The British Association of Aesthetic Plastic Surgeons

BAPRAS British Association of Plastic Reconstructive and Aesthetic Surgeons

Patient consent form for breast augmentation (enlargement) surgery

Part 2 of 3

This is an 'informed consent document'. It explains the risks of and alternatives to breast augmentation surgery. **It is important that you read this information carefully and completely. Please initial each page** to show that you have read it. Also sign the consent form at the end of this part 2 for the surgery you have agreed to. For more information on breast augmentation surgery, see part 1. For information on care after breast augmentation surgery, please see part 3.

What is breast augmentation surgery?

Breast augmentation surgery is an operation to enlarge the breasts, usually by inserting an implant beneath the breast tissue.

What is the alternative treatment?

A simple alternative to breast augmentation is to wear padded bras. The only alternative surgical technique to enlarge the breast is lipofilling. This is where fat removed by liposuction from another part of the body (such as the hips or thighs) is injected into the breast area. Because only a relatively small amount of fat can be injected at a time, and some of the fat is reabsorbed into the body, you would need several injections to get a permanent enlargement.

Your own fat is the only substance that can be safely injected into the breast. Other materials have been tried, and then banned. Do not allow anyone to inject anything other than your own fat into your breasts.

What are the main risks and complications of breast augmentation surgery?

As with all operations, there are risks involved in breast augmentation surgery. Although the risks are unlikely, it is important to weigh them up against the potential benefit of the surgery. Discuss each of them with your plastic surgeon to make sure you understand the potential complications and consequences.

Complications associated with the surgery

Please bring this document with you on the day of surgery.
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- **Scars**
  There will be scars from the surgery. These will usually be red at first, then purple, and then fade to become paler over 12 to 18 months. Occasionally, scars may become wider, thicker, red or painful and you may need to have surgery to correct them.

- **Bleeding**
  Bleeding around the implant (haematoma) is unusual but possible, and you may need another operation to stop the bleeding. Bleeding usually happens immediately after, or soon after, surgery. Before the surgery your surgeon will discuss any medicines that increase your risk of bleeding, and it is important to control high blood pressure.

- **Seroma**
  This is where fluid collects within the breast cavity. It may need to be drained by having a needle through the skin, or by having another operation, and can affect the final result.

- **Infection**
  If you get an infection of the wound or around the implant you may need antibiotics or another operation to remove the implant. It is normal to wait at least three to six months for the infection to clear before a new implant is inserted.

- **Extrusion**
  This is where deep stitches poke out through the skin. These can easily be removed.

- **Swelling, bruising and pain**
  There will be some swelling and bruising of the breasts after the operation, and this can take weeks to settle. There may be long-term pain, but this is uncommon.

- **Asymmetry**
  This is where the breasts are not symmetrical.

- **Increased or reduced sensation**
  After the surgery, most patients will get some alteration in the sensation in their breasts, most commonly numbness near the scar and oversensitivity of the nipples. Loss of sensation to the nipple, though rare, may be permanent. Rarely, the loss of or increase in sensation can affect breastfeeding.

- **Damage to deeper structures**
  Although rare, the surgery can damage deeper structures, including nerves, blood vessels, muscles and lungs. This damage may be temporary or permanent.

- **Unsatisfactory result**
  Sometimes, patients are not satisfied with the result of their breast augmentation surgery. This may be to do with the look or feel of the breasts, or the breast shape not meeting expectations. It

is very important that you talk to your surgeon, before you have the surgery, about the size and shape you want, and whether this can be safely achieved with a good outcome.

- **Change over time**
  The appearance of the breast will change as a result of aging, pregnancy or other circumstances not related to your surgery, such as putting on or losing weight. You may need further surgery or other treatments to maintain the results of the breast augmentation.

  Many patients choose breast augmentation because they feel the skin on the breast is loose or saggy, and they want the implant to fill the skin out. You should bear in mind that large implants are heavier and the weight of them can make the breast droopy in the future, and so you may need a further operation. Sometimes, having a breast uplift would be preferable to using an overly large implant.

