



endomag⁺

Improving the global
standard of cancer care for
everyone, everywhere

 **EBOS**
HEALTHCARE

ESSENTIAL TO HEALTH





Our focus on you: simplicity + confidence

Magnetic Sentinel Lymph Node Biopsy

The incidence of cancer is growing worldwide, and with it the demand for better, faster and less expensive solutions for diagnosis and treatment.

Endomag is developing a new, effective clinical platform that uses safe magnetic fields to power diagnostic and therapeutic devices. These will avoid the safety, workflow and availability concerns associated with ionising radiation.

Without changing clinical procedures or outcomes, Endomag products put the surgeon in control and improve the experience for patients. They will save time and money in hospitals across the world by improving workflow and efficiency.

The future of cancer staging

The first two Endomag products are the Sentimag[®] probe and Sienna+[®], a magnetic tracer solution. Sienna+[®] is injected into the body and the Sentimag[®] is used to track its presence, locating lymph nodes for the staging of breast cancer.

By avoiding the need for traditional radioisotopes in sentinel lymph node biopsy (SLNB), and the flexibility to inject in the OR up to seven days before the procedure, Sentimag[®] and Sienna+[®] improve workflow and lower costs, enhance patient comfort and quality of life, and provide a better standard of care available to everyone, everywhere.

Key advantages for clinicians

- Allows best practice SLNB to be performed anywhere, by any trained practitioner
- Issues with radioactive materials are eliminated, but with equivalent clinical outcomes [1-7]
- Delivers ultrasensitive detection and intuitive location of sentinel lymph nodes
- Sienna+® tracer is safe, easy to transport and has a long shelf life
- Increases workflow, efficiency and cost-effectiveness
- Sentimag® and Sienna+® are a CE-approved system for SLN localisation

Sienna+® Tracer

Sienna+® is a dark brown suspension of organically coated iron oxide particles. It is injected subcutaneously where the natural physical action of the lymphatic system filters out the particles, enabling sentinel nodes to be located using Sentimag®.

- Optimised – Particle size is optimised for filtration and retention by sentinel lymph nodes
- Easy to use – Simple to store and handle, which means it significantly improves workflow compared with radioactive tracers
- Flexible – Sienna+® can be injected up to seven days ahead of sentinel node biopsy.
- Fast – Localisation can start just 20 minutes after injection†

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

Sentimag® Probe

The Sentimag probe activates the iron oxide particles in Sienna+®. The magnetic signature generated by the Sienna+® particles is then detected by the Sentimag® probe.

- Ultrasensitive detection – Proximity-based sensing for naturally intuitive and accurate node localisation
- Intuitive location of nodes – Audible pitch variation allows the surgeon to focus on the patient, not the instrument
- Flexible – Suitable for both pre- and post-incision use

Clinical results

Since its launch at the end of 2012, the system has treated over 12,000 patients and has produced a strong base of clinical results confirming its safety and efficacy in the nodal staging of breast cancer. It has been involved in over 10 clinical studies and trials recruiting over 1,500 patients across 12 European countries that have demonstrated clinical equivalence to the standard of care for SLNB – either Technetium (99mTc) alone or the combination technique (99mTc and blue dye) [1-7].

Parameter*	Sentimag®	Standard technique
Detection rate	97%	97%
Concordance	98%	
Malignancy detection rate	95%	93%
Malignancy concordance	97%	
Mean number of nodes	1.9	1.8

*All parameters calculated on a per-patient basis



About Endomag

Since 2007, we've been devoted to developing new and effective techniques for diagnosing and treating cancer. Our focus is on perfecting methods that improve the experience of patients, whatever their stage of treatment.

The Sentimag® and Sienna+® device system was developed to increase access to the standard of care in breast cancer staging by providing an alternative approach to locating sentinel lymph nodes. The Endomag system avoids the need for traditional radioisotopes in sentinel lymph node biopsy (SLNB), improving workflow and

costs at the same time as increasing standard of care and improving patient comfort and quality of life.

The Sentimag® and Sienna+® are CE-approved for marketing and sales in Europe, the Middle East, Africa and Australasia. Endomag is seeking marketing authorisation in other countries to deliver its technology to global markets.

Comparison with traditional approaches

Technique/advantage	Sentimag®	Gamma probe	Fluorescent probe
Avoids radiation	Yes	–	Yes
Surgeon-controlled	Yes	–	Yes
Established working practice	Yes	Yes	–
Suitable for both pre- and post-incision use	Yes	Yes	–
Spatial imaging	Yes (MRI - high res)	Yes (Scintigraphy - low res)	–
Quantitative detection	Yes	Yes	–
Intra-operative injection	Yes	No	Yes
Maximum injection time	7 days before	24 hours before	2 hours before

Sentimag® and Sienna+® avoid the use of radioisotopes while maintaining standard working practice and delivering equivalent detection rates to the standard of care.

