Magtrace™ and Sentimag® Magnetic Localization System Patient Brochure

Caution: Federal law restricts this device to sale by or on the order of a Physician.

Description of the device

Your doctor has advised the use of Magtrace™ and Sentimag® Magnetic Localization System because you have breast cancer and will be having a sentinel lymph node (SLN) biopsy procedure. Sentinel lymph nodes are the first lymph nodes where cancer cells are most likely to spread from the original tumor site. In the sentinel lymph node biopsy procedure, a tracer is injected into the breast which flows to the sentinel lymph nodes. The surgeon, guided by the Sentimag®, removes those nodes so that they can assess whether the cancer has spread to the nodes. This is part of staging the cancer.

Indications and Usage

The Magtrace™ and Sentimag® Magnetic Localization System is indicated to assist in localizing lymph nodes draining a tumor site, as part of a sentinel lymph node biopsy procedure, in patients with breast cancer undergoing a mastectomy.

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

Contraindications

- Known hypersensitivity to iron oxide or dextran compounds.
- Iron overload disease
- A metal implant in the axilla or in the chest.

The Magtrace™ and Sentimag® Magnetic Localization System is made up of 2 parts. Magtrace™ is a magnetic liquid that is injected into your breast tissue and flows to the SLN(s). Sentimag® is a probe that can detect Magtrace™ in the body using magnetic sensing.

Sentimag® System with vials of Magtrace™

Risks

Magtrace™ can alter magnetic resonance imaging (MRI) studies of the injection and drainage site. Some amount of alteration may be long-term. Magtrace™ may travel to regions away from the injection site such as liver, spleen etc

if injected directly into the blood stream. In such cases the presence of Magtrace™ may cause image artefacts during Magnetic Resonance Imaging (MRI). Some manipulation of scan parameters may be required to compensate for the artefact.

In addition, Magtrace™ can cause skin discoloration near the site of injection, this coloring may persist long-term.

Magtrace™ have 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.

Magtrace™ 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.

Benefits

The Magtrace™ and Sentimag® Magnetic Localization System allow your doctor to assess whether breast cancer has spread to your lymph nodes. The main alternative for sentinel node biopsy uses a radioactive tracer (technetium radioisotope) in combination with a blue dye to identify the SLN(s). In a small proportion of patients (1-2%), blue dye causes an allergic reaction that can be severe.

Magtrace™ and Sentimag® are not radioactive and has not been determined to carry the risk of an allergic reaction to blue dye.

In certain situations, the alternative to the sentinel node biopsy procedure is to remove all the lymph nodes in the armpit (axillary clearance). Axillary clearance can lead to an increased risk of fluid swelling in the arm (lymphedema).

What to Expect from Device Use

Your doctor will inject the Magtrace™ into your breast tissue (in the nipple area) with a needle and will massage the area where the liquid was injected to improve flow to the lymph nodes. The injection can happen either after you undergo anaesthesia or you fall asleep, or beforehand.

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 identified using the Sentimag®. The identified SLN(s) will be removed and sent to the testing lab for analysis (histopathology).

Additional information

Summary of Clinical Studies:

The Magtrace™ and Sentimag® Magnetic Localization System have been tested in two clinical trials (studies) to assess how safe and effective the system is for locating sentinel lymph nodes.

Study 1 compared the Magtrace™ and Sentimag® Magnetic Localization System with the combined radioisotope and blue dye tracers. Patients who took part in the trial had breast cancer and were due to have a sentinel node biopsy. Patients received both the radioisotope, and blue dye given in the standard way at each hospital. Magtrace™ was injected at least 20 minutes prior to starting surgery.

Any lymph nodes found using the radioactive probe (gamma probe) or Sentimag®, or any nodes that were coloured blue from the blue dye or black/brown from Magtrace™ were removed, along with any nodes judged to be suspicious by the surgeon. The nodes were sent to the lab for testing (histopathology). The number of nodes detected by the Magtrace™ and Sentimag® Magnetic Localization System was compared with the number detected by the standard technique using radioisotope and blue dye. One hundred forty-seven (147) female patients underwent sentinel lymph node biopsy (SLNB). The average age was 61 years.

In Study 1, a total of 369 lymph nodes were removed. The standard technique (radioisotope and blue dye) detected 345/369 (93.5%) of the nodes and the Magtrace™ and Sentimag® Magnetic Localization System detected 348/369 (94.3%) of the nodes. Overall, the per patient concordance comparing the Magtrace™ and Sentimag® Magnetic Localization System and the control method was 98.0%.

Study 2 compared Sentimag® and Sienna+ (an earlier version of Magtrace™) with the combined radioisotope and blue dye tracers. Patients who took part in the trial had breast cancer and were due to have a sentinel node biopsy. Patients received the radioisotope given in the standard way at each hospital. 45/108 (42%) of patients also received a blue dye injection prior to surgery at sites where blue dye was used as standard. Sienna+ was injected at least 20 minutes prior to starting surgery.

Any lymph nodes found using the radioactive probe (gamma probe) or Sentimag®, or any nodes that were coloured blue from the blue dye or black/brown from Sienna+ (Magtrace™) were removed, along with any nodes judged to be suspicious by the surgeon. The nodes were sent to the lab for testing (histopathology). The number of nodes detected by Sienna+ (Magtrace™) and Sentimag® was compared with the number detected by the standard technique using radioisotope and blue dye. One hundred eight (108) female patients underwent SLNB. The median age was 58 years.

In Study 2, a total of 214 lymph nodes were evaluated. The standard technique (radioisotope) detected 193/214 (90.2%) of the nodes and Sienna+ (Magtrace™) detected 208/214 (97.2%) of the nodes. Overall, the per patient concordance comparing Sienna+ (Magtrace™) and Sentimag® System and the control method was 96.3%.

The data from these trials demonstrated that the Magtrace™ and Sentimag® Magnetic Localization System is as effective as traditional radioisotope and blue dye in detecting lymph nodes draining a breast tumor.

Adverse events:

Some temporary or longer-term skin dis-coloration may occur near the site of injection (23 out of 147 subjects in the U.S. clinical trial developed skin staining). Erythema may also occur near the injection site (1 out of 147 subjects in the U.S. clinical trial). One event of anaphylaxis and one event of bradycardia occurred during the U.S. clinical trial but were not clearly related to Magtrace™ and Sentimag® Magnetic Localization System use.

Potential adverse events:

Magtrace™ is intended for injection into the breast ONLY (interstitial injection).

When similar material to that used in Magtrace™ has been injected directly into the bloodstream (intravenously), the following undesirable effects have been reported:

- Common (<2%) – pain at the injection site, vasodilation, paresthesia
- Uncommon (≥0.1% to <1%) – asthenia, back pain, injection site reactions, chest pain, nausea, vomiting, headache, taste changes, itching, rash, inflammatory response (localized redness and swelling) with intradermal injection.
- Rare (≥0.01% to <0.1%) – Hypersensitivity and anaphylaxis, hypertension, phlebitis, hyperesthesia, anxiety, dizziness, convulsion, parosmia, dyspnea, increased cough, rhinitis, eczema, urticaria.

Glossary of medical terms

Axillary clearance: A surgical procedure in which all the lymph nodes in the armpit area are removed.

Histopathology: Analysis under the microscope of changes in tissue caused by diseases such as cancer.

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.

Sentinel node(s): The first lymph nodes (glands) where cancer cells are most likely to spread from the original tumor 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.

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