BREAST AUGMENTATION

ARE YOU THINKING ABOUT BREAST AUGMENTATION?

If you are considering surgery, your plastic surgeon wants you to be thoroughly informed about this procedure. Reading this brochure is the first step. However, a personal consultation with your surgeon is the best way to obtain the additional information you will need.

What is Breast augmentation?

Breast augmentation, also called Augmentation mammaplasty is a cosmetic surgical procedure to increase the size of breasts. Augmentation mammaplasty will also correct slight sagging of the breast and can increase breast firmness. It involves surgical placement of an implant behind each breast to increase its volume and enhance its shape.

Following breast enlargement, it may be easier to find clothing that fits you well, and you may feel more confident about your appearance.

Is breast augmentation right for me?

You may want to consider breast augmentation if you feel your breasts are smaller than you would like or are out of proportion with the rest of your body. Two different circumstances usually spark an interest in surgical breast enlargement.

The first is natural under development or an imbalance in the amount of breast tissue . In this instance, there may be problems with breast asymmetry or shape deformities.

The second situation is caused by natural loss of breast volume which follows a large weight loss, ageing or pregnancy. The breast often takes on a collapsed or deflated appearance and clothing no longer fits well around the chest.

One or more of the following feelings or conditions may indicate that you are a good candidate for breast augmentation:

- You are bothered by the feeling that your breasts are too small
- Clothes that fit well around your hips are often too large at the bustline
- You feel self-conscious wearing a swimsuit or form-fitting top
- Your breasts have become smaller and lost their firmness after having children
- Weight loss has changed the size and shape of your breasts
- One of your breasts is noticeably smaller than the other

Breast augmentation can enhance your breast size and shape, and give you a more proportional figure. Breast augmentation can be performed at any age after the breasts are fully developed. A good candidate for breast enlargement is emotionally mature, understands her personal motivations and has realistic goals for the procedure.

INITIAL CONSULTATION

During the initial consultation, you may be asked to point out exactly what you would like to see improved. This will help your plastic surgeon to understand your expectations and determine whether they can be realistically achieved. You should always keep in mind that the desired result is improvement, not perfection.

You will be asked about your medical history including previous operations, past and present medical conditions and current medications. You will also be asked about previous breast conditions, you may have had. In order to provide you with the best information and safest options, it is important that you give your surgeon complete information. This will include information about any medical conditions, drug allergies, medical treatments you have received, previous operations including breast biopsies, and medications that you currently take. You will be asked whether you have a family history of breast cancer and about results of any mammograms. Your plastic surgeon may recommend a baseline mammogram before surgery if you have not had one.

It is important for you to provide complete information. The medical conditions that may

increase risks of surgery include high blood pressure, thyroid problems, diabetes and bleeding problems.

If you are planning to lose a significant amount of weight, be sure to tell your plastic surgeon. He or she may recommend that you stabilise your weight prior to undergoing surgery.

If you think that you may want to become pregnant in the future, you should mention this to your surgeon. Pregnancy can alter breast size in an unpredictable way and could affect the long-term results of your breast augmentation. There is no evidence that breast implants will affect pregnancy or your ability to breast-feed, but if you have questions about these matters, you should ask your plastic surgeon.

Your plastic surgeon will examine your breasts, take measurements and take photographs for your medical record. He will consider such factors as the size and shape of your breasts, the quality of your skin and the placement of your nipples and areolas (the pigmented skin surrounding the nipples).

A number of measurements will be made, such as the distance from your breastbone to the nipples, the thickness of tissue in the upper part of the breast and from nipples to the crease under your breast. Breast diameter and the distance between the breasts is another important measurement in planning. If your breasts are droopy, a breast lift may be recommended in conjunction with augmentation.

Choice of Implants

All implants are composed of a shell and filler.

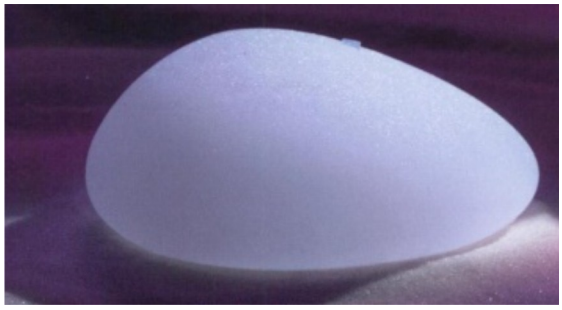
Implant shells can be smooth or rough. Most prostheses currently in use have silicone shells. Smooth-shelled implants are easy to insert but have a disadvantage of being more likely to develop a capsular contracture or "implant hardening". The textured-shell implants were invented to combat the problem of capsular contracture. The current implants with textured shells have a much smaller risk of capsular contracture. Whereas smooth shell implants had a risk of contracture of 20-50%, the textured implants have reduced the risk to 1-5%.

Recently, implants covered with polyurethane foam have come on the Australian market. These have a furry, foam coating that has been shown to significantly reduce the risk of capsular contracture. In long-term studies, the capsular contracture risk is around 1%. However, these implants do have a slightly higher risk of rippling as they don't conform to the implant pocket as easily as silicone shell implants. They also require a slightly longer incision to insert.

Shape The shape of the implant also varies. Some varieties are round whilst some are made in a teardrop or "anatomic" shape that more closely resembles the natural shape of a breast.

