



Breast Implants:

Local Complications and Adverse Outcomes

This booklet highlights the most common problems associated with silicone gel-filled and saline-filled breast implants: those that occur in the breast or chest area, known as “local complications.” The most common local complications and adverse outcomes are capsular contracture (hardening of breast area around the implant), reoperation (additional surgeries), implant removal and rupture or deflation of the implant. Other local complications include implant wrinkling, asymmetry, scarring, pain, and infection at the incision site. These local complications often result in reoperation or implant removal.



Local Complications and Adverse Outcomes

The following is a list of local complications and adverse outcomes that occur in one percent or more of patients at any time after breast implant surgery. They are listed in alphabetical order—not in order of prevalence.

- **Asymmetry**—when breasts are uneven in appearance in terms of size, shape, or breast level
- **Breast feeding difficulties**
- **Breast pain**
- **Breast sagging**, also called “ptosis”
- **Calcium build-up in breast tissue**, also called “calcification”
- **Capsular contracture**—hardening of the breast area around the implant
- **Chest wall deformity**—when the chest wall or underlying rib cage appears deformed
- **Deflation of the breast implant**—when filler material leaks from the breast implant often due to a valve leak or a tear or cut in the implant shell
- **Delayed wound healing**
- **Extrusion**—when the skin breaks down and the implant appears through the skin
- **Hematoma**—collection of blood near the surgical site
- **Iatrogenic injury or damage**—when new injury or damage occurs to the tissue or implant as a result of implant surgery
- **Implant displacement or malposition**—when the implant is not in the correct position in the breast
- **Implant palpability or visibility**—when the implant can be felt through the skin
- **Implant removal**—with or without implant replacement
- **Implant visibility**—when the implant can be seen through the skin
- **Implant wrinkling or rippling**
- **Infection, including Toxic Shock Syndrome**—when during breast implant surgery, wounds are contaminated with micro-organisms, such as bacteria or fungi
- **Inflammation or irritation**
- **Necrosis**—when there is dead skin or tissue around the breast
- **Nipple or breast changes**, including change in or loss of nipple sensation
- **Redness or bruising**
- **Reoperation**—additional surgeries
- **Rupture of the breast implant**—when there is a tear or hole in the implant’s outer shell
- **Scarring**
- **Seroma**—the collection of fluid around the breast implant
- **Skin rash**
- **Swollen or enlarged lymph nodes**, also called “lymphedema or lymphadenopathy”
- **Thinning and shrinking of the skin**, also called “breast tissue atrophy”
- **Unsatisfactory appearance** due to implant style or size

If you experience any of the local complications listed above after breast implant surgery, you may need specific treatments, including additional surgery. Maintain an active role in your health care and inform your doctor immediately if you experience any new health issues.

The Most Common Local Complications and Adverse Outcomes

The most common local complications and adverse outcomes associated with breast implants—silicone gel-filled and saline-filled—are capsular contracture, reoperation, implant removal, and rupture or deflation of the implant.

Capsular Contracture

Capsular contracture is the hardening of the breast area around the implant. It can occur in the tissue surrounding one or both implants. This hardening causes the tissue to tighten, which can be painful.

There are four grades of capsular contracture, known as Baker Grades:

Grade I	breast is normally soft and looks natural
Grade II	breast is a little firm but looks normal
Grade III	breast is firm and looks abnormal
Grade IV	breast is hard, painful, and looks abnormal

Grades III and IV capsular contracture are considered severe, and may require reoperation or implant removal. Capsular contracture, whether mild, moderate or severe, may occur more than once in the same implant.



Photograph 1 shows Grade IV capsular contracture in the right breast of a 29-year-old woman seven years after placement of silicone gel-filled breast implants. Photograph courtesy of Walter Peters, M.D., Ph.D., F.R.C.S.C., University of Toronto.

Reoperation

Breast implants are not lifetime devices. You may need to have one or more reoperations over the course of your life due to any one or combination of local complications. You may also need one or more reoperations to improve breast appearance if you are unsatisfied with the outcomes of the surgery aimed at correcting any local complications.

