

Immediate breast reconstruction using an implant and Acellular Dermal Matrix

affix patient label

What is an immediate breast reconstruction?

Reconstruction of the breast mound carried out at the same time as your mastectomy.

The aim of breast reconstruction is to produce a replacement breast with a satisfactory appearance both in and out of clothes, avoiding the need for an external prosthesis in the bra. This can be achieved by either:

- a) producing a 'replica' sized and shaped breast to the one which has been lost - matching the other (contralateral) breast.

or

- b) if it is not possible or desirable to produce a replica breast, then your surgeon may suggest to you producing the best breast possible (usually smaller and more youthful). In this case you will need cosmetic surgery to the other (contralateral) breast in the future if you wish it to match your breast reconstruction.

Skin sparing mastectomy

What is a skin sparing mastectomy?

If an immediate breast reconstruction is planned, then the breast tissue (with or without the nipple) is removed, preserving the breast skin.

The aim of the mastectomy is to remove the breast tissue meticulously and delicately from inside the breast skin envelope and only remove any skin that may be unhealthy. In most cases the breast skin is usually perfectly healthy and can be preserved to keep the shape of the original breast.

Reduction pattern skin sparing mastectomy - in some cases the skin envelope may be reduced or crafted into a more ideal size or shape.

Nipple preserving, skin sparing mastectomy - in certain circumstances a patient may be able to keep her nipple. Your surgeon will have discussed this with you if it is an option.

Nipple sacrificing, skin sparing mastectomy - sometimes it is safer for the nipple to be removed at the time of the mastectomy. The nipple can then be reconstructed at some time in the future once the breast reconstruction has fully healed.

Skin sparing mastectomy has been proven to be as safe as simple mastectomy and is no more likely to lead to a future problem (with cancer recurrence or delaying future cancer treatments because of complications) than if a simple mastectomy is performed. If you need further clarification about this please ask your breast surgeon.

Acellular Dermal Matrix aided implant based immediate breast reconstruction

Why are we recommending this procedure?

This method of reconstruction allows a quicker recovery and less scarring than a reconstruction which involves transferring tissue from elsewhere in the body (flap based reconstruction). This is usually the most suitable form of breast reconstruction when there is minimal ptosis (breast droop) and in a small to moderate volume breast.

Your surgeon may not recommend this form of reconstruction if you are diabetic or a smoker. Its use when postoperative radiotherapy is anticipated will be discussed with you at length by your surgeon.

Are there any alternatives?

When mastectomy is necessary, the option of breast reconstruction will be discussed with you. Some patients may not be suitable for an immediate breast reconstruction. This may be because of the type of cancer they have developed or because of other health conditions. Others may choose to complete their cancer treatment first and have a breast reconstruction at a later date – this is known as delayed breast reconstruction.

If immediate breast reconstruction is not done, a patient will be offered a simple mastectomy or if appropriate, medical cancer treatment.

How do I prepare for it?

Most patients attend a pre-admission clinic where we will ask for details of your medical history and carry out any necessary clinical examinations and investigations. Please ask us any questions about the procedure, and feel free to discuss any concerns you might have. You will also have the opportunity to discuss any concerns or queries with a member of the breast care nursing team.

You must **not** eat anything for at least **6 hours** before your operation. This is to make sure your stomach is empty when you have your anaesthetic. Drinks containing fats (e.g. tea or coffee with milk) and sweets all count as food.

You **can** drink water or a drink without fats in it (e.g. black coffee) until **2 hours** before your operation. You may also have small sips of water to take tablets. There is a hospital leaflet about having an anaesthetic. Ask the staff for a copy if you would like one.

You will be given a general anaesthetic during the operation which will keep you asleep. The anaesthetist will come and see you before your operation to discuss this with you. You will be able to ask them questions about the anaesthetic.

A member of the surgical team will also see you on the ward. This is usually the surgeon that will perform your operation. Feel free to ask any questions you have about the operation or what will happen afterwards.

