



Consent Form

While every effort has been made by Allergan to ensure the accuracy of the information contained in this booklet, Allergan accepts no responsibility and/or liability for errors or omissions. The information contained herein, has been compiled from studies into breast implants and tissue expanders, and from generally accepted practices. Due to the on-going research into the safety of breast implants and tissue expanders, you should discuss with your surgeon, all known risks and benefits of breast implant surgery, prior to your surgery.

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Considering Breast Enhancement

Individual **Women**, Individual **Choices**

Introduction

Breast enhancement is one of the most frequently performed plastic surgery procedures today, but the decision whether or not to have breast implants is very important. Allergan want you to feel confident in making your decision and to be fully informed of your options before doing so. You may have concerns that you want eased, questions to be answered and some reassurances of the procedure's success before proceeding. With this booklet we will take you through the steps involved to help you make an informed decision.

We recommend you spend good time evaluating whether breast enhancement is right for you, carefully consider all the factors and talk with your surgeon. This booklet is not intended to replace any discussions between you and your surgeon.

The choice is yours

Women seek breast enhancement surgery for many personal reasons, including:

- Reshaping their breasts
- Enlarging their breasts
- To restore their breasts following significant life events such as child bearing
- Balancing breasts that differ in size or shape

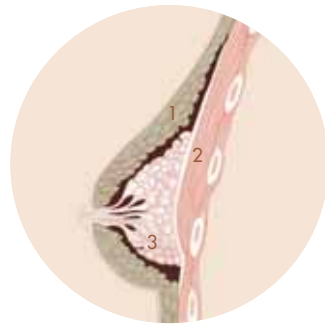
As every woman is different, and will have different desires and needs, there are many breast implant options available today and this booklet will help you to understand these options and which one might be right for you.

Having breast enhancement will be a very personal decision and the benefits will be personal to you too. Some women say that they have improved self confidence and personal satisfaction, a maintained or increased sense of wellbeing, and feel satisfied with their appearance. There are various factors that influence satisfaction and these might not be the same for everyone.

Understanding your breasts

Your breasts are made up of fatty tissue, glandular tissue, milk ducts, blood vessels, nerves and lymph ducts, covered with skin. Behind the breast lies the pectoralis major muscle.

A breast implant can be placed either partially under or over this muscle, depending on the thickness of your breast tissue and its ability to adequately cover the breast implant. It is the fatty tissue that makes your breast feel soft and gives it its shape. The shape also depends on the elasticity of the skin.



- 1 Fatty tissue
- 2 Pectoralis major muscle
- 3 Glandular tissue

What is a breast implant?

As every woman is different and has different desires, there are many implants to suit each individual need. A breast implant consists of a silicone envelope that is filled with either silicone gel or saline (salt-water) solution. Implant shapes are either round or teardrop shaped (anatomical), the surfaces are either textured or smooth, and they also come in a large range of projections and sizes. The different options can help to achieve the appearance you desire. Your surgeon can tell you more about the different types of implants and will help you choose the implant that's right for you.



- 1 A breast implant

Types of implants available

Shape options: As every woman is different, implants are also available in different shapes and sizes to suit every need. Some implants are round, while others are shaped more like a teardrop, closely resembling the natural shape of a breast (these are sometimes called anatomical implants).

Round implants: In general round implants will make the upper part of your breasts fuller.

Anatomical implants: These are shaped more naturally, like a teardrop and follow the body's natural contour. This can give your breasts a more natural shape.

Both types of implants can increase the size of your breasts.

Size & Projection options: As well as considering the shape of the implant, the projection and size is also important in achieving the look you desire. Allergan implants come in a wide range of projections and sizes so that the implants can be tailored specifically to your needs. Discussing what you have in mind with your surgeon is important, so that he or she can take your expectations into account when the implant size and shape is selected.

Limiting factors: The implant size you desire may be limited by your existing breast tissue characteristics. For example the elasticity of your skin, or the amount of breast tissue you have, may keep you from increasing your breast size as much as you want. Implants that are too large for the quantity of skin and breast tissue may remain visible below the skin and this may spoil the effect that you want to achieve. Furthermore, you may face a greater risk of surgical complications. You should ask your surgeon to explain any limitations during your consultation.

Filler options: There are two types of implant fillers: silicone implants are pre-filled from the manufacturer and saline implants are filled during and /or after surgery. Each has advantages and disadvantages.