The choice of implant shape is mainly going to be determined by your preference, but some inherent differences exist.

Round implants tend to give you a more rounded, full and higher looking breasts, whereas the teardrop implants tend to give a more natural, softer look with a naturally sloping upper pole.



Teardrop Implant

Round Implant

The advantages of round implants are their lower cost and no risk of implant rotation.

Your plastic surgeon can discuss the advantages of each with you in more detail.

The Filler. Gel filled Implants: These implants are used in over 99% of breast augmentation procedures in Australia. A new, cohesive form of silicone gel was recently developed and is now used in the new generation implants. Because the gel is cohesive, meaning it sticks together in a predetermined shape, it minimises the risk of dispersal should the implant rupture. It also can maintain a breast shape more effectively than a saline implant, especially in the upper pole of the implant. Cohesive gel filled implants are produced in both the anatomical and round shape. Cohesive gel implants also have a smaller risk of visible implant rippling.

In recent years, some patients have raised concerns about silicone causing diseases. To date, however, these claims have not been substantiated by carefully performed scientific studies that have examined the health of thousands of women who underwent the procedure in the past. If you wish to find out more about the silicone controversy, please read this information on page 8.

Saline filled implants are readily available though they are no longer commonly used in Australia at the present time. They are known to be safe. In the event of prosthetic rupture, saline is released from the implant and is absorbed by the body. They are available in either "round" or "anatomical" (tear drop) shape. Many patients will prefer the saline filled implant because of the inherent safety of the saline. However, saline implants do have certain disadvantages as well. Saline implants are not as durable and deflation of the implant is one of the potential risks of using a saline implant. Saline implants also feel firmer than silicone implants and are more prone to visible rippling and wrinkling.

During the consultation for breast augmentation, discussion will lead to a decision regarding the amount of breast augmentation that best meets your needs.

YOUR OPERATION

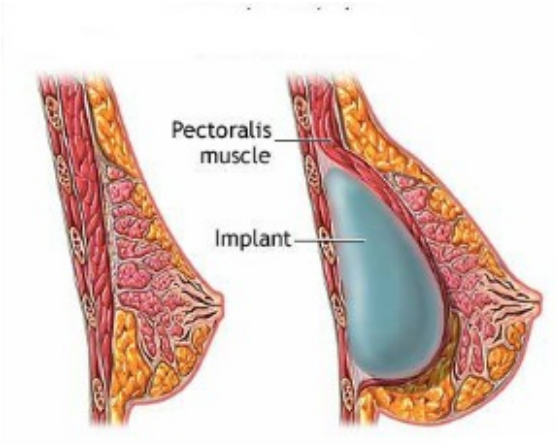
Because of individual factors, not everyone will achieve the same results from breast augmentation surgery. There are many variables which need to be considered before a final surgical plan is formulated. After discussion with you, your plastic surgeon will select the surgical technique that he feels will obtain the best outcome for you.

Choice of Implant Placement

Breast Implants can be placed either under the breast tissue or partially under the muscle of the chest wall (pectoral muscle). The placement depends on your pre-existing breast shape and size, the amount of tissue in your upper chest, the amount of physical activity you do and the size of implant you wish to have. Excellent results can be achieved with the use of both placements but each has certain limitations.

Behind the muscle. In this operation, the pectoral muscle is cut and lifted. A pocket for the implant is made between the muscle and the ribcage.

The main reason to place implants behind the muscle is to prevent the edge of the implants being visible through the skin. The extra tissue overlying the implant also reduces the visibility of any rippling in the implant. Round implants are commonly placed behind the muscle as the muscle softens the round and visible upper edge. The tissue thickness in the upper pole of your breast should also be measured by your surgeon to determine if you have enough tissue to minimize the visible implant edge.

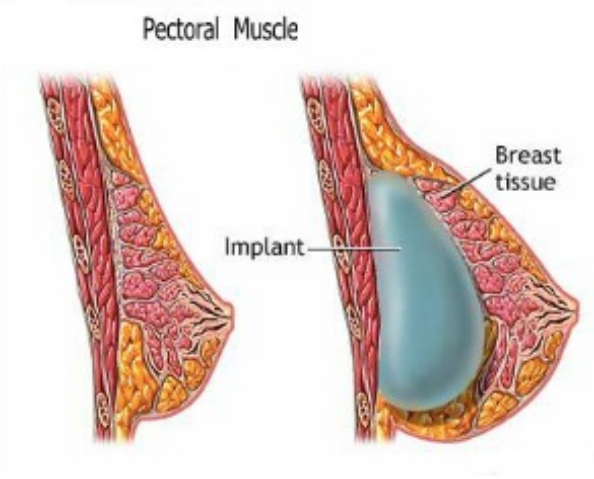


This operation is more painful and consequently has a slightly longer recovery. With teardrop implants, there may be an increased risk of the implants rotating. Perhaps most importantly, the muscle which now drapes over the implant, exerts force on the implant every time the muscle is tensed. This causes the implant to move, usually upwards and outwards during movement and exercise, which can look quite unnatural. Dividing the muscle can also produce unnatural looking tension lines and tethering in the skin.

On top of the muscle. The main drawback of this approach is that if you are thin and have little tissue in the upper breast, the implant edge may be visible, which is not a desirable look. Visible rippling is also more common with this approach.

However if you have sufficient upper breast tissue, this operation is less painful, has faster recovery and minimal risk of movement and distortion of the implant. In breasts with moderate droop, this placement will give you more of a lift and breast fullness.