- **Allergic reaction**
  Rarely, local allergies to tape, stitches or solutions have been reported. If you have an allergic reaction you may need extra treatment.

Complications associated with the implant

- **Capsular contracture**
  It is normal for a scar or capsule to form around the implant. This usually feels soft and looks natural. In about 10% of patients, the scar contracts around the implant and feels firm. If this happens, the breasts can feel tender and look abnormal, and you may need an operation to replace the implant. After 10 years, about 10 to 30% of women will have had another operation, and painful or unsightly capsular contracture is the most common reason for this.

- **Noticable implants**
  Slim patients may be able to see or feel the edges of the implant. With time, ripples or folds may be noticeable. Very occasionally, teardrop implants can rotate behind the breast. These can usually be pushed back into position gently, but if the problem is persistent, an operation may be needed.

- **Implant failure**
  Occasionally implants can leak. This can be as a result of their age, an injury or a tight capsule. Normally the leak is contained within the capsule and does not cause a problem. If the size, shape or consistency of the breast changes as a result, a further operation may be needed to replace the implant.

- **Breast droop**
  The breast may droop over time due to the weight of the implant.

Risks of anaesthetic

- **Allergic reactions**
  You could have an allergic reaction to the anaesthetic.

- **Chest infection**
  There is a small risk of chest infection. The risk is higher if you smoke.

- **Blood clots**
  Blood clots can form in the leg (called a deep vein thrombosis or 'DVT'). These cause pain and swelling and need to be treated with blood-thinning medication. In rare cases, part of the clot breaks off and goes to the lungs (called a pulmonary embolus or 'PE'). The risk of this is higher if you smoke, are overweight or are taking the contraceptive pill.

- **Heart attack or stroke**
  A heart attack or stroke could be caused by the strain surgery places on the heart. You will be assessed for the risk of this before your surgery.

- **Death**
  As with all surgery, it is possible to die as a result of the operation.

Further information

Breast implants do not make it any more difficult for you to check your breasts for lumps. However, they do interfere with mammograms (X-rays of the breast to look for signs of breast cancer). Mammograms are used as a screening test in the UK from the age of 50 years. If you are called for a mammogram, you need to tell the mammography service you have breast implants. They may scan you at a different centre and take special views. The more of your total breast volume that consists of implant, the greater the problem with mammography. Sometimes a different kind of scan (such as an MRI) is preferred for patients with breast implants. You can discuss this with your surgeon.

Breast augmentation does not usually interfere with breastfeeding, and there is no evidence that any silicone is found in breast milk.

Most implants will need replacing at some point, usually after 10 years. For this reason, you should be prepared, personally and financially, to have surgery again at some point in the future. However, it is not recommended to have implants replaced routinely.

Further risks specific to you or the procedure

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Your initials ……..

It is important that you have all of your questions answered before signing the consent form on the next page.

You can change your mind at any time, even after you have signed the consent form.

Disclaimer
this document is designed to give you useful information. It is not advice on your specific needs and circumstances. It does not replace the need for you to have a thorough consultation, so you should get advice from a suitably qualified medical practitioner. We – The BAAPS and BAPRAS – have no liability for any decision you make about the surgery you decide to have.

Date of review: **August 2021** (produced August 2016)

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Your initials ……..

Patient consent form – breast augmentation

(Affix identification label here)

Name:
Address:

Date of birth:

Hospital number:

NHS number:
Sex: Male [] Female []

Side of procedure: Left side [] Right side [] Both sides []

Further procedures that may become necessary:

……
Type of anaesthetic to be used:
General [] Regional [] Local [] Sedation only []

Consultant's name:

Has the procedure, alternative procedures and treatments and all associated risks (as well as any risks of not having this procedure) been explained to you? Yes [] No []

Have you been able to ask questions and raise concerns with the doctor? Yes [] No []

Have any questions you had been answered to your satisfaction? Yes [] No []

Do you understand the risks of the procedure and those specific to you (including scars, bleeding, infection, swelling, pain, capsular contracture, noticeable implants, implant failure, extrusion of stitches, change in sensation, asymmetry, damage to other structures, unsatisfactory result, change over time, need for a future procedure)? Yes [] No []

Do you understand the risks of the anaesthetic and those specific to you (including allergic reaction, chest infection, DVT, PE, heart attack, stroke, death)? Yes [] No []

Do you agree to the following?