Silicone: Newer types of implants come pre-filled with a silicone gel that has a shape retaining structure, and come in a variety of cohesivity levels. This means some gels will offer a firmer result, where other gels allow the breast to feel softer to touch. You should discuss the best option with your surgeon.

Silicone is considered to be very safe and is used widely in

the pharmaceutical and food industries, and in many medical devices such as heart valves and suture materials. Silicones are even found in lipsticks, suntan creams, deodorants and baby-care products. In addition to its proven safety, the consistency of silicone provides a very natural feel to the breast.

The silicone used in breast implants is a cohesive form which gives a natural feel and should not leak due to its thick consistency. Benefits of silicone implants include giving a more natural form than other implants.

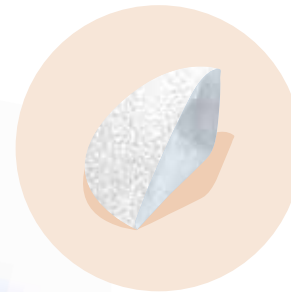
Saline: Saline implants are filled with salt water solution during surgery. A disadvantage to saline is the 'slushy' consistency. There are also less options available with saline implants.



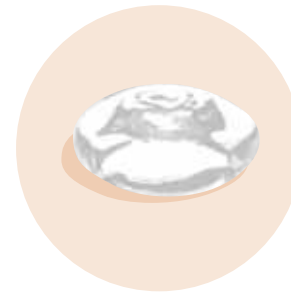
Round implants



Anatomical implants



Silicone filler



Saline filler

Types of implants available

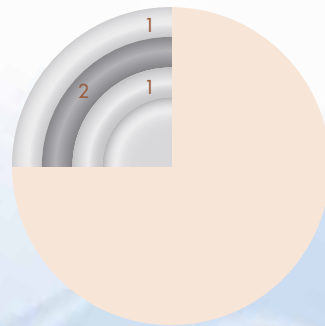
Implant shell options:

Implant envelopes may be smooth or textured, your surgeon will discuss which option is best for you.

Over the years, the design, construction and production process of breast implants has been improved with regard to the durability and life expectancy of the implant.

Allergan implants are manufactured under strict quality control guidelines to greatly reduce the possibility of these complications. All Allergan round and anatomical shaped implants also have a special barrier layer designed to reduce silicone diffusion. Allergan textured implants have a unique texture designed to maintain implant positioning and promote tissue adherence which may help to reduce capsular contracture. (See page 17).

Allergan implants shell design



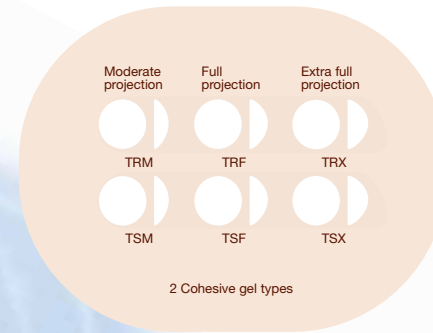
- 1 High Performance Elastomer Layer
- 2 Patented Barrier-coat

Choosing the right implant

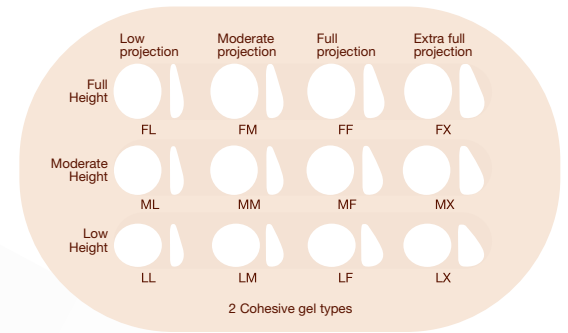
Allergan provide a wide range of implants. You should decide, together with your surgeon, which implant would suit you best to achieve the look you desire.

During your consultation, your surgeon will take some measurements and will consider breast width, height and projection to help with the decision on implant selection. Many surgeons also have tools to help you understand what your new breasts will look like following your surgery.

INSPIRA™



Style 410



A comprehensive range of round and anatomical implants.

Life expectancy of breast implants

It is important to remember that breast implants have a limited lifetime and may not necessarily be in place for life, the implant may have to be removed or replaced, which may require revision surgery.

On average, the expected lifetime of a breast implant is between 10 and 20 years, depending on many individual factors. Various factors, including the type of implant inserted, the type of surgery you have, injury to the breast, and excessive repetitive compression of the implant may impact the longevity of the implants and replacement should be considered. Personal choice or complications other than rupture may necessitate removal of the device even though it is intact.

