



ISSUE BRIEF

COMPLICATIONS OF SALINE BREAST IMPLANTS: WHAT YOU SHOULD KNOW BEFORE RECONSTRUCTION

By Elizabeth Nagelin-Anderson, M.A. and Diana Zuckerman, Ph.D.

How risky are breast implants? This is a controversial question, but implant manufacturers have done research showing that local complications, including pain, rupture, and the need for additional surgery, are very common within the first three years.

The FDA required breast implant manufacturers Mentor Corporation and Inamed Aesthetics (formerly called McGhan) to conduct research on the complications of saline breast implants for breast reconstruction and breast augmentation patients. The purpose of this research was to provide women with information so that they can make a more informed decision about whether or not they want saline implants. This information is supposed to be made available by plastic surgeons to all patients before they make their decision. The studies did not include diseases or conditions such as cancer, lupus, or fibromyalgia.

This CPR issue brief is based on the FDA's analyses of data collected by Mentor Corporation and Inamed Aesthetics. It is based on research, not opinion. The 3-year data were analyzed by the FDA in 2000 and the 5-year data were analyzed by the FDA in 2002. This fact sheet is only about reconstruction.

Mentor Saline Implants

Mentor conducted a 5-year study on reconstruction patients. Unfortunately, so many women (almost 60%) dropped out of the study before the five years were completed, that the information is not reliable. For that reason, we are only providing the information collected during the first 3 years after getting implants, which included 78% of the patients.

Important Points from the Mentor Data

- ▶ Most women can expect at least one complication within the first 3 years.
- ▶ 40% of reconstruction patients can expect to have additional surgery within the first 3 years.

Mentor Reconstruction Patients 3-Year Complication Rate

Reconstruction patients experienced the following problems within the first 3 years of receiving their implants:

- 40% Needed another operation
- 30% Capsular contracture (hardening of breast)
- 28% Asymmetry (breasts look different from each other)
- 27% Implant removal
- 20% Wrinkled appearance of breast
- 17% Breast pain
- 9% Infection
- 9% Implant leaks/deflates
- 8% Irritation/inflammation
- 6% Delayed wound healing
- 6% Seroma (watery portion of blood collects around implant or incision)
- 5% Scarring complications
- 2% Extrusion (implant comes through the skin)
- 2% Necrosis (death of skin or tissue)
- 1% Hematoma (blood collects around implant)
- 1% Position of implant changes

Loss of nipple sensation is not listed since nipples are removed during mastectomy.

Only 78% of the reconstruction patients who originally enrolled in the study completed all 3 years. Women who had their implants removed, and women who left the study for any reason were not followed. Complications were measured up until a woman left the study, but percentages were based on the total number of women who started the study. So, the complication rate is actually even higher.

Inamed Saline Implants

Inamed, formerly called McGhan, conducted a 5-year study on breast reconstruction patients. They collected information at the 3-year point from 71% of the reconstruction patients who originally enrolled in the study.

At the 5-year point they collected information from 57% of the reconstruction patients. This is a problem, since no information is available for 43% of the patients. Women who had their implants removed, and women who left the study for any reason were not followed. Complications were measured up until a woman left the study, but percentages were based on the total number of women who started the study. So, the complication rate is actually even higher, and the 3-year data are more reliable than the 5-year data.

Important Points from the Inamed Data

- ▶ Most women can expect to experience at least one complication at some point within 5 years after implant surgery.
- ▶ 40% of reconstruction patients can expect to have additional surgery within the first 5 years.

Most complications for Inamed patients through the first 5 years are similar to those reported after the first 3 years. Since it is well known that some complications, such as rupture and capsular contracture, increase over time, women with complications were apparently more likely to leave the study than those who continued. Some of these women have left their plastic surgeons and could not be contacted and some probably had their implants removed.

Inamed Reconstruction Patients 3-Year and 5-Year Complication Rates

Reconstruction patients experienced the following complications during the first three years and first five years after surgery.

3-Year 5-year

39%	45%	Needed another operation
33%	39%	Asymmetry (breasts look different from each other)
25%	36%	Capsular contracture (hardening of breast)
23%	28%	Implant replacement/removal - any reason
20%	27%	Implant can be felt or seen
23%	25%	Wrinkled appearance of breast
15%	18%	Breast pain
12%	17%	Implant is in a bad position
6%	8%	Implants leaks/deflates
7%	7%	Irritation/inflammation
6%	6%	Intense skin sensation
6%	6%	Scarring complications
5%	6%	Infection
5%	5%	Calcium deposits form around implant
4%	4%	Seroma (watery portion of blood collects around implant or around incision)
4%	4%	Skin/tissue necrosis (formation of dead tissue around the implant)
3%	3%	Delayed wound healing
3%	3%	Implant extrusion (implant comes through the skin)
3%	3%	Skin rash
1%	1%	Hematoma (blood collects around implant)

Loss of nipple sensation is not listed since nipples are removed during mastectomy.

References:

http://www.fda.gov/cdrh/breastimplants/labeling/mentor_patient_labeling_5900.html#_Toc20548932

http://www.fda.gov/cdrh/breastimplants/labeling/Inamed_patient_labeling_5900.html#_Toc20904704

National Center for Policy Research (CPR) for Women & Families

1901 Pennsylvania Ave., NW, Suite 901, Washington DC 20006

Phone (202) 223-4000 Fax (202) 223-4242

www.center4policy.org