



You decide

The choice is yours

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Introduction

This brochure presents an overview of breast implants and breast enhancement procedures. It is not intended to make any representations or warranties about the outcome of any procedure and is not a substitute for a thorough, in-person consultation with your surgeon. The consultation should inform you about all aspects of surgical procedures using breast implants. It should include a discussion of your goals, an evaluation of your individual case, the options available and the likely outcomes, risks and potential complications.

Each woman has a personal sense of how she wishes to look. Breast implant surgery may be of psychological benefit when it cosmetically improves appearance, corrects a loss in breast size, or rebuilds a breast shape after surgery, aging or illness.

Breast augmentation enlarges a woman's breasts through the surgical placement of breast implants. In general, it is a cosmetic procedure performed to fulfill a woman's personal desire for fuller breasts or to restore breast volume lost after weight reduction or pregnancy. Breast implants may also be used for reconstruction to restore a breast after mastectomy, injury or other reason.

Women choose breast implants for a variety of reasons. Some feel dissatisfied because their breasts never developed to a size that meets their expectations. Others want to bring balance to a breast that is smaller than the other. Often, women want the procedure to restore their natural breast volume, which may have decreased as a result of pregnancy, weight loss or aging.

Women who have undergone mastectomy say that breast reconstruction with implants has helped their recovery by restoring a more natural appearance and a sense of wholeness. Whether it is performed immediately following mastectomy or at a later time, breast reconstruction can dramatically improve a woman's appearance, self-confidence and overall quality of life.

The decision to have breast implants is a very personal one. Each woman must decide if implants will achieve her goals and if the risks and potential complications are acceptable. Every surgical procedure has potential complications, which can include infection, bleeding and scarring. Additionally, there are some potential complications that are specific to breast implants. It is important to understand these potential problems and put them in perspective before making the decision to have surgery using breast implants.

This document is designed to provide information about the risks and benefits of surgery using breast implants. For those who decide that implants are the right choice, we have included information about selecting a specific size or type of implant.



What are breast implants?

Today there are two types of breast implants available: silicone gel-filled or saline-filled. There are advantages and disadvantages to both types and your surgeon will be able to explain what is the best choice for you.

Silicone gel-filled implants consist of an outer shell constructed from several layers of elastic silicone material. These are filled with silicone gel, which is a clear and cohesive material. Silicone is widely used in implantable medical devices. Saline-filled implants consist of a silicone elastomer shell which has an integrated valve. These are filled with a sterile saline solution during surgery.

Surface of the implant

The surface of a breast implant may be smooth or textured (rough surface). There is some evidence that textured implants have a lower incidence of tight scar formation (capsular contraction) around them. However, because a textured implant adheres to the surrounding tissue, it may cause visible rippling (wrinkling) in the skin. This can occur if there is not adequate implant coverage of soft tissue over the implant. Consult your surgeon, who will be able to explain this in more detail.

Position

Implants may be placed either beneath the breast tissue or on top of the pectoralis muscle (subglandular) or partially beneath the pectoralis major muscle (submuscular). There are advantages and disadvantages of each placement. Generally, placement of an implant beneath the muscle gives an extra layer of muscle coverage and may be the choice for patients with minimum breast tissue. Placement of the implant on top of the muscle in a patient with adequate breast tissue to cover the implant can be carried out under local anaesthesia, if desired. Generally, this placement has less postoperative discomfort and a quicker return to activities.

Incisions

Breast implants can be inserted through an incision in the infra-mammary fold (crease under the breast). Depending on the implant size this incision may vary from 3-6 cm in length. An implant may also be inserted through an incision around the nipple (a peri-areolar incision). This incision is hidden to some extent by the color change at the edge of the areola. The incision in the infra-mammary fold is often hidden by the slight droop of the breast and is not seen unless an observer is looking up under the breast. Implants can also be inserted through an incision in the armpit (axilla).



Selecting an implant and type of surgery

Breast size and shape should be an important focus of discussion with your surgeon. You will also want to discuss whether to use round or anatomical shaped implants and review the many choices of size and weight available. Many women believe they will be too large after surgery and therefore direct their surgeon to choose a smaller size than they really desire. However, you will likely become more comfortable with your new breast shape after surgery. Some women have wished they had opted for a larger size. On the other hand, some women desire a larger implant than fits their body proportions. These are all good topics for discussion with your surgeon, who can advise you on your specific concerns and the likely aesthetic improvement attainable.

It may be difficult to visualize your ultimate breast size and shape before surgery. Breast implant manufacturers have improved the shape of implants so it is worthwhile to not only consider size but also the width of your chest and desired projection.

A wider implant may provide more cleavage, but less fullness of the breast. A higher profile implant will provide more projection and fullness but have less width and cleavage. Once you determine the shape and overall size that you are seeking, talk with your surgeon about which implants will get you as close to your desired shape as possible.

