**Mr Michael Cadier**

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**Removal of Breast Implants (without replacement)**

Breast augmentation is one of the most popular cosmetic surgical procedures. In most cases it is associated with extremely high rates of patient satisfaction and in many patients the implants will last for many years. However, some patients require or request implant removal. This information sheet provides some guidance about this procedure and supplements the information sheet on breast augmentation.

**What are the reasons for implant removal?**

* Patient preference.
* Concerns regarding Breast Implant Illness.
* ALCL.
* Implant recall.
* Implant problems including:
	+ Rupture or significant leakage.
	+ Capsular contracture.
	+ Recurrent seroma.
	+ Breast tissue dropping off implant mound (waterfall effect).
	+ Delayed infection.

This information sheet will discuss each of these in turn and then describe the operations available for breast implant removal.

**Patient preference for further surgery**

Patient preference is one of the commonest reasons for removing implants. Some patients seek removal because of concerns regarding having foreign material in their bodies, because their breasts have got larger, following a scare or simply because they wish to go smaller.

**Concerns regarding Breast Implant Illness**

Breast Implant Illness is a condition in which women with breast implants develop a large variety of symptoms including chronic tiredness, joint pains, skin rashes and memory loss. There are up to 52 symptoms. Breast Implant Illness has only been apparent in the last few years and sufferers attribute their problems to their breast implants. The vast majority of patients feel better after implant removal.

It should be stressed however that there are no tests or investigations to confirm the diagnosis and all other causes of such symptoms should be excluded first. Patients should seek help through their GPs, and may need specialist referrals with Rheumatologists, Dermatologists and Neurologists to make sure that there is no other cause for their symptoms.

This condition is not new. In 1975, in the US, the breast implant manufacturer Dow Corning was successfully sued by women complaining of similar problems following silicone breast implant insertion. This was termed Human Adjuvant Disease. No specific cause was ever found. The US banned the use of silicone breast implants for several years whilst waiting for the results of comparison studies of women with silicone breast implants compared to women without implants. No association was found between silicone breast implants and the symptoms and the ban was reversed. All subsequent patients in the US having silicone breast implants were meant to be followed up long term, though this has not really been successful with many patients being lost to follow up.

Since that time there have been many studies but no real conclusive evidence of either Human Adjuvant Disease or Breast Implant Illness. However, there are several findings with silicone breast implants that have never been explained. When a silicone breast implant ruptures many women have no symptoms and it is picked up as an incidental finding on a breast scan or when the breast is being operated on to replace implants for other reasons (size change, capsular contracture). However, some women develop an instant reaction when their implants rupture with massive swelling and inflammatory changes. Likewise, with the scandal with PIP implants (manufactured with silicone gel meant for beds) when these ruptured the implants frequently changed colour and became surrounded with a large amount of sterile pus. These findings have never been explained but it is likely that some women react to the products within the implants differently. Implants do not just contain pure silicone but have a variety of substances (catalysts, breakdown products during the manufacturing process amongst others). The reactions will be with the immune system and many of the symptoms are reminiscent of autoimmune diseases.

Despite this the condition is not common and the vast majority of women are delighted with the result of breast augmentation with many demonstrable self-esteem and psychological benefits.

The following is the most recent statement from the UK organisations that represent aesthetic breast surgeons (BAAPS, BAPRAS and ABS):

*Another concern is whether implants can make some people ill. Breast Implant Illness (BII), or Autoimmune Syndrome Induced by Adjuvants (ASIA), is a collection of multiple symptoms, most of which are common in the general population who do not have breast implants. BII/ASIA is not a WHO recognized disease, but there is much ongoing work and an enormous amount of data being collected and analysed internationally to establish if BII is a classifiable disease or not. Our three surgical Associations are represented on the Plastic, Reconstructive and Aesthetic Surgery, Expert Advisory Group (PRASEAG), which advises the MHRA. The group also has a representative on the International Global Network Forum and ICOPLAST (International Confederation of Plastic Surgery)*

*The MHRA is also looking at the published literature on both BIA-ALCL and BII. The PRASEAG expert advisory group will review the literature to build on the knowledge already gained as part of the Independent Review Group’s (IRG’s) report, which was commissioned by the Chief Medical Officer in the 1990s. This detailed review looked at the safety of breast implants from a number of different perspectives and considered evidence from a number of sources. The IRG published its report in 1998 (*[*https://webarchive.nationalarchives.gov.uk/20110504132647/http:/www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Product-specificinformationandadvice/Product-specificinformationandadvice-A-F/Breastimplants/Siliconegelbreastimplants/IndependentReviewGroup-siliconegelbreastimplants/index.htm*](https://webarchive.nationalarchives.gov.uk/20110504132647/http%3A/www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Product-specificinformationandadvice/Product-specificinformationandadvice-A-F/Breastimplants/Siliconegelbreastimplants/IndependentReviewGroup-siliconegelbreastimplants/index.htm)*)*