The surgeon will spend a short time with you measuring and planning the exact steps of the operation and will usually draw and make notes of important landmarks on your skin with a special marker pen. This is called the 'marking-up' process and may be done whilst you are sitting, standing and lying down. An arrow will also be drawn on the side to be operated on and a check made that this consent form has been completed and signed.

What does it involve?

Acellular dermal matrix (ADM) is a biological mesh derived from animal skin. It has been processed to make it completely safe to use in humans. Your surgeon will have discussed with you where the implant will be placed. It is likely to be placed below the skin and above your pectoralis muscle. The implant is likely to be placed entirely within or beneath the mesh, which provides an additional layer beneath the skin.

The type of skin incision will vary depending on a number of individual factors and your surgeon will have discussed and planned this with you beforehand.

Your surgeon may leave 1 or 2 soft plastic drainage tubes to drain away the tissue fluid which will be produced as a result of your surgery. When these drains are removed will be decided by your surgeon but they may stay in for up to 2 weeks.

All the stitches used are dissolvable and paper stitches (steristrips) are used to cover the scar lines. A waterproof dressing is put over this. You should leave the dressing intact if possible until you see your surgeon in the out-patient clinic.

What happens afterwards?

Many patients only need to spend one or two nights in hospital after this operation. If your personal social situation means you need to spend longer in hospital that is fine but we would encourage you to be up and about as much as possible.

You will be able to go home with the drains in and the district nurses will take over the management and removal of the drain.

Before you go home, the nursing staff will want to be sure that you are well enough and that the conditions at home are such that you can manage safely. They will offer advice about dressings and painkillers. Taking regular simple painkillers is recommended for the first week. You will be prescribed stronger painkillers for the first couple of days if necessary.

You will be given a leaflet about arm and shoulder exercises depending on the type of axillary surgery you have had in conjunction with this breast operation.

You will be able to shower briefly but you need to be careful to keep your dressings dry.

Your surgical and breast care nursing team will advise you of any special instructions about your postoperative care. You will need a full cup, well-fitting support bra to wear over your dressings night and day until you are seen again back in the clinic.

Are there any risks or complications?

As with all procedures, there are risks from having this operation:

General risks

Risk from the anaesthetic: The risk to a healthy patient of problems arising from an anaesthetic is very small. However, each year in the UK a few healthy people will die or suffer serious heart, lung or brain injury following an anaesthetic. For a woman who is otherwise in good health, the risk of a serious complication due to general anaesthesia is less than 1%.

Bleeding: This is usually minor and is stopped during the operation. Occasionally patients develop a collection of blood called a haematoma, which requires a second operation. For this procedure it is about 1-2 in every 100.

Infection: All surgery has a risk of infection. If the wound becomes red, hot or weeps, or you feel unwell you should consult your doctor. There is also a risk of the implant becoming infected. About 5 in every 100 women undergoing this type of procedure will lose their implant after surgery. If this happens to you, you will undergo extensive counselling by your breast team about further reconstructive options which may be available to you in a delayed setting. Further surgery will only occur when your wounds have healed and you have finished any additional cancer treatment you may need.

Pain: A degree of pain is likely after any surgery. We aim to manage your pain with painkillers to an acceptable level postoperatively. There is evidence to suggest that if we get on top of your pain early following your operation we can reduce the chance of it becoming a chronic problem. If the pain or numbness and tingling continues to be troublesome please let your surgeon or breast care nurse know and we can give you a medication to manage the pain.

DVT/PE: With all surgical procedures there is a risk of developing a clot in the deep veins of the leg, deep vein thrombosis (DVT). In a very small number of patients a bit of this clot breaks off and lodges in the lungs. This is a pulmonary embolus and in very extreme cases can be life-threatening. Your surgical team will prescribe you compression stockings and/or blood thinning medication after careful assessment of your individual risk.

