

GEL-FILLED
BREAST IMPLANT SURGERY
Making an Informed Decision



 **MENTOR**[®]

Johnson & Johnson

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Making an Informed Decision

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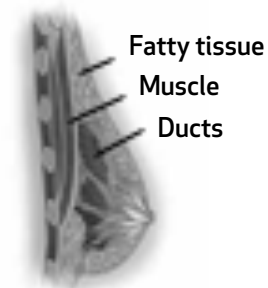
1. INTRODUCTION

Purpose of the Brochure

The purpose of this brochure is to assist patients in making informed decisions about breast augmentation and breast reconstruction surgery. This educational brochure is designed to help patients talk with their doctors, as well as provide patients with general information on breast implant surgery and give them specific details about MENTOR® Breast Implants.

What Gives the Breast Its Shape?

The breast consists of milk ducts and glands, surrounded by fatty tissue that provides its shape and feel. Situated beneath the breast is the pectoralis major muscle or chest muscle. Factors such as pregnancy (when milk glands are temporarily enlarged), rapid weight loss, and the effects of gravity as a woman ages combine to stretch the skin, which may cause the breast to droop or sag.



What is a Breast Implant?

Currently, there are three main types of breast implants:

- saline-filled breast implants,
- cohesive silicone gel-filled breast implants and
- combination cohesive gel/saline-filled breast implants.

All of these implants consist of silicone elastomer shells, filled with saline (salt water), cohesive silicone gel or both saline and cohesive silicone gel. The surface of the shells may be either textured or smooth.



Saline-Filled Breast Implant



Gel-Filled Breast Implant



Combination Gel/Saline-Filled Breast Implant

What is Silicone?

Silicones are polymers made up of silicon, oxygen, carbon and hydrogen. Silicone can come in the form of liquid, gel or solid. There are many uses of silicone, including cosmetics, cures for stomach gas and in many medical devices, such as foldable intraocular lenses, heart pacemakers and tissue expanders.

Silicon is a common chemical element occurring in nature. It is found in sand, rocks and glass.

Is Silicone Safe?

There have been several prestigious multispecialty panels of scientific experts who have reviewed and studied the available data on silicone breast implants. The following describes the findings of three such panels.

The Independent Review Group (IRG)

This panel commissioned by the British Minister of Health with experts in many scientific disciplines was charged with reviewing the scientific evidence of the possible health risks associated with silicone breast implants and examining issues related to preoperative patient information. The IRG report released in 1998 made the following conclusions:

- “There is no epidemiological evidence for any link between silicone gel breast implants and any established connective tissue disease. If there is a risk of connective tissue disease, it is too small to be quantified. The IRG cannot justify recommending further epidemiological studies to investigate this hypothesis.” For more information on connective tissue disease, please refer to the section on BREAST IMPLANT COMPLICATIONS.
- The overall biological response to silicone is consistent with conventional forms of response to foreign materials, rather than an unusual toxic reaction.
- There is no evidence that children of women with breast implants are at increased risk of connective tissue disease.

The Scientific and Technical Options Assessment (STOA) Programme

This panel was commissioned by the European Parliament to issue a report on the policy options on silicone gel breast implants based on a comprehensive, unbiased analysis of the scientific literature. The STOA report published in 2000 made the following conclusions:

- “Studies do not point to an association between silicone implants and serious health risks, such as cancer and connective tissue diseases.”
- “... studies have concluded that there does not appear to be evidence of harmful effects to infants breast fed by women with silicone breast implants ...”

The Institute of Medicine (IOM)

This panel commissioned by the US Congress with experts in many scientific disciplines was charged with conducting an independent review of past and ongoing research on silicone and other types of breast implants. The IOM report released in 1999 made the following conclusions:

- There is no increased risk of connective tissue disease in women with breast implants. Women with breast implants are no more likely than the rest of the population to develop cancer, immunologic diseases or neurological problems.
- Breast-feeding is safe and beneficial.
- There are no second generation effects on children of women with breast implants.

2. DECIDING TO HAVE BREAST IMPLANTS

Reasons for Considering Breast Implants

Implants are to be used for the following indications:

- Breast Augmentation – This procedure is performed to increase the size and proportions of a woman’s breasts. The European Parliament “recommends that implants in women under 18 years of age should be authorised only on medical grounds.”
- Breast Reconstruction – This procedure is performed to restore a woman’s breast shape after a mastectomy or injury that resulted in either partial or total loss of the breast(s), or to correct a birth defect.
- Replacement or Revision – This procedure is performed as replacement or revision surgery for patients with previous augmentation or reconstruction with silicone gel-filled or saline-filled implants.

Reasons Why Breast Implants May Not Be an Option

The use of this prosthesis is contraindicated in patients who have any of the following conditions:

- Pregnancy or nursing mothers.
- Lupus (e.g., SLE and DLE).
- Scleroderma (e.g., progressive systemic sclerosis).
- Currently has a condition that could compromise or complicate wound healing (except reconstruction patients).
- Infection or abscess anywhere in the body.
- Demonstrates tissue characteristics, which are clinically incompatible with implant (e.g., tissue damage resulting from radiation, inadequate tissue, or compromised vascularity).
- Possesses any condition, or is under treatment for any condition which, in the opinion of the consulting physician(s), may constitute an unwarranted surgical risk.
- Anatomic or physiologic abnormality, which could lead to significant postoperative complications.
- A history of sensitivity to foreign materials or repeated attempts and failures at breast augmentation or reconstruction.
- An unwillingness to undergo any further surgery for revision.
- Unrealistic expectations, such as inappropriate attitude or motivation, or a lack of understanding of the risks involved with the surgical procedure and implants.
- Premalignant breast disease without a subcutaneous mastectomy.
- Untreated or inappropriately treated breast malignancy, without mastectomy.

What Types of Silicone Gel-Filled Breast Implants Are Available From Mentor?

All MENTOR® Gel Breast Implants contain silicone gel which is cohesive. The breast implants are offered with three degrees of cohesive filling material: Cohesive I™ (standard), Cohesive II™ (moderate) and Cohesive III™ (high). The implants come in a variety of shapes, surface textures, and sizes. Breast implants are available with either a smooth or textured surface. Mentor has a textured breast implant surface called SILTEX™. Also, implants are available with a single silicone shell filled with cohesive silicone gel or as expander/breast implants with an inner silicone shell filled with saline and an outer silicone shell filled with cohesive silicone gel.

The following is a description of MENTOR® Breast Implant styles. Be sure to familiarize yourself with the different features of breast implants and to discuss the most appropriate type(s) of implants for you with your surgeon.

Gel-Filled Breast Implant Family (fixed volume)

Round Styles:

- Smooth shell surface with Cohesive I™ Gel.
- Low, Moderate, Moderate Plus, High and Ultra High Profiles.
- See example of a MENTOR® Smooth Round Moderate Profile Gel Breast Implant Cohesive I™.



