

Capsular contracture may be more common if you have had a breast infection, hematoma (a solid swelling of clotted blood within the tissue) or seroma (collection of fluid that builds up under the surface of your skin). 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. It also seems that women who have additional surgery to replace their implants (revision surgery) are more likely to have capsular contracture than women having their first augmentation or reconstruction.

Reoperation

It is likely that you will need additional surgery (a reoperation) at some point after your first breast implant surgery, either to correct a problem with or replace your breast implants. Patients may decide to change the size or type of their breast implants, requiring additional surgery. Problems such as rupture, capsular contracture, asymmetry (lack of proportion of shape, size and/or position between the two breasts), hypertrophic scarring (irregular, raised scar), infection, and shifting can require additional surgery. Some changes to your breast(s) after having breast implants are irreversible (cannot be changed or fixed). These may include dimpling, puckering, wrinkling, or the appearance that the breast is empty or deflated.

Implant Removal

Your breast implants may be removed (with or without being replaced) at some point during the course of your life. You and

your doctor may decide to remove an implant or implants because of a complication or to improve the cosmetic result. Because these are not lifetime devices, the longer you have your breast implants, the more likely it will be for you to have them removed for any reason, either because of dissatisfaction, an unacceptable cosmetic result, or a complication such as severe capsular contracture.

Rupture

Breast implants are considered to have ruptured when the implant shell develops a tear or hole. 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 will leak. Breast implants may rupture or leak because of any of these reasons:

- Damage by surgical instruments at the time of implantation or during any subsequent surgical procedure,
- Stress to the implant during implant surgery that weakens it,
- Folding or wrinkling of the implant shell,
- Excessive force to the chest (for example, during closed capsulotomy, which is a procedure that should not be used),
- Trauma (like being in a car accident),
- Compression during a mammogram,
- Severe capsular contracture, or
- Normal use over time.

Additional information, the most common local complications, and adverse outcomes with breast implants can be found at: www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/UCM259894.pdf