

Consumer Information on: Sientra Silicone Gel Breast Implants - P070004

U.S. Food & Drug Administration



This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness Data (SSED) and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name: Sientra Silicone Gel Breast Implants

PMA Applicant: Sientra Inc.

Address: 6769 Hollister Avenue, Suite 201, Santa Barbara, California 93117

Approval Date: March 9, 2012

Approval Letter: http://www.accessdata.fda.gov/cdrh_docs/pdf7/p070004a.pdf [1]

What is it? The Sientra Silicone Gel Breast Implant is a silicone shell filled with clear silicone gel. The implants are available in different shapes and sizes.

How does it work? The breast implant is intended to make the breast larger (breast augmentation) or to restore or replace breast tissue (breast reconstruction). It is surgically implanted beneath the breast tissue, either on top of the chest muscle or underneath part or all of the chest muscle.

When is it used? The Sientra Silicone Gel Breast Implants are indicated for women for the following uses (procedures):

- **Breast augmentation for women at least 22 years old.** [Breast augmentation](#) [2] includes primary breast augmentation, as well as revision surgery to correct or improve the result of a primary breast augmentation surgery.
- **Breast reconstruction.** [Breast reconstruction](#) [3] includes primary reconstruction to replace breast tissue that has been removed due to cancer or trauma or that has failed to develop properly due to a severe breast abnormality. Breast reconstruction also includes revision surgery to correct or improve the result of a primary breast reconstruction surgery.

What will it accomplish? The implant increases the size of the breast. A majority of subjects in the clinical study reported favorable satisfaction and Quality of Life

results.

Common adverse effects identified in the clinical study include:

- Tightening of the area around the implant (capsular contracture)
- Additional surgeries, including those to change style or size (Reoperation)
- Implant removal with or without replacement
- Uneven appearance (asymmetry)
- Infection
- Breast mass/cyst/lump
- Breast pain
- Enlarged scar remaining after the wound heals (hypertrophic/abnormal scarring)
- Implant placed incorrectly or has moved/shifted from the original position (malposition)
- Implant rupture
- Nipple sensation changes
- Sagging/drooping of the breast (ptosis)
- Redness
- Watery portion of the blood collects around the surgical incision or around the breast implant (seroma/fluid accumulation).

Refer to the labeling for the clinical study.

When should it not be used? Breast implant surgery should not be performed in women:

- with active infections anywhere in their body
- with existing cancer or precancerous conditions who have not received adequate treatment for those conditions, or
- who are currently pregnant or nursing

Additional information: The [Summary of Safety and Effectiveness Data and labeling](#) [4] are available online.

Other Resources:

- [FDA News Release](#) [5]
- [FDA's Breast Implant Website](#) [6]

[SOURCE](#) [7]

Source URL (retrieved on 01/27/2015 - 10:04am):

<http://www.mdtmag.com/news/2012/03/consumer-information-sientra-silicone-gel-breast-implants-p070004>

Links:

[1] http://www.accessdata.fda.gov/cdrh_docs/pdf7/p070004a.pdf

[2] http://www.nlm.nih.gov/medlineplus/ency/presentations/100205_1.htm

[3] <http://www.nlm.nih.gov/medlineplus/breastreconstruction.html>

[4] <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/pma/pma.cfm?num=p070004>

[5]

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm295437.htm>

[6] <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/default.htm>

[7] <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm296484.htm>