- SILTEX™ Textured Surface with Cohesive I™ and II™ Gel.
- Moderate, Moderate Plus, High and Ultra High Profile with Cohesive I™ Gel and Moderate, Moderate Plus and High Profile with Cohesive II™ gel.
- See example of a SILTEX™ Round Ultra High Profile Gel Breast Implant Cohesive I™.



CONTOUR PROFILE™:

- SILTEX™ Textured Surface with Cohesive III™ Gel.
- Low, Medium and Tall Heights.
- See example of a SILTEX™ Medium Height CPG™ Gel (CONTOUR PROFILE™ Gel) Breast Implant 321 Cohesive III™, Moderate Projection



BECKER™ Expander/Breast Implant Family (postoperative adjustment of volume):

- SILTEX™ BECKER™ 25 Expander/Breast Implant Style: SILTEX™ Textured Surface, Round, 25% Cohesive I™ Gel.
- SILTEX™ BECKER™ 50 Expander/Breast Implant Style: SILTEX™ Textured Surface, Round, 50% Cohesive I™ Gel.
- SILTEX™ CONTOUR PROFILE™ BECKER™ 35 Expander/Breast Implant Style: SILTEX™ Textured Surface, CONTOUR PROFILE™, 35% Cohesive II™ Gel.
- See example of a SILTEX™ Round BECKER™ 25 Expander/Breast Implant Cohesive I™.



SPECTRA™ Adjustable Gel Breast Implant Family:

Smooth or SILTEX™ Textured Surface with Cohesive I™ Gel.

- Round style.
- High profile.
- See example of a SILTEX™ SPECTRA™ Adjustable Gel Breast Implant Cohesive I™.



Factors to Consider in Breast Implantation

Potential Benefits

Women choose primary breast augmentation surgery to increase the size and proportion of their breast(s). Women choose primary breast reconstruction surgery to replace breast tissue that has been removed because of cancer or injury, or to replace breast tissue that has failed to develop properly because of a severe breast abnormality. In addition, women choose revision surgery (replacement of an existing breast implant) to correct or improve the result of a primary augmentation or primary reconstruction surgery.

Living With Breast Implants

- Whether undergoing augmentation or reconstruction, be aware that breast implantation may not be a one time surgery. Additional doctor visits are likely needed and additional surgery(ies) may be needed over the course of a breast implant patient's life.
- Breast implants are not considered lifetime devices. Implant removal with or without replacement may be needed over the course of a breast implant patient's life.
- Although rupture can occur at any time following implantation, a number of studies examining rupture of current generation, single-lumen, CE marked products, round and shaped silicone gel-filled breast implants of various manufacturers over time (using MRI evaluations) have consistently reported similar results indicating the average expected lifetime exceeds 10 years. [With respect to adjustable breast implants, the cumulative incidence of rupture at 5 years (identified by physician exam rather than MRI) for MENTOR® BECKER™ Expander/ Breast Implants (double-lumen breast implants) was 6% among 1,428 primary reconstruction patients, 9% among 490 revision reconstruction patients, and 11% among 60 revision augmentation patients (all with follow-up at 5 years).]

- Many of the changes to a patient's breast following implantation are irreversible (cannot be undone). If a patient later chooses to have her implant(s) removed, unacceptable dimpling, puckering, wrinkling, or other cosmetic changes of the breast may be experienced.
- Breast implants may affect a patient's ability to produce a sufficient supply of milk for breast-feeding. Also, breast implants will not prevent a patient's breast from sagging after pregnancy.
- With breast implants, routine screening mammography may be more difficult, and a patient may need to have additional views, which means more time and radiation.

Steps to Implantation

Choosing a Surgeon

When choosing a surgeon who is experienced with breast implantation, the following questions should be answered:

1. How many breast augmentation or reconstruction implantation procedures does the surgeon perform per year?
2. How many years has the surgeon performed breast implantation procedures?
3. What is the most common complication the surgeon encounters with breast implantation?
4. What is the surgeon's reoperation rate with breast implantation, and what is the most common type of reoperation the surgeon performs?

The following options in breast implant surgery should be understood and discussed with the surgeon:

Implant Size

Generally, the larger the cup size wanted, the larger the breast implant (measured in cubic centimetres, or cc's) the surgeon will consider implanting. The surgeon will also evaluate the existing tissue to determine if there is enough to cover the breast implant. If a breast implant size too large for the available tissue is desired, the doctor may warn that the breast implant edges may be apparent or visible postoperatively. This may even risk surgical complications. Also, excessively large breast implants may speed up the effects of gravity and result in earlier droop or sag.

Surface Texturing

SILTEX™ is the trade name for the surface texturing on MENTOR® Breast Implants. The textured surface was designed to provide a disruptive or rough surface for the body's collagen tissue to interface with the implant. Mentor also offers nontextured or smooth-surfaced implants.

Implant Shape, Projection and Height

Mentor offers cohesive gel-filled breast implants with a round or contour profile shape. The round implants are available in various projections (low, moderate, moderate plus, high and ultra high profile) and the contour profile shaped implants are available in various heights (low, medium and tall).

Gel Cohesivity Levels

Mentor's silicone gels are cohesive polymers, not liquids. Although soft and fluid feeling, they act as a unit. Mentor's gels hold together uniformly, while retaining the natural 'give' that resembles actual breast tissue. Mentor's gel breast implants are available in three different levels of cohesivity, however, they are all cohesive.

Cohesive I™

The standard cohesive level gel used in Mentor's implants. This is Mentor's softest gel.

Cohesive II™

A slightly firmer gel, for a firmer feeling implant.

Cohesive III™

Mentor's most cohesive gel, providing shape retention with a pleasing level of firmness.

Palpability

The following may cause implants to be more palpable (more easily felt): textured implants, larger implants, subglandular placement, and the lack of adequate skin/tissue available to cover the implant.

Implant Placement

The breast implant can be placed either partially under the pectoralis major muscle (submuscular) or on top of the muscle and under the breast glands (subglandular). The pros and cons of the implant placement should be discussed with the surgeon.

The submuscular placement may make surgery and recovery last longer, may be more painful, and may make it more difficult to have some reoperation procedures than the subglandular placement. The possible benefits of this placement are that it may result in less palpable implants and easier imaging of the breast with mammography.

The subglandular placement may make surgery and recovery shorter, may be less painful, and may be easier to access for reoperation than the submuscular placement. However, this placement may result in more palpable implants and more difficult imaging of the breast with mammography.



Subglandular

Submuscular

Incision Sites

The pros and cons of the incision site should be discussed with the surgeon. There are three common incision sites: under the arm (axillary), around the nipple (periareolar), or within the breast fold (inframammary). If the incision is made under the arm, the surgeon may use a probe fitted with a miniature camera, along with minimally invasive instruments, to create a “pocket” for the breast implant. A fourth incision site: through the navel (umbilicus) using an endoscopic technique has not been studied and is therefore not recommended.