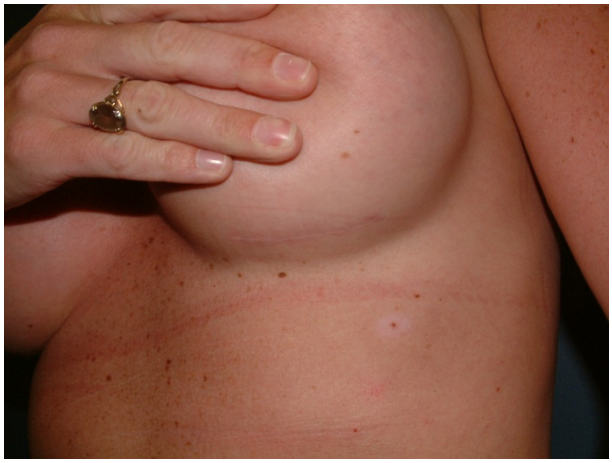
This will be discussed with you and the appropriate choice determined at the time of consultation.



Choice of Incision

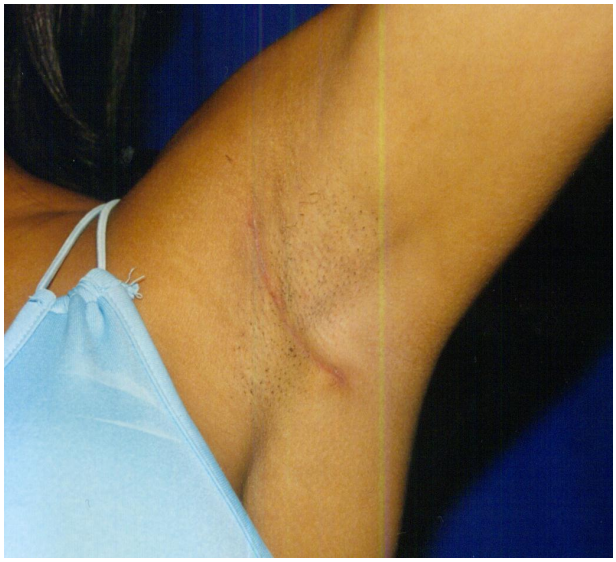
You have three choices here and the decision is mostly up to you.

In the breast crease. This is the commonest incision and has the advantage of being the most direct approach to the breast. It also conceals the scar in the breast crease. Generally, the only people who will ever see the scar is you and your partner.

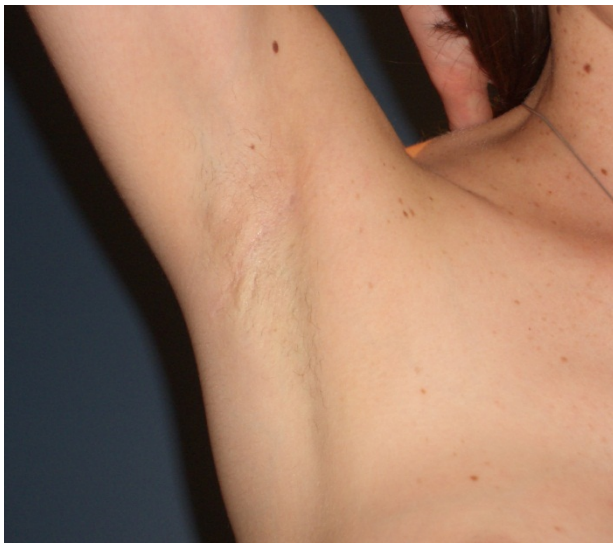


Under-breast incision after 3 months

Through the armpit. Some patients do not want to have any scars on the breast at all. The incision is placed in one of the skin creases in the armpit where it is invisible with your arms down. However it may be visible if you wear a strapless dress. Then again, most people do not associate an armpit scar with breast surgery. It is a good incision for judging the shape and symmetry of your breast while you are still asleep on the operating table.

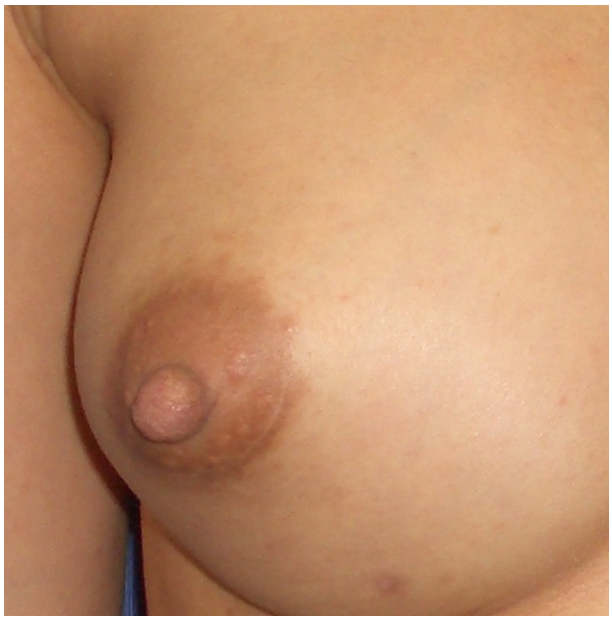


Underarm incision after 6 weeks



Underarm inciiosn after 12 months

Around the nipple. This the least common approach in Australia though it is popular in Europe and South America. The incisions around the nipple tend to heal well, but they also have drawbacks. The main is that if you have relatively small nipples, the implant selected may not physically fit through this incision. Also, this incision may significantly distort your nipples, a problem which may then be difficult to correct. Nipple sensation may also be affected more than with other incisions.



