

Clinical Results

The Sentimag® and Sienna+® tracer were developed in the clinic with direct input and feedback from surgeons. Since it was launched at the end of 2012, the system has been used to treat over 20,000 patients and has produced a strong base of clinical results that confirms its safety and efficacy in sentinel node localisation, a vital part of nodal cancer staging, e.g. by One-Step Nucleic Acid Amplification (OSNA®).

Clinical studies involving over 1,000 breast cancer patients across 12 European countries have demonstrated non-inferiority to the standard of care for SLNB – either Technetium (^{99m}Tc) alone or the combination technique (^{99m}Tc and blue dye) [1–2]. Other cancer entities besides breast cancer are currently being evaluated throughout Europe. Initial clinical data and user feedback has been collected for magnetic SLNB in prostate, colon and endometrial cancer, suggesting that the magnetic SLNB method is suitable for an increasingly wide range of cancer indications [3–6].

Results for Breast Cancer SLNB



References :

- [1] Karakatsanis et al. (2016). *Breast Cancer Res Treat*; 157(2):281–294. – Meta-analysis of 7 clinical studies of magnetic SLNB in breast cancer.
 - [2] Teshome et al. (2016). *Ann Surg Oncol*; 23(5):1508-14. – Meta-analysis of 6 clinical studies of magnetic SLNB in breast cancer.
 - [3] Winter et al. (2016). *J Urol*; 195(4):E987.
 - [4] Winter et al. (2015). *Ann Surg Oncol*; 21(13):4390-6.
 - [5] Pouw et al. (2016). *Colorectal Dis*; 18(12):1147-53
 - [6] Rzepka et al. (2014). *J Clin Oncol*; 32:(suppl); abstr E16550).
- For further clinical results, please visit www.sysmex-europe.com

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Sentimag®

Magnetic localisation of sentinel lymph nodes – easy, flexible and effective



Best practice SLNB for more patients, at any hospital, at any time

Many treatments for early-stage cancer involve 'sentinel lymph node biopsy', or SLNB. This method, which identifies the lymph nodes with the highest potential for harbouring metastases, helps to determine the nodal stage of the cancer and make informed decisions for surgery and subsequent treatment.

Standard SLNB uses radioisotopes for sentinel node localisation. We offer an effective clinical solution that uses safe magnetic fields instead. This eliminates concerns related to the safety, workflow and availability associated with ionising radiation. Best practice SLNB is now possible everywhere, with no time restrictions.

Our system consists of the SentiMag[®] probe and the Sienna+[®] magnetic tracer. First, the tracer is injected into the interstitial tissue to provide a traceable signal. Next, using the SentiMag[®] probe, you locate the sentinel lymph nodes to determine how far the cancer has spread.

SentiMag[®] – An effective clinical solution

- Perform best practice SLNB in any clinical setting
- Eliminate issues with radioactive materials; reach equivalent clinical outcomes [1–2]
- As a surgeon, organise and manage the SLNB procedure to suit your needs
- Inject the tracer at the best moment, up to seven days in advance
- No evidence of anaphylaxis with interstitial tracer injection
- SentiMag[®] and Sienna+[®] are CE-approved for SLN localisation

As effective as the radiotracer, as easy as blue dye

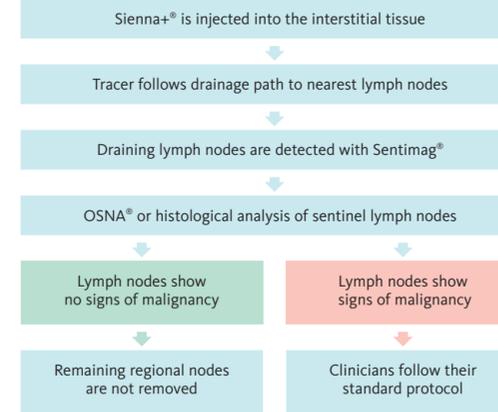
With the SentiMag[®] /Sienna+[®] system, you can quantify the amount of tracer located in a specific node relative to others. This higher tracer loading is a hallmark of the sentinel node identification process and is similar to the radioactive method. With Sienna+[®], however, neither you nor your patients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

A unique benefit of the Sienna+[®] tracer is that it can be injected up to seven days before surgery. Thanks to this flexible workflow, which requires no scheduling between departments and almost no pre-operative preparation, you can arrange more SLNB procedures per day, help those who need treatment sooner, and conduct more out-patient surgery.

If you are a gamma system user, you will have no issues adapting to the SentiMag[®] procedure as the probe handling is remarkably similar. This also means you will need almost no additional training. There are no special procedural requirements either, such as darkening the room required for fluorescent localisation systems.

Technique/ Benefit	SentiMag [®]	Gamma system	Fluorescent system
Quantifiable SLNs	✓	✓	x
Avoids radiation	✓	x	✓
7-day injection window	✓	x	x
Surgeon-controlled	✓	x	✓
Established practice	✓	✓	x

Magnetic SLNB procedure



The magnetic way to detect SLNs

SentiMag[®] Probe

The SentiMag[®] instrument uses the principle of magnetic susceptometry and generates a magnetic field that temporarily magnetises the iron oxide particles in Sienna+[®]. The SentiMag[®] probe then detects the tiny magnetic signature generated by the Sienna+[®] particles.

Since SentiMag[®] sensing is proximity-based, localising nodes is particularly intuitive. You can use the system both before and after incision and adjust its sensitivity as required according to tracer accumulation in the nodes.

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. Injected subcutaneously, the lymphatic system's natural filtration ensures the particles are caught in the sentinel nodes. You can now locate the SLNs using the SentiMag[®] probe.

The magnetic tracer has a good safety profile and a long shelf life. It is also compatible with standard histological techniques, as well as the OSNA[®] assay. Since it has a brownish colour, Sienna+[®] is traceable both magnetically and visually.

Key features of SentiMag[®]

- Highly accurate, proximity-based detection for intuitive node localisation
- Audible pitch variation means you can focus on the patient and not on the display
- Use it for both pre- and post-incision use
- 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 with a long shelf-life
- Fast – Start localisation just 20 minutes after injection*
- Flexible – Seven-day window from injection to surgery
- Compatible with OSNA[®] assay

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