

Common Complications - MENTOR BREAST IMPLANTS

As with any medical device, there are risks involved with breast implants. The most common complications associated with breast implants are reoperation, capsular contracture, implant removal, and rupture.

Following your breast surgery, it's important that you have regular follow up exams and follow your doctor's instructions to monitor your breast implants. If you notice any changes to your breast implants or experience any unusual signs or symptoms of health issues, contact your health care provider promptly to schedule an appointment.

Reoperation

It is likely that you will need reoperation sometime in your life after your initial breast surgery either to correct a problem or replace or remove your breast implant. Problems such as rupture, capsular contracture, asymmetry, hypertrophic scarring (irregular, raised scar), infection and shifting can require additional surgery.

Capsular Contracture

After your breast implant surgery, your breasts will begin to heal and adapt to the presence of the breast implants. A regular part of this process is that the breast tissue typically forms an internal scar immediately surrounding the implant. In many cases, this tissue forms a capsule that helps hold the implant in place. However, in some women, the scar tissue around the implant tightens and squeezes the implant. When scar tissue squeezes an implant, it is called capsular contracture. There are four grades of capsular contracture - Baker Grades I through IV, and surgical treatment is typically recommended for Grades III and IV.

Capsular contracture causes the breast to feel abnormally firm and can cause pain. The chances of having contracture typically increase the longer you have your implants. Capsular contracture is a risk factor for implant rupture, and it is one of the most common reasons for reoperation.

The estimated risk of augmentation patients experiencing Baker Grade III/IV capsular contracture based on our 10-year studies are:

- 12% through 10 years for MemoryGel® Breast Implants
- 18% through 10 years for Saline Breast Implants
- 4% through 10 years for CPG™ Breast Implants

Long-term clinical data support lower capsular contracture rates with the use of MENTOR® SILTEX® Microtextured breast implants compared to Mentor smooth implants in augmentation patients.

Data from the primary augmentation cohort of our 10-year studies.

Implant Removal

You and your doctor may decide to remove an implant because of a complication or to improve the cosmetic result. It's important for you to know that breast implants aren't expected to last a lifetime, and the longer you have your breast implants, the more likely it will be for you to have them removed, with or without replacement, for any reason.

Rupture

Breast implants are considered to have ruptured when the implant shell develops a tear or hole. Your breast implants could rupture or leak for several reasons, including: damage by surgical instruments at the time surgery, stress to the implant during surgery that weakens it, excessive force to the chest, trauma, compression during a mammogram, or normal use over time.

Implants could rupture any time after your implant surgery, but the longer the implants are in place, the higher the possibility that the implants will rupture, or the gel or saline will leak.

In our 10-year study, the overall occurrence of rupture among augmentation patients was:

- 9.8% for MemoryGel® Breast Implants
- 3.2% for CPG™ Breast Implants

An analysis was also done to try and estimate the probability of a rupture or deflation by a specified years after surgery using the Kaplan-Meier method. This method attempts to account for patients not returning for follow-up and adjusts the estimated rupture rate accordingly. The accuracy of the Kaplan-Meier estimate for Mentor ruptures is limited by the low follow-up rates observed across all cohorts of the MRI sub- study at 10 years, as well as competing risks such as device removal for reasons other than rupture.

Data from primary augmentation cohort (1st and 2nd MRI Cohort pooled).

<https://breastimplantsbymentor.net/en-EMEA/common-complications>