

Breast Implants

Information for women considering breast implants

This publication is for all women who are considering having breast implants. It summarises the issues in breast implant surgery and includes questions to ask in order to enable you to make an informed choice about breast implants, based on independent advice, before agreeing to surgery.

The information in this publication was prepared for the Department of Health by women who have had breast implants, health professionals, and representatives of interested organisations. The content is based on the recommendations of the report of the Silicone Gel Breast Implants Independent Review Group (IRG) published in July 1998. The IRG Report, which is evidence based, reflects current scientific knowledge about breast implants.

The Medicines and Healthcare products Regulatory Agency (MHRA), part of the Department of Health, has produced this revised version of the original booklet.

Since April 2004, independent healthcare providers have been regulated by the Healthcare Commission (the Commission for Health Audit and Inspection). They are required to meet national minimum standards that ensure the quality of care provided reaches a recognised standard. If you wish to find out more about the independent hospital in which you are considering having your operation, you should contact the regional office of the Healthcare Commission that is in your area. Contact details can be found in section 10.

This publication is relevant to anyone considering breast implants for any reason. It refers to women because they make up the great majority of people having breast implants.

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1 What are the reasons for having breast implants?

It is important to be clear about your reasons for having breast implants. Breast enlargement is the most common cosmetic surgical procedure performed on women in the United Kingdom. Women may seek breast enlargement because they:

- are dissatisfied with the size and shape of their breasts
- have a congenital absence or deformity of one or both breasts
- wish to regain breast shape or size, for example, after having children
- wish to correct uneven breasts (asymmetry).

Breast implants can bring psychological benefits for women who may feel that their breasts are unwomanly and inadequate. They can help restore lost self-esteem and improve the quality of life. However, you should think carefully about your reasons for having implants and be sure that breast implants are the best solution. Your surgeon will wish to

explore with you the psychological aspects of having breast implants.

Breast reconstruction

Women who consider having breast implants as part of breast reconstruction following mastectomy will find the principles discussed in this leaflet of value. They are, however, also advised to seek specialist advice and information from their surgeon and breast care nurse as the procedures and possible complications are different.

Ask yourself:

- why do I want breast implants?
- what do I expect of breast implant surgery?
- am I prepared for long-term follow up and possible future surgery and expense?

2 Are breast implants an appropriate choice?

Breast implants may not achieve what you hope for and you should make sure that your surgeon discusses all the options with you.

You should have realistic expectations and you should not expect perfection. Your surgeon must take into account your existing breasts, the position of your nipples, your age, skin texture, healing properties and your general health. These will affect the results of your surgery.

The appearance of droopy breasts, for example, may be improved by implants.

Occasionally, however, droopy and heavy breasts may have a worse appearance following implants.

Women with large breasts may wish to consider the alternative option of an operation to tighten the skin of the breasts, known as mastopexy, with or without implants.

Make sure that you have access to appropriate advice and that you are not responding to external pressures to have breast implants. It is important to make your own informed decision and to weigh up the risks of breast implant

surgery. You should also remember that any operation carries a risk and you may wish to consider non-surgical options.

You should be aware that breast implants do not come with a lifetime guarantee. They are likely to need

replacing in the future, with further surgery and expense.

Detailed information about breast implants as part of breast reconstruction can be obtained from your breast surgeon and breast care nurse.

3 What types of breast implants are available?

Several types of breast implants are available.

Natural tissue

The use of body tissue is rarely an appropriate solution for breast enlargement carried out for cosmetic reasons. While it is possible to move areas of body tissue, this is a complicated procedure which is seldom used for purely cosmetic purposes. Injection of fat does not result in a satisfactory increase in breast volume. Body tissue is, however, commonly used in breast reconstruction.

Synthetic implants

All synthetic breast implants are surrounded by a firm elastic (silicone elastomer) shell. The surfaces of the implants may be smooth or textured.

At the time of preparing this information, there are two types of implant filler available in the UK: silicone gel (semi-liquid or cohesive) and saline.

Note: soya bean oil-filled (Trilucent) implants are no longer available and in June 2000, the MDA (now the MHRA) advised women with these implants to have them removed.

Hydrogel/PIP implants are also no longer available in the UK. The MHRA is continuing to monitor their safety but does not recommend their removal unless problems are experienced.