Your body's size and characteristics, along with your desire for a specific shape and size, will usually dictate what is possible. You should be aware that after implant surgery one woman's breasts will be different than another's even though the same implant size and shape were used. Also be aware that each woman's body is different, and before and after photos of women who have had breast implant surgery, often shown in the media, are not likely to apply to you.

Risks related to breast implants

Silicone Bleed and Implant Rupture

Some silicone gel may diffuse or "bleed" through the shell of an intact implant into the scar tissue or capsule that surrounds the implant. Implant shell and silicone gel improvements have reduced this bleeding to a minimum. Breast implants may rupture over time and need to be removed or replaced. Rupture may also be related to force or trauma, such as a blow to the chest in an auto accident. If an implant ruptures, the silicone gel may be contained within the scar capsule that has formed around the implant. Removal or replacement of the implant is necessary.

In case of a shell rupture with a saline filled implant the implant deflates, loses volume which results in a breast asymmetry and the saline solution is absorbed by the body. The asymmetry can surgically be corrected by an implant replacement.

Capsular Contracture - What is it and what causes it?

In the simplest terms, capsular contracture is breast firmness. As your body heals after the placement of breast implants, it forms a capsule of scar tissue around the implant. Over time, the scar capsule may contract or tighten excessively, causing a change in breast shape and/or discomfort. The appearance of the breast may appear artificially round and/or feel unnaturally firm to the touch. There are four grades of capsular contracture, using the Baker Grades I – IV scale. The Baker grading is as follows:

Grade I the breast is normally soft and looks natural

Grade II the breast is a little firm but looks normal

Grade III the breast feels firmer than normal and looks somewhat abnormal (change in shape)

Grade IV the breast is hard, may be painful and clearly looks abnormal (greater distortion)

Capsular contracture may occur on one side, both sides or not at all. The degree or severity of tightening may also be different on one side compared to the other. Although both breasts never match exactly, if any of these deformities occur, differences in the two breasts may be more noticeable and may not be correctable.

Can capsular contracture be corrected?

In severe cases (Baker Grade IV), the disfigurement or discomfort resulting from capsular contracture will require surgery to remove the scar tissue around the implant and/or implant replacement. Capsular contracture may recur after surgical procedures to correct this condition.

How often does capsular contracture occur?

Excessive firmness of the breasts can occur soon after surgery or years later. The occurrence of bothersome capsular contracture is not predictable, some believe the chance of it happening increases with time. Medical literature describes capsular contracture rates of less than 5% up to 40%, however, breast implant innovations have reduced the occurrence of this complication significantly.

Visible Skin Wrinkling and Rippling

Visible rippling can result when an implant pulls on the overlying tissues or when the natural folds in the implant are visible through the skin. Additional surgery may be necessary to correct this situation.

Calcification

Calcium deposits can form in the scar tissue surrounding the implant and may cause pain and firmness. The calcifications may interfere with mammography. These deposits must be differentiated from calcium deposits that are a sign of breast cancer. Should this occur, additional surgery may be necessary to remove and examine calcifications which may cause damage to the implant.

Implant Extrusion

If the skin or breast tissue covering the implant is very thin and/or if there is a problem with wound healing, the implant may break through the skin and become exposed. This will require removal of the implant. Surgery is needed to correct this and can result in unacceptable scarring or breast tissue loss.

Change in Nipple and Skin Sensation

Some change in nipple sensation is not unusual immediately following surgery. After several months, most patients have normal sensation. Occasionally, partial or permanent loss of nipple and skin sensation or hypersensitivity may occur in one or both breasts. Changes in sensation may affect sexual response or the ability to breast feed a baby.

Malposition

A breast implant may rotate or shift position after initial placement. This may cause discomfort and/or distortion in breast shape, and additional surgery may be necessary to correct this condition. Excessive sagging or stretching of the lower breast tissue may result in an implant that appears too low or causes the nipple to point excessively upwards. The implants can also shift toward the side, widening the apparent gap

between the breasts. Contracture or tightening of the lower implant pocket may cause an upward displacement of the implant. This is more common when the chest or breast has been treated with radiation as part of cancer treatment.

Asymmetry

Most women's breasts have at least some asymmetry. Breast implants may improve size differences but may make nipple-areola angle and position more accentuated. There is no accurate way of measuring breast size so it is difficult to determine the difference in volume of an implant to correct size differences.

Breast Tissue Atrophy

Pressure from breast implants may cause the surrounding tissue to thin and shrink. This may also occur normally with aging. Thinning of tissues over the implant may result in it becoming more visible or palpable (able to be felt).

Palpability

The edges or shell of the implant can sometimes be felt, especially in thin women, after weight loss or after breast reconstruction where there is limited tissue covering the implant.