Removal

One type of reoperation involves the surgical removal of your implants, which may or may not include implant replacement. As many as 20 percent of women who receive breast implants for breast augmentation have to have their implant removed within 8-10 years. Over the course of your life, you may need to have your implant removed due to local complications. Many women have their implants replaced, but some women do not. Women who do not have their implants replaced may have cosmetically undesirable dimpling, puckering, or sagging of the natural breast following implant removal.



Photograph 2 shows a 29-year-old woman one year after having her silicone gel-filled breast implants removed. This is the same woman from Photograph 1. Photograph courtesy of Walter Peters, M.D., Ph.D., F.R.C.S.C., University of Toronto.

Rupture / Deflation

Although the term rupture is used for silicone gel-filled and saline-filled breast implants, the term deflation is typically used only for saline-filled implants. Rupture is a tear or hole in the outer shell of the breast implant. When this occurs in a saline breast implant, it deflates, meaning the saltwater (saline) solution leaks from the shell. Silicone gel is thicker than saline, so when a silicone gel-filled implant ruptures, the gel may remain in the shell or in the scar tissue that forms around the implant (intracapsular rupture). Some breast implants rupture in the first few months after surgery and some after several years. Others may rupture after 10 or more years. Some possible causes of rupture include:

- capsular contracture;
- compression during a mammogram;
- damage by surgical instruments;
- damage during procedures to the breast, such as biopsies and fluid drainage;
- normal aging of the implant;
- over-filling or under-filling of saline-filled breast implants;
- physical stresses to the breast such as trauma or intense physical pressure;
- placement through a belly button (umbilical) incision site, which requires more handling of the implant; or
- too much handling during surgery.

FDA recommends removing both saline-filled and silicone gel-filled breast implants if they have ruptured. You and your doctor will need to decide whether or not your implant has ruptured and if you should have it replaced or removed without replacement.

Silicone Gel-filled Breast Implants and Rupture

When silicone gel-filled implants rupture, silicone gel may escape from the scar tissue capsule around the implant and migrate away from the breast. This can cause lumps to form in the breast, chest wall, armpit, arm, or abdomen.

When a silicone gel-filled breast implant ruptures, some women may notice decreased breast size, hard knots, uneven appearance of the breasts, pain or tenderness, tingling, swelling, numbness, burning, or changes in sensation. However, most ruptures occur without any symptoms. These are known as “silent ruptures.”

Magnetic Resonance Imaging (MRI) is the most effective way to detect silent rupture of a silicone gel-filled breast implant. The FDA and implant manufacturers recommend that women with silicone gel-filled breast implants undergo MRI screening three years after they receive a new implant and every two years after that for early detection of a silent rupture. The FDA recommends using MRI equipment that is specifically designed for imaging the breast for evaluating patients with suspected rupture or leakage of their silicone gel-filled implants.

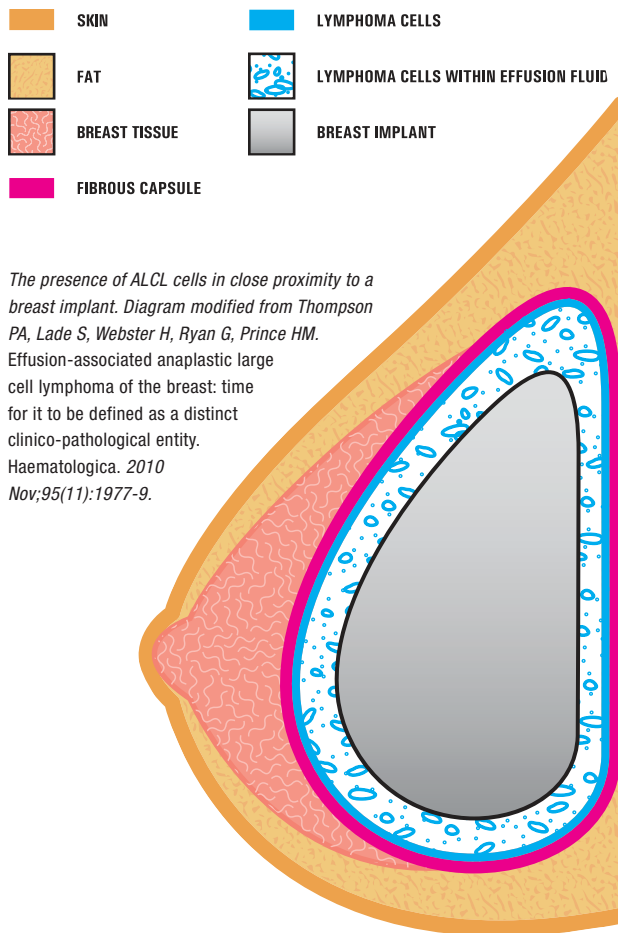
Saline-filled Breast Implants and Deflation