The shell of some silicone gel implants is coated with polyurethane foam that breaks down over time. Polyurethane coated implants were reintroduced in the UK in April 2005. The MHRA has informed the surgery professional bodies of the risks and claimed benefits. Letter and patient information sheet are available on the MHRA website www.mhra.gov.uk/mhra/BreastImplants

Note: The shell of some other implants can be coated with titanium. These titanium coated implants are not currently available for sale in the UK.

The table on the next page summarises briefly the advantages and disadvantages of silicone gel and saline filled breast implants.

Ensure that you obtain full information about the different types of implants when you discuss your particular situation with the surgeon. Manufacturers also provide information about their products which can be obtained from your surgeon.

A brief summary of breast implant fillers currently available in the UK

All breast implants are surrounded by a firm, elastic (silicone elastomer) shell.

Type of filler	Description of implant	Advantages	Disadvantages
Silicone gel	<p>Filled with a soft or firm silicone substance.</p> <p>Firm or cohesive gel implants contain a more solid, jelly-like gel which will keep its shape if the shell ruptures. Soft implants are filled with a more fluid-like gel.</p>	<p>Long history of use</p> <p>The soft silicone filler is the softest implant available. It is less prone to wrinkling and feels more natural than other implants.</p> <p>Available in either round or anatomical (breast shaped) designs.</p> <p>The 1998 IRG found no evidence that silicone implants pose a danger to women's health.</p>	<p>Insertion of firm cohesive gel may result in a slightly larger scar than surgery using an implant with a soft silicone filler.</p>
Saline	<p>Filled with a salt and water solution of similar concentration to that found in body tissue.</p> <p>May be pre-filled or filled through a valve at the time of surgery.</p>	<p>Long history of use.</p> <p>Available in either round or anatomical (breast shaped) designs.</p> <p>Filled with a solution which can be absorbed and excreted by the body.</p>	<p>May be more prone to rupture or deflation at an earlier stage than other implants.</p> <p>Prone to wrinkling, may feel and look less natural than other implants and may lose volume over a period of time. Less satisfactory in women with little breast tissue.</p>

4 Finding out about the operation

The consultation

It is advisable to be referred to a surgeon by your general practitioner (GP) because your GP will have an overview of your health. You may wish to seek more than one opinion.

Make sure that you obtain as much information as necessary to enable you to make a fully informed choice about your operation. Obtain answers to all of your questions and use the checklist at the end of this publication to cover your own particular circumstances.

You may wish to take notes, take someone with you or, possibly, tape record the discussion with the surgeon so that you can listen to it again. This is quite acceptable and is indeed encouraged in many clinical situations.

The surgeon will wish to write to your GP giving details of the operation so that if there are any problems associated with surgery in the short- or long-term, the GP is aware of the surgery.

About the operation

You will have the opportunity to discuss detailed aspects of the operation with your surgeon. A number of issues are included in the checklist at the end of this publication, for example, the position of the incision and placing of the implant.

The operation is usually performed under general anaesthetic. It may be carried out as day surgery or you may need to stay in hospital.

The checklist at the end of this publication suggests detailed questions about the operation that you may wish to ask.

Performance of implants

It is essential for healthcare professionals and manufacturers to have information about the clinical performance of implants to be able to assess their safety. To achieve this, the MHRA, a part of the Department of Health, analyses reports of suspected problems with medical devices.

Clinicians and/or patients are urged to report any breast implant related adverse incidents to the MHRA's Adverse Incident Centre (telephone 020 7084 3080, or fax 020 7084 3109, or e-mail aic@mhra.gsi.gov.uk, or online at www.mhra.gov.uk, or by writing to the address given in section 10).

5 What are the consequences and potential risks?

It is important to be aware of some of the short-term effects of breast implant surgery and the longer-term potential risks.

Some short-term effects

- You are likely to have swelling at first, with hardness and discomfort. Bruising, twinges and pains may continue for the first few weeks, although any symptoms that are causing concern, or cannot be explained, should be reported immediately to your surgeon or GP.

Warning symptoms include: excessive swelling, deflated breast, offensive wound discharge, excessive pain or heat in breasts.

- Changes in breast sensation are common; most are temporary, some are permanent.
- It can take several months for breasts to look more natural.
- As with any surgical operation, you may need to take some time off.

Potential risks

Capsular contracture

The human body puts a wall of scar tissue (fibrous capsule) around any implanted foreign material and breast implants are no exception. Scar tissue shrinks, but the extent of the shrinkage varies from person to person and even from breast to breast. This shrinkage, or capsular contracture, is noticeable as an apparent hardening of the breast.