Axillary

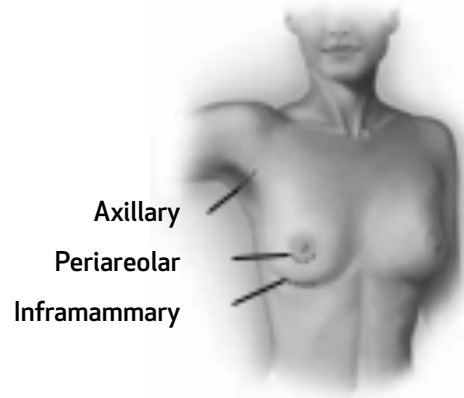
This incision is less concealed than periareolar and associated with less difficulty than the periareolar incision site when breast-feeding.

Periareolar

This incision is most concealed, but is associated with a higher likelihood of inability to successfully breast-feed, as compared to the other incision sites.

Inframammary

This incision is less concealed than periareolar and associated with less difficulty than the periareolar incision site when breast-feeding.



Axillary

Periareolar

Inframammary

3. SPECIAL CONSIDERATIONS FOR BREAST AUGMENTATION

What Are the Alternatives to Breast Augmentation?

- Accept your breasts as they are.
- Wear a padded bra or external prostheses.

Should You Have Breast Augmentation?

You may consider consulting your family, friends, breast implant support groups, and counselor(s) to help you in making this decision. You are advised to wait a minimum of two to four weeks after reviewing and considering the information in this brochure before deciding whether to have augmentation surgery.

Surgical Setting and Anesthesia

Augmentation surgery is usually performed on an outpatient basis, either in a hospital operating room (theater) or surgery center. General anesthesia is commonly used, although local anesthesia is also an option. The surgery usually lasts one to two hours. Your surgeon will make an incision and create a pocket for the breast implant. Then, the breast implant will be placed in the pocket and positioned. Finally, the incision will be closed, usually with stitches, and possibly taped.

Postoperative Care

You will probably feel somewhat tired and sore for several days following the operation, and your breasts may remain swollen and sensitive to physical contact for a month or longer. You may also experience a feeling of tightness in the breast area as your skin adjusts to the new breast size.

Postoperative care may involve the use of a postoperative bra, compression bandage, or sports bra for extra support and positioning while you heal. At your surgeon's recommendation, you will most likely be able to return to work within a few days, although any strenuous activities that could raise your pulse and blood pressure should be avoided for at least a couple of weeks. Your surgeon may also recommend breast massage exercises.

Note: If you experience fever or noticeable swelling and/or redness in your implanted breast(s), you should contact your surgeon immediately.

What Questions Should You Ask Your Surgeon About Breast Augmentation?

The following list of questions may help to remind you of topics to discuss with your doctor.

1. What are the risks and complications associated with having breast implants?
2. How many additional operations in my implanted breast(s) can I expect over my lifetime?
3. How will my breasts look if I opt to have the implants removed without replacement?
4. What shape, size, surface texturing, incision site, and placement site is recommended for me?
5. How will my ability to breast-feed be affected?
6. How can I expect my implanted breasts to look over time?
7. How can I expect my implanted breasts to look after pregnancy? After breast-feeding?
8. What are my options if I am dissatisfied with the cosmetic outcome of my implanted breasts?
9. What alternate procedures or products are available if I choose not to have breast implants?
10. Do you have before and after photos I can look at for each procedure, and what results are reasonable for me?

4. SPECIAL CONSIDERATIONS FOR BREAST RECONSTRUCTION

What Are the Alternatives to Breast Reconstruction?

You may choose not to undergo breast reconstruction. In this case, you may or may not decide to wear an external breast form (prosthesis) inside your bra. Breast forms are available in a variety of shapes, sizes, and materials such as foam, cotton, and silicone. Custom prostheses are also available to match the size and shape of your breast.

Should You Have Breast Reconstruction?

Whether you decide to have breast reconstruction depends on your own individual case, medical condition, general health, lifestyle, emotional state, and breast size and shape. You may consider consulting your family, friends, breast implant support groups, breast cancer support groups and counselor(s) to help you in making this decision. You are advised to wait a minimum of two to four weeks after reviewing and considering the information in this brochure before deciding whether to have reconstruction surgery.

If you are considering breast reconstruction and do not have a plastic surgeon, ask your general surgeon for a referral for the names of experienced plastic surgeons in your area. Your general surgeon, plastic surgeon, and oncologist should work together to plan your mastectomy and reconstruction procedure to give you the best possible results.

What Are the Choices in Reconstructive Procedures?

The type of breast reconstruction procedure available to you depends on your medical situation, breast shape and size, general health, lifestyle, and goals. Women with small- or medium-sized breasts are the best candidates for breast reconstruction.

Breast reconstruction can be accomplished by the use of a prosthesis (a breast implant, either silicone gel-filled, saline-filled or a combination gel/saline-filled), your own tissues (a tissue flap), or a combination of the two. A tissue flap is a section of skin, fat and/or muscle which is moved from your stomach, back or other area of your body, to the chest area, and shaped into a new breast.

Whether or not you have reconstruction with or without breast implants, you will probably undergo additional surgeries to improve symmetry and appearance. For example, because the nipple is often removed with the breast tissue in mastectomy, the nipple is often reconstructed by using a skin graft from the opposite breast or by tattooing the area. Nipple reconstruction is usually done as a separate outpatient procedure after the initial reconstruction surgery is complete.

Breast Reconstruction With Breast Implants

Your surgeon will decide whether your health and medical condition makes you an appropriate candidate for breast implant reconstruction. Women with larger breasts may require reconstruction with a combination of a tissue flap and an implant. Your surgeon may recommend breast implantation of the opposite, unaffected breast in order to make your breasts more alike (maximize symmetry) or he/she may suggest breast reduction (reduction mammoplasty) or a breast lift (mastopexy) to improve symmetry. Reduction mammoplasty involves removal of breast tissue and skin. Mastopexy involves removing a strip of skin from under the breast or around the nipple and using it to lift and tighten the skin over the breast. If it is important to you not to alter the unaffected breast, you should discuss this with your surgeon, as it may affect the breast reconstruction methods considered for your case.