In on-going studies, the durability of silicone filled implants is being assessed. The implant rupture rate has been found to be between less than 1.0% (lowest reported rate) after 6 years, to 8.0% after 11 years.

The durability of saline implants was assessed via the implant deflation rate and was found to be 10.5% after 10 years, for both enhancement and reconstruction implants.

Allergan are committed to providing the best products for you and are committed to ongoing research and development to ensure long term safety for all patients.



Peace of mind with Allergan implants

Warranty

For peace of mind all Allergan implants are covered by a replacement policy, which will replace free of charge any implant that needs to be changed due to loss of shell integrity resulting in rupture or any other product defect confirmed by the manufacturer, within 10 years of implantation. You should ask your surgeon for further details of the Allergan warranty program.

Surgical procedure – what’s involved?

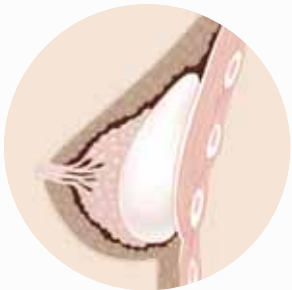
Preparing for the operation:

Your surgeon will want to begin by making sure you are in good health, you are well informed and have realistic expectations of the result, risks and the post operative period before planning the operation. It is also important for the surgeon to understand your size requirements. Before the operation, breast measurements are taken and the surgeon will make markings on the chest.

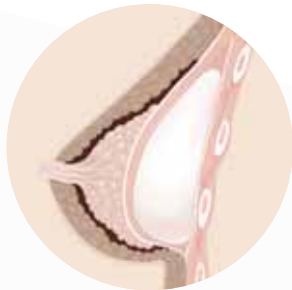
Your surgeon will also make a decision regarding the positioning of the implant. It can be placed either partially or totally under the pectoralis major muscle (submuscular) or on top of the muscle and under the glands (subglandular). The surgeon, in consultation with you, will choose the location depending on your physical characteristics.



1. Breast before enhancement



2. Breast after subglandular enhancement



3. Breast after submuscular enhancement

Surgical incisions

There are 3 possible incision sites for breast enhancement operations:

1. Inframammary. An incision is placed along the crease below the breast. This is the most widely used method.
2. Periareolar. An incision is made along the border of the areola, beside the nipple.
3. Transaxillary. An incision is made in the armpit.

After your operation

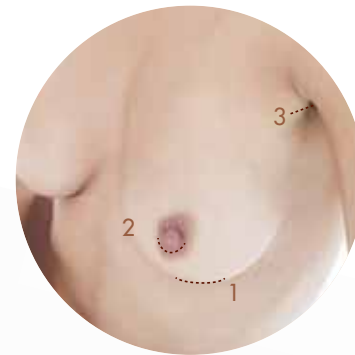
It is very simple to care for your breasts in the first few days after the operation. You will be advised against washing or bathing for a period of time. You may still be wearing a supporting bandage, which can be replaced after a few days by a supporting bra. Once your stitches have been removed, your doctor may instruct you to massage the scar and the breasts gently with cream or lotion (one recommended by your doctor) to prevent the skin from drying out.

These are only general guidelines. Every woman is different, so it is important to follow your doctor’s specific instructions carefully and consult a surgeon for medical follow up.

You should also always consult a physician or a pharmacist before the use of topical medicines (e.g. steroids) in the breast area after breast enhancement.

If any clinical examination or surgery in the breast area is planned you should inform your doctor or nurse of the presence of an implant.

It is recommended to carry the patient card provided at all times to facilitate medical care in case of emergency (for example, in case of a road accident).



1. In breast fold (inframammary) incision
2. Around nipple (periareolar) incision
3. Under arm (transaxillary) incision



Checking your implants

All women with breast implants should practice breast self-examination. If you find that self-examination is difficult with breast implants we would recommend you speak to your doctor or physician for help, as you may find it difficult to feel your breast tissue depending on the position of your implant and particularly if the capsule around your implant has contracted. Your doctor may recommend you have a mammogram and/or ultrasound to check your implants, but this is not always necessary.

If you have any unusual breast symptoms, you should consult your doctor immediately.

