

Plastic Surgery NEWS

AMERICAN SOCIETY OF
PLASTIC SURGEONS

SPECIAL BULLETIN

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FDA issues white paper on silicone breast implant safety

The Food and Drug Administration (FDA) yesterday issued an updated white paper on the safety of silicone gel-filled breast implants. ASPS agrees with the FDA statement that "silicone gel-filled breast implants have a reasonable assurance of safety and effectiveness when used as labeled," and it accepts the Agency's position that women who receive silicone gel-filled breast implants for reconstructive or cosmetic purposes will need to monitor the devices over their lifetime. Both the FDA and ASPS agree that breast implants are not lifetime devices.

ASPS believes that the FDA white paper is informative and will be a fruitful resource for plastic surgeons - as well as for patients considering reconstructive or cosmetic breast augmentation.

ASPS shares the FDA's view in the white paper that more than 90 percent of patients are satisfied with their outcomes from breast implantation and report an improved quality of life.

ASPS has collaborated - and will continue to collaborate - with the FDA to ensure that science forms the basis for all decision-making on breast implants, as well as all other medical devices. The Society supports post-market breast implant surveillance and ongoing data collection related to the safety and efficacy of breast implants. ASPS will continue to reiterate that patient safety is its No. 1 priority.

The FDA has provided the following links to related documents:

[FDA - Breast Implants](#)

[Update on the Safety of Silicone Gel-Filled Breast Implants \(2011\) - Executive Summary](#)

The FDA also has made available a [Consumer Update](#) that contains current and background information on breast implants, as well as other links to additional documents and FAQs.

ASPS has posted additional resources for members and consumers on its website at plasticsurgery.org.

The Society is determined to work collaboratively with the FDA to ensure that plastic surgery patients, consumers and ASPS members are provided the information they need to make informed decisions.