

Cosmetic Breast Augmentation- Patient Risk Awareness Tool and Breast Implant Record

Breast augmentation surgery is surgery to make the breasts bigger or change the way they look. It can be a life-enhancing procedure; however, it is not without risks and is a major surgery. It is important to be fully informed about the risks of the operation and breast implants both in the short and long term.

This list is designed for anyone considering breast implants for breast augmentation surgery to aid discussion with your surgeon. You can also refer to the '<u>Your Guide to Breast Augmentation</u>' booklet to help you understand the procedure better and for guidance on any risks you should be aware of. The list is not necessarily a complete list of what you will discuss with your surgeon and does not replace the informed consent process.

The Breast Implant Record is for you to keep a record of the type and model of your breast implant. Breast implants are medical devices and as such, it is important for you to keep specific information related to your implant.

You can use the list and Breast Implant Record below to identify any areas where you may need more information. You can take this document with you to your next consultation.

My details Name:	My Surgeon's details Name:		
Contact number:	Contact number:		
Date of surgery (implant)://	Hospital / Clinic address:		
My appointments Notes	My Breast Implant details Manufacturer:		
	Model/Brand:		
	Serial Number: LOT Number: (L): (L): (R):		
	Surface texture: Smooth / Textured / PU		
	Material:		

This document has been produced by the Medicines and Healthcare Products Regulatory Agency (MHRA) with advice from the Plastic, Reconstructive and Aesthetic Surgery Expert Advisory Group (PRASEAG).

Patient Risk Awareness Tool

This list should be used by patients as guidance material to support your understanding of the potential risks of surgery and breast implants in discussion with your surgeon.

My surgeon has...

General

	Provided me with information on breast augmentation and the potential risks, such as the 'Your Guide to Breast Augmentation' booklet
	Discussed whether I may be at a risk for a poor result with breast augmentation surgery with implants or potential alternatives
	Discussed my expectations of breast implant surgery and what is achievable in my case
	Explained about the different types of breast implants (including shape/size/texture) and what would be appropriate for me, and the pros and cons of each
	Explained breast implant surgery to me, including where the implants can be placed, either over or partly under the pectoral muscle
	Explained about the approximate cost of the surgery and what is included
	Explained that breast implants do not last a lifetime and revision (removal or replacement) surgery will be needed in the future, and explained that the cost of revisional surgery and future consultations should be considered
S	urgery Risks
	urgery Risks surgeon has explained to me the risks of surgery in general which include: Bleeding
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Complications

My surgeon has explained complications specific to breast implants, which may need more surgery at my expense, including but not limited to: Capsular contracture (scar tissue around the implant has shrunk which can leave the breast feeling hard or tender)

☐ Implant failure (rupture or leaking of the implant)

□ Wrinkling of the implant and being able to see the implant under the skin

☐ Movement of the implant (including 'animation')

☐ Altered sensation (less or more sensitivity to touch) in the breast and or the nipples

☐ Asymmetry (breasts do not look symmetrical to each other)

☐ Seroma (fluid build-up around the implant)

Ptosis (sagging) including 'Double bubble' (implant sits below the natural breast fold creating the appearance of two folds) and 'Waterfall' (sliding of breast tissue over the top of the implant) appearance

New and old stretch marks

☐ Cleavage issues and that implants will not improve a wide cleavage

Changes with age

☐ Feeling 'bubbles' and 'lumps' related to the implants

Risk of Cancer

☐ Explained to me the risk of Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) and other non- BIA-ALCL lymphomas of the breast implant capsule

☐ Explained to me the risk of Breast Implant-Associated Squamous Cell Carcinoma (BIA-SCC)

Breast Implant Illness

☐ Explained to me about symptoms sometimes referred to as breast implant illness

Mammograms

Explained that breast implants interfere with mammograms (breast screenings to look for cancer)

Discussed whether a mammogram is recommended before breast augmentation surgery

Follow-up

■ Explained the follow-up procedures and what to do if complications arise

☐ Explained that I can report side effects relating to breast implants to the MHRA Yellow Card scheme

Consultation

Explained that you have the opportunity to ask your surgeon or their team any questions you may
have at any point during the consultation process and before and after surgery
Explained about the Breast and Cosmetic Implant Registry and how to consent for inclusion in

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My Notes