- Receiving a blood transfusion, if necessary, during or after the procedure Yes [] No []
- Tissue taken from you being used for research Yes [] No []

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Your initials ……..

- Photos being taken for diagnosis and treatment Yes [] No []
- Anonymous photos being used for teaching Yes [] No []
- Medical students being in the theatre for the purposes of learning Yes [] No []

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Your initials ……..

Do you want to go ahead with the procedure? Yes [] No []

Patient's signature:…… Date:……
Patient's name (in block capitals):……

Surgeon
Sign below to confirm that you have explained the information in this document to the patient and you believe that they understand it.
Doctor's signature:…… Date:……
Doctor's name (in block capitals):……
Phone number:……
Job title:……

Anaesthetist
Sign below to confirm that you have explained the information in this document to the patient and you believe that they understand it.
Anaesthetist's signature: …… Date:……
Anaesthetist's name (in block capitals):……
Phone number:……
Job title:……

Interpreter
Sign below to confirm that you have explained the information in this document to the patient and you believe that they understand it.
Interpreter's signature:…… Date:……
Interpreter's name (in block capitals):……

Doctor's confirmation of consent (to be signed on the day of surgery if this form was signed before then)
Sign below to confirm that you have made sure that the patient has no further questions and that they would still like to go ahead with the procedure.
Doctor's signature:…… Date:……
Doctor's name (in block capitals):……
Phone number:……
Job title:……

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Your initials ……..

BAAPS

Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) – what we know and what we don't know

What is BIA-ALCL?
This is a rare type of lymphoma that affects women with breast implants. It is not a cancer of the breast itself but can form on the capsule that surrounds a breast implant. In 2016 the WHO provisionally classified BIA-ALCL as a novel type of lymphoma.

How common is BIA-ALCL?
We do not know the exact incidence but it is thought to be around 1:20,000 to 1:60,000. For comparison the general incidence of breast cancer in the UK is 1 in 9 and affects women with and without breast implants equally. Cases of BIA-ALCL have occurred between 2-28 years after breast implant insertion with the average time being 8 years. Up to 2018 there were 414 reported cases of BIA-ALCL and 16 confirmed deaths worldwide from BIA-ALCL. In the UK, the Medicines and Healthcare products Regulatory Agency (MHRA) collect all the data regarding suspected cases and publish regular updates, the latest of which can be linked here.

What causes BIA-ALCL?
We do not know, but it is thought to be associated with the coating around some breast implants. Most of the cases worldwide have occurred in women with textured breast implants with a higher incidence seen in women with implants that have a coarser texture than those with a finer texture.

Not all textured surfaces are manufactured in the same way and they appear to convey different levels of risk, hence it is difficult to draw definite conclusions at this time. Texturing of an implant surface also offers advantages, particularly with more anatomically shaped implants. Hence many surgeons in the UK still advocate the use of textured implants for their patients. It is vital however, that the risks of using textured or smooth surfaced implants are fully discussed with all patients prior to surgery so that patients are able to make informed choices.

Several different companies manufacture breast implants for both aesthetic and reconstructive use. These implants can have different types of texturing on their surface and some research has indicated that BIA-ALCL might be related to a particular type of texturing or manufacturing processes. One major company, Allergan, produces implants known as Natrelle® with a surface called Biocell®. These implants have been available Worldwide but only under licence. In Europe this licence is known as a CE mark.

Are there some types of implant that are not associated with BIA-ALCL?
BIA-ALCL is a rare condition so there are certain implants which the manufacturers say haven't been associated with BIA-ALCL but the condition is too rare to say this

for certain. It does appear that smooth implants have a lower risk of BIA-ALCL compared to textured implants.

Why don't all plastic surgeons use smooth implants then?
Plastic surgeons are trained to use the full range of implants and there are significant advantages and disadvantages of both textured and smooth implants – BAAPS recommends you have a frank discussion about implant choice with your surgeon during your consultation to ensure you are fully informed about both implant types.

