

Magnetic localisation system

Sentimag® – Magtrace®



Staging your cancer

Your doctor has advised the use of the Magtrace® and Sentimag® magnetic localisation system as a way to assess whether cancer has spread to your lymph nodes. Sentinel lymph nodes (SLNs) are the first lymph nodes where cancer cells are most likely to spread to. A sentinel lymph node biopsy will help your doctor determine the 'stage' of your cancer.

The procedure

In order to identify the sentinel lymph nodes during the biopsy in the surgery, your doctor will inject a small amount (just up to 2 ml) of Magtrace® tracer close to the cancer. After being injected, the Magtrace® tracer will flow through the lymphatic system and will 'mark' your sentinel lymph nodes.

The injection can happen up to 30 days prior to surgery or in the operating theatre after you undergo anaesthesia and fall asleep.

During your surgery, the doctor will use the Sentimag® probe to scan over your skin to learn the general location of the SLN(s), which is near where they will make the biopsy incision.

Once the incision is made, the SLN(s) will be detected using the Sentimag® system. The identified SLN(s) will be removed and sent to the pathology lab for analysis

Benefits

The Magtrace® tracer is an established technique that has been used in over 75,000 breast cancer patients. It enables more flexibility for both patients and physicians as it can be injected in a 30-day window, at a time most convenient.

Another method of marking the SLNs for a biopsy uses a radioactive tracer (technetium radioisotope), sometimes in combination with a blue dye. In a small proportion of patients (1-2%), the blue dye



causes an allergic reaction that can be severe. The Magtrace® tracer is not radioactive and has been determined not to carry the risk of an allergic reaction.

In certain situations, the alternative to the sentinel node biopsy procedure is to remove all the lymph nodes which can lead to an increased risk of fluid swelling (lymphoedema). This is something which the Magtrace® tracer can avoid when used as part of a sentinel node biopsy procedure.

Risks

The Magtrace® tracer can alter magnetic resonance imaging (MRI) studies of the injection and drainage site - this method may be used in certain patients' aftercare plan. Some amount of alteration may be long-term. For instance, MRI is used in certain cases in aftercare of cancer to identify recurrences. Standard methods of aftercare include either ultrasound or mammography. Neither of these two imaging techniques are impacted by the Magtrace® tracer.

The Magtrace® tracer is not intended to be injected into the blood stream.

The Magtrace® tracer can cause a brown skin discolouration near the site of injection; this colouring may persist long-term.

The Magtrace® tracer has not been tested in pregnant women or nursing mothers. For this reason, if you are pregnant or nursing a child, you must tell your doctor.

The Magtrace® tracer contains iron oxide and dextran. If you have previously been diagnosed with iron overload disease or shown sensitivity to iron oxide or dextran, you must tell your doctor.

There is no evidence of adverse reaction following interstitial injection. When similar material to that used in Magtrace® has been injected intravenously, the following selection of undesirable effects have been reported: pain at the injection site, vasodilation, paraesthesia. However, Magtrace® is not intended for intravenous injection. There have been a small number of reports of inflammatory and hypersensitivity response with intradermal injection.

The Sentimag® probe should not be placed within 15 mm of any part of an operating pacemaker. Your doctor will take this into account.

Indication and usage

The Magtrace® and Sentimag® magnetic localisation system is indicated to mark and locate lymph nodes in cancer patients prior to their surgical removal.

Magtrace® tracer is intended and calibrated for use ONLY with the Sentimag® system.

Contraindications

- 1. Magtrace® is contraindicated in any patient with hypersensitivity to iron oxide or dextran compounds.
- 2. Do not administer to any patient with an iron overload disease.
- 3. Do not administer to any patient with a metal implant close to the expected sentinel lymph node location.

The Magtrace® and Sentimag® magnetic localisation system is made up of two parts:

- 1. Magtrace® a magnetic liquid that is injected into your tissue and flows to the SLN(s).
- 2. Sentimag® a probe that can detect Magtrace® in the body using magnetic sensing.

Glossary of medical terms

Lymphoedema

A long-term condition that causes swelling in the body's tissues which develops when the lymphatic system doesn't work properly.

MRI (Magnetic Resonance Imaging)

A procedure using magnetic fields and radio waves to form an image of structures inside the body, e.g. in order to identify recurrences.

Paraesthesia

Abnormal sensation of the skin (e.g., tingling or numbness) with no apparent physical cause

Sentinel node(s)

The first lymph nodes (glands) where cancer cells are most likely to spread from the original tumour site.

Sentinel lymph node biopsy

A surgical procedure in which only the sentinel lymph nodes in the armpit area are removed for analysis.

Technetium radioisotope

A tracer containing a small amount of radioactive Technetium used to locate sentinel lymph nodes.

Vasodilation

Widening of blood vessels.

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