

FDA OKs New Silicone Gel Breast Implant

The FDA has approved a new silicone gel breast implant for augmentation and reconstruction of women's breast tissue.

The Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-Gel Filled Breast Implant is indicated for women ages 22 and older for augmentation, and for women of any age in reconstruction, the agency said in a statement released Wednesday.

The approval makes the Natrelle 410 the fourth FDA-approved silicone gel-filled breast implant.

The device contains more cross-linking silicone gel -- a bond linking one silicone chain to another -- than has been used in previously approved products by manufacturer Allergan, though the FDA noted that the "clinical significance of this type of silicone gel is not known."

Approval was based on data from 941 women who received the implants over a 7-year period. Adverse events over the study period were similar to those found in previous breast implant studies and included capsular contracture, reoperation, implant removal, asymmetry, and infection. A unique event to the Natrelle 410 was cracking in the implant.

[Continue reading...](#) [1]

Source URL (retrieved on 02/01/2015 - 7:32pm):

<http://www.surgicalproductsmag.com/articles/2013/02/fda-oks-new-silicone-gel-breast-implant>

Links:

[1] <http://www.medpagetoday.com/PublicHealthPolicy/FDAGeneral/37475>