Capsular contracture is the most common complication with breast implants although modern implants, which have a textured silicone shell, have a lower incidence of capsular contracture. Capsular contracture is also the most common reason for further surgery.

Recent evidence in the UK suggests that in approximately 1 in 10 women who have had breast implants, the fibrous capsules can contract causing the implant to deform, become hard and, in some cases, painful. The implant may have to be removed along with the capsule and replaced, if appropriate, with another implant.

Rupture rates and life expectancy of implants

Rupture means the development of a split or hole in the silicone shell of a breast implant. Rupture was common with early, thin-walled implants. There is little information on the overall rupture rate of breast implants although modern implants, available in the UK since the early 1990s, appear to rupture less. Their life expectancy is, as yet, unknown.

It is difficult to establish the rate of rupture because imaging techniques can fail to detect ruptures or can incorrectly identify intact implants as ruptured.

Rupture does not necessarily create a medical problem; different fillers will react differently. In the majority of cases of silicone gel filled implants, the silicone gel will remain within the capsule that the body forms and can be removed if the ruptured implant is removed.

Occasionally, the silicone can spread outside the capsule into the breast and create a series of lumps known as siliconomas. These may give rise to local symptoms such as tenderness. In a small number of cases the gel has been found in the breast tissue, the muscles under the breast, the armpit or (rarely) around the nerves to the arm. Breast tissue may be lost when the implants are removed.

If any symptoms such as excessive pain, burning sensation, lumps or aching occur and cause concern, it is advisable to contact your surgeon or GP.

Scarring

The scars resulting from the insertion of breast implants are normally satisfactory. However, in a small number of women, (up to 1 in 20) as with any surgical procedure, scars will be red, or highly coloured, thick, painful and will take several years before they improve.

Appearance of the implanted breasts

The position of the breast may be unsatisfactory as a result of the implant and the shape of the breast tissue may be unpredictable. It may not always be possible to produce a natural cleavage and the implant may not drop to the side when the woman lies down. The breast will feel relatively firm but for most women the implant will approximate to the normal feel of the breast.

The silicone controversy

A number of women have reported serious illness following silicone gel breast implant surgery. This has been said to relate mainly to silicone gel leakage and possible migration to other parts of the body. Stated symptoms include: muscle spasm and pain; swollen and painful joints; rashes; changed eye and saliva fluid; hair loss.

The Independent Review Group (IRG) set up by The Department of Health to review the safety of silicone gel filled breast implants published its report in 1998 (copies can be obtained from their website at www.silicone-review.gov.uk or by calling 020 7084 3077). More detailed information can be found on the IRG website. The IRG found no scientific relationship between silicone gel implants and immune reactions.

No relationship was shown between silicone gel implants and long-term systemic illness (affecting the whole body), nor with specific connective tissue disease or non-specific systemic illness.

The MHRA takes the safety of all breast implants seriously and will continue to evaluate carefully any new scientific evidence. Should the conclusions formerly reached about breast implants change in the light of this continuing evaluation, then further advice will be communicated to the public.

Implanted breast size

A specific size of implant does not necessarily equate to a certain cup size increase. Augmentation can magnify small differences in breasts, and these may become more obvious after surgery.

Creasing and folds

The nature of the implant capsule may enhance less desirable characteristics such as creasing, kinking, vertical ripple folds and rippling in the breast. These are seen most frequently in women with very little breast tissue.

Nipple sensation

As a result of the surgery to insert the implants under the breast, there may be a loss of or diminished nipple sensation in approximately 1 in 7 women. Nipple sensation may be increased for a period of 3 to 6 months following surgery and this may be painful.

Infection, bleeding and fluid collection

Infection of cosmetic breast implants is rare, as is bleeding surrounding the implant. Infection and bleeding may, however, be more frequent after surgery for breast reconstruction following mastectomy and may indeed delay further medical management. On the rare occasion where infection occurs, the breast implant may have to be removed.

In a very small number of women, fluid builds up around the implant (this is known as seroma). Additional surgery may be needed to remove this fluid.

6 General issues – other questions you may have

Pregnancy and breast feeding

Implants do not interfere with the ability to breast feed. There is some evidence which suggests that the amount of milk produced by some women with breast implants is reduced. Reduction in milk production may also occur if the implants are inserted into the periareolar area, as this technique tends to cut the milk ducts. There is no evidence of an increase of illness in children of women with silicone gel breast implants.