You should also see your doctor if you notice: a lump or dimpling of the skin on your breast or nipple; a nipple discharge; a change in the position or shape of your implant; or if you have had a recent injury to your breast, in particular, in the case of trauma or compression caused, for example, by extreme massaging of the breast region, by some sports activities or by using seat belts. If your implant has been damaged, it may need to be removed.

Things to be aware of

Breast cancer & Mammography: There is no medical evidence to date showing that women with breast implants are at increased risk of breast cancer. Following breast enhancement you should continue to consult a physician to carry out normal checks to detect breast cancer.

You should be aware that breast implants may interfere with mammograms, which assist in the early detection of breast cancer. It is important that you inform the radiographer (person taking the x-rays) that you have breast implants before mammography as special techniques will need to be used to get the best possible views of the breast tissue.

If you have a silicone breast implant, mammography might be more difficult to evaluate, because the implant shows up on the X-ray as a dense shadow, which may hide small cancerous tumours. Some implants may also have orientation marks, which may be misdiagnosed as small tumours. It should be noted that the pressure applied by the mammography machine could damage the implant, causing rupture or increased gel diffusion, however the risk of this is considered to be very small.

Things to be aware of

Breast-feeding: There is no medical evidence to show that breast implants interfere with breast-feeding. However, breast surgery may affect the shape, function and sensation of the nipple and surrounding breast tissue. This may make it difficult for you to breast-feed. It is suggested that you discuss any possible problems with your doctor or midwife.

Studies indicate that there is no evidence to show an increased risk of connective tissue disease in children of women with breast implants.



It is important to consider all the complications and risks

Local complications

Implant rupture: If the outer shell of a silicone implant breaks (this is called implant rupture) the gel is usually contained within the capsule around the implant, or some very small amounts of silicone might move into other parts of the body, including the lymph nodes. However, with improved modern implants this migration of silicone is diminished. Current research does not indicate any adverse effects from this 'free' silicone gel, except the presence of some local enlarged lymph nodes. In some cases rupture might be "silent" and not cause any symptoms. However when symptoms occur, they may include lumps in the breast, decreased breast size or distorted shape of the breast, pain or tenderness. Rupture of an implant may occur without warning, and in some cases removal of the

implant may be necessary. Causes may include: injury, normal wear and tear of the implant envelope, implant age, mammography, and capsular contracture.

Gel leakage: Minute quantities of silicone might diffuse through the shell of gel-filled implants. However with the advance of implant technology and shell design, such as barrier coating, gel diffusion is drastically reduced. If gel did leak out, it would mostly be contained by tissue that the body forms around the implant which helps prevent the gel from seeping into surrounding tissues.

Deflation: This can occur with saline implants immediately or slowly over a period of time and is noticed by loss of size or shape of your breast.

Causes of deflation include damage during surgery, capsular contracture, trauma or intense physical manipulation and unknown/unexplained reasons. Deflated implants require additional surgery to remove and to possibly replace the implant.

Rippling of the implant: Visible rippling may occur with implants.

Capsular formation and contracture: Capsule formation is a normal body reaction which occurs around any foreign object. With breast implants, the capsule sometimes contracts after it forms, and in some cases this results in very firm breasts which may also have associated tenderness or pain. This is called capsular contracture and is the most common complication with breast enhancement operations. This condition might cause hardening of the breast, pain, increased sensitivity to touch, rippling or distortion of the breast, or movement or displacement of the implant.

In many patients contractures will never occur, in other patients contractures can occur weeks or years after implantation, as the body's response to any foreign object varies greatly from person to person. How much the capsule will contract, if at all, is hard to predict.

Correction of capsular contracture requires surgery and it is possible for capsular contracture to reoccur.

Improvements in breast implant design and surgical techniques have contributed to declining rates of capsular contracture. Lower rates are associated with implant placement and textured implants.

Potential undesirable effects of breast implants

Pain: As expected following any invasive surgical procedure, pain of varying intensity and duration may occur following breast implant surgery. Very occasionally severe pain associated with arm movement has been reported. If you have any pain following surgery you should contact your surgeon or doctor for prompt investigation.

Infection: Infection is possible in any operation. If you develop an infection you will need to see your doctor as soon as possible and you may need to have a further operation to remove the implant or tissue expander until the infection has cleared and then replace your implant. Although most infections can be treated successfully, infections can cause serious problems and may result in increased scarring. In a small number of cases these infections may come back.

Aesthetic consequences: Scar deformity, pronounced scarring, asymmetry, displacement, incorrect size, unanticipated contour, palpability, and sloshing (with saline-filled implants) may occur.

