

INFORMATION REGARDING SILICONE IMPLANTS

WHAT ARE BREAST IMPLANTS?

Breast implants are medical devices that are implanted either under breast tissue or under the chest muscle for breast augmentation or reconstruction. There are two major types: saline-filled and silicone gel-filled. Saline-filled breast implants are silicone shells that are either prefilled or filled with saline during surgery, and some of these allow for adjustments of the filler volume after surgery. Silicone gel-filled breast implants are silicone shells prefilled with silicone gel. Breast implants vary in profile, size, and shell surface (smooth or textured).

WHAT TYPES ARE APPROVED BY FDA?

FDA has approved four breast implants for marketing in the U.S.

- In May 2000, Mentor and Allergan (formerly Inamed) received approval for saline-filled breast implants. These implants were approved for breast augmentation in women 18 years or older and for breast reconstruction in women of any age.
- In November 2006, Allergan and Mentor received approval for their silicone gel-filled breast implants. These implants were approved for breast augmentation in women 22 years or older and for breast reconstruction in women of any age.
More recently Sientra implants have also been approved in the US.
They are not widely available yet in Canada.

Similar clinical parameters are suggested for breast implants in Canada.

HOW ARE BREAST IMPLANTS USED?

Breast implants are used for:

- primary augmentation (to increase breast size for cosmetic reasons)
- revision-augmentation (revision surgery to correct or improve the result of an original breast augmentation surgery)
- primary reconstruction (to replace breast tissue that has been removed due to cancer or trauma or that has failed to develop properly due to a severe breast abnormality)
- revision-reconstruction (revision surgery to correct or improve the result of an original breast reconstruction surgery)

ARE THERE ANY AGE LIMITS WITH RESPECT TO WHO CAN GET BREAST IMPLANTS?

Mentor and Allergan (formerly Inamed) saline-filled breast implants are approved for: (1) **reconstruction** (primary reconstruction and revision-

reconstruction) in women of any age and (2) **augmentation** (primary augmentation and revision-augmentation) in women 18 years or older.

Mentor and Allergan silicone gel-filled breast implants are approved for: (1) **reconstruction** (primary reconstruction and revision-reconstruction) in women of any age and (2) **augmentation** (primary augmentation and revision-augmentation) in women 22 years or older.

FDA restricts the marketing of breast implants for augmentation to women of a minimum age because young women's breasts continue to develop through their late teens and early 20s and because there is a concern that young women may not be mature enough to make an informed decision about the potential risks. However, there is no age restriction on the marketing of these products for reconstruction, so as to allow young women to have access to breast implants to replace breast tissue that has been removed due to cancer or trauma or that has failed to develop properly due to a severe breast abnormality.

DR SANJAY AZAD at Revere Esthetique

CURRENTLY RECOMMENDS THE USE OF ROUND, GUMMY BEAR, SILICONE, SMOOTH SURFACE IMPLANTS

WHY IS THE AGE MINIMUM DIFFERENT FOR AUGMENTATION FOR SALINE-FILLED AND SILICONE GEL-FILLED BREAST IMPLANTS?

FDA approved saline-filled breast implants for augmentation in women ages 18 and older. FDA approved silicone gel-filled implants for women ages 22 and older. The age restrictions are different because the risks are different for the two products. For example, silicone gel-filled implants will require frequent MRI monitoring to detect silent rupture (a rupture that can go undetected by you or your doctor). There is no risk of silent rupture for saline-filled implants. In addition, the health consequences of a ruptured saline-filled breast implant are different from those of a ruptured silicone gel-filled breast implant.

WHAT ARE THE RISKS OF BREAST IMPLANTS?

Some of the risks of breast implants include:

- reoperations (additional surgeries), with or without removal of the device
- capsular contracture (hardening of the area around the implant)
- breast pain
- changes in nipple and breast sensation
- rupture with deflation for saline-filled implants
- rupture with or without symptoms for silicone gel-filled implants
- migration of silicone gel for silicone gel-filled breast implants.

HOW LONG DO BREAST IMPLANTS LAST?

Breast implants do not last forever. If you decide to get breast implants, you will likely need additional surgeries on your breasts over your lifetime due to rupture, other complications (for example, capsular contracture, breast pain), or unacceptable cosmetic outcomes (for example, asymmetry, unsatisfactory style/size, wrinkling/rippling).

WHAT CAUSES BREAST IMPLANTS TO RUPTURE?

We do not know all of the causes of breast implant rupture. We do know that breast implants can rupture from:

- damage during implantation or during other surgical procedures
- folding or wrinkling of the implant shell
- trauma or other excessive force to the chest
- compression of the breast during mammography.

HOW WILL I KNOW IF MY BREAST IMPLANT HAS RUPTURED?

If your **saline-filled** breast implant ruptures, you or your doctor will be able to tell. When saline-filled breast implants rupture, they deflate and the saline solution leaks into your body immediately or over a period of days. You will notice that your implant loses its original size or shape.

If your **silicone gel-filled** breast implant ruptures, it is likely that neither you nor your doctor will know. This is known as a silent rupture. This is why MRI is recommended at three years after implantation and then every two years thereafter to screen for rupture. However, sometimes there are symptoms. These symptoms include hard knots or lumps surrounding the implant or in the armpit, change or loss of size or shape of the breast or implant, pain, tingling, swelling, numbness, burning, or hardening of the breast.

IF MY BREAST IMPLANT RUPTURES, SHOULD I HAVE IT REMOVED?

The patient labeling for the Mentor and Allergan (formerly Inamed) silicone gel-filled breast implants recommends removal of ruptured implants.

You and your doctor will need to decide whether or not to have a ruptured implant removed.

WILL THE PLATINUM IN SILICONE BREAST IMPLANTS HARM ME?