Breast cancer

There is good evidence that there is no increased risk of developing breast cancer for women who have breast implants. Indeed the risk may be less. If a woman who has breast implants develops breast cancer, scientific studies have consistently shown that the risk of cancer recurring is no greater than in women without implants, and that there is no difference in their survival.

Mammography

The presence of silicone gel-filled breast implants may interfere with standard mammography used to detect breast cancer. In addition, calcium salt deposits around implants can be seen on mammograms and may interfere with findings. However, studies indicate that breast cancer in women with implants is not diagnosed at a later stage compared with women without implants.

Women with breast implants should be sure to tell their radiographer that they have implants so that the most appropriate method of screening can be used.

Travelling

Breast implants are not subjected to strain or rupture when travelling in aircraft.

7 Breast implants are a long-term commitment

Remember that breast implants do not come with a lifetime guarantee. They are likely to need replacing with consequent further surgery and expense. A young woman who has implants may expect to have further operations in her lifetime to maintain the beneficial effects of the implants.

The length of time a breast implant lasts is unknown and may vary depending on an individual's personal factors.

Commitment to follow-up

Keep to the aftercare schedule provided by your surgeon and ensure that you attend all post-operative consultations.

Ensure that you are given and keep full details of your implants: manufacturer, style, catalogue number and batch/lot number.

Commitment to breast awareness

Women should be aware of what is normal for them about their breasts and should look and feel for any changes during everyday activities such as bathing, showering or dressing. Advice on breast checks can be obtained from your GP.

8 Consent for the operation

Consenting to the surgery should be the last stage in a thoroughly researched process, when you have asked questions and feel comfortable with the decisions you are making

When asked to sign a consent form, assure yourself that you have had the following:

- an explanation of what it means when you sign a consent form
- an opportunity to work through the questions included in the checklist at the end of this publication
- full details of the surgery and the treatment that you will be receiving when undergoing surgery and afterwards
- full details of what you are likely to experience immediately after the operation and as you recover
- full details of the most common long-term and short-term side effects of the operation itself and those which might arise from the use of implants
- advice that you have the legal right to refuse surgery, even at the last minute, if you change your mind.

9 Checklist of questions to ask

Below is a suggested checklist of some issues recommended to be discussed with the surgeon. There may be others that occur to you during the consultation process. Take the opportunity to make sure that you understand all the medical terms used. If you are considering reconstructive surgery, you will want to discuss the particular aspects of this operation.

Independent hospitals

- Contact the Healthcare Commission via telephone or website
- Inspection reports can be accessed at www.healthcarecommission.org.uk under: Service provider information – Independent healthcare (private and voluntary)- Independent healthcare providers inspection reports.

The experience of the surgeon

- How many successful breast implant operations has he/she done in the past two years?
- How many implants has he/she had complications with?
- Is he/she on the GMC Specialist Register for Plastic Surgery?

- Is he/she a member of a relevant association, e.g. the British Association of Plastic Surgeons, British Association of Aesthetic Plastic Surgeons, British Association of Surgical Oncology?

The types of implant

- Which implants are available and what are the advantages and disadvantages of each?
- Ask to see breast implants before the operation.

Size

- What size do you wish to be?
- Be sure to discuss the differences between cup size and implant size.

Cosmetic effects of the operation

- What will be the position of the implants, the position of the scar and the appearance of the scar?
- What are the advantages and disadvantages of the different positions for the incision, through the armpit, (axilla), surrounding the nipple (periareolar), or under the breast (sub-mammary)?
- What are the advantages and disadvantages of placing the implant above or under the muscle?

The operation

- Will a general or local anaesthetic be used?
- What is the competence of the anaesthetist? Is it someone the surgeon has worked with regularly?
- How long does the surgery take?
- What are the side effects of the operation, e.g. bruising?
- What kind of response can I expect in the event of an emergency situation?
- Will surgical drains be necessary?
- Will it be necessary to take medication after surgery, to alleviate pain?
- How long is the recovery period?
- How long should I be off work?
- Is there a properly equipped recovery unit?
- Is it unsafe to have breast implants whilst suffering from an illness?
- How long will the stay in hospital be?
- When can I drive, lift heavy objects?

Immediate post-operative effects

- Will there be any bruising, pain, swelling, bleeding or infection?
- Will the nipples be sensitive or not?
- What is the likely recovery time?

