

# FDA approves new silicone breast implants

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(HealthDay)—MemoryShape breast implants have been approved by the U.S. Food and Drug Administration for breast augmentation in women 22 and older, and for breast reconstruction, the FDA said Friday.

In a news release, the manufacturer, Mentor Worldwide LLC, said the implants have been approved outside of the United States for more than a decade. The product is available in a range of sizes and is tear-drop shaped to mimic the natural shape of a breast.

The product has been clinically studied among 955 augmentation and reconstruction patients participating in an ongoing 10-year study, Mentor said. After six years, the study has found a low rate of "adverse events," including rupture, the company added.

The FDA said in a news release that the approval was based on six years of data from 955 women showing a reasonable assurance of safety and

effectiveness for this implant. Mentor's MemoryShape Breast Implant showed similar rates of complications and outcomes as previously approved breast implants. These complications included tightening of the area around the implant, re-operation, implant removal, an uneven appearance (asymmetry), and wrinkling. Fissures or cracks were observed in the gel of some MemoryShape Breast Implants, a characteristic called gel fracture.

"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, M.D., director of the FDA's Center for Devices and Radiological Health, said in a statement.

Breast implant surgery should not be performed on women with any active infection, untreated cancer, or who are pregnant or nursing, Mentor said.

With Friday's approval, there are now five FDA-approved [silicone gel](#)-filled [breast implants](#) available in the United States manufactured by three companies: Allergan, Mentor, and Sientra.

**More information:** [More Information](#)

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