Specific risks

Partial or full skin flap loss (necrosis): This is a rare but serious complication (2 to 5 in every 100 women) which may result in the implant and affected skin having to be removed. If the circulation to the skin over the reconstruction is compromised, then some or all of the skin may not be healthy enough to survive. Although it may heal gradually with appropriate nursing care and dressings, in more serious cases the skin cannot be saved. In those cases the skin must be removed. If the implant becomes infected or exposed, it is not usually possible to save it with antibiotics and in most cases it will need to be removed.

Seroma: This is a collection of fluid in the surgery site. If the seroma persists after the drains are removed it may need to be drained under ultrasound guidance in the Mermaid Centre.

Red breast syndrome: Occasionally there is a transient immune reaction to the acellular dermal matrix causing the skin to become red. Whilst this is not infection it is best treated as such in order to reduce the risk of implant loss.

Numbness: The nerves, which supply the sensation to the skin, are disturbed by the surgery. This numbness usually lessens slowly over time, but may persist in some places long term. Most patients do become accustomed to the numbness over time.

Nipple preserving skin sparing mastectomy

Nipple sensation: If your nipple is preserved there is a very high chance that the nipple will be numb and also unable to become erect with touch or cold.

Nipple colour: If your nipple is preserved there is up to a 50% risk of loss of colour of the nipple. This can be improved with micro-pigmentation (nipple tattooing), which is carried out at St Michael's Hospital after nipple reconstruction.

Nipple loss: The majority of nipples survive well, but in the early weeks after surgery the tip of the nipple has up to a 20% chance of developing some scabbing or discolouration. This may also involve the areola (pigmented area around the nipple). This situation does not usually require any surgical intervention and usually will settle down within 2-4 weeks.

If the blood supply of the nipple is threatened immediately after the operation it may be necessary to use special measures to prevent the nipple from perishing. Special drug plasters can improve the circulation as can deflating an expander implant and releasing sutures.

Rarely, (in about 1 in 100 women) the nipple does not survive despite these measures. If a nipple does not survive then it is usually possible to perform a full nipple reconstruction at a later stage, but the old nipple may need to be removed to prevent deeper infection spreading to the implant and ADM.

Recurrent cancer in a preserved nipple: The risk of a further cancer problem in your preserved nipples is tiny and theoretical (<1 %). If your surgeon has offered you the option of nipple preservation, then your risk is likely to be very small indeed.

Risks specific to implant surgery

Palpable / visible implants: No breast reconstruction can replace the breast you have lost in terms of feeling and movement. Inevitably close palpation of the breast will reveal the presence of an implant. The implant may also move when the chest muscles are tensed. You may also notice some rippling of the implant.

Rotation and movement: Shaped or 'tear drop' implants can rotate. The implants will move differently to normal breast tissue and in particular can move outward when lying down to produce a 'gap' in the middle of your cleavage if not supported by a bra.

Contracture: A contracture is a tight fibrous capsule that the body forms around the breast implant causing it to become less natural looking. Approximately 1 in 4 women will develop a contracture with around 1 in 20 requiring surgical correction. It should be regarded as a side effect of implant surgery rather than a complication and it is not possible to predict pre-operatively. However, smoking and any infection such as urinary tract or dental infections dramatically increases the risk.

Your surgeon will have discussed the risks of radiotherapy to an implant based reconstruction as part of your pre-operative discussion. There is an increased chance of developing a capsular contracture after radiotherapy.

Need for further surgery: There is a significant (more than 50%) chance that you will need some further aesthetic (non-cancer) surgery at some point in the future. This may be a small adjustment to the reconstruction or you may need the implant replacing.

Asymmetry: No surgery can guarantee a complete match between your breasts. It is not possible to predict how the breast will change shape in the longer term. Shape, volume and nipple position may alter due to the effects of aging of the tissues and changes in your body weight.

