

Firmer Breast Implant Gets FDA Nod

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The FDA gave the go ahead to a new firmer silicon gel implant for breast augmentation or reconstruction but will require long-term safety reassurance.

The MemoryShape Breast Implant has more cross-linking of silicon chains to boost the firmness of the implants, which is of unknown clinical significance, according to the agency.

Fissures or cracks in the gel have been seen in some cases during the 6 years of follow-up among 955 women who received the implants in the study that lead to approval. Other outcomes and complication rates were similar to what has been seen with the other four approved silicon gel implants.

"It's important to remember that breast implants are not lifetime devices," Jeffrey Shuren, MD, director of the FDA's Center for Devices and Radiological Health, noted in a statement.

"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."

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