Nipple incision after 12 months

All three approaches can achieve excellent results. Your plastic surgeon can discuss these with you at the time of consultation to determine the most appropriate approach for you. Incision placement is influenced by such factors as clothing preferences and implant placement. Should you have a preference, your plastic surgeon is trained in all three methods.

Scars are an unavoidable result of the incisions required to place breast implants, but they generally are small and can be placed inconspicuously. One of the advantages of a saline-filled implant is that, because it is filled with saltwater after being inserted, only a small incision is needed. Often, an incision of less than one inch is made underneath the breast, just above the crease, where it is usually quite inconspicuous.

Once the incision is made, the surgeon creates a pocket into which the implant will be inserted. After insertion and positioning, the incisions are closed with sutures.

How long does the operation take?

The operation takes 1 to 1.5 hours, depending on the incision, placement and size of implants.

Preparation for surgery

Smokers will be asked to stop smoking 3 weeks before surgery.

Aspirin and some anti-inflammatory drugs used for the treatment of arthritis can cause increased bleeding, so you should avoid taking these medications for 2 weeks before surgery. The medications you should avoid taking prior to surgery include the following: *Aspirin, Dispirin, Cartia, Nurofen, Advil, Voltaren, Brufen, Plavix, Clopidogrel, Warfarin*. Please note that this list is not exhaustive and you should specifically check with our office if you are taking any medications tp make sure you don't need to stop them prior to surgery. Also, please make sure you tell your surgeon about all medications you may be taking.

The operation is performed on a day surgery basis, meaning you can leave after the operation is finished and you have recovered sufficiently form the anaesthetic. If this is the case, make certain you have someone drive you home after surgery

and to stay with you at least the first night following surgery.

The day of surgery

You will be admitted to the hospital or day surgery by the admitting staff. This requires about 15 minutes of paperwork after which you will be seen by the anaesthetist. This is the doctor responsible for putting you to sleep and keeping you safe during the operation. The anaesthetist will ask you again about your previous medical history to ensure that giving you anaesthetic is in fact safe. During the anaesthetic, various monitors are used to check your heart, blood pressure, pulse and the amount of oxygen circulating in your blood.

Your surgeon will mark your skin before the operation and if you have not already done so, you will need to sign the consent form for your operation. You will also have the last opportunity to ask any last minute questions you may have.

You will then be moved to the operating theatre. There, you will be placed on the operating table. The anaesthetist and his assistant will prepare you for the anaesthetic and put you to sleep. You will also be given antibiotics intravenously to minimise the chance of infection.

After Surgery

When surgery is completed, you will be taken into a recovery area where you will continue to be closely monitored. You will feel drowsy for several hours after the procedure and you will remember very little of this time. Generally, you will be ready to leave the day surgery about 3-4 hours after the operation is finished.

Because the area is infiltrated with long-lasting local anaesthetic, you will have little or no pain when you wake up. As the anaesthetic wars off, some discomfort will return. This can generally be well controlled by taking oral medications such as Panadeine Forte. Resting also helps decrease the discomfort. The pain will settle over several days to a point where you will be taking only Panadol by 4th day or so. It is important to realise that the amount of time it takes for recovery varies greatly among individuals. Some discomfort arises from the stretching of the breast tissues, but it largely resolves within two to three days and is well-controlled with simple oral medication such as Panadeine. Showering is one or two days after surgery.

Straining, bending and lifting must be avoided, since these activities might cause increased swelling or even bleeding. Some discolouration and swelling will occur initially, but this will disappear quickly. Most residual swelling will resolve within 6 weeks.

The wounds are generally sutured with dissolving sutures so that no stitches need be removed after surgery. The wounds are sometimes covered with a sticking tape to ensure optimal healing of the incision.

You will wear a sports bra for about six weeks.

When can I resume my normal activities?

Patients generally return to work within one week depending on your job, but should avoid exertional activities especially sport and occupation involving arm movement, may be restricted for two to three weeks required for bruising and swelling to resolve.

Sexual activity should be avoided for at least the first week following surgery. After that, care must be taken to be extremely gentle with your breasts for at least the next month.

Lower body exercise, such as walking can be resumed anytime. However, be careful to be sensible: do not go for a long run straight after surgery. Upper body exercise can be started after six weeks. Contact sports should be avoided for 3 months.

RESULTS OF YOUR SURGERY

Since the healing process is gradual, you should expect to wait at least 6 to 8 weeks to get an accurate picture of the results of your surgery. The breast shape will continue to settle and change slightly for 3-6 months. Incisions will fade over a number of months until they become barely visible.

