FDA Approves New Silicone Breast Implant from J&J

Matthew Perrone - AP Health Writer - Associated Press

The Food and Drug Administration said last Friday it approved a next-generation silicone breast implant from Johnson & Johnson unit Mentor.

The company's MemoryShape breast implant uses a cross-linking gel design that the FDA says is firmer than previous implants.

FDA regulators approved the new implant for breast enhancement and reconstruction in women at least 22 years old.

Silicone gel implants have made a comeback recently after safety concerns kept them off the market for nearly 25 years.

The FDA banned sales of silicone breast implants in 1992, saying manufacturers had not provided enough medical data showing their safety and effectiveness. At the time, there were worries about a connection to a variety of diseases, including cancer and lupus. Alarming cases of ruptures added to the concern.

But in 2006 the agency returned the implants to the market after most studies failed to find a link between silicone breast implants and disease.

Since then the FDA has required manufacturers to track the health and complications of women who receive the implants. The most recent data from Mentor and competitor Allergan confirm that the devices are prone to rupture and often need to be replaced.

The FDA said Friday it approved Mentor's new implant based on studies tracking six years of data in 955 women. The agency said complications with Mentor's MemoryShape implants were similar to those from previously approved silicone gel implants.

FDA is requiring Mentor to meet a number of requirements in connection with the new approval, including:

— Tracking the 955 women with the new implant

— Conducting a new study of 2,500 women who receive the new implant

— Evaluating women's comprehension and perception of the implant's labeling

— Analyzing any implants that are removed from women and returned to the manufacturer

More than one in five women who get implants for breast enhancement will need to have them replaced within five years, accord to an FDA analysis of company data released in 2011. Despite that relatively high failure rate, FDA regulators concluded that the silicone-gel implants are basically safe, as long as women understand they come with complications. Some critics of the implants say the failure rate may be even higher, since many women have dropped out of the company studies.

Problems with rupturing and scar tissue are also seen with saline-filled versions of breast implants, which are less popular. Many women prefer silicone implants because they generally look and feel more like natural breast tissue.

The FDA has approved silicone gel breast implants from three companies: Mentor, Allergan and Sientra, a privately-held manufacturer.

Mentor is based in Santa Barbara, Calif.