

From Medscape News

FDA Approves New Silicone Implant

The US Food and Drug Administration (FDA) has approved a new silicone gel-filled breast implant for breast augmentation in women at least 22 years old and for breast reconstruction in women of any age, the [agency announced](#) on June 14.

The FDA said it approved the *MemoryShape* breast implant, manufactured by Mentor Worldwide LLC, on the basis of 6 years of data from 955 women, which provide "reasonable assurance of safety and effectiveness for this implant."

The new implant showed similar rates of complications and outcomes as previously approved breast implants. These complications include tightening of the area around the implant, reoperation, implant removal, asymmetry, and wrinkling. Fissures or cracks were observed in the gel of some of the new implants, the FDA said.

Discuss Risks

"It's important to remember that breast implants are not lifetime devices. Women should fully understand the risks associated with breast implants before considering augmentation or reconstruction surgery, and they should recognize that long-term monitoring is essential," Jeffrey Shuren, MD, director of the FDA's Center for Devices and Radiological Health, commented in a statement.

"The data we reviewed showed a reasonable assurance of safety and effectiveness," Dr. Shuren said. "We will be looking at the results from post-approval studies that will focus on the implants' long-term safety and effectiveness."

The silicone gel in the MemoryShape Breast Implant contains more cross-linking compared with the silicone gel used in a previously approved implant, which results in a silicone gel that is firmer, although the clinical significance of this type of silicone gel is not known, the FDA said.

As a condition of approval, Mentor Worldwide LLC must conduct a series of postapproval studies. "Lessons learned from previous post-approval studies on silicone gel-filled breast implants informed the design of post-approval studies for Mentor's MemoryShape Breast Implant," the FDA said. The company must do the following:

1. Continue to follow-up 955 women who received the new implants as part of the premarket core study that provided safety and effectiveness data for the device approval. These patients will be followed-up until they have completed their 10-year evaluations for long-term device performance.
2. Continue to follow-up approximately 350 patients who were implanted with the MemoryShape Medium Height Moderate Profile (CPG Style 321) breast implants as part of a premarket continued access study (not part of the premarket core study). The patients will be followed up until they have completed their 5-year evaluations.
3. Conduct a new study of approximately 2500 women receiving the new breast implants to collect information on both long-term local complications (eg, capsular contracture, reoperation, removal of implant, implant rupture) and less-common potential disease outcomes (eg, rheumatoid arthritis, breast and lung cancer, reproductive complications). These patients will be followed up for 10 years.
4. Conduct 5 case-control studies by enrolling 10,750 women to evaluate the potential association between any silicone gel-filled breast implant (including MemoryShape Breast Implants) and 5 rare diseases: rare connective tissue disease, neurological disease, brain cancer, cervical/vulvar cancer, and lymphoma.
5. Evaluate women's perceptions of the patient labeling.
6. Analyze the MemoryShape Breast Implants that are removed from patients and returned to the manufacturer.

With the approval of the MemoryShape Breast Implant, there are now 5 FDA-approved silicone gel-filled breast implant products available in the United States, manufactured by 3 companies (Allergan, Mentor, and Sientra).