RISKS AND POSSIBLE COMPLICATIONS OF SURGERY

Fortunately, significant complications from augmentation surgery are infrequent. Every year,

many thousands of operations are performed with no major problems and good results. However, everyone considering surgery should be aware of both the benefits and risks. The subject of risks and potential complications of surgery is best discussed on a personal basis between you and your plastic surgeon

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- *Some of the potential complications include **bleeding** and blood accumulation that may need to be drained surgically. The risk of such bleeding is less than 3%*
- *Although uncommon, (around 2%), an **infection** that does not subside with appropriate treatment may require temporary removal of the implant.*
- *Changes in **nipple** or breast **sensation** occur in approximately 15% of breast augmentation surgery, although they are usually temporary.*
- *When a breast implant is inserted, a scar capsule forms around it as part of the natural healing process. The capsule may sometimes tighten and compress the implant, causing the breast to feel firmer than normal. **Capsular contracture** can occur to varying degrees. If it is severe, it can cause discomfort or changes in the breast's appearance. In such cases, more surgery may be needed to modify or remove the scar tissue, or perhaps remove or replace the implant. The risk of capsular contracture occurring varies widely and is not possible to predict. With modern textured implants, the risk is as low as 3% but may be significantly higher.*
- *Breast implants are not lifetime devices and cannot be expected to last forever. **Deflation, leak or Rupture** can occur as a result of trauma to the chest, but more commonly it occurs spontaneously with no apparent cause. Surgery will be required to replace the implant, if desired.*
- ***Scarring** can be unpredictable and thick, stretched scars may result. Most of these can be treated well by steroid injections and silicone sheet application.*
- *Implant **movement** may occur, resulting in asymmetry of the breasts. Pre-existing breast asymmetry may be accentuated by augmentation surgery.*
- *Implants make **mammographic screening** more difficult and they may shield some of the breast from mammographic examination. It is possible that the presence of breast implants could delay or hinder the early detection of breast cancer. Implants placed behind the pectoral muscle interfere with mammography less than those placed under the breast.*
- ***Calcification**. Calcium deposits may form in the tissue around the implant in rare cases. This may cause hardening and pain. This type of calcium deposit may also resemble the type of calcium deposit associated with early breast cancer.*
- ***Wrinkling and folds**. The implant surface may wrinkle. This may be noticeable on the surface of the skin, depending on how the implant is placed and where the implant surface wrinkles. Large wrinkles, or folds, may irritate or damage the surrounding tissue. Crease-fold failure may also occur, resulting in implant rupture or deflation.*
- ***Changes in sensation**. The implant may affect sensation. Sensation may increase or decrease, temporarily or permanently.*
- ***Extrusion**. In rare cases, the implant may push through the tissue covering and become exposed. This is most likely to occur if the overlying tissue is already damaged, or becomes damaged from pressure ischaemia (i.e., lack of blood circulation) associated with an excessively large or displaced implant.*
- *Dissatisfaction with cosmetic results. Dissatisfying results may include scar deformities, displacement, migration, incorrect size, asymmetry. Unanticipated contour, palpability, ptosis, and sloshing of the saline in saline-filled implants.*
- ***Replacement**. You should not consider your implants lifetime devices; revision surgery, including explantation and replacement, may be needed at any time. Medical management of any of the complications described above may include explantation.*
- ***No guarantee of Cup size**. Although your surgeon is expert at predicting and recommending the size of implant that*

You can help to minimise certain risks by following the advice and instructions of your plastic surgeon, both before and after your surgery.

MAINTAINING A RELATIONSHIP WITH YOUR PLASTIC SURGEON

Should there be any questions regarding breast augmentation surgery, be sure they are answered in advance. Well meaning friends are not a good source of information. Find out everything before proceeding with the operation - a well informed patient is a happy one.

After surgery, you will return to your plastic surgeon's office for follow-up care at prescribed intervals, at which time your progress can be evaluated. Once the immediate postoperative

follow-up is complete, many surgeons encourage their patients to come back for periodic check-ups to observe and discuss the long-term results of surgery.

Please remember that the relationship with your plastic surgeon does not end when you leave the operating room. If you have questions or concerns during your recovery, or need additional information at a later time, you should contact your surgeon.

Silicone gel and your body

A. Introduction

The U.S. Food and Drug Administration (FDA) published a Final Rule for silicone gel-filled breast prostheses (April 10, 1991) and a Proposed Rule for saline inflatable breast prostheses. In these rules, the Agency listed a variety of risks that it believed were potentially associated with the use of these devices.

This document provides a critical review of pertinent information concerning the safety of silicone gel-filled and saline-filled mammary prostheses, covering each of these identified risks, as well as the recently publicized issue of potential health effects in breastfed children.

B. Fibrous Capsular Contracture

Capsule formation is a normal wound healing process that commonly occurs within the first few months of surgery. The fibrous tissue capsule isolates the implant from the surrounding tissue. In some instances the capsule contracts around the implant causing the breast to become firm, and in severe cases, painful and distorted. The subjectively defined Baker scale has been widely used by the medical profession as a measure of capsular contracture severity. When the Baker scale is used to evaluate fibrous capsular contracture (FCC), only Grade III and Grade IV contractures are identified as "clinically significant".

FCC can develop on one or both sides. To date, no single factor has been demonstrated to be the sole cause of contracture. The range of potential causal factors includes non-specific and specific foreign body reaction, periprosthetic infection, haematoma, inadequate surgical dissection, and a variety of others. It is likely that the development of FCC is multifactorial.

Capsular contracture appears to be minimized by textured surface prostheses.

For saline-filled mammary prostheses, the estimated average incidence of Grades III and IV contracture is approximately five percent. A recent prospective study of saline-filled mammary prostheses with a textured surface reported a significantly lower incidence of clinically significant FCC of approximately two percent.