*to IRG report) finding there was no evidence of a link between silicone breast implants and the symptoms reported at that time.*

**Breast Implant Associated - Anaplastic Large Cell Lymphoma.**

Anaplastic large cell lymphoma (ALCL) is an extremely rare type of cancer that can occur in adults and children. Over the last two decades, there have been rare reports of ALCL occurring in the scar tissue surrounding breast implants. This has led the medical community to recognise a new and different type of ALCL, referred to as Breast Implant- Associated ALCL (or BIA-ALCL for short). BIA-ALCL does not appear to behave in the same way as ALCL and in most cases is less severe. It should be noted that this is a very rare condition: at the time of writing (March 2020) there have been 700 cases reported worldwide since 1997, with an estimated 10 million implants inserted during the same period. Although there have been 19 reported deaths to date, BIA-ALCL in most cases is readily treatable by removing the scar tissue surrounding the implant and replacing the implant. It usually presents in women 8 - 10 years following implant insertion with sudden swelling of the breast as a result of a fluid collection – a seroma. Should this occur patients should seek urgent medical advice.

BIA-ALCL appears to occur when the implants have a macro-textured surface. This texturing is designed to reduce the risk of capsular contracture. In the UK in the last 20 years most implants that have been inserted have macro-texturing. The commonest implants used worldwide were made by Allergan. When evidence mounted that BIA-ALCL was associated with Allergan macro-textured implants most countries imposed a ban on their use and in 2018 Allergan voluntarily recalled all stocks of these implants. It should however be stressed that at the current time the risk of developing and dying from BIA-ALCL is extremely low, and that the very small mortality risk of the routine procedure to remove or replace the implants would be higher.

The following is the most recent statement from the UK organisations that represent aesthetic breast surgeons (BAAPS, BAPRAS and ABS):

*One concern is about Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL). The World Health Organisation (WHO) defined BIA-ALCL as a disease in 2016 and our current information suggests that BIA-ALCL happens with 1 in every 24,000 implants inserted in the UK. Athough it is not yet known exactly why, significant variations in incidence rates are being reported between countries who have reported cases of BIA-ALCL.  By comparison Breast cancer, which is not related to having breast implants, occurs in 1 in 8 women in the Western World. BIA-ALCL typically presents on average 8-10 years after breast augmentation with visible, painless swelling of a breast over a period of a few weeks due to fluid accumulation called a seroma, or less frequently with a lump in the scar tissue (‘capsule’), which can develop around any breast implant. In July 2018 the MHRA advised that the very small risk of ALCL should henceforth be discussed with all patients considering having breast implants for either cosmetic or reconstructive reasons.*

*BIA-ALCL is usually treatable and curable with surgery, although other treatment may be required. Whereas BIA-ALCL continues to be a rare disease in the UK, we are monitoring both UK and international events closely with the UK regulator, the Medicines and Healthcare products Regulatory Agency (MHRA). The full clinical details are only known in approximately one third of BIA-ALCL patients worldwide.  It is therefore essential to obtain as much information as possible about each case to help understand this disease. The national Breast and Cosmetic Implant Registry (BCIR) (*[*https://digital.nhs.uk/data-and-information/clinical-audits-and-registries/breast-and-cosmetic-implant-registry*](https://digital.nhs.uk/data-and-information/clinical-audits-and-registries/breast-and-cosmetic-implant-registry)*) is in regular contact with other international Registries, and it is important that UK government funding should continue to support this.*

*Advice for clinicians and patients in the UK on BIA-ALCL has been published by MHRA, produced with the help and advice of world renowned, independent experts, including toxicologists, bacteriologists, material scientists, lymphoma specialists, radiology specialists, representatives of breast cancer charities and surgeons from our Associations:*

