MedicalXpress

FDA approves new silicone gel-filled breast implant

February 21 2013

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(HealthDay)—The Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-Gel Filled Breast Implant has been approved by the U.S. Food and Drug Administration for breast augmentation in women aged 22 years or older and for reconstruction in women of all ages.

The FDA approval was based on data from 941 women followed for seven years. Complications included capsular contracture, re-operation, implant removal, asymmetry, and infection, most of which have been identified in previous breast implant studies. In addition, gel fractures or fissures were observed in the gel of some Natrelle 410 implants.

The FDA has required that the manufacturer, Allergan, conduct post-approval studies, including a five-year follow-up involving about 3,500

women who received the implants as part of the company's access study; a 10-year follow-up of more than 2,000 women to identify long-term complications; and five case-control studies to examine the correlation of the implants with rare diseases. They have also required an assessment of women's perceptions of the patient labeling and analysis of implants removed from patients and returned to the manufacturer.

The implant is manufactured by Allergan Inc., based in Irvine, Calif.

More information: More Information