Postoperative Care

Your surgeon will have recommendations on how to take care of yourself after you have had breast surgery. These may include recommending that you wear a supportive bra 24 hours a day, while others may just advise you to change the band aid when necessary. Your surgeon may also prescribe antibiotics. These and other measures are at your surgeons discretion and are based on his personal experience and overall treatment plan. Not following the surgeon's recommendations may lead to any of the complications mentioned in this brochure. You should be careful when choosing sporting activities. Contact sports, however, are not recommended. Tanning at salons or sun bathing can influence scar healing and direct scar exposure to the sun should be avoided for about 6 months after surgery.

Cost involved with Breast Implant Surgery

Your surgeon should inform you about the cost of implants, surgery, anaesthesia and after care. Be aware of the fact that the cost of treatment of complications might be higher than the initial breast surgery. Ask your surgeon what he will charge for additional surgery. Check with your health insurance company if complication cost are covered before undergoing surgery.

Risks and potential complications related to surgery

Risks of Anaesthesia

There are three types of anaesthesia used during surgery, all of which carry some level of risk.

Local Anaesthetic:

The lowest level of risk is a local anaesthetic, which involves minimal I.V. sedation with injection of local anaesthetic in the area beneath the breasts. Some patients have an allergic reaction to the local anaesthetic or experience a rapid heart beat due to the epinephrine that is used to reduce bleeding. There may be some discomfort intermittently throughout the procedure with a local anaesthetic.

I.V. Sedation:

A second method of anaesthesia is I.V. sedation (intravenous medications delivered without a tube in the throat). This carries risks of respiratory distress, reactions to the medications or medication overdose. It is recommended that a professional trained in the use of I.V. sedation be available to monitor and administer the medications. The cost for this type of anaesthesia is generally higher due to the cost of the medication and personnel to administer them.

General Anaesthesia:

A third option is general anaesthesia in which a patient is asleep during the surgical procedure. The risks of general anaesthesia are the same as those of a general anaesthetic used for other operations and can involve respiratory problems, blood clots in the legs, etc. As a rule, the risk is low because women having implant surgery are generally in good health. The expense of general anaesthesia is higher because of the anaesthesia professional needed and the equipment and medications used.

Infection

An infection following breast implant surgery is unusual, in the range of 0-4% in cosmetic augmentation, and up to 12% % in breast reconstruction with an implant. It may appear shortly after surgery or at any time following the insertion of a breast implant. A low-level infection may be difficult to diagnose. Infection around a breast implant is more difficult to treat than an infection in normal body tissues. If an infection occurs, antibiotics are usually given, and if the infection does not respond to antibiotics, the implant may have to be removed.

After the infection is treated, a new breast implant can usually be inserted several months later.

Wound Healing Problems or Tissue Necrosis

Some patients experience delayed healing, and for others the incision site may not heal well. It may open from injury or infection or after the chest has been treated with radiation as part of cancer treatment. This can result in an unattractive scar. If the implant is exposed, further surgery will be required.

Tissue necrosis is the development of dead tissue around the implant. It will delay wound healing, may cause wound infection and may require surgical correction and/or implant removal. Tissue necrosis has been reported following the use of steroid drugs, chemotherapy, radiation to breast tissue, and smoking, but in some cases it may occur without any known cause.

Hematoma

A hematoma is collection of blood that may occur around a breast implant following surgery. It occurs in 2 - 4% of breast implant procedures. Each woman's experience may be different. In some cases, this is a simple matter that can be handled in the plastic surgeon's office, but more frequently it will require a general anaesthetic and additional surgery to remove the hematoma and stop the bleeding. A hematoma may contribute to capsular contracture, infection or other problems. Aspirin, other medications that contain aspirin, and anti-inflammatory medications should not be taken for ten days before or after surgery, as their use may increase the risk of bleeding. After a few weeks, the risk of an early problem with bleeding is low. However, a hematoma can occur at any time following an injury to the breast.

Seroma

Fluid may accumulate around the implant following surgery, trauma or vigorous exercise. Additional treatment may be necessary to drain the fluid accumulation. A seroma may contribute to infection, capsular contracture, or other problems. If one or both breasts seems to increase in size over time or if it seems that there is fluid around the implant, this may indicate a seroma condition and require secondary treatment.

Scars

All surgery results in scarring - it is nature's way of healing - and the quality of a scar may vary quite a bit from one person to another. Healing is an individual patient's response to surgery and it is often not within the control of the surgeon. Most scars following breast augmentation are pale thin lines. They may, however, become red, firm and elevated. Scars such as this are called "hypertrophic." They usually fade with time, but may leave more visible permanent scarring. Another type of scar, which occurs in some surgical patients, is called a keloid. This is an enlarged scar that does not fade or flatten with time. A surgical correction of the scar might be necessary.