[*www.gov.uk/guidance/breast-implants-and-anaplastic-large-cell-lymphoma-alcl#current-uk-advice*](https://urldefense.proofpoint.com/v2/url?u=http-3A__www.gov.uk_guidance_breast-2Dimplants-2Dand-2Danaplastic-2Dlarge-2Dcell-2Dlymphoma-2Dalcl-23current-2Duk-2Dadvice&d=DwMFaQ&c=bXyEFqpHx20PVepeYtwgeyo6Hxa8iNFcGZACCQj1uNM&r=H2BoBWoZmXJggRDvUTWQtXszkXsL69uJ3vtHURRArsI&m=4nG-IOVk6pE1r0MA1tjexJwAJkwILwtvA3BmBl91ZtQ&s=bZjWSEeo3AaNd1gwlHvEcQqGcKeeFCGE0ii9Nq85mOw&e=)

*The UK Plastic and Breast Surgery associations are closely involved in a growing international collaboration by the healthcare community to collect the information needed to find out more about breast implants and inform our patients. Patient safety is of paramount importance and our guidance will be updated in the light of new evidence.*

*Current advice from MHRA and all regulators world-wide is that those patients who have breast implants do not need to have them removed as the risks associated with surgery to remove implants and capsules outweigh the risks of potential disease. However, should patients develop any breast symptoms such as swelling, lumps or pain they should seek immediate advice from their family doctor and or operating surgeon and should be referred for assessment.*

***Advice for individuals with breast implants:***

*If you have breast implants and experience any problems with your breasts, in particular swelling, lumps or change in shape, then you should seek medical advice.*

*If you think your breast implants are causing general health problems you should seek the advice of your original implanting surgeon or the hospital/clinic where the implant operation took place. If you cannot contact either of those, please consult your GP.*

***Advice for patients with Allergan (McGhan / Natrelle) implants with a textured Biocell® surface:***

*Following a ruling by the French regulator over the possible link with Allergan’s textured surface (Biocell®), the CE mark was not re-awarded for this product in December 2018. Allergan subsequently recalled all of their textured implants Worldwide. Their recall was for implants already sent out to distributers and hospitals. It was not a recall of implants in patients and does not change the advice from the MHRA regarding patients currently with implants.*

**Implant recall.**

Over the years there have been several implants recalls most notably the Trilucent soya bean oil filled implants (the first publication of the problems of Trilucent implants was by Mr Cadier, directly resulting in a request for widespread removal by the MHRA regulatory body), the Hydrogel implants and the fraudulently poorly manufactured PIP implants.

Although all attempts are made to try to use well established and reputable implants with good long-term safety data it is impossible to predict potential problems. In the past patients were often unaware what breast implants they had and there was limited data collected. However, since 2017 a nationally organized breast registry has been set up (Mr Cadier was on the committee) so that in the future if there is any concern regarding a breast implant type the patients with those implants can be identified and contacted and appropriate action taken in an expedient manner.

**Implant related problems:**

**Implant rupture or significant leakage**

All breast implants leak tiny quantities of silicone into the surrounding tissue. This microscopic leakage has been known about for many years and initially it was thought that it might be associated with skin and joint conditions. This is now not believed to be the case, though there are on-going studies and patients may wish to keep informed by looking at the web sites of key associations such as BAAPS, BAPRAS, ISAPS and ASAPS – these are all associations of plastic surgeons whose web sites will provide up to date information on silicone breast implants. It should be noted that modern implants incorporate special shells and the filler gel is cohesive, these both being designed to minimize any silicone leakage.

The breast implants used by Mr Cadier are all state of the art being made by highly reputable companies and are extremely well designed and subjected to rigorous tests. Breast implants will not rupture when going in airplanes, contrary to some popular belief. It is recognized that with some implants over the course of many years the shell of the implant may develop cracks and silicone gel can be found between the capsule and the implant shell (termed intra-capsular rupture). Usually this is not associated with any symptoms and may be picked up when a patient is having a scan or mammogram for some other reason. In these cases, patients are advised that it is probably appropriate for the implants to be changed as it is possible that over the course of several more years that free silicone gel may be found outside of the capsule in the breast tissue (termed extra-capsular contracture). This free silicone gel can form lumps in the breast (granulomas) which in themselves are not dangerous but can be potentially confused with breast cancers. It should be stressed that even with the implants used 15 - 20 years ago (which neither had cohesive gel nor extra barriers as found in the modern implants) that the incidence of granuloma development, even after 20 years, is very small. The surgery to remove and replace breast implants that have leaked or ruptured takes about an hour to perform and is usually undertaken under general anaesthetic. The recovery, expectations, aims and limitations and risks will need to be gone over on a case by case basis.