The Timing of Your Breast Implant Reconstruction

The following description applies to reconstruction following mastectomy but similar considerations apply to reconstruction following breast trauma or for reconstruction for congenital defects. The breast reconstruction process may begin at the time of your mastectomy (immediate reconstruction) or weeks to years afterwards (delayed reconstruction). Immediate reconstruction may involve placement of a breast implant, but typically involves placement of a tissue expander, which is eventually replaced with a breast implant or immediate reconstruction may involve placement of an expander/breast implant (BECKER™ Expander/Implant). A BECKER™ Expander/Implant serves as both a tissue expander and a breast implant. It is expanded over time by adding saline through a filling port located beneath the skin. Once the BECKER™ Expander/Implant has expanded to the desired fullness, the filling port is removed. It is important to know that any type of surgical breast reconstruction may take several steps to complete. Two potential advantages to immediate reconstruction are that your breast reconstruction starts at the time of your mastectomy and that there may be cost savings in combining the mastectomy procedure with the first stage of the reconstruction. However, there may be a higher risk of complications such as rupture with immediate reconstruction, and your initial operative time and recuperative time may be longer.

A potential advantage to delayed reconstruction is that you can delay your reconstruction decision and surgery until other treatments, such as radiation therapy and chemotherapy, are completed. Delayed reconstruction may be advisable if your surgeon anticipates healing problems with your mastectomy, or if you just need more time to consider your options.

There are medical, financial and emotional considerations to choosing immediate versus delayed reconstruction. You should discuss with your surgeon, plastic surgeon, and/or oncologist, the pros and cons of the options available in your individual case.

Surgical Considerations to Discuss With Your Doctor

Discuss the advantages and disadvantages of the following options with your surgeon and/or your oncologist.

- **Immediate Reconstruction**
One-stage immediate reconstruction with a breast implant (breast implant only) or with an expander/breast implant (BECKER™ Expander/Implant).
Two-stage immediate reconstruction with a temporary tissue expander followed by delayed reconstruction several months later with a breast implant.
- **Delayed Reconstruction**
One-stage delayed reconstruction using an expander/breast implant (BECKER™ Expander/Implant).
Two-stage delayed reconstruction with a temporary tissue expander followed several months later by replacement with a breast implant.

What Is the Breast Implant Reconstruction Procedure?

One-Stage (Immediate or Delayed) Breast Implant Reconstruction

Immediate one-stage breast reconstruction may be done at the time of your mastectomy. After the general surgeon removes your breast tissue, the plastic surgeon will then implant a breast implant or an expander/breast implant (BECKER™ Expander/Implant) that completes the one-stage reconstruction. If a BECKER™ Expander/Implant is used, saline is gradually added over time (up to six months) until the expansion is completed at which time the filling port is removed. The filling port removal is usually done using local anaesthesia at the outpatient or day unit section of the hospital. One-stage delayed breast reconstruction is done several months or years later by placement of a breast implant or a BECKER™ Expander/Implant.

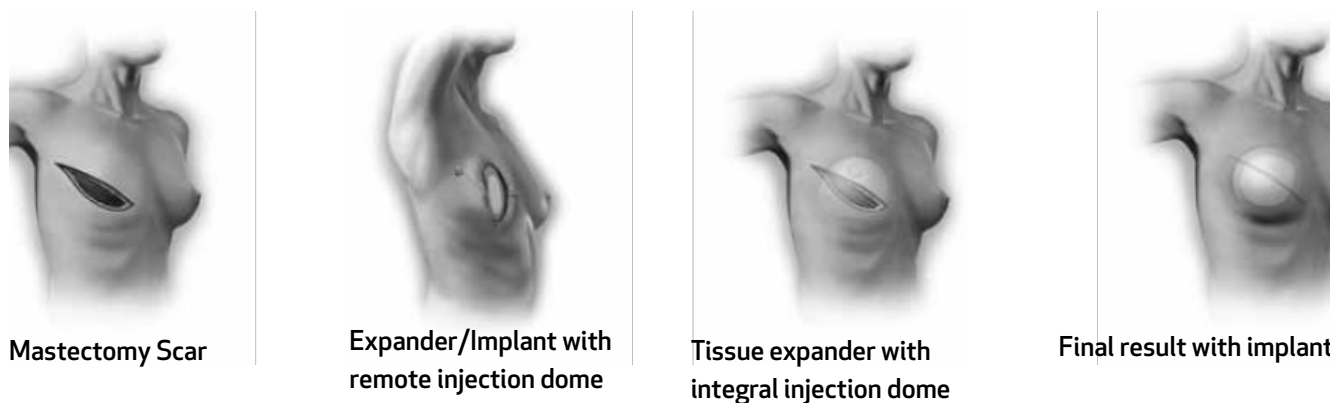
Two-Stage (Immediate or Delayed) Breast Implant Reconstruction

Breast reconstruction with a MENTOR® Gel-Filled Breast Implant usually occurs as a two-stage procedure, starting with the placement of a temporary breast tissue expander, which is replaced several months later with a breast implant.

The tissue expander placement may be done immediately, at the time of your mastectomy, or be delayed until months or years later.

The tissue expander may have a filling port or an injection dome that is integral (attached) to the expander shell or an injection dome that is remote (attached to the expander by a fill tube). If an expander with a remote dome is used, the dome is situated under the arm or axilla.

Stage 1: Tissue Expansion



During a mastectomy, the general surgeon often removes skin as well as breast tissue, leaving the chest tissues flat and tight. To create a breast-shaped space for the breast implant, a tissue expander is placed under the remaining chest tissues.

The tissue expander is a balloon-like device made from elastic silicone rubber. It is inserted unfilled, and over time, sterile saline fluid is added by inserting a small needle through the skin to the filling port of the device. As the tissue expander fills, the tissues over the expander begin to stretch, similar to the gradual expansion of a woman's abdomen during pregnancy. The tissue expander creates a new breast-shaped pocket for a breast implant.

Tissue expander placement usually occurs under general anaesthesia in an operating room (theatre). Operative time is generally one to two hours. The procedure may require a brief hospital stay, or be done on an outpatient basis. Typically, you can resume normal daily activity after two to three weeks.

Because the chest skin is usually numb from the mastectomy surgery, it is possible that you may not experience pain from the placement of the tissue expander. However, you may experience feelings of pressure or discomfort after each filling of the expander, which subsides as the tissue expands. Tissue expansion typically lasts four to six months.

Stage 2: Placing the Breast Implant

After the tissue expander is removed, the breast implant is placed in the pocket. The surgery to replace the tissue expander with a breast implant (implant exchange) is usually done under general anaesthesia in an operating room (theatre). It may require a brief hospital stay or be done on an outpatient basis.

Breast Reconstruction Without Implants: Tissue Flap Procedures

The breast can be reconstructed by surgically moving a section of skin, fat and muscle from one area of your body to another. The section of tissue may be taken from such areas as your abdomen, upper back, upper hip, or buttocks.

