IMPORTANT INFORMATION
FOR WOMEN CONSIDERING BREAST IMPLANTS
COMMON COMPLICATIONS

What are the most common local complications and adverse outcomes with breast implants?
The most common local complications and adverse outcomes associated with breast implants are capsular contracture, reoperation, implant removal, and rupture or deflation of the implant.

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.

Capsular contracture causes the breast to feel abnormally firm and can cause pain. There is a scale for describing the severity of the contracture. It is called the Baker Grading Scale. The grades are:

<table>
<thead>
<tr>
<th>Grade</th>
<th>Symptoms</th>
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<tbody>
<tr>
<td>Grade I</td>
<td>The breasts feel soft and look normal (it is soft)</td>
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<tr>
<td>Grade II</td>
<td>The breasts feel firm but look normal</td>
</tr>
<tr>
<td>Grade III</td>
<td>The breasts feel hard, painful, and look abnormal</td>
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Capsular contracture may be more common if you have had a breast infection, trauma (like being in a car accident), 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 breasts 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, especially because of deflation, 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 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 compression-mammogram.
- Severe capsular contracture.
- Normal use over time.

Implant rupture can occur at any time and can vary from a small leak to complete deflation. Implant rupture often occurs spontaneously, but it may result from trauma (like being in a car accident) or infection. If you experience any of these symptoms, contact your health care provider promptly to schedule an appointment.

Additional information, the most common local complications, and adverse outcomes with breast implants can be found at: https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm259296.htm

BREAST-IMPLANT ASSOCIATED ANAPLASTIC LARGE CELL LYMPHOMA (BIA-ALCL)

What is BIA-ALCL?

Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) is an uncommon type of lymphoma that has been found in women with breast implants. It usually appears as a swelling of the breast caused by fluid surrounding the implant, usually occurring at least one year after surgery. Other late onset symptoms may include pain, lumps, swelling, or asymmetry. The recommended treatment is the removal of the breast implant and the surrounding tissue, treatment has been successful when caught early. 8, 11

How often does BIA-ALCL occur?

Health authorities globally state the incidence of BIA-ALCL is uncommon. 1, 2, 11

As of November 2018, there have been 626 unique, pathology confirmed cases of BIA-ALCL reported worldwide. 1, 2 The FDA had previously estimated that there were 5-10 million women with breast implants worldwide. 1, 2, 11

The FDA has noted that BIA-ALCL occurs more frequently following implantation of breast implants with textured surfaces. 3, 4, 5, 11

Mentor continues to work with industry groups, physician scientists and health authorities globally to better understand the associated risks and causes of BIA-ALCL. As patient safety has been and always will be Mentor’s first priority, Mentor continues to closely monitor reports and of information about BIA-ALCL.

Where can I find additional resources about BIA-ALCL?

The U.S. Food and Drug Administration (FDA), French National Security Agency of Medicines and Health Products (ANSM), Australian Therapeutic Goods Administration (TGA), and Medicines and Healthcare products Regulatory Agency (MHRA) The American Society of Plastic Surgeons (ASPS), the American Society for Aesthetic Plastic Surgery (ASAPS), The Plastic Surgery Foundation (PSF) and the International Society of Aesthetic and Plastic Surgery (ISAPS) provide up to date resources about the risks and benefits of breast implant surgery as well as information about BIA-ALCL. 1, 2, 5, 11, 15

What should I do if I already have breast implants?

The FDA does not recommend changes to your routine medical care and does not recommend the removal of implants. 1, 2, 11

Health authorities state that BIA-ALCL is uncommon; it has occurred in only a very small number of the millions of women who have breast implants. 1, 2, 3, 11

The FDA notes that symptoms of BIA-ALCL are typically late onset, meaning they occur at least one year after surgery. Symptoms typically include pain, lumps, swelling, or asymmetry. If you experience any of these symptoms, contact your health care provider promptly to schedule an appointment. 1, 2, 3, 11

Although not specific to BIA-ALCL, the FDA recommends that you follow standard medical recommendations including: 1, 2, 11
- Monitor your breast implants, if you notice any changes, contact your health care provider promptly to schedule an appointment. For more information on self breast exams, visit MedlinePlus. Self Breast Exam at: https://medlineplus.gov/ency/article/001993.htm.
- Get regular mammography screenings.
- If you have silicone gel-filled breast implants, get periodic magnetic resonance imaging (MRI) to detect ruptures as recommended by your health care provider. The FDA-approved product labeling for silicone gel-filled breast implants states that the risk of rupture should occur three years after implant surgery and every two years thereafter.

CHOOSE OF IMPLANTS

Why should I consider textured implants?

Textured implants have certain advantages over smooth implants. The newest generation of shaped breast implants are textured to reduce movement of the implant. Textured implants have other benefits in reducing complications, which may require reoperation, that occur much more frequently than BIA-ALCL, including capsular contracture. 11 Selection of the most appropriate implant for you should be a conversation between you and your doctor.

Are Mentor implants safe?

MENTOR Breast Implants are backed by substantial clinical data demonstrating safety and effectiveness in both augmentation and reconstruction, including 10-year clinical trials. 14 The evidence continues to support the safety and effective use of MENTOR Breast Implants in breast surgery. 2, 11

Individuals who have been implanted with textured breast implants may, at some point during their clinical history, have a risk of developing BIA-ALCL. While textured breast implants have established clinical benefits, leading researchers recommend that clinicians should consider the relative risk of developing BIA-ALCL when selecting a textured implant for their patient; clinical need should be adequately justifed when selecting higher surface area implants like Biocell and Polyurethane. Current literature concludes that the risk of developing BIA-ALCL differs between different textured devices and has been shown to be rare with Mentor breast implants. 2, 11

BREAST IMPLANT ILLNESS

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Breast implant illness is a general term describing a broad range of symptoms and signs that are under consideration for being associated with breast implants. Scientific studies do not support claims that silicone gel breast implants cause systemic illness. For more information about the inherent risks associated with breast implants, please speak with your surgeon and review the Product Insert Data Sheets and patient brochures that your surgeon provides to you.