An estimate of the average incidence of Grades Ill and IV contracture for silicone gel-filled prostheses with textured shells is approximately 1%-5%.

The incidence of all grades of contracture has been steadily decreasing since silicone gel-filled implants were first introduced.

C. Silicone Gel leakage & Migration

Leakage and migration of silicone gel from silicone gel-filled mammary prostheses has been shown to occur. Gel leakage can result from either rupture of the envelope or passage of minute amounts of gel through the silicone envelope ("gel bleed"). Migration of the silicone gel involves the movement of gel released from the breast implant to distant locations in the body.

Rupture of silicone gel-filled mammary prostheses is an infrequent event that in the majority of cases has resulted from external capsulotomy. Reported incidence rates for rupture range from 0.5 to 6.6 percent. There is no conclusive evidence to suggest that minute amounts of gel bleed from silicone gel-filled prostheses represent a risk. The incorporation of "low bleed" shells containing a barrier membrane in breast implants manufactured over the last ten years has still further reduced the small amounts of gel that might bleed from an implant. Further, although silicone lymphadenopathy and silicone granulomas may occur in cases of gel bleed or implant rupture, in most cases gel bleed represents an incidental finding of no clinical significance.

D. Rupture and Deflation of Saline Breast Prostheses

Rupture and deflation of saline-filled mammary prostheses have been reported to occur hours to years after surgery. The release of the saline from the ruptured device poses no known risks to the patient; nevertheless, such rupture generally leads to reoperation to remove or replace the prosthesis. Several potential contributing factors for rupture and deflation have been proposed, including composition and structure of early devices, fold-flaw failure, closed capsulotomy, and surgical factors. In the published literature, the reported historical incidence of deflation of saline-filled mammary prostheses is highly variable ranging from 0 percent to 76 percent (average 5%) on a per patient basis. As a result in improvements in prosthesis design over the years, the incidence rate for deflation has decreased. The approximate current incidence of deflation is 1.5 percent (ranging from 0% to 19%).

E. Infection

Infection is an inherent risk of any invasive surgery, and the incidence of infection associated with implantation of silicone gel-filled and saline-filled mammary prostheses falls within the normal range observed for other implant procedures. The actual incidence rates have been reported to range from 1 % to 9% with the vast majority of studies reporting incidences of approximately 2% to 4%. These results

are based on studies that differ with respect to implant type, augmentation versus reconstruction, surgical approaches, and variations in the use of antibiotics before, during, or after surgery. Furthermore, the studies cover a time period of approximately 20 years. Overall, the rate of infection appears to be lower following augmentation for cosmetic purposes than following augmentation after mastectomy. A review of the literature indicates that infection is an infrequent event following breast augmentation. The role of infection in capsular contracture remains speculative.

F. Interference with Early Tumour Detection

There has been a great deal of controversy surrounding the issue of early tumour detection in women with breast implants. There are two issues of concern regarding cancer detection in these patients: 1) whether available techniques are capable of detecting abnormalities, and 2) whether patients are at risk for having more advanced disease at first detection. Review of the available studies indicates that questions remain concerning the effectiveness of various techniques in examining patients with breast implants. It is difficult to draw conclusions from the studies as they differ with respect to protocol, patient population, types and position of implants, and mammographic techniques. Nevertheless, there is no conclusive evidence that silicone breast prostheses significantly obstruct or hinder the ability to detect breast tissue abnormalities or breast cancer at an early stage.

The best way to alleviate the problems encountered when examining patients with breast implants is to employ techniques suitable for attaining the most sensitive examination. This may involve revised techniques of manual examination, appropriate manipulation of the breast tissue during mammography (i.e., Eklund technique), obtaining additional views of the breast tissue, and if necessary, employing additional methods of examination such as ultrasound. Evidence also suggests that submuscular implantation provides for the best visualization of breast tissue during mammography. The most important consideration is that radiologists recognize the available methods of examination for patients with breast implants and that the proper techniques are employed. It is equally important to inform patients of the potential problems of detection, to educate them on self-examination of their breasts, and to encourage them to seek breast cancer screening on a regular basis with a mammographer experienced in dealing with breast implant patients.

G. Carcinogenicity

There is no evidence to suggest that silicone gel-filled or saline-filled mammary prostheses are associated with carcinomas in humans. There have been several reports in the literature of breast cancer following augmentation mammoplasty. However, since carcinoma of the breast is likely to affect nearly one in ten women, and it is not uncommon to find malignancies even during the augmentation procedure, these reports are not unexpected.

The most convincing evidence to date for the lack of carcinogenicity of silicone breast prostheses comes from two epidemiological studies with long-term follow-up in women with augmented breasts. In a retrospective cohort study Deapen et al. (1986), and its update by Deapen and Brody (1992), showed no increase in breast cancer or any other malignancies in 3,111 women with breast implants followed for a median of 10.6 years. A population-based nonconcurrent cohort-linkage study by Berkel et al. (1992) yielded similar results to that of Deapen and Brody. There was no increase in breast cancer incidence in 11,676 Canadian women who underwent breast augmentation, with 58.1% of the cohort having at least 10 years of follow-up. The results of these two epidemiology studies support the finding that silicone breast implants are not associated with an increased risk of cancer.

