

Magnetic seed localisation for breast cancers Information Sheet

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Introduction

You are being invited to take part in an audit into a new technique used to mark where in the breast a cancer is located.

This leaflet provides information on the new technique and explains what would happen if you agreed to take part.

Please read the leaflet carefully.

What is the purpose of the seed?

Currently, women having lumpectomy surgery for small breast cancers have a wire placed into the breast on the morning of surgery so that their surgeon knows which part of the breast to remove. This is because many of the cancers we find are too small for the surgeon to be able to feel.

The audit will use a small magnetically responsive metallic seed instead of a wire to locate cancers in the breast. The aim is to see if the magnetically responsive seed is more acceptable for women, as it can be positioned in the breast any time up to four weeks before surgery, and whether it is easier and more accurate for the surgeon to use than the wire. It can be difficult for a surgeon to know exactly where the tip of a wire is, especially in a large breast. The magnetically responsive seed should direct the surgeon straight onto the cancer, making the surgery easier and potentially more accurate.

The seeds have been trialled in several centres in the UK over the last year, and over 500 have been placed safely in patients in the US. There is increasing evidence the seeds are an effective way of locating small breast cancers in surgery.

Why have I been invited to take part?

You have been invited to take part as you are having a lumpectomy operation (removal of some of the breast tissue) to remove your breast cancer and your tumour is not easy to feel (so will require a marker to be placed before surgery).

What is the Magseed device?

Magseed is a small magnetically responsive seed about 5mm x 1mm, about the size of a grain of rice. It is very similar to the clips your doctors currently use to mark where a biopsy has been taken in the breast, and is so small you wouldn't know it was there. The only real difference is that this seed is made of a magnetic form of medical steel. The magnetically responsive seed can be found using a handheld magnetic detector (Sentimag) that makes noises when held over the breast and close to the seed.

What does having the seed placed involve?

If you decide to take part in the study, you will be asked to come in at a convenient time before your operation date when the magnetic seed is put in using a local anaesthetic. The procedure is similar to having a biopsy taken, though should be less uncomfortable as the delivery device does not "snap" like the biopsy device.

A mammogram will be taken and the handheld magnetic detector will be used to check if the seed can be detected in the breast. The lumpectomy will take place as normal and the seed will be removed with the breast tissue. Your surgeon will see you as normal two weeks after your surgery to give you the results and to plan any further treatment.

Do I have to take part?

Before you decide, we ask you to read this information leaflet.

If you decide to take part in the study, we will ask you to sign a consent form. You are free to withdraw at any time, without giving a reason. If you decide not to take part, you do not need to give a reason, and your cancer will be marked using a wire on the morning of surgery, which is our current standard practice.

What are the possible disadvantages and risks of taking part?

There is no clear disadvantage of taking part and it may make the surgery easier for your surgeon. We need to check with this study that the seeds accurately mark the cancers and that we can use them to remove cancers accurately.

The magnetic seed is inserted into the breast using a needle which may cause some discomfort. Before the procedure, a local anaesthetic will be given to make it less uncomfortable. It is similar to having the core biopsy to diagnose your cancer, although it should be less uncomfortable. Possible complications are similar those of a biopsy. These include pain, bleeding, infection and inflammation.

The needle used to insert the seed contains beeswax. There is a very small risk of allergic reaction. If this happens you will be looked after by the doctor.

There is a small chance that the magnetic seed may move slightly within the breast. If that happens, it will move back up the path that the needle created. Any misplaced seeds can be removed under local anaesthetic by suctioning out of that small area of the breast tissue using ultrasound guidance. A further magnetic seed or wire can then be placed to mark the lesion.

What are the possible benefits of taking part?

Usually you would need a wire placed in the cancer on the morning of your operation which can be a stressful experience. We can place the seed into the cancer in advance which should make the day of surgery less busy and stressful for you.

Sometimes, placing a wire on the day of surgery can be technically challenging, and can delay the start of your operation. This technique may therefore reduce waiting times and delays in theatre.

Taking part in the audit may help us to improve breast cancer care for women in the future, in particular those who undergo lumpectomy surgery for their breast cancer, by reducing the stress of a further procedure on the day of their operation.

What if there is a problem?

If you have a concern about any aspect of this, you should ask to speak to your breast surgery consultant who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this by following the standard James Paget Complaints Procedure. The contact for complaints is the Patient Advice and Liaison Service.

What if new information becomes available?

If new information becomes available your doctor will discuss this with you. You are free to withdraw from the study at any point, without giving a reason. If you do choose to withdraw your care will not be affected.

Involvement of the General Practitioner (GP)

Your GP will be informed of the treatment that you undergo as a part of our standard communication with them about your care.

What will happen to the results of the audit?

The results will initially be reported to our surgical governance meetings and audited to ensure the seed has worked. In addition, all centres trialling these seeds will provide anonymised feedback directly to the manufacturers, to ensure the device is safe and that any issues are reported and shared between hospitals.

If the seed works as intended we may adopt this technology to replace the wire marking for all our patients in the coming months.

Contact Details:

If you have any further questions or general enquires about this audit, please contact:

Melanie Taylor, Head of Breast Imaging or Sue Down, Consultant Breast Surgeon

They can be contacted via your assigned Breast Care Nurse Specialist.

Feedback

We want your visit to be as comfortable as possible. Please talk to the person in charge if you have any concerns. If the ward/ department staff are unable to resolve your concern, please ask for our Patient Advice and Liaison (PALS) information. Please be assured that raising a concern will not impact on your care. **Before you leave the hospital you will be asked to complete a Friends and Family Test feedback card.** Providing your feedback is vital in helping to transform NHS services and to support patient choice.

Trust Values

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| <ul style="list-style-type: none">Courtesy and respect• A welcoming and positive attitude• Polite, friendly and interested in people• Value and respect people as individuals <p>So people feel welcome</p> <p>Attentively kind and helpful</p> <ul style="list-style-type: none">• Look out for dignity, privacy & humanity• Attentive, responsive & take time to help• Visible presence of staff to provide care <p>So people feel cared for</p> | <ul style="list-style-type: none">Responsive communication• Listen to people & answer their questions• Keep people clearly informed• Involve people <p>So people feel in control</p> <p>Effective and professional</p> <ul style="list-style-type: none">• Safe, knowledgeable and reassuring• Effective care / services from joined up teams• Organised and timely, looking to improve <p>So people feel safe</p> |
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The hospital can arrange for an interpreter or person to sign to assist you in communicating effectively with staff during your stay. Please let us know.

For a large print version of this leaflet, contact PALS 01493 453240