**Capsular contracture**

When a breast implant is inserted the body will automatically put a layer of scar tissue (a capsule) around the implant. In most cases this is of no consequence. However, in some patients, for reasons not fully understood, the scar tissue thickens and squeezes the implant. This is termed capsular contracture. This may occur at any stage following augmentation, though it is unusual in the first year. It can come on slowly or rapidly and affect one or both breasts. In many cases it is manifest by firmness of the implant, but in severe cases the implant becomes hard and painful and the breast shape is distorted. Capsular contracture is detected in about 1:10 to 1:20 patients at 10 years following augmentation, though only about 1:25 to 1:50 require treatment. The surgical options include:

* Release of the scar tissue envelope – capsulotomy.
* Partial removal of the scar tissue envelope – partial capsulectomy.
* Full removal (often en bloc) of the scar tissue envelope – full capsulectomy.
* Change of implant.
* Change of implant plane (usually repositioning from in front to behind the muscle).
* Fat transfer to increase tissue coverage.
* Removal without replacement in recurrent cases.

All of these options require a general anaesthetic and which is most appropriate, as well as expectations, recovery times, aims, limitations and risks will all be discussed at the consultation.

**Recurrent seroma.**

Seromas are an unusual problem following breast augmentation and represent an accumulation of blister-like fluid around the implant on one or both sides. Patients notice a sudden swelling of the breast. This can occur several years following surgery and may be precipitated by a violent bout of exercise. In most cases this is a not a significant problem and treatment is usually non-surgical and includes wearing a compression bra, avoiding the precipitating exercise and taking anti-inflammatory medication. However, because of the very rare risk of BIA-ALCL (see below) patients should always seek medical advice, and ideally return to Mr Cadier for review. When recurrent seromas occur implant removal and capsulectomy with either immediate, or delayed replacement may be required.

**Breast tissue dropping off implant mound (waterfall effect).**

With the natural changes that occur with ageing, sometimes aggravated by breast feeding or weight change, the breast tissue can start drooping off the implant mound. This appears to be more common when the implant has been placed behind the muscle and when the patients natural pre implant insertion breast was droopy or lax. The options for treatment if required include:

* Change of implant plane usually from behind to in front of the muscle
* Change of implant size.
* Breast uplift surgery with/without implant change or removal.

**Delayed infection.**

This is a rare problem and usually occurs when there is a focus of infection in another part of the body that has spread to the implant through the blood. The treatment specific to the implant is in most cases urgent removal and delayed reinsertion several months later.

**Breast Implant Removal Surgery.**

Breast implant removal surgery is a very variable procedure in terms of complexity and recovery.

When there is no significant scar tissue (capsule) around the implant and there is no implant rupture (this would require a scan pre-operatively) then the surgery can be performed under local anaesthetic as a day case. Recovery is rapid and risks minimal however this is not appropriate in the majority of cases.

In most some or all of the capsule needs to be removed either partially or fully. In patients with concerns regarding Breast Implant Illness en bloc removal is usually requested. In this procedure the incision is placed in the crease under the breast and is much longer than the normal incision. The scar tissue envelope is dissected away from the normal tissues and ideally the implant cavity is never entered. This may however not always be possible if the scar tissue is thin or in submuscular placements when trying to remove the capsule would cause damage to the chest wall structures. En bloc removal may take up to 2 hours to perform, requires a general anaesthetic and a one night stay in hospital. Drains are frequently necessary.

When the implant has ruptured all attempts to remove all of the free silicone are undertaken. The silicone gel does not dissolve and so has to be scooped and wiped out with gauze swabs. Complete removal may not be possible.

Following the surgery patients are advised to wear a bra for 2 weeks day and night to help the breast mould back into a normal shape. Because of the variable nature of the surgery advice regarding restrictions (driving, work, gym) are done on a case by case basis.

The risks of surgery are relatively low but increase with the complexity of the procedure. They include:

* Bleeding requiring a return to the operating theatre.
* Infection.
* Accumulation of blister like fluid in the cavity (seroma).
* Breast asymmetry.
* Distortion of the breast shape.
* Poor scarring.
* Psychological distress.
* Deep vein thrombosis and life-threatening pulmonary embolism
* Anaesthetic complications – these will be discussed with you by the anaesthetist before surgery.
* Death

Bleeding may occur into the cavity where the implant was situated. This usually occurs within a few hours of returning to the ward and results in swelling on one side. In most cases a return to theatre is required. Infections can occur in any wounds and may necessitate local or oral antibiotic treatment. Sometimes blister like fluid accumulates in the cavity. This seroma usually develops after a few days and causes swelling. Drainage in clinic may be required.