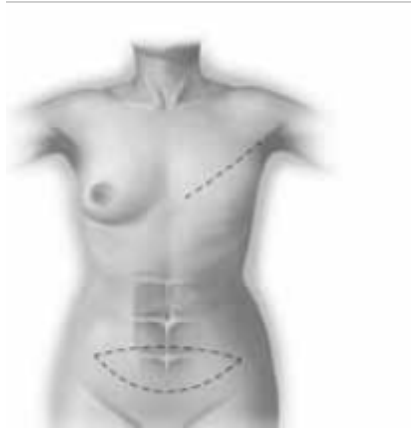
The tissue flap may be left attached to the blood supply and moved to the breast area through a tunnel under the skin (a pedicled flap), or it may be removed completely and reattached to the breast area by microsurgical techniques (a free flap). Operating time is generally longer with free flaps, because of the microsurgical requirements.

Flap surgery requires a hospital stay of several days and generally a longer recovery time than implant reconstruction. Flap surgery also creates scars at the site where the flap was taken and possibly on the reconstructed breast. However, flap surgery has the advantage of being able to replace tissue in the chest area. This may be useful when the chest tissues have been damaged and are not suitable for tissue expansion. Another advantage of flap procedures over implantation is that alteration of the unaffected breast is generally not needed to improve symmetry.

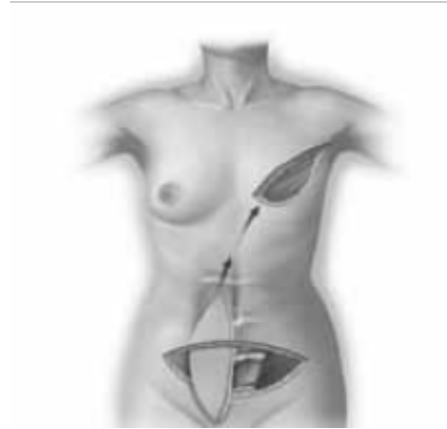
The most common types of tissue flaps are the TRAM (Transverse Rectus Abdominus Musculocutaneous flap) (which uses tissue from the abdomen) and the Latissimus Dorsi flap (which uses tissue from the upper back).

It is important for you to be aware that flap surgery, particularly the TRAM flap, is a major operation, and is more extensive than your mastectomy operation. It requires good general health and strong emotional motivation. If you are very overweight, smoke cigarettes, have had previous surgery at the flap site, or have any circulatory problems, you may not be a good candidate for a TRAM flap procedure. Also, if you are very thin, you may not have enough tissue in your abdomen or back to create a breast mound with this method.

The TRAM Flap (Pedicle or Free)



Step 1: Mastectomy is performed and the donor site is marked



Step 2: The flap of rectus muscle and tissue is tunneled to the breast



Step 3: Final Result

During a TRAM flap procedure, the surgeon removes a section of tissue from your abdomen and moves it to your chest to reconstruct the breast. The TRAM flap is sometimes referred to as a “tummy tuck” reconstruction, because it may leave the stomach area flatter.

A pedicle TRAM flap procedure typically takes three to six hours of surgery under general anaesthesia; a free TRAM flap procedure generally takes longer. The TRAM procedure may require a blood transfusion. Typically, the hospital stay is two to five days. You can resume normal daily activity after six to eight weeks. Some women, however, report that it takes up to one year to resume a normal lifestyle. You may have temporary or permanent muscle weakness in the abdominal area. If you are considering pregnancy after your reconstruction, you should discuss this with your surgeon. You will have a large scar on your abdomen and may also have additional scars on your reconstructed breast.

The Latissimus Dorsi Flap With or Without Breast Implants



A skin flap and muscle are taken from donor site in the back.



The tissue is tunneled to the mastectomy and used to create a breast mound.



An implant can also be used to create the breast mound.

During a Latissimus Dorsi flap procedure, the surgeon moves a section of tissue from your back to your chest to reconstruct the breast. Because the Latissimus Dorsi flap is usually thinner and smaller than the TRAM flap, this procedure may be more appropriate for reconstructing a smaller breast.

The Latissimus Dorsi flap procedure typically takes two to four hours of surgery under general anaesthesia. Typically, the hospital stay is two to three days. You can resume daily activity after two to three weeks. You may have some temporary or permanent muscle weakness and difficulty with movement in your back and shoulder. You will have a scar on your back, which can usually be hidden in the bra line. You may also have additional scars on your reconstructed breast.

What Questions Should You Ask Your Surgeon About Breast Reconstruction?

The following list of questions may help to remind you of topics to discuss with your doctor.

1. What are all my options for breast reconstruction?
2. What are the risks and complications of each type of breast reconstruction surgery and how common are they?
3. What if my cancer recurs or occurs in the other breast?
4. Will reconstruction interfere with my cancer treatment?
5. How many steps are there in each procedure, and what are they?
6. How long will it take to complete my reconstruction?
7. How much experience do you have with each procedure?
8. Do you have before and after photos I can look at for each procedure, and what results are reasonable for me?
9. What will my scars look like?
10. What kind of changes in my implanted breast can I expect over time?
11. What kind of changes in my implanted breast can I expect with pregnancy?
12. What are my options if I am dissatisfied with the cosmetic outcome of my implanted breast?
13. Can I talk with other patients about their experiences?
14. For staged reconstruction, what is the estimated total cost of each procedure?
15. How much pain or discomfort will I feel, and for how long?
16. How long will I be in the hospital?
17. Will I need blood transfusions, and can I donate my own blood?
18. When will I be able to resume my normal activity (or sexual activity, or athletic activity)?

5. WHAT ARE CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS TO BE CONSIDERED?

A contraindication is a condition or circumstance that, if present, means a procedure should not be done. MENTOR® Breast Implants are contraindicated in the following circumstances because the risk of undergoing breast augmentation or reconstruction with implants outweighs the benefits:

- Women with active infection anywhere in their bodies,
- Women with existing cancer or precancer of their breast who have not received adequate treatment for those conditions, and in
- Women who are pregnant or nursing.

Surgical practices that are contraindicated in breast implantation:

- Injection through implant shell.
- Stacking of implants: more than one implant per breast.

Safety has not been established in patients with the following conditions:

- Autoimmune diseases such as lupus and scleroderma.
- Conditions that interfere with wound healing and blood clotting.
- A weakened immune system (e.g., currently receiving immunosuppressive therapy).
- Reduced blood supply to breast tissue.

Further considerations

Pre-implantation Mammography

You may wish to undergo a preoperative mammogram and another one 6 months to one year after implantation to establish a baseline.

Interference With Mammography

The implant may interfere with finding breast cancer during mammography and also may make it difficult to perform mammography. Therefore, it is essential that you tell your mammography technologist that you have an implant before the procedure. The technologist can use special techniques to minimize the possibility of rupture and to get the best possible views of the breast tissue. Because the breast is squeezed during mammography, it is possible for an implant to rupture during the procedure. More x-ray views are necessary with these special techniques; therefore, women with breast implants will receive more radiation. However, the benefit of the mammogram in finding cancer outweighs the risk of the additional x-rays.