Platinum is a metal used in the manufacture of the shell and gel components of silicone breast implants. FDA fully evaluated the scientific literature on platinum. Based on the existing literature, FDA believes that the platinum contained in the implant shell and gel is in the zero oxidation state, which poses the lowest health risk. This is further supported by the available

biocompatibility testing, gel bleed testing, and clinical data on these implants.

WHAT ARE SOME OF THE IMPORTANT FACTORS I SHOULD CONSIDER WHEN DECIDING WHETHER OR NOT TO GET BREAST IMPLANTS?

Some important factors to consider include:

- Breast implants do not last forever. If you decide to get breast implants, you will likely need additional surgeries on your breasts over your lifetime due to complications or unsatisfactory cosmetic outcomes
- Many of the changes to your breasts following implantation cannot be undone. If you later choose to have your implants removed and not replaced, your breasts will not change back to the way they looked before your implant surgery. You may have permanent dimpling, puckering, wrinkling, or other cosmetic changes.
- When you have your implants replaced (revision), your risk of complications increases compared to your first (primary) surgery.
- Routine mammograms to screen for breast cancer will be more difficult with breast implants.
- Breast implants may affect your ability to breast feed, either by reducing or eliminating milk production.

Factors to consider specifically about silicone gel-filled breast implants include:

- If your silicone gel-filled breast implant ruptures, you may have no symptoms. This is called a silent rupture because, most of the time, neither you nor your doctor will know that your implant has ruptured.
- The best way to determine whether or not your silicone gel-filled implant has ruptured is with an MRI examination. You should have your first MRI three years after your implant surgery and every two years thereafter. This is a recommendation, but not routinely applicable in Canada at the moment.

WHAT ARE “GUMMY BEAR” GEL BREAST IMPLANTS?

The so-called “gummy bear” implants are more cohesive silicone gel-filled breast implants made of a firmer silicone gel filler to help maintain the shape of the implant. This type of implant is the one routinely used by Dr Sanjay Azad in his practice.

WHO CAN GET MENTOR AND ALLERGAN SILICONE GEL-FILLED BREAST IMPLANTS?

The Mentor and Allergan (formerly Inamed) implants were approved for:

- Breast reconstruction in women of any age. Breast reconstruction includes:
 - primary reconstruction to replace breast tissue that has been removed due to cancer or trauma or that has failed to develop

- properly; and
- revision-reconstruction to correct or improve the result of breast reconstruction surgery.
- Breast augmentation in women 22 years or older. Breast augmentation includes:
 - primary augmentation to increase the breast size; and
 - revision-augmentation to correct or improve the result of breast augmentation surgery.

POTENTIAL LOCAL COMPLICATIONS AND REOPERATIONS

The Institute of Medicine (IOM) completed its independent review of past and ongoing scientific research of both silicone gel-filled and saline-filled breast implant safety in June 1999.¹ Below are some of the major findings.

Local complications

- are the primary safety issue because they are frequent enough to be a concern
- accumulate over the lifetime of the implant and have not been well studied
- are crucial for women deciding if they want breast implants

COMMON ISSUES

Capsular contracture and rupture/deflation are the most common local complications that occur with both silicone gel-filled and saline-filled breast implants.

CAPSULAR CONTRACTURE

Capsular contracture occurs when the scar tissue or capsule that normally forms around the implant tightens and squeezes the implant. It can happen to one or both of the implants. There are four grades of capsular contracture known as Baker grades.

The Baker grading is as follows:

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

Capsular contracture may require reoperation, usually for Grades III and IV, and it may occur again.

RUPTURE/DEFLATION

Breast implants do not last a lifetime. Some breast implants may rupture/deflate in the first few months after surgery and some after several years. Others may take 10 or more years to rupture/deflate.

The reasons for rupture are not well understood and are currently being studied. Some possible causes of rupture/deflation include:

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

When silicone gel-filled implants rupture, 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. Other women may unknowingly experience a rupture without any symptoms (silent rupture).

Magnetic resonance imaging (MRI) with equipment specifically designed for imaging the breast may be used for evaluating patients with suspected rupture or leakage of their silicone gel-filled implant. Silicone gel may

- escape from the scar tissue capsule around the implant
- migrate away from the breast
- cause lumps, called granulomas, to form in the breast, chest wall, armpit, arm, or abdomen

Plastic surgeons usually recommend removal of the implant if it has ruptured, even if the silicone is still enclosed within the scar tissue capsule, because the silicone gel may eventually leak into surrounding tissues.

When saline-filled breast implants deflate, the saline solution leaks either through an unsealed or damaged valve or through a break in the implant shell. Implant deflation can be immediate or progress over a period of days, months, or years and is noticed by loss of size or shape of the implant. Additional surgery is needed to remove deflated implants.

REOPERATIONS

It is likely that you will need to have one or more reoperations over the course of your life because of local complications from breast implants. Reasons for reoperations could include any of the potential local complications above. Multiple reoperations to either improve the appearance of the breasts, to remove ruptured/deflated implants, or both may result in an unsatisfactory cosmetic outcome.

REMOVALS

One type of reoperation is the removal of the implant(s), with or without replacement. Removal involves surgery. You are likely to have your implant removed at some time over the course of your life because of one or more local complications above. Many women decide to have the 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 breast following removal of the implant.

KEY POINTS TO CONSIDER

- Breast implants will not last a lifetime.
- Either because of rupture or other complications, you will probably need to have the implants removed.
- You are likely to need additional doctor visits, reoperations, or removals because of one or more complications over the course of your life.
- Many of the changes to your breast following implantation may be cosmetically undesirable and cannot be reversed.
- If you later choose to have your implants removed, you may experience unacceptable dimpling, puckering, wrinkling, breast tissue loss, or other undesirable cosmetic changes of the breasts.