No two breasts are identical and sometimes following implant removal underlying asymmetries may become more apparent. If marked further surgery may be indicated – this would incur additional fees. With the removal of the implant the breast will obviously be smaller. Some distortion of the normal shape may also occur as a result of the squeezing of the breast tissue over many years or because of scarring developing after implant removal. If marked further surgery may be indicated – again this would incur additional fees. In most cases the scar under the breast fades nicely over a few weeks or months. In some patients it becomes red, lumpy and / or stretched and may require non-surgical measures to improve the appearance.

Patients will be very use to their breast size and shape, and some develop marked psychological distress following implant removal. Patients are advised not to look at their breasts for 2 weeks postoperatively to allow the skin envelope to retract a bit and the breast tissue to remould to a better shape.

Some patients request additional tests including CD-40 (a marker for ALCL) and specialised histology. These may incur additional costs.

Following any surgery there is a risk in developing a deep vein thrombosis (DVT). This is a clot in the calf vein of the leg. In itself it may result in pain and swelling. The risk is that should the clot separate from the vein it can move to the lungs resulting in a pulmonary embolism. This is a potentially life-threatening situation. All attempts are made to reduce the risk using compression stockings during and for two weeks after surgery, using pneumatic compression devices on the legs at surgery and in the immediate post-operative period, by encouraging early mobilization, advising patients to stop the combined oral contraceptive pill or Hormone Replacement Therapy (HRT) four weeks prior to surgery, and where it is felt appropriate using injections of blood thinning agents.

All surgical and anaesthetic procedures have risks, and some are life threatening, these include pulmonary embolism, anaphylaxis (severe allergic response to a medication) and adverse drug reactions. Death however remains an extremely rare complication.

When complications do occur, all attempts are made not only to remedy the problem in as speedy a manner as possible but also to optimise the final result. As with all cosmetic surgical procedures undertaken by Mr Cadier, there is a fixed fee policy, which means that no further charges are incurred for the treatment of complications that are identified within 6 months following the initial surgery. Revisional policies for aesthetic concerns have changed and, in most cases, additional fees will be incurred. Patients need to be aware regarding the limitations of surgery and have very realistic expectations about outcomes.

**You are advised to refrain from flying for 4 weeks before surgery and for at least four weeks post-operatively. Please discuss any travel plans you may have around the time of surgery with Mr Cadier before proceeding with the booking.**

**Outcome:**

In most patients the outcome following implant removal is surprisingly good despite sometimes many years of the skin envelope having been stretched. In some patients the skin does not retract, and an uplift may be required to produce a satisfactory breast shape. This is usually best undertaken as a second procedure after several months.

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**About your Surgeon:**

Michael Cadier was educated at the French Lycée in London, studied at Oxford University and undertook Medicine at St Thomas’ Hospital, London. After training in London, Salisbury and Bristol he became an NHS Consultant in the Supra-regional Plastic Surgery Unit in Salisbury in 1996, becoming Head of this Service in 1999. In his NHS practice he developed a breast reconstruction service in Portsmouth, and in 2000 was appointed as cleft surgeon to the newly established Spires Cleft Centre, for which he also became the first Clinical Director in 2002. He undertook yearly cleft lip and palate Charity missions in rural Pakistan from 1996 to 2009. He has a busy aesthetic surgery private practice along the South Coast, undertaking the full range of aesthetic surgery procedures. He has performed over a thousand facelifts, and over 1500 breast augmentations, with similar numbers for all of the more common aesthetic procedures. In 2015 he became fully private, concentrating solely on aesthetic surgical practice.

He is widely published and lectures and teaches on aesthetic surgery both nationally and internationally. In 2006 he was invited to become an examiner for the FRCS (Plast). He is the Program Director for the South Coast Reconstructive Cosmetic Surgery Fellowship, was part of the first UK delegation in the CEN in cosmetic surgery (European regulation) and chaired the CSIC Royal College committee on Clinical Quality and Outcomes in Cosmetic Surgery.

The British Association of Aesthetic Surgeons (BAAPS) is the leading organization for aesthetic surgery in the UK. He was elected to BAAPS Council in 2006 and was President of BAAPS from 2014 to 2016. One of his key objectives is to ensure that UK plastic surgeons of the future will practice aesthetic surgery to the highest possible and with that aim he has helped establish a comprehensive national training program in aesthetic surgery.

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