with MENTOR® MemoryShape® Breast Implants include reoperation for any reason, implant removal with or without replacement, and ptosis. A lower risk of complication is rupture, which is most often silent (meaning neither you nor your doctor will know you have a rupture) and can only be detected by appropriate imaging techniques such as MRI. 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.

Detailed information regarding the indications, contraindications, warnings, precautions, risks and benefits associated with MENTOR® MemoryShape® Breast Implants are provided in three brochures available from your surgeon (*Patient Educational Brochure - Breast Augmentation with MENTOR® MemoryShape® Breast Implants*, *Patient Educational Brochure - Breast Reconstruction with MENTOR® MemoryShape® Breast Implants*, and *Quick Facts about Breast Augmentation & Reconstruction with MENTOR® MemoryShape® Breast Implants*) or [www.mentorwwllc.com](http://www.mentorwwllc.com). It is important that you read and understand this information when considering MENTOR® Breast Implants prior to deciding on surgery.

#### About Mentor Worldwide LLC

Founded in 1969, Mentor Worldwide LLC is a leading supplier of medical products for the global aesthetic market. The company develops, manufactures, and markets innovative, science-based products for surgical and non-surgical medical procedures that allow patients to improve their quality of life. The company is focused on three strategic areas: breast, body and facial aesthetics and is the only manufacturer whose breast implants

are made in the U.S.A. Mentor joined the Johnson & Johnson Family of Companies in 2009 and is part of its Global Surgery Group. For more information about Mentor visit: [www.mentorwllc.com](http://www.mentorwllc.com) or either of Mentor's two breast aesthetic websites: [www.LoveYourLook.com](http://www.LoveYourLook.com) or [www.YourBreastOptions.com](http://www.YourBreastOptions.com).

Dr. Hammond is a paid consultant for Mentor.

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