Sentimag® – Magnetic sentinel lymph node localisation
The future of cancer staging

Most treatments for early breast cancer involve ‘sentinel lymph node biopsy’, or SLNB. This method, which identifies the lymph nodes with the highest potential for harbouring metastases, lets clinicians determine the stage of the cancer and make informed decisions for post-operative care.

Standard SLNB uses radioisotopes. Instead, we offer an effective clinical solution that uses safe magnetic fields to power our diagnostics. This eliminates the concerns related to the safety, workflow and availability associated with ionising radiation. Our system consists of the Sentimag® probe and the Sienna+® magnetic tracer. The tracer is injected into the interstitial tissue to provide a traceable signal. Using the Sentimag® probe, surgeons then locate the sentinel lymph nodes – vital for determining how far the cancer has spread.

Surgeons retain full control, can improve their workflow and provide better patient comfort as they can inject Sienna+® and locate the lymph node without the need for nuclear medicine or special licensing. The Sentimag® and Sienna+® system is an effective and valuable alternative that can be offered in the widest range of hospitals and clinics.

A new state-of-the-art approach

- Best practice SLNB can be performed anywhere, by any trained practitioner
- Issues with radioactive materials are eliminated, but with equivalent clinical outcomes [1 – 6]
- Surgeon alone is in full control of the SLNB procedure
- Ultrasensitive detection and intuitive localisation of sentinel lymph nodes
- Sienna+® tracer is safe and has a long shelf life
- Sentimag® and Sienna+® are a CE-approved system for SLN localisation
Clinical Results

The Sentimag® and Sienna+® tracer were developed in the clinic with direct input and feedback from surgeons during the design and prototyping process. Since it was launched at the end of 2012, the system has been used to treat over 5,000 patients and has produced a strong base of clinical results that confirms its safety and efficacy in diagnosing and treating breast cancer.

Clinical studies and trials involving over 1,000 patients across 12 European countries have demonstrated clinical equivalence to the standard of care for SLNB – either Technetium (99mTc) alone or the combination technique (99mTc and blue dye) [1 – 6].

<table>
<thead>
<tr>
<th>Technique / Parameter*</th>
<th>Sentimag®</th>
<th>Standard technique</th>
</tr>
</thead>
<tbody>
<tr>
<td>Detection rate</td>
<td>97%</td>
<td>97%</td>
</tr>
<tr>
<td>Concordance</td>
<td>98%</td>
<td></td>
</tr>
<tr>
<td>Malignancy detection rate</td>
<td>95%</td>
<td>93%</td>
</tr>
<tr>
<td>Malignancy concordance</td>
<td>98%</td>
<td></td>
</tr>
<tr>
<td>Mean number of nodes</td>
<td>1.9</td>
<td>1.8</td>
</tr>
</tbody>
</table>

*All parameters calculated on a per-patient basis

References


As sensitive as the radiotracer, as easy as blue dye

With the Sentimag®/Sienna+® system, clinicians can quantify the amount of tracer located in a specific node relative to others. This higher tracer loading is a hallmark of the sentinel node identification process and is similar to the radioactive method. With Sienna+®, however, neither clinicians nor patients are exposed to any radiation at any stage.

Gamma system users have no issues adapting to the Sentimag® procedure as the probe handling is remarkably similar. As a result, almost no additional training is required. There aren't special procedural requirements either, such as darkening the room for fluorescent localisation systems.

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Thanks to the flexible workflow, which requires no scheduling between departments and almost no pre-operative preparation, surgical departments can arrange more SLNB procedures per day, can help those in need be treated sooner, and promote more out-patient surgery.

Magnetic SLNB procedure

1. Sienna+® is injected into the interstitial tissue
2. Tracer follows drainage path to nearest lymph nodes
3. Draining lymph nodes are detected with Sentimag®
4. OSNA® or histological analysis of sentinel lymph nodes
5. Lymph nodes show no signs of malignancy
6. Remaining regional nodes are not removed
7. Lymph nodes show signs of malignancy
8. Clinicians follow their accepted protocol

<table>
<thead>
<tr>
<th>Technique / Benefit</th>
<th>Sentimag®</th>
<th>Gamma system</th>
<th>Fluorescent system</th>
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<tbody>
<tr>
<td>Quantifiable SLNs</td>
<td>✓</td>
<td>✓</td>
<td>x</td>
</tr>
<tr>
<td>Avoids radiation</td>
<td>✓</td>
<td>x</td>
<td>✓</td>
</tr>
<tr>
<td>Surgeon-controlled</td>
<td>✓</td>
<td>x</td>
<td>✓</td>
</tr>
<tr>
<td>Established practice</td>
<td>✓</td>
<td>✓</td>
<td>x</td>
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</table>
The magnetic way to detect SLNs

**Sentimag® Probe**
The detection of sentinel lymph nodes using Sentimag® is ultrasensitive – and as it is proximity-based, localising nodes is highly intuitive. The system is suitable for both pre- and post-incision use, and its sensitivity can be adjusted according to three levels from the front panel control. The Sentimag® instrument uses the principle of magnetic susceptometry and generates an alternating magnetic field which transiently magnetises the iron oxide particles in Sienna+®. The tiny magnetic signature generated by the Sienna+® particles is then detected by the Sentimag® probe.

**Sienna+® Tracer**
Sienna+® is a dark brown suspension of organically coated, superparamagnetic iron oxide (SPIO) particles with a tight size distribution of around 60 nm. It is injected subcutaneously where the lymphatic system’s natural physical action filters out the particles and so enables sentinel nodes to be located using the Sentimag® probe. The magnetic tracer is safe, easily stored and has a long shelf life. It is also compatible with standard histological techniques, as well as the One-Step Nucleic Acid Amplification (OSNA) assay. Due to its brownish colouration Sienna+® is traceable both magnetically and visually.

**Key features of Sentimag®**
- Ultrasensitive detection – Proximity-based sensing for accurate node localisation
- Intuitive localisation of nodes – Audible pitch variation means the surgeon can focus on the patient
- Flexible – Suitable for both pre- and post-incision use
- Large two-colour digital display, easy to read even in low light
- Simple to use after a short period of familiarisation

**Benefits of Sienna+®**
- Optimised – Particle size is optimised for filtration and retention by sentinel lymph nodes
- Easy to use – Simple to store and handle, significantly improving workflow compared with radioactive tracers
- Fast – Localisation can start just 20 minutes after injection*
- Compatible with OSNA assay

*Migration time can increase with patient age, weight or breast size