



ISSUE BRIEF

COMPLICATIONS OF SALINE BREAST IMPLANTS: WHAT YOU SHOULD KNOW BEFORE YOU DECIDE ON AUGMENTATION

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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 breast implants. This information is supposed to be made available by plastic surgeons to all patients before they make their decision.

This CPR issue brief is based on the FDA's analyses of data collected by Mentor Corporation and Inamed Aesthetics. They are based on research, not opinion. This fact sheet is only about augmentation patients.

Mentor Saline Implants

Mentor conducted a 5-year study on augmentation patients. Unfortunately, so many women 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 76% of the patients.

Important Points from the Mentor Data

- ▶ Most women can expect at least one complication within the first 3 years.
- ▶ 1 in 8 (12.5%) augmentation patients can expect to have additional surgery within the first 3 years

Mentor Augmentation Patients 3-Year Complication Rates

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

21%	Wrinkled appearance of breast
13%	Needed another operation
10%	Loss of nipple sensation
9%	Capsular contracture (hardening of breast)
8%	Implant removal
7%	Asymmetry (breasts look different from each other)
5%	Intense, painful nipple sensation
5%	Breast pain
3%	Implant leaks/deflates
2%	Implant can be felt
2%	Infection
2%	Sagging
2%	Scarring complications
2%	Hematoma (blood collects around implant)

Only 76% of the augmentation 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 3-year study and a 5-year study on breast augmentation patients. They collected information at the 3-year point from 77% of augmentation patients who originally enrolled in the study.

At the 5-year point they collected information from only 62% of augmentation patients. This is a problem, since no information is available for more than one-third 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.
- ▶ More than 1 in 4 augmentation patients can expect to have additional surgery within the first 5 years.

Most complications through the first five 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.

Inamed Augmentation Patients Complication Rates

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

3-Year 5-year

21%	26%	Additional operation
16%	17%	Breast pain
11%	14%	Wrinkled appearance of breast
10%	12%	Asymmetry (breasts look different from each other)
9%	12%	Implant can be felt or seen
8%	12%	Implant replacement/removal - any reason
9%	11%	Capsular contracture (hardening of breast)
9%	10%	Intense, painful nipple sensation
8%	10%	Loss of nipple sensation
8%	9%	Implant is in a bad position
7%	8%	Intense skin sensation
6%	7%	Scarring complications
5%	7%	Implant leaks/deflates
3%	3%	Irritation/inflammation
3%	3%	Seroma (watery portion of blood collects around implant or incision)
2%	2%	Hematoma (blood collects around implant)
2%	2%	Skin rash
1%	2%	Calcium deposits form around implant
1%	1%	Delayed wound healing
<1%	1%	Infection

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

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