There have been some reports of a possible association between breast implants and anaplastic large cell lymphoma (ALCL). These reports are of a tiny number of cases when compared to the numbers of breast implants in the community. At this stage, it is not clear whether having breast implants truly increases your risk of breast lymphoma or whether this is a coincidental observation only. If over time it is proven that there is a slightly increased risk, and you had implants and were unlucky enough to get lymphoma in the breast it would mean removal of the implants, chemotherapy and probably radiotherapy. While chances of cure are good, there would be a remote chance of the disease spreading or not responding to treatment. The Therapeutic Goods Administration (TGA) is the Government body responsible for the approval of the use of all medical devices. ASPS has proactively advised the TGA of the reported cases and the TGA is monitoring the situation.

H. Human Reproductive Toxicity and Teratogenicity

Review of the literature identified a number of studies relevant to assessing the teratogenic potential of silicone materials. Considered together, they provide a relatively large database from which the teratogenic potential can be assessed. The available data shows that silicone materials are not teratogenic in animals.

The conclusions drawn from the animal studies are reinforced by the published clinical literature showing no reports of human birth defects or other reproductive effects associated with implantation of silicone mammary prostheses of any type. Therefore, the weight of the evidence strongly indicates that silicone is neither a reproductive toxicant nor a potential human teratogen.

I. Immunological and/or Connective Tissue Disorders

Review of clinical case reports and animal data describing cellular immunoreactivity and immunotoxicity of silicone materials indicated that some questions concerning the effects of these materials on immune system function are still unanswered. Nevertheless, there is no conclusive evidence that silicone mammary prostheses are causative agents in the development of connective tissue diseases.

Case reports describing connective tissue disease or immune related disorders among these patients (most appearing only after the recent controversy was made public) represent a small percentage of the population. Not one, but a variety of conditions have been potentially associated with silicone breast implants. Almost all of the alleged disorders are normally most prevalent in women of child-bearing age, the same population that undergoes augmentation mammoplasty. Therefore, it is not surprising, that some cases of conditions are reported coincidental to the presence of breast implants. Although these reports may raise suspicions about the immune system reactivity of silicone, they certainly do not represent any proof of a causal link between disease pathogenesis and silicone.

The lack of an association between silicone mammary prostheses and connective tissue disorders is supported by the available animal data. One study has shown that silicone gel can act as an adjuvant in rats while another demonstrated that silicone gel, even in combination with an adjuvant did not alter lymphocytic responses or produce host sensitization. Silicone has also been shown to be one of the least reactive polymers when tested for its ability to stimulate macrophage activity. Considered together, these animal data provide no evidence that silicone gel-filled and saline-filled mammary prostheses should be considered immunoreactive.

An additional dataset available for review addressed the immunotoxicity of silicone materials, including silicone elastomer gel and fluid. Comprehensive testing by both the National Toxicology Program and Dow Corning have shown that silicone materials are not immunotoxic and do not demonstrate immunogenicity. These data combined with the clinical data and human case reports suggest that implantation of silicone breast implants does not result in immune system responses that are consistent with any pattern of effects related to the development of connective tissue diseases.

J. Calcification

It has been suggested that calcification of the implant capsule may interfere with tumour detection in women with breast implants. In the view of a leading expert in the use of mammography in women with breast implants, calcifications may occur within the fibrous capsule surrounding the implant but do not compromise the mammographic study. Such calcifications are generally not characteristic of, or likely to be confused with, calcifications associated with malignancies. There are no published reports that document any actual occurrences of missed or delayed diagnoses attributable to capsule calcification.

K. Biological Effects of Silica

Fumed silica is a distinct form of amorphous silica that is used to strengthen the elastomer shells of both silicone gel-filled and saline-filled breast implants. As a consequence of its different physical structure, the biological activity of amorphous silica is significantly less than that of the crystalline forms. For example, while it is well documented that inhalation of crystalline silica causes Silicosis, this toxicological effect has not been observed following inhalation of amorphous compounds. Although there is limited literature on the toxicity of fumed silica following implantation or subcutaneous administration, the available data indicate a low degree of toxicity. Indeed, amorphous silica has a long history of safe use in both food and drugs. The data also show that amorphous silica is tightly bound in the elastomer shell, is not released from the mammary envelope surface, and is not converted to crystalline silica under physiological conditions.

L. Silicone in Breast Milk

Although the issue of silicone transfer into breast milk of women with silicone gel-filled or saline-filled breast prostheses was not raised by the U.S. Food and Drug Administration in the 515(b) Rules for these devices, there has been a great deal of speculation recently on this issue. Two recently published papers discussed the cases of several children of women with silicone breast implants that have developed symptoms such as arthralgias and abdominal pain. Neither of the papers presents data demonstrating the presence of silicone in breast milk nor any definitive link between the reported symptoms and the presence of silicone breast implants in the mothers. Unpublished data indicate that background levels of silicone are in fact detectable in breast milk from both mothers with and without silicone breast prostheses. Approved over-the-counter medications for infants also contain silicone. Therefore, based upon the current data, silicone in breast milk should not be considered an issue relevant to the safety of silicone breast implants.

MEDICATIONS TO AVOID PRIOR TO SURGERY

There are several drugs which are very important to avoid prior to your operation. These drugs affect the ability of your blood to clot and thus increase the risk of bleeding during and after your operation.

Please make sure that you check this list carefully and avoid the following medications for 10 days prior to your surgery.