Breast Implant Associated Anaplastic Large Cell Lymphoma: this is an extremely rare and treatable condition which may have a link with breast implants (all manufacturers). It is thought to be associated with, and contained within the capsule which forms around the implant. It tends to present with rapid swelling of the breast usually a year or more after the reconstruction. It is however, extremely uncommon with the risk being about 1 in 20,000 patients having breast implants. Surgery to remove the capsule and implant is usually all that is necessary for treatment of BIA-ALCL.

If you would like this leaflet in large print, Braille, audio version or in another language, please contact the General Office on 01872 252690

CONSENT FORM 1
PROCEDURE SPECIFIC PATIENT AGREEMENT

_____ side **Skin sparing mastectomy**

+/- Nipple preserving / Nipple sacrificing

**Acellular Dermal Matrix (ADM) aided
immediate implant based breast reconstruction**

NHS number: _____
 Name of patient: _____
 Address: _____
 Date of birth: _____
 CR number: _____

AFFIX PATIENT LABEL

STATEMENT OF HEALTH PROFESSIONAL (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in consent policy)

I have explained the procedure to the patient. In particular, I have explained the intended benefits and summarised the risks, as below:

- *To remove the disease or reduce the risk of disease and produce a replacement breast.*

Significant, unavoidable or frequently occurring risks:

- *Bleeding, infection, pain, DVT/PE, seroma, red breast syndrome, numbness, altered nipple sensation and colour (nipple preserving mastectomy). Implant complications: palpable/visible implants, rotation and movement, contracture, need for further surgery, asymmetry.*

Uncommon but more serious risks:

- *Partial or full skin flap loss, implant loss, nipple loss, BIA-ALCL.*

Rare but serious risks:

- *Anaesthetic risk which includes a very small risk to life from complications such as heart attack and stroke, recurrent cancer in a preserved nipple.*

Any extra procedures which may become necessary during the procedure:

- *Blood transfusion (required very infrequently)*
- *Other (please specify):*

I have also discussed what the procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient.

I have given and discussed the Trust's approved patient information leaflet for this procedure: Immediate breast reconstruction using an implant and ADM CHA3276 which forms part of this document.

I am satisfied that this patient has the capacity to consent to the procedure.

This procedure will involve: General and/or regional anaesthesia Local anaesthesia Sedation

Health Professional signature: _____ Date: _____

Name (PRINT): _____ Job title: _____

STATEMENT OF INTERPRETER (where appropriate)

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe he/she can understand.

Interpreter signature: _____ Name (PRINT): _____ Date: _____

affix patient label

STATEMENT OF PATIENT

Please read this form carefully. If your treatment has been planned in advance, you should already have a copy of the patient information leaflet which describes the benefits and risks of the proposed treatment. If not, you will be given a copy now. If you have any further questions, do ask - we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

I agree to the procedure or course of treatment described on this form.

I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate experience.

I understand that I will have the opportunity to discuss the details of anaesthesia with an anaesthetist before the procedure, unless the urgency of my situation prevents this. (This only applies to patients having general or regional anaesthesia).

I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my life or to prevent serious harm to my health.

I understand that tissue samples will only be taken in relation to the procedure explained to me. No samples will be taken for quality control, clinical education or research purposes.

I have been told about additional procedures which may become necessary during my treatment. I have listed below any procedures **which I do not wish to be carried out** without further discussion.

I have received a copy of the Consent Form and Patient Information leaflet: Immediate breast reconstruction using an implant and ADM CHA3276 which forms part of this document.

Patient signature: _____ Name (PRINT): _____ Date: _____

A **witness** should sign below if this patient is unable to sign but has indicated his or her consent. Young people / children may also like a parent to sign here (see guidance notes).

Witness signature: _____ Name (PRINT): _____ Date: _____

CONFIRMATION OF CONSENT (to be completed by health professional when the patient is admitted for the procedure, if the patient has signed the form in advance).

On behalf of the team treating the patient, I have confirmed with the patient that they have no further questions and wish the procedure to go ahead.

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Important notes (tick if applicable):

See advance decision to refuse treatment Patient has withdrawn consent (ask patient to sign/date here)

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