Distinguishing the implant from breast tissue during breast self-examination

You should perform breast self-examination monthly on your implanted breast. In order to do this effectively, you should ask your surgeon to help you distinguish the implant from your breast tissue. Any new lumps or suspicious lesions (sores) should be evaluated with a biopsy. If a biopsy is performed, care must be taken to avoid puncturing the implant. The presence of breast implants may improve the detection of tumors by selfexam (palpation).

Long-Term Effects

The long-term safety and effectiveness of breast implants are currently being studied; however, Mentor is monitoring the long-term (i.e., 10 years) risk of implant rupture, reoperation, implant removal, and capsular contracture (hardening of the tissues around the implant). As new data becomes available, Mentor will include this information in the product inserts, which are packaged with the products and sent to the doctors. You should contact your doctor about updated information.

Capsule Procedures

You should be aware that closed capsulotomy, the practice of forcible squeezing or pressing on the fibrous capsule around the implant to break the scar capsule, is not recommended as this may result in rupture or breakage of the implant.

Radiation Therapy

You should be aware that testing has not been done to show the effects of radiation therapy on tissues of patients who have breast implants; however, the literature suggests that radiation therapy may increase the likelihood of experiencing capsular contracture. The decision regarding the use of radiation therapy following breast implantation should be made by your surgeon and radiation oncologist.

MRI

The MRI scan has been determined to be the best way to find out if your implant has ruptured without performing surgery. If you undergo an MRI scan, you will have to lie on your stomach with your breast in a special holder. You will then be placed in the machine, which may be open or may be like going into a tunnel. Some patients experience an uneasiness at being in a closed space. While the machine is taking images of your breast, it will make a noise. In order to have an MRI scan, you should not have had metal devices implanted in your body, or a history of claustrophobia.

6. WHAT ARE THE BREAST IMPLANT COMPLICATIONS?

Undergoing any surgical procedure may involve the risk of complications such as the effects of anaesthesia, infection, swelling, redness, bleeding, and pain.

In addition, there are potential complications specific to breast implants. These complications include:

Deflation/Rupture

When the shell of a gel-filled breast implant breaks, the gel can leak from the implant. BECKER™ Expander/Implants deflate when saline solution leaks either through an unsealed or damaged valve, or through a break in the implant shells. This may be noticed by a change in shape of the implant or it might be unnoticed ("silent" rupture) and detected by mammogram or MRI. Deflation or rupture may occur in the first few months after being implanted or after several years. Causes of deflation or

rupture include damage by surgical instruments during surgery, overfilling or underfilling of the implant with saline solution, capsular contracture, closed capsulotomy, stresses such as trauma or intense physical manipulation, excessive compression during mammographic imaging, umbilical incision placement, and unknown/unexplained reasons. You should also be aware that the breast implant may wear out over time and deflate/rupture.

Deflated or ruptured implants necessitate additional surgery to remove and to possibly replace the implants.

Capsular Contracture

The scar tissue or capsule that normally forms around the implant may tighten and squeeze the implant and is called capsular contracture. Capsular contracture is more common following infection, hematoma, and seroma. Symptoms range from firmness and mild discomfort, to pain, distortion, palpability of the implant, and/or displacement of the implant.

Additional surgery is needed in cases where pain and/or firmness is severe. This surgery ranges from removal of the implant capsule tissue to removal and possibly replacement of the implant itself.

Capsular contracture may recur after these additional surgeries.

Pain

Pain of varying intensity and duration may occur and persist following breast implant surgery. In addition, improper size, placement, surgical technique, or capsular contracture may result in pain associated with nerve entrapment or interference with muscle motion. You should tell your doctor if you experience severe pain.

Additional Surgeries

Women should understand there is a chance they will need to have additional surgery(ies) at some point to replace or remove the implant. Also, problems such as deflation/rupture, capsular contracture, infection, shifting, and calcium deposits can require removal of the implants. Many women decide to have the implants replaced, but some women do not. Those who do not may have cosmetically unacceptable dimpling and/or puckering of the breast following removal of the implant without implant replacement.

Dissatisfaction With Cosmetic Results

Dissatisfying results such as wrinkling, asymmetry, implant displacement (shifting), incorrect size, unanticipated shape, implant palpability, scar deformity, hypertrophic (irregular, raised) scarring, and/or sloshing (with implants containing saline) may occur. Careful surgical planning and technique can minimize but not always prevent such results.

Infection

Infection can occur with any surgery. Most infections resulting from surgery appear within a few days to weeks after the operation. However, infection is possible at any time after surgery. Infections with an implant present are harder to treat than infections in normal body tissues. If an infection does not respond to antibiotics, the implant may have to be removed, and another implant may be placed after the infection is resolved.

In rare instances, Toxic Shock Syndrome has been noted in women after breast implant surgery, and it is a life-threatening condition. Symptoms include sudden fever, vomiting, diarrhea, fainting, dizziness, and/or sunburn-like rash. A doctor should be seen immediately for diagnosis and treatment.

Hematoma/Seroma

A hematoma is a collection of blood inside a body cavity, and a seroma is a collection of the watery portion of the blood (in this case, around the implant or around the incision). Postoperative hematoma and seroma may contribute to infection and/or capsular contracture. Swelling, pain, and bruising may result. If a hematoma occurs, it will usually be soon after surgery, however this can also occur at any time after injury to the breast. While the body absorbs small hematomas and seromas, large ones will require the placement of surgical drains for proper healing. A small scar can result from surgical draining. Implant deflation or rupture can occur from surgical draining if damage to the implant occurs during the draining procedure.

Changes in Nipple and Breast Sensation

Feeling in the nipple and breast can increase or decrease after implant surgery. The range of changes varies from intense sensitivity to no feeling in the nipple or breast following surgery. Changes in feeling can be temporary or permanent and may affect sexual response or the ability to breast-feed.

Breast-Feeding

At this time, it is not known if a small amount of silicone may diffuse (pass through) from the silicone gel-filled breast implant shell and may find its way into breast milk. If this occurs, it is not known what effect it may have on the breast-feeding infant. Although there are no current methods for detecting silicone levels in breast milk, a study measuring silicon (one component in silicone) levels did not indicate higher levels in breast milk from women with silicone-filled gel implants when compared to women without implants. The IOM report concluded that mothers with breast implants should attempt breast-feeding due to the benefits to their children. The periareolar incision site may significantly reduce the ability to successfully breast-feed by decreasing the amount of milk produced.

Calcium Deposits in the Tissue Around the Implants

Deposits of calcium can be seen on mammograms and can be mistaken for possible cancer, resulting in additional surgery to biopsy and/or removal of the implants to distinguish them from cancer.

Delayed Wound Healing

In some cases, the incision site fails to heal normally.

Extrusion

Unstable or compromised tissue covering and/or interruption of wound healing may result in extrusion, which is when the breast implant comes through the skin.

