

## **MENTOR RECEIVES FDA APPROVAL FOR MENTOR® MEMORYSHAPE™ BREAST IMPLANTS**

*Newly Available Teardrop-Shaped Breast Implants Provide Natural Silhouette and Youthful Feel*

SANTA BARBARA, Calif., June 14, 2013 /PRNewswire/ -- Mentor Worldwide LLC, the U.S. market leader in breast aesthetics, today announced the U.S. Food and Drug Administration (FDA) has approved MENTOR® MemoryShape™ Breast Implants, providing new options for women looking for a more natural shape and youthful feel from breast enhancement or reconstruction surgery.

"We understand each woman has different needs and specific, personal reasons for choosing to undergo breast surgery," said David J. Wilson, Worldwide President, Mentor Worldwide LLC. "As the U.S. market leader in breast aesthetics, Mentor constantly strives to develop products that celebrate a woman's uniqueness. The FDA approval of MENTOR® MemoryShape™ Breast Implants allows us to meet this need by delivering the perfect balance of shape and feel to obtain the natural and youthful look patients desire."

Unlike round 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. The combination of teardrop shape and distinct gel formulation creates the optimal balance of shape and feel. MENTOR® MemoryShape™ Breast Implants are indicated for breast augmentation in women at least 22 years old and for breast reconstruction.

"I knew that I wanted to have breast augmentation because I came to a point in my life where I was self-conscious about my appearance, and I wanted to change that," said Jessica White-Hatinger, a 30-year-old breast augmentation clinical trial participant. "I really wanted a natural result, and after speaking with my surgeon, we decided on the MENTOR® MemoryShape™ Breast Implants. I am very happy with my new look and the confidence the implants have given me."

"Over the past 25 years, we have been exploring opportunities to improve breast implants. MENTOR® MemoryShape™ Breast Implants incorporate several new design features, such as the cohesive gel that allows the implant to be formed into a teardrop shape to fit each individual patient," said Dennis Hammond, M.D. of Partners in Plastic Surgery of West Michigan, and lead investigator of the MENTOR® MemoryShape™ Breast Implants clinical trial. "I am pleased women in the U.S. now have an implant that offers an enhanced yet subtle breast appearance with a proven safety profile."

To help surgeons find the ideal size and fit for their patients, MemoryShape™ Breast Implants are available in a range of sizes. Like all breast implants in the company's product portfolio, MENTOR® MemoryShape™ Breast Implants can be sized using the BodyLogic® System, an innovative implant sizing system. The BodyLogic® System helps surgeons determine the right breast implants for their patients, by providing selection tools and materials to identify a range of implants for the patient, which will ultimately increase the patient's level of satisfaction.

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### **MENTOR® MemoryShape™ Breast Implants Supported by Extensive Clinical Data**

The open-label, multi-center MENTOR® MemoryShape™ (CPG™ Core) Breast Implant Core Study consists of 955 patients who undergo post-surgery follow up annually for 10 years. This study is designed to assess the safety and effectiveness of these implants in primary augmentation, revision (augmentation and reconstruction), and reconstruction patients. Effectiveness is assessed by bra and cup size, patient satisfaction, and quality of life (QoL) measurements. Safety is assessed by complications, such as implant rupture, capsular contracture, and reoperation.

In the clinical trial, MENTOR® MemoryShape™ Breast Implants were shown to be safe and effective in both reconstruction and augmentation patients at 6 years, with a low rate of adverse events, such as rupture and capsular contracture Baker grades III and IV. Overall, the Core Study patients also had high satisfaction rates with their breast appearance, and 97 percent of patients who have MemoryShape™ Implants reported they would repeat the procedure.

Post approval studies will be conducted to collect additional clinical data for the MENTOR® MemoryShape™ Breast Implants.

### **About MENTOR® MemoryShape™ Breast Implants**

The latest addition to the Mentor Breast Aesthetics portfolio in the U.S., MemoryShape™ Breast Implants are uniquely tapered to match the silhouette of the natural breast and are filled with a uniquely formulated, highly cohesive gel. They 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 Mentor's MemoryShape™ Device Training is required for all physicians in order to gain access to Mentor's 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). For detailed product and safety information, visit [www.mentorwwllc.com](http://www.mentorwwllc.com).

### **MENTOR® MemoryShape™ Breast Implants Important Safety Information Disclaimer**

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.

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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 and the 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 visit [www.mentorwllc.com](http://www.mentorwllc.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 our two breast aesthetic websites: [www.LoveYourLook.com](http://www.LoveYourLook.com) or [www.YourBreastOptions.com](http://www.YourBreastOptions.com).

#### **CONTACT:**

##### **Mentor Worldwide LLC**

Francesca DeMartino

Director, Worldwide Communications

(805) 879-6335

[fdemarti@its.jnj.com](mailto:fdemarti@its.jnj.com)

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