I have textured implants – should I be worried?
Whilst there exists some differences around the World regarding the availability and current use of some textured implants, there is no recommendation that patients with textured implants should have them removed as a precautionary measure.

The British Association of Aesthetic Plastic Surgeons (BAAPS) advises that concerned patients need not take any action currently. They should continue their routine follow up with their healthcare professional and discuss any questions they have about their breast implants. There is no need to remove or exchange any current implants based on the most up-to-date scientific data available. Indeed, unnecessary surgery may cause additional harm in a small number of patients.

How will patients know they have BIA-ALCL?
Any onset of swelling, pain, increase in size in the breast over days or weeks should be investigated for BIA-ALCL. There are however, many causes for breast swelling which are not BIA-ALCL.

Is there any screening test for BIA-ALCL?
Currently there is no screening test but if patients with breast implants have any symptoms of swelling, lumps or pain they should seek urgent advice from their implanting surgeon or a BAAPS member plastic surgeon.

How is BIA-ALCL investigated?
This involves an ultrasound scan or MRI to look at the swelling, then a needle is used to take a sample of the fluid which is tested in the pathology laboratory to see if there any cells present showing markers for lymphoma.

How is BIA-ALCL treated?
This is treated by complete *en-bloc* surgical excision of the implant with surrounding capsule and involved local tissues. If the disease is confined to the capsule then surgical removal is usually adequate, however if there is disease outside of the capsule then patients may require chemotherapy. Recent developments in treatments that manipulate a patient's own immune system appear to be very promising in gaining control of the disease, particularly if it has spread to outside of the breast.

This information sheet is produced for patients based on the most recent and accepted scientific research available – June 2019.

BAAPS

Breast Implant Illness – what we know, and what we don't know

What is Breast Implant Illness?
A small proportion of women who have breast implants (for both aesthetic and reconstructive purposes) self-identify as having a number of symptoms they believe arise from the presence of their implants. Whilst not a medical diagnosis, they refer to their symptoms as Breast Implant Illness (BII).

What are the symptoms of Breast Implant Illness?
As stated above, Breast Implant Illness is not a medical diagnosis, but rather a term developed by those who have a variety of symptoms they feel are related to their breast implants. These include tiredness, "brain fog", joint aches, immune-related symptoms, sleep disturbance, depression, hormonal issues, headaches, hair loss, chills, rash, hormonal issues and neurological issues.

Why has BII suddenly come to light?
It appears that the recent increase in patients reporting symptoms of BII is related in great part to social media. One Facebook group alone has more than 50,000 members who report symptoms of BII. This may account for the sudden increase in awareness of BII, however, BII is not an official medical diagnosis (see below).

Could these symptoms be caused by any other factors?
There are a variety of other reasons these symptoms might be found. These include other background illnesses or hormonal changes. In addition, there have been a number of scientific studies investigating similar symptoms experienced by women in the population in general.

For example, a Swedish study looking at a random sample of 4,200 women between 35-64 years old found a significant number experienced similar symptoms to those ascribed to BII, although they did not have breast implants. They concluded that the symptoms related to stress and depression.

A 20-year study on a Danish study population with breast implants regarding musculoskletal symptoms concluded that interestingly, the occurrence of mild, moderate and severe musculoskeletal symptoms was generally lower among women with implants, compared with women with other cosmetic surgery and women in the general population.

Do symptoms of BII improve when breast implants are removed?
On the whole, around 50% of women who self-identify as having BII feel that their symptoms improve after implant removal – sometimes temporarily and sometimes permanently. It therefore appears that removing breast implants does not necessarily improve symptoms in everyone. There is no research

demonstrating which symptoms may or may not improve with implant removal – with or without removing its surrounding capsule (scar tissue).

In more detail:
A study on breast implant removal from 1997 (when older, less robust implants were still in use) looked at women in whom 186 implants had been removed. Over half the implants were ruptured or leaking, and many had other issues. Therefore, in this study population, the women would theoretically have had a significant exposure to silicone from within the implants (compared with the more modern implants used today). Immune system blood tests showed no difference in levels of autoimmune antibodies between the study population and a control group of women without breast implants. The small number of women in the study group with diagnosed autoimmune conditions did not have any improvement when questioned over 2-years after implant removal. However, the majority of women reported an improvement in their psychological well-being after implant removal.