Necrosis

Necrosis is the formation of dead tissue around the implant. This may prevent wound healing and require surgical correction and/or implant removal. Permanent scar deformity may occur following necrosis. Factors associated with increased necrosis include infection, use of steroids in the surgical pocket, smoking, chemotherapy/radiation, and excessive heat or cold therapy.

Breast Tissue Atrophy/Chest Wall Deformity

The pressure of the breast implants may cause the breast tissue to thin and shrink. This can occur while implants are still in place or following implant removal without replacement.

In addition to these common complications, there have been concerns with certain diseases, of which you should be aware:

Connective Tissue Disease

Concern over the association of breast implants to the development of autoimmune or connective tissue diseases, such as lupus, scleroderma, or rheumatoid arthritis, was raised because of cases reported in the literature in small numbers of women with implants. A review of several large epidemiological studies of women with and without implants indicates that these diseases are no more common in women with implants than in women without implants. However, some women with breast implants believe that their implants caused a connective tissue disease.

Cancer

Published studies indicate that breast cancer is no more common in women with implants than in those without implants.

Anaplastic Large Cell Lymphoma

Women with breast implants may have a very small, but increased risk of developing anaplastic large cell lymphoma, or ALCL, in the scar tissue and fluid adjacent to the implant. ALCL is not breast cancer—it is a rare type of non-Hodgkin's lymphoma (cancer of the immune system).

ALCL has been reported globally in patients with an implant history that includes Mentor's and other manufacturer's breast implants.

Most patients were diagnosed when they sought medical treatment for implant-related symptoms such as pain, lumps, swelling, or asymmetry that developed after their initial surgical sites were fully healed. In the cases reported, ALCL was typically diagnosed years after the implant surgery.

Your physician should consider the possibility of ALCL if, after your surgical site is fully healed, you see changes in the way the area around the implant looks or feels—including swelling or pain around the implant. If ALCL is suspected, your physician will refer you to an appropriate specialist for evaluation which may involve obtaining fluid and tissue samples from around your breast implant. If ALCL is confirmed, your physician will develop an individualized treatment plan for you. Because of the small number of cases worldwide and variety of available treatment options, there is no single defined treatment.

If you have breast implants and have no symptoms, you do not need to do anything additional, but you should continue to routinely monitor your breast implants and follow your routine medical care. Removing the implants is not recommended in women with no symptoms without a diagnosis of ALCL.

If you do not currently have breast implants but are considering breast implant surgery, you should discuss the risks and benefits with your healthcare provider. You may also visit the FDA's Breast Implants website for additional information.

For additional and the most up-to-date information, please visit:

www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239995.htm.

Second Generation Effects

There have been concerns raised regarding potential damaging effects on children born of mothers with implants. The IOM report concluded that there are no second generation effects on children of women with breast implants.

Gel Bleed and Granulomas

The gel in an implant consists of large three-dimensional mesh-like molecules that constitute about 20% of the total weight of the gel. The spaces within these molecules are filled with a mix of medical grade silicone oils. These oils are similar to the materials available in many products including anti-gas medication, available without prescription for infants and adults. A small amount of these oils can bleed through the shell of the implant. The major portion of this oil stays on the implant wall. A smaller amount moves into the scar capsule where it is gradually picked up by certain body cells, called macrophages, the probable mechanism by which it is transported into regional lymph nodes.

It is possible for a granuloma to form around a tiny amount of silicone. Although these lumps are noncancerous, they can be difficult to distinguish from cancerous lumps without being removed (biopsied) and examined.

7. IF YOU EXPERIENCE A PROBLEM, SHOULD YOU CONTACT YOUR DOCTOR?

Consult a physician if you suspect any complications with your breast implant(s), in particular in the case of trauma or compression caused, for example, by extreme massaging of the breast region, by some sport activities or by using seat belts.

8. ADDITIONAL RECOMMENDATIONS FOR PATIENTS

The following are additional recommendations for patients with breast implants:

- Patients should return to their surgeon for necessary postoperative visits.
- Consult a physician or pharmacist before the use of topical medicines such as steroids in the breast area.
- Continue to consult a physician for routine examinations to detect for breast cancer.
- Inform a physician or surgeon of the presence of an implant if any surgery of the breast area is scheduled.
- Keep the Patient ID Card provided by your surgeon (with the style and lot number of your breast implant[s]) permanently and carry it with you to facilitate medical care in case of emergency (e.g., in case of a road accident).

9. PROBLEM REPORTING FOR AUSTRALIAN PATIENTS

For Australian patients, if you experience difficulties with your implant(s), you are encouraged to report those difficulties to the Therapeutic Goods Administration (TGA) via the Device Incident Reporting Scheme. For information contact: Reply Paid 32, Medical Device Incident Report Investigation Scheme, P.O. Box 100, Woden ACT 2606, phone 1800 809 361, email: iris@health.gov.au.

10. STATUS/LEGAL POSITION OF BREAST IMPLANTS FOR EUROPEAN PATIENTS

All breast implants sold within the European Community are governed under the Medical Device Directive (93/42/EEC) and are Class III devices according to the Commission Directive 2003/12/EC of 3 February 2003.

11. INFORMATION SOURCES ABOUT BREAST IMPLANTS

General Resources About Breast Implants

Upon request, you will be provided with a copy of the Directions for Use (package insert). You can request a copy from your surgeon or from Mentor.

Mentor Worldwide LLC

(+1-805-879-6000)

www.mentorwwllc.com

Institute of Medicine Report on the Safety of Silicone Implants

www.nap.edu/catalog/9618.html

Independent Review Group Report on Silicone Breast Implant

www.silicone-review.gov.uk

National Science Panel Report on Silicone Breast Implants

www.fjc.gov/BREIMLIT/SCIENCE/summary.htm

US Food and Drug Administration

(+1-301-827-3990)

www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/default.htm

Breast Reconstruction Resources

The following list of resources may help you to find more information and support for your breast reconstruction decision.

US Websites

National Cancer Institute

www.cancernet.nci.nih.gov

American Cancer Society

www.cancer.org

BreastCancer Net

www.breastcancer.net

Australian Websites

Australian Cancer Society

www.cancer.org.au/

BreastScreen Australia

www.breastscreen.org.au/

Plastic Surgery Australia

www.plasticsurgery.com.au/

European Websites

British Association of Plastic Surgeons

www.baps.co.uk

Cancerworld

www.cancerworld.org/Home.html

The Netherlands Cancer Institute

www.nki.nl

The Dutch Federation for the Cancer Patient

www.kankerpatient.nl

The Wave (Breast Reconstruction Information)

www.ping.be/the-wave/fr/indexfr.htm

Breast Cancer Information

www.murgo.yucom.be/index.htm

Breast Cancer Information

www.brustkrebs.de/

German National Cancer Institute

www.dkfz-heidelberg.de/Patienteninfo/pdq-text/breast.htm

Breast Cancer Information

www.senologia.net

Spanish Association Against Cancer

www.aecc.es

Spanish Society of Reconstructive and Aesthetic Plastic Surgery

www.cirugia-plastica.org

12. GLOSSARY

ALCL – An aplastic Large Cell Lymphoma – a rare type of non-Hodgkin’s lymphoma (cancer of the immune system).

