MENTOR®

IMPORTANT INFORMATION

ABOUT 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:

Grade I	Grade II	Grade III	Grade IV
Contracture is observed, but the breast feels and looks normal (it is soft)	The breast is a little firm, but looks normal	The breast is firm and looks abnormal	The breast is hard, painful, and looks abnormal

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:
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.[1-5, 29] It usually appears as a swelling of the breast caused by fluid surrounding the implant, usually occurring at least one year after surgery.[6] Other late onset symptoms may include pain, lumps, swelling, or asymmetry.[5] The recommended treatment is the removal of the breast implant and the surrounding tissue; treatment has been successful when caught early.[6, 7]

How often does BIA-ALCL occur?

Health authorities globally state the incidence of BIA-ALCL is uncommon.[1-5, 29]

As of November 2018, there have been 626 unique, pathology confirmed cases of BIA-ALCL reported world wide.[20] The FDA had previously estimated that there were 5-10 million women with breast implants worldwide.[1, 2, 29]

The FDA has noted that "BIA-ALCL occurs more frequently following implantation of breast implants with textured surfaces." [5]

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 of and information about BIA-ALCL.

Where can I find additional resources about BIA-ALCL?

The U.S. Food and Drug Administration (FDA), Health Canada, French National Security Agency of Medicines and Health Products (ANSM), Australian Therapeutic Goods Administration (TGA), and Medicines & 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) all provide up to date resources about the risks and benefits of breast implant surgery as well as information about BIA-ALCL.[1-5, 8-13, 29, 30]

What should I do if I already have breast implants?

The FDA does not recommend changes to your routine medical care and follow-up, nor does it recommend the removal of implants.[1, 2, 5, 29] 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.[1-5, 29]

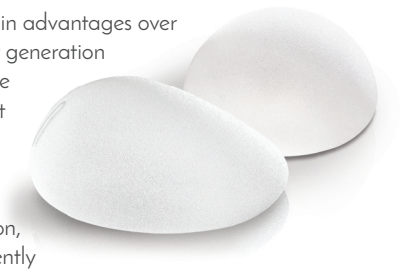
The FDA notes that symptoms of BIA-ALCL are typically late onset, meaning they occur at least one year after your surgery. Symptoms typically include pain, lumps, swelling, or asymmetry. If you experience any of these symptoms, contact your health care provider promptly to schedule an appointment.[5]

Although not specific to BIA-ALCL, the FDA recommends that you follow standard medical recommendations including:[2, 5, 29]

- 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: Breast Self Exam at: https://medlineplus. gov/ency/article/001993.htm.
- Get routine mammography screening.
- 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 first MRI should occur three years after implant surgery and every two years thereafter.

CHOICE 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.[14, 15] 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.[14-19] The evidence continues to support the safe and effective use of MENTOR® Breast Implants in breast surgery.

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. 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.[21-29]

BREAST IMPLANT ILLNESS

Breast Implant Illness is a general term describing a broad range of signs and symptoms 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.

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Important Safety Information

MENTOR® MemoryGel™ Breast Implants and MENTOR® Saline-filled Breast Implants are indicated for breast augmentation in women (at least 22 years old for MemoryGel™ Implants, and 18 years old for Saline Implants) or for breast reconstruction. MENTOR® MemoryGel™ SILTEX™ BECKER™ Expander/Breast Implants are indicated for breast reconstruction. Breast implant surgery should not be performed in women with active infection anywhere in their body, with existing cancer or pre-cancer of their breast who have not received adequate treatment for those conditions, or who are currently pregnant or nursing.

Breast implants are not lifetime devices and breast implantation may not be a one-time surgery.

The most common complications for breast augmentation and reconstruction with MemoryGel™ Implants include any reoperation, capsular contracture, breast pain, and implant removal with or without replacement, and ptosis. A lower risk of complication is rupture. The health consequences of a ruptured silicone gel breast implant have not been fully established. MRI screenings are recommended three years after initial implant surgery and then every two years after to detect silent rupture.

The most common complications for MemoryGel™ SILTEX™ BECKER™ Expander/Breast Implants are consistent with types of complications associated with other gel filled breast implant studies.

The most common complications with MENTOR® Saline-filled Implants include reoperation, implant removal, capsular contracture, breast pain, wrinkling, and implant deflation.

For MemoryGel® Implants, patients should receive a copy of *Important Information for Augmentation Patients about MENTOR® MemoryGel™ Breast Implants* or *Important Information for Reconstruction Patients about MENTOR® MemoryGel™ Breast Implants.* For MemoryGel® BECKER™ Expander/Breast Implants, patients should receive a copy of *Important Information for Reconstruction Patients About MENTOR® MemoryGel™ BECKER™ Expander/Breast Implants.* For MENTOR® Saline-filled Implants, patients should receive a copy of *Saline-Filled Breast Implants: Making an Informed Decision.* Your patient needs to read and understand the information regarding the risks and benefits of breast implants, with an opportunity to consult with you prior to deciding on surgery.

The CONTOUR PROFILE® Breast Tissue Expander can be utilized for breast reconstruction after mastectomy, correction of an underdeveloped breast, scar revision, and tissue defect procedures. The expander is intended for temporary subcutaneous or submuscular implantation and is not intended for use beyond six months. Do not use the CONTOUR PROFILE® Tissue Expander in patients where an MRI may be needed. The device could be moved by the MRI causing pain or displacement, potentially resulting in a revision surgery. The incidence of extrusion of the expander has been shown to increase when the expander has been placed in injured areas.

For detailed indications, contraindications, warnings, and precautions associated with the use of all MENTOR® Implantable Devices, which include MENTOR® Saline-filled Implants, MemoryGel™Implants, MemoryGel™ BECKER™ Expander/Breast Implants, and CONTOUR PROFILE® Expanders, please refer to the Product Insert Data Sheet provided with each product or visit https://www.jnjmedicaldevices.com/en-CA/mentor.

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