Longer term, local effects

- Will there be any wrinkles; capsule formation; or bleed from the implant?
- Will nipple sensation be affected?
- What is the incidence of rupture?
- How is screening for rupture carried out?
- What does it mean if rupture occurs?
- What symptoms may be noted if rupture occurs?
- What actions need to be taken under these circumstances?
- What is capsular contracture?
- Does this always occur and is it painful?
- Does it require further surgery?

Follow-up

- How long is the follow-up?
- Is follow-up at your own request or on development of certain symptoms?
- How can rupture, leakage or any other complication be detected?
- Is the filler retrievable in the case of leakage or rupture?
- Is appropriate screening for leakage or rupture available and who will pay the costs?
- When a breast implant is removed, will there be breast tissue loss?
- Are guidelines or protocols (such as the Clinical Practice Guidelines for Breast Implant Surgery) produced by a reputable/recognised professional body followed?
- Will chemotherapy or radiation therapy affect breast implants?

Financial implications

- What are the financial implications?
- What are the costs of the initial consultation; follow-up; possible screening for rupture and possible removal of the implants and re-implantation?

- If corrective surgery is necessary, or if an implant fails, will there be further costs?

Breast screening

- What kind of breast screening is considered the most appropriate for women with breast implants?
- Is mammography suitable for women with breast implants?
- Will breast screening unit staff be familiar with procedures and techniques required for breast implant imaging?
- Will a breast implant impair the ability to view any changes which may indicate breast cancer?

Breast feeding

- Do breast implants interfere with breast feeding?
- Are there any effects on the children of women with breast implants?

If things go wrong

- What measures are available if things go wrong?
- What is the hospital's complaints process?
- If I am not satisfied can I go to another organisation?
- How do I report problems with my implants?

10 Sources of further information

You may wish to access further information.

The following may be useful:

NHS Direct : Telephone 0845 4647 www.nhsdirect.nhs.uk

They can provide consumer health information on specific conditions and treatments, local NHS services, national and local self-help, support and advice groups and information.

Report of the Independent Review Group, 'Silicone Gel Breast Implants' available from their website www.silicone-review.gov.uk or from:

Medicines and Healthcare products Regulatory Agency (MHRA)

4/1 C02 Market Towers

1 Nine Elms Lane

London

SW8 5NQ

Tel: 020 7084 3077

Fax: 020 7084 3124 www.mhra.gov.uk

Healthcare Commission

Details of area offices are in the yellow pages, or contact the Healthcare Commission,

Finsbury Tower

103-105 Bunhill Row

London

EC1Y 8TG

Tel: 020 7448 9200 www.healthcarecommission.org.uk

Professional associations:**British Association of Aesthetic Plastic Surgeons (BAAPS)**

Royal College of Surgeons
35-43 Lincoln's Inn Fields
London WC2A 3PE
www.baaps.org.uk

British Association of Plastic, Reconstructive and Aesthetic Surgeons (BAPRAS)

Royal College of Surgeons
35-43 Lincoln's Inn Fields
London WC2A 3PE
www.bapras.co.uk

British Association of Surgical Oncology (BASO)

Association for Breast Surgery
Royal College of Surgeons
35-43 Lincoln's Inn Fields
London WC2A 3PE
www.baso.org.uk

General Medical Council

Regent's Place
350 Euston Road
London NW1 3JN
www.gmc-uk.org

RCN Breast Care

Nurse Forum
Royal College of Nursing
20 Cavendish Square
London W1G 0RN
www.rcn.org.uk

Consumer interest groups:**Breast Cancer Care**

Kiln House
210 New Kings Road
London SW6 4NZ
Tel: 020 7384 2984
www.breastcancercare.org.uk

CancerBACUP

3 Bath Place, Rivington Street
London EC2A 3DR
Tel: 020 7696 9003
www.cancerbacup.org.uk

Consumers' Association

2 Marylebone Road
London NW1 4DF
Tel: 020 7770 7000
www.which.net

Patients' Association

PO Box 935
Harrow
Middlesex HA1 3YJ
Helpline: 0845 608 4455
www.patients-association.org.uk

Support groups:**Breast Implant Information Society (BIIS)**

Highway Farm
Horsley Road, Cobham
Surrey KT11 3JZ
Tel: 07041 471225
E-mail: info@biis.org
www.biis.org

Silicone Support UK

9 Casimir Road
Clapton
London E5 9NU
Tel: 020 8806 6923
E-mail: Christinewilliamson@compuserve.com