Areola – The pigmented or darker colored area of skin surrounding the nipple of the breast.

Asymmetry – Lack of proportion of shape, size and position between the two breasts.

Autoimmune disease – A disease in which the body mounts an “attack” response to its own tissues or cell types. Normally, the body’s immune mechanism is able to distinguish clearly between what is a normal substance and what is foreign. In autoimmune diseases, this system becomes defective and produces antibodies against normal parts of the body, causing tissue injury. Certain diseases such as rheumatoid arthritis and scleroderma are considered to be autoimmune diseases.

Axillary – Pertaining to the armpit area.

Bilateral – Relating to, or affecting, the right and left breast.

Biopsy – The removal and examination of tissue, cells or fluid from the body.

Breast augmentation – A surgical procedure that increases the size and proportions of a woman’s breast.

Breast reconstruction – A surgical procedure that restores the natural breast contour and mass following mastectomy, trauma, or injury.

Capsular contracture – A tightening of the scar tissue surrounding an implant, resulting in firmness or hardening of the breast.

Capsulectomy – Surgical removal of the capsule (scar tissue).

Capsulotomy (closed) – A breakage in the capsule (scar tissue) by massage or compression on the outside of the breast.

Capsulotomy (open) – Incision or opening in the capsule (scar tissue) made by an open surgical approach.

Carcinoma – A malignant (cancerous) tumor.

Congenital anomaly – A deviation from a normal body part, existing at or dating from birth.

Connective tissue disease – A disease or group of diseases affecting connective tissue. The cause of these diseases is unknown. The diseases are grouped together on the basis of clinical signs, symptoms, and laboratory abnormalities.

Deflation/rupture – Leakage of saline solution from the implant, often due to a valve leak or a tear or cut in the implant shell, with partial or complete collapse of the implant.

Delayed reconstruction – Breast reconstruction that takes place weeks, months, or years after a mastectomy.

Displacement – Movement from the usual or proper place.

Epidemiological – Relating to the incidence, distribution and control of disease in a population.

Extrusion – The pressing out of the implant through the surgical wound.

Fibrous tissues – Connective tissues composed mostly of fibers.

Flap – A portion of tissue (which may include muscle, fat and skin) with its blood supply moved from one part of the body to another.

Hematoma – A mass or swelling containing blood.

Immune response – A bodily response to the presence of a foreign substance.

Inframammary – Below the breast.

Inframammary fold/incision – An incision made in the fold below the breast.

Inpatient surgery – A surgical procedure in which the patient is required to stay overnight in the hospital.

Latissimus dorsi – Two triangular muscles running from the spinal column to the shoulder.

Mammoplasty – Plastic surgery of the breast.

Mammary – Pertaining to the breast.

Mammography – X-ray examination of the breasts (as for early detection of cancer).

Mastectomy – The removal of breast tissue due to the presence of a cancerous or precancerous growth.

Mastopexy – Plastic surgery to move sagging breasts into a more elevated position.

Modified radical mastectomy – Surgical removal of the entire breast including the nipple, areola, and overlying skin, as well as the lymphatic-bearing tissue in the axilla.

Necrosis – Death of living tissue.

Oncologist – A doctor specializing in the study of tumors.

Outpatient surgery – A surgical procedure in which the patient is not required to stay in the hospital overnight.

Palpability – Capability of being touched or felt.

Palpate/palpability – To feel with the hand.

Pectoralis – Major muscle of the chest.

Plastic surgery – Surgery intended to repair, restore, or improve the body following trauma, injury, or illness.

Prosthesis – Any artificial device used to replace or represent a body part.

Ptois – Breast sagging that is usually the result of normal ageing, pregnancy, or weight loss.

Radical mastectomy – Surgical removal of the entire breast including the nipple, areola, and overlying skin, as well as the pectoral muscles, lymphatic-bearing tissue in the axilla, and various other neighboring tissue.

Rectus abdominus – A long, flat muscle extending the whole length of the front of the abdomen (stomach).

Saline – A solution that is made up of water and a small amount of salt. Approximately 70% of an adult's body weight consists of this saltwater solution.

Seroma – Accumulation of fluid in tissue.

Serratus – Muscle located beneath the chest's pectoralis major and minor muscles and the rib cage.

Silicone elastomer – A type of silicone that has elastic properties similar to rubber.

Subcutaneous mastectomy – Surgical removal of the breast tissues, but sparing the skin, nipple, and areola.

Subglandular placement – Placement underneath the mammary gland and on top of the chest muscle.

Submuscular placement – Placement wholly or partially underneath the pectoralis major (chest) muscle.

Surgical incision – A cut or wound of body tissue made during surgery.

Tissue expander – An adjustable implant that can be inflated with saltwater to stretch the tissue at the mastectomy site to create a new tissue flap for implantation of the breast implant.

Total mastectomy – Surgical removal of the breast including the nipple, areola, and most of the overlying skin.

Transaxillary incision – An incision made across the long axis of the armpit.

Umbilical – Relating to the navel.

Unilateral – Affecting only one side.



**SILTEX™ AND SMOOTH GEL BREAST IMPLANTS,
SILTEX™ BECKER™ EXPANDER/BREAST IMPLANTS AND
SPECTRA™ ADJUSTABLE GEL BREAST IMPLANTS**



PATIENT SIGNATURE FORM

It is the responsibility of the individual surgeon to decide the best method by which to counsel a patient prior to surgery.

Mentor relies upon the surgeon to advise the patient of all potential complications and risks associated with the use of breast implants.

The surgical procedures associated with the use of gel breast implants are not without potential complications and risks. The use of this product is an elective procedure. I (the patient) have been counselled prior to surgery regarding the benefits and possible risks associated with tissue reconstruction and/or breast augmentation using breast prostheses and alternative procedures. I (the patient) have been advised by my doctor that breast implants should not be considered lifetime implants.

I was provided with the brochure, "Gel-Filled Breast Implant Surgery: Making an Informed Decision" in advance prior to surgery (except in cases of emergency surgery for cancer or other reasons).

I have read this brochure. Yes No

The information from the brochure was discussed with me by my surgeon and understood by me. All my questions have been answered to my satisfaction and I have been provided a copy of this form.

Patient's Signature

Date

Patient's Printed Name

Physician's Signature

Date

Physician's Printed Name

(Note to Physician: A copy of the signed form is to be kept in the patient's file.)



Manufacturer

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The Netherlands

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