Deflation occurs when the shell of a saline-filled breast implant tears or when the seal around the valve used to fill the implant is broken and liquid saline leaks out from the implant. When saline-filled breast implants deflate, loss of size or shape of the implant can be noticed immediately, or it may progress slowly over a period of days.



Photograph 3 shows deflated saline-filled breast implants in a 30-year-old woman. Photograph courtesy of Walter Peters, M.D., Ph.D., F.R.C.S.C., University of Toronto.

Anaplastic Large Cell Lymphoma (ALCL)



Recent scientific reports have suggested a possible association between anaplastic large cell lymphoma (ALCL) and breast implants. The FDA is aware of approximately 60 case reports of ALCL in women with breast implants worldwide. ALCL is a rare type of lymphoma or cancer involving cells of the immune system. In women with breast implants, ALCL is generally found next to the implant itself and is usually contained within the fibrous capsule that the body forms around the implant. ALCL is not breast cancer.

Most of the breast implant patients found to have ALCL were diagnosed after they sought medical treatment for implant-related symptoms such as pain, lumps, swelling, or asymmetry that developed after their initial surgical sites had fully healed. In most cases, the ALCL was treated with surgery to remove the implant and surrounding scar tissue. Some patients also received radiation therapy, chemotherapy or both.

Women with breast implants may have an increased risk of developing ALCL, though current literature indicates that the risk is extremely low. If you have breast implants, there is no need to change your routine medical care and follow-up.



Things to Consider, Before You Get Breast Implants

There are several important things to consider before deciding to undergo breast implant surgery, including understanding your own personal expectations and reasons for having the surgery. Below are some things the FDA thinks you should consider before undergoing breast augmentation, reconstruction or revision surgery.

- Breast implants are not lifetime devices; the longer you have your implants, the more likely it will be for you to have them removed.
- The longer you have breast implants, the more likely you are to experience local complications and adverse outcomes.
- The most common local complications and adverse outcomes are capsular contracture, reoperation, implant removal, and rupture or deflation of the implant. Other complications include wrinkling, asymmetry, scarring, pain, and infection at the incision site.
- You should assume that you will need to have additional surgeries (reoperations).
- Many of the changes to your breast following implantation may be cosmetically undesirable and irreversible.
- If you have your implants removed but not replaced, you may experience changes to your natural breasts such as dimpling, puckering, wrinkling, breast tissue loss or other undesirable cosmetic changes.
- If you have breast implants, you will need to monitor your breasts for the rest of your life. If you notice any abnormal changes in your breasts, you will need to see a doctor promptly.
- If you have silicone gel-filled breast implants, you will need to undergo periodic MRI examinations in order to detect ruptures of the implant that do not cause symptoms (“silent ruptures”). For early detection of silent rupture, the FDA and breast implant manufacturers recommend that women with silicone gel-filled breast implants receive MRI screenings 3 years after they receive a new implant and every 2 years after that. MRI screening for implant rupture is costly and may not be covered by your insurance.
- If you have breast implants, you may have a very low but increased risk of developing a rare type of cancer called anaplastic large cell lymphoma (ALCL) in the breast tissue surrounding the implant. (ALCL is not breast cancer.) Women diagnosed with ALCL in the breast may need to be treated with surgery, chemotherapy and/or radiation therapy.

For more detailed information about breast implants, visit www.fda.gov/breastimplants.