Changes in nipple and breast sensation: Implant surgery may result in changes in nipple or breast sensation.

The breast and nipple may become painfully sensitive or all sensation may be lost. In most cases these changes are temporary but in as many as 1 in 7 women, changes in nipple sensation can be permanent. You should discuss this possibility with your surgeon.

Potential general effects on health

Several large studies have failed to establish a link between breast implants and well-defined connective tissue diseases. Even though few studies have been carried out, current high quality literature suggests that there is no association between breast implants and connective tissue disease-like syndromes (atypical connective tissue diseases). Moreover, it is difficult to define atypical connective tissue diseases. These diseases seem to occur at the same rate in women with or without breast implants, which makes it difficult to conclude whether breast implants play a role in the development of such diseases. If you have any concerns you should speak to your surgeon.

We hope this information has helped you to understand all aspects of having breast enhancement, it is important that you consider all the information and discuss fully with your surgeon to ensure you make a fully informed decision to proceed.

The following list of questions will help you to ask your doctor the right questions prior to surgery.

- Q What are the breast enhancement options available to me?
- Q Can you give me a step by step explanation of the various surgical approaches?
- Q Which different types of breast implants can I choose from, and what are the advantages and disadvantages of each type?
- Q What tools do you have to help me understand how I will look after the surgery?

- Q Can I choose any size I want?
- Q Which incision technique do you use and why ?
- Q What are the risks and complications, and how often do they occur?
- Q How long will it take me to recover completely from the operation?
- Q How long will it be before I see the results?
- Q What will the scars be like?
- Q How much experience do you have with breast enhancement?
- Q Do you have before and after photographs of patients on whom you have performed surgery that I can review?
- Q If I have any problems who should I contact?

Glossary of terms

Asymmetry: Imbalance in the proportion, size and shape of the left and right breasts.

Breast enhancement: Surgery to change the size or enhance the shape of the breast through the use of breast implants.

Capsule: The tissue which forms around a breast implant. This is the body's normal response to the presence of any foreign object.

Capsular contracture: Where the capsule surrounding a breast implant contracts. Extreme cases can cause the breast to feel hard and painful. It may also lead to disfigurement where the capsule surrounding one implant contracts and the other does not, or if the capsule contracts unevenly. Women experience different degrees of capsular contracture for reasons as yet unknown.

Connective tissue: Fibrous tissue connecting and supporting the body organs and the cells within these organs.

Gel diffusion: Where tiny amounts of silicone gel pass through the intact implant envelope or shell into the surrounding capsule and breast tissue. This silicone gel can also travel to other body tissues, particularly through the body's lymphatic system.

Envelope: Outer layer that encloses the contents (saline or silicone gel) of the breast implant. It is usually made of a silicone elastomer.

Mammogram: A special X-ray to detect breast cancers or other breast abnormalities including breast implant rupture. The radiographer should be informed that you have breast implants, as special techniques must be used.

Reconstruction: Breast reconstruction refers to the operation performed to create a new breast after mastectomy.

Rupture: Rupture of an implant refers to a break in the envelope of an implant. The rupture can be a pinhole sized defect or a large tear of the envelope.

Saline: Salt water used to fill saline breast implants and tissue expanders. Saline is absorbed easily by the body if the implant ruptures or leaks.

Silicone: Is a polymer made partly from silicon. Silicone can come in solid, liquid or gel forms. Silicone breast implants consist of a solid silicone outer shell filled with silicone gel.

Tissue expander: A saline breast implant, which is used to stretch the skin of the breast during the first stage of breast reconstruction. Saline is regularly injected into the expander through a valve under the skin until it stretches enough to allow insertion of a permanent implant.

Ultrasound: Is the use of ultrasonic waves to detect abnormalities including rupture of breast implants.



Allergan informed consent form

Please use a black ball-point pen when filling out this card.

I confirm that my surgeon has:

- Provided me with sufficient information about the procedure in order to make an informed decision
- Given me the opportunity to ask all remaining questions I may have about the procedure, and has answered them to the best of their ability
- Given me the time to consider the procedure
- Received the relevant medical history information from me to the best of my knowledge

I therefore consent to undergoing the procedure as discussed with my surgeon.

Patient name (printed):

Patient signature:

Date:

Surgeon name:

Clinic:

Address:

This consent form is designed to be signed following an informed discussion with your surgeon in connection with your surgeon's recommended treatment.