Is there medical evidence linking medical grade silicone to immune system problems or other diseases?
In short, the answer so far is no. Medical grade silicone is derived from the natural element, silica. Whilst silica has been shown to activate the immune system, silicone used in breast implants is very different, and to date has not been shown to cause any disease. Medical silicone does not exist is nature and is created to form polydimethylsiloxane. Medical grade silicone has had antioxidants, dyes, and plasticizers removed during processing.

Whilst there is no current evidence to support a direct link between breast implants and any specific disease process, it does not mean further research is not indicated. As stated below, further new research is being conducted principally in Australia and USA. It is important to recognize that in rare diseases (of any type), it can take many years to come to a scientific conclusion. In addition, there are many factors that can influence and confound the interaction of a patient and her breast implants – all of which have an impact on studying an entity such as BII.

A lack of evidence to date does not mean that the symptoms experienced by patients are not real. Therefore, as plastic surgeons, we take these symptoms seriously and are committed to supporting further investigation and research in this area.

Do tests exist for BII?
There are no tests that can show BII. However, there are a number of research studies underway, principally in Australia and the USA hoping to provide further information. In the meantime, there are tests that can be performed for autoimmune conditions. In a similar way to the population without breast implants, there are breast implant patients who have symptoms

(they attribute to BII) with positive immune testing and others where all tests show no abnormalities.

What scientific data are there that shows that breast implants actually cause the symptoms of BII or any other disease?
To date there is no demonstrable link between breast implants and any systemic illness. There have been a variety of studies designed to look at the safety of breast implants and these have also looked at specific autoimmune disorders and diseases. Overall, these studies have shown few or zero links between breast implants and any disease. These studies have not shown any consistent laboratory test abnormalities to enable a distinct syndrome to be defined or categorized.

However, as in all areas of science, “absence of evidence does not equal evidence of absence”. Therefore, further studies are on-going to investigate other possible links and symptoms in women with breast implants.

What should I do if I think I might have symptoms I identify with BII?
If you experience symptoms you feel might be related to your implants it is important you see a doctor. It is important to bear in mind that your symptoms might not be related to the implants, and that other medical investigations should not be overlooked or ignored. Therefore, you should involve your GP in the first instance to exclude any other underlying disease processes, such as autoimmune conditions, inflammatory conditions or neurological disease processes.

Should you wish for your implants to be removed, you should discuss this with your plastic surgeon. Most commonly, when patients are seeking to have their implants removed for symptoms they attribute to BII they request that their capsule is removed. This can either be done “en bloc”, referring to the whole capsule being removed containing the implant, or by other techniques. There is no evidence that “en-bloc” removal offers any benefit to the patient, and indeed this technique is more invasive and requires larger incisions. This should be borne in mind when discussing your situation with your plastic surgeon.

The “en-bloc” concept is one of the medical inaccuracies perpetuated on the internet and on social media. It is important to appreciate that sometimes it is impossible to remove the capsule without making a hole in it, even in the most experienced surgeon’s hands. Sometimes it is also not possible to remove the whole capsule, depending on how adherent it may be to the ribs, for example.

What is the risk of developing BII?
Due to the lack of official medical diagnosis, the disparate array of symptoms reported and the lack of definitive evidence, there is no “known” risk for BII. Many of the symptoms described by those identifying with BII are experienced by the general public on a regular basis, with or without implants. It is also

important to understand the other recognized risks of having breast implants – related to the surgery itself and the long-term possible effects of having breast implants.

In summary, Breast Implant Illness is a phenomenon being discussed increasingly on the internet. As no link between silicone breast implants and a specific disease has yet been identified, more research is underway. Plastic surgeons need to listen and acknowledge that their patients may be experiencing symptoms, but must also ensure a general medical work-up to investigate other causes. Any woman concerned about symptoms of BII should feel comfortable bringing this up with their plastic surgeon.

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