Toxic Shock Syndrome

In extremely rare instances, life-threatening infections, including toxic shock syndrome can occur.

Pain

Pain may develop after breast implant surgery. Some women who did not have pain prior to surgery may have persistent pain after surgery. These pain symptoms are unpredictable and in some patients no cause can be found. Ask your surgeon what pain medication you can take.

Other risks and complications

Pregnancy

The presence of a breast implant will have no effect on your ability to become pregnant, deliver a baby, or even breastfeed. Breast implants have not been shown to have an effect on children or future offspring.

Breast Feeding

Breast implant surgery should not prevent you from following any desire you may have to breast feed. Be aware that the surgical approach used for implant placement may influence breast feeding as the option of placing the scar around the nipple area could, theoretically, interfere with the breast ducts. While this is uncommon and still theoretical, discuss options with your surgeon and be sure to indicate any interest you may have in breast feeding in the future.

Mammography

Women who have breast implants should have mammograms at a certified mammography center. Be sure to inform the personnel of your breast implants. The presence of a breast implant may make screening mammography more difficult. To maximize the results from the breast tissue that can be seen, additional mammography views will be taken.

Breast and Nipple Piercing Procedures

Women with breast implants seeking to undergo body piercing procedures to the breast region must consider the possibility that an infection could develop anytime following this procedure. Should an infection occur, it is possible that it could spread to the breast implant space. Treatment including antibiotics, possible removal of the implant, or additional surgery may be necessary.

Dissatisfaction with Implant Size

Discussion with your surgeon before the surgery about your goals for breast size and shape are very important. After surgery, a silicone gel breast implant cannot be adjusted. If you wish to have different size implants, this will mean a second operation and additional costs. You should understand that the female breast will change over time, and your breasts will sag and droop with age and lose some volume over time. Pregnancy and breast feeding may influence this as well as weight gain or loss.

Additionally, you should understand that the breast size that you desire and the implants that you choose today may be not be the same as what you might choose at a different stage of your life. In the future you may need a change of implant and breast shaping to achieve your desired result at that time.

Breast Deformity After Implant Removal

If breast implants are removed for any reason, the appearance of the breasts may not be desirable or pleasing. Older patients and those with large implants may have more cosmetic deformity if they choose not to replace the implants or to undergo additional reconstructive surgery. Typical problems include asymmetry and drooping of the breast skin.

Implant Replacement

If you decide after surgery that your implants are too large or too small, you may decide you want to have the implants replaced with a larger or smaller size. The cost of replacement, including the surgical facility fee and anaesthesia, will be similar to that of the original surgery.

Long-term issues

Connective Tissue Disease: Immune System Diseases and Unknown Risks

A small number of women with breast implants have reported symptoms similar to those of known diseases of the immune system, such as systemic lupus erythematosus, rheumatoid arthritis, scleroderma, and other arthritis-like conditions.

To date (status 2009), after several large epidemiological studies of women with and without implants, there is no scientific evidence that women with silicone gel breast implants have an increased risk of these diseases. These diseases appear no more common in women with implants than in women without implants. The effects of breast implants in individuals with pre-existing immune system and connective-tissue disorders is unknown.

Cancer and breast implants

At this time (status 2009) there is no scientific evidence that silicone gel-filled breast implants increase the risk of cancer in women. However, this possibility cannot be completely ruled out. The follow-up time of completed studies of women with implants has not been long enough to be fully conclusive. Only the future will determine the significance of this potential risk.

Reoperation Estimates

Devices placed within the body do not last forever, and breast implants, like many other implanted devices, may need to be replaced or removed after a period of time. Ask your surgeon about his experiences of implant longevity and re-operation for implant replacement.

Future Risks of Silicone

There is the possibility of risks, yet unknown, which could be associated with breast implants.

Immediate Breast Reconstruction Surgery

Patients who choose immediate breast reconstruction at the time of mastectomy must consider the risks and uncertain outcomes from the mastectomy operation. These include the surgical complications related to the mastectomy, possible need for additional surgery to remove residual breast cancer discovered at the time of the mastectomy, possible need for additional breast cancer treatments (radiation and chemotherapy), and local recurrence of breast cancer. In breast reconstructive surgery the use of a permanent or temporary tissue expander in combination with a silicone gel-filled breast implant has become a normal procedure but also increases the risk of complications due to additional surgery. All of these could adversely affect the outcome of immediate breast reconstruction procedures.

Delayed Breast Reconstruction Surgery

Patients who wish to opt for reconstruction at a later stage (i.e. after radiation therapy) instead of immediate breast reconstruction, are exposed to the same risks as with the immediate breast reconstruction procedure.

**Whether you choose Nagor for your breast implant surgery or not, we hope that this information has given you more understanding and knowledge about the subject.
For additional information visit our website www.nagor.com**



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