Warfarin and Related

Coumadin, Coumidin, Dindevan, Elmiron, Fragmin, Heparin, Marevan, Orgaran

Aspirin containing medications

Alka-Seltzer, Asasantin SR, Aspalgin, Aspro Clear Extra Strength, Aspro Preparations, Astrix 100, Astrix tablets, Bayer Aspirin Extra Strength, Cardiprin 100, Cartia, Codiphen, Codis, Codox, Codral Forte, DBL Aspirin, Disprin, Disprin Forte, Ecotrin, Solprin and Veganin

Clopidogrel containing medications

Plavix
Iscover

Non-steroidal anti-inflammatory medications

Aclin (sulindac)
Advil (ibuprofen)
Aleve (naproxen)
Anaprox (Anaprox)
Arthrexin (indomethacin)
Arthrotec (diclofenac)
Brufen (ibuprofen)
Bugesic (ibuprofen)
Butalgin (ibuprofen)
Crysanal (naproxen)
Diclofenac (diclofenac)
Diclohexal (diclofenac)
Dinac (diclofenac)
Eazydayz (naproxen)
Feldene (piroxicam)
Fenac (diclofenac)
Indocid (indomethacin)
Inza (naproxen)
Iprofen (ibuprofen)
Naprogesic (naproxen)
Naprosyn (naproxen)
Nurofen (ibuprofen)
Nurolast (naproxen) Orudis (ketoprofen)
Oruvail (ketoprofen)
Panafen (ibuprofen)
Ponstan (mefenamic acid)
ProVen (ibuprofen)
Proxen SR (naproxen)
Rafen (ibuprofen)
Surgam (tiaprofenic acid)
Toradol (ketorolac)
Tri-Profen (ibuprofen)
Viclofen (diclofenac)
Voltaren (diclofenac)
Voltfast (diclofenac)

Herbal and natural preparations

Garlic tablets
Ginger
Gingko
Ginseng
St. John's Wort
Fish Oil

Smoking and Surgery

Q: Why should I quit smoking before I have surgery?

A: By quitting smoking, you will not only reduce the likelihood of experiencing surgery-related complications, but also improve your overall health and even add years to your life. The benefits of quitting smoking include:

- Adding six to eight years to your life.
- Reducing your risk of lung cancer and heart disease.
- Saving an average of $1,400 each year.
- Reducing your loved ones' exposure to second-hand smoke.

Q: What risks will I face during surgery if I do not quit smoking?

A: Smoking increases both anesthetic risks, as well as risks of complications during surgery and recovery.

Anaesthetic risks:	**Surgical and Recovery Risks**
• More coughing • Developing lung collapse • Developing pneumonia • More risk of postoperative and longterm pain	• Increased infection • Increased risk of bleeding • Poor healing • Wound splitting apart • Poor scars

Q: Why is it important to the anaesthetist that I quit smoking before surgery?

A: Anaesthetists are the heart and lung specialists in the operating room, and they are responsible for the total-body health of patients. Therefore, they directly witness the immense toll smoking takes on a person's body and must manage smoking-related complications.

Anaesthetists also witness the tremendous benefits patients experience as a result of not smoking before surgery, and are committed to helping all patients realize these advantages. It is important that your anaesthetist knows about your smoking so he or she can take precautions to reduce your risk of having problems.

Q: How long before my surgery should I quit smoking?

A: The earlier you quit, the greater your chances are of avoiding surgery-related complications. It is especially important not to smoke on the day of your surgery. Fortunately, the body begins to heal within hours of quitting. Twelve hours after a person quits, his or her heart and lungs already begin to function better as nicotine and carbon monoxide levels drop. It takes less than a day for blood flow to improve, which reduces the likelihood of post-operative complications. **We recommend patients abstain from smoking at least 3 weeks before and after surgery**, but even quitting for a brief period is still beneficial.

Q: Is it worth quitting if I decide to do so right before surgery, such as the day before the procedure?

A: Quitting right before your operation may make you cough more, potentially increasing your risk of post-operative bleeding. Therefore, you are best quitting well before your surgery. If you decide to quit smoking the morning of surgery, it can still reduce the rate of some other surgical complications such as infection and poor wound healing.

Q: If my surgery is minimally invasive, do I still need to quit smoking?

A: Smoking will impact your body before and after surgery regardless of the type of procedure you have. We recommend that all surgical patients abstain from smoking for as long as possible before and after surgery.

Q: Before surgery, should I also quit smoking additional substances such as marijuana?

A: It is critical that patients quit smoking all substances before surgery, including marijuana. They can have the same detrimental effects on surgery as nicotine. For example, they can make patients more or less susceptible to anesthetics. The carbon monoxide found in any kind of smoke affects blood pressure, making it more difficult for the blood to carry oxygen.

Please note: Do not be afraid to tell your anaesthetist or your surgeon if you have been smoking or using other substances before surgery. This information will remain confidential and is important to your care.

Q: How long should I wait after surgery before smoking again?

A: Continuing to smoke after surgery greatly heightens a person's risks of complications, such as infections in the surgical incision. In one study, more than half of patients who continued smoking after surgery developed complications, compared with less than 20 percent of those who quit. Fewer complications means less time in the hospital and a quicker recovery. **We recommend you do not smoke at all during the first 3 weeks after your procedure.**

Q: What is the best way to quit smoking?

A: When confronted with surgery, many patients decide to take stock of their lives and change their behaviors. This defining moment is a great opportunity to commit to quitting, as it will have a significant impact on your quality of life for years to come.