Clinical references:

1. Douek M, Klass J, Monypenny I, et al. Sentinel node biopsy using a magnetic tracer versus standard technique: the SentiMAG Multicentre Trial. *Ann Surg Oncol*. 2014;21:1237–45.
2. Thill M, et al. The Central-European SentiMag study: sentinel lymph node biopsy with super paramagnetic iron oxide (SPIO) vs. radioisotope. *Breast* 2014;23:175–9.
3. Rubio IT, et al. The super paramagnetic iron oxide is equivalent to the Tc99 radiotracer method for identifying the sentinel lymph node in breast cancer. *Eur J Surg Oncol*. 2015;41:46–51.
4. Pinero-Madrona A, et al. Superparamagnetic iron oxide as a tracer for sentinel node biopsy in breast cancer: a comparative non-inferiority study. *Eur J Surg Oncol*. 2015;41:991–7.
5. Ghilli M, et al. The supramagnetic iron oxide tracer: a valid alternative in sentinel node biopsy for breast cancer treatment. *Eur J Cancer Care (Engl)*. 2015. doi:10.1111/ ecc.12385
6. Houpeau JL, et al. Sentinel lymph node identification using superparamagnetic iron oxide particles versus radioisotope: The French Sentimag feasibility trial. *J Surg Oncol*. 2016 Jan 12. doi: 10.1002/jso.24164
7. Teshome M, Wei C, Hunt KK, et al. Use of a Magnetic Tracer for Sentinel Lymph Node Detection in Early-Stage Breast Cancer Patients: A Meta-analysis. *Ann Surg Oncol*. 2016 Feb 18.



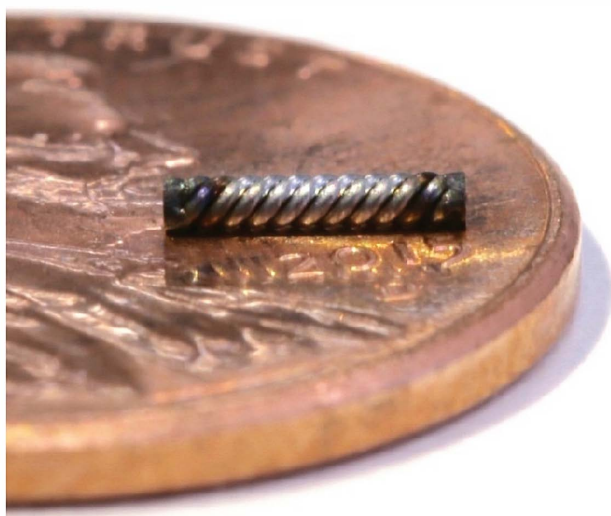
Magnetic Seed Localization

Magnetic Seed Localization (MSL) is a new technique to help Radiologists and Surgeons localize impalpable breast lesions.

Magseed® (the size of a grain of rice) is inserted into the lesion under image guidance, up to 30 days prior to surgery. This flexibility simplifies the scheduling of patients, and allows them to go straight to the OR on the day of surgery minimizing delays and enhancing the patient experience.

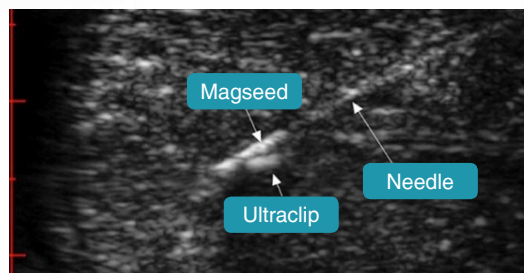
In the OR Magseed® is located using the Sentimag® probe and can be detected from any direction, regardless of seed orientation. The seed has no moving parts and can't be damaged when implanted. It is still detectable even if accidentally cut during dissection.

During surgery, through a combination of audio and visual feedback, the surgeon can use location of the seed to orientate the specimen and guide dissection.

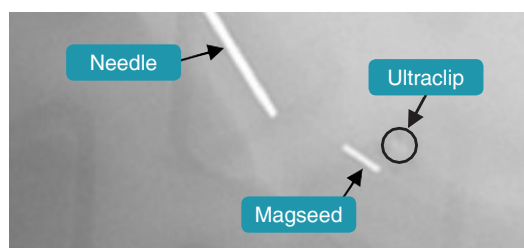




Endomag:	1mm x 5mm
Delivery System:	18-gauge needle
Implantation:	Up to 30 days
Image Guidance:	Ultrasound of Mammography
Sensing Depth:	40mm - or greater with palpation
Sensing Direction:	Detectable from any orientation
Sensing Accuracy:	Pinpoint to within a few millimeters
Seed Signal:	No decay in signal over time No requirement for tissue contact Can't be damaged during placement Still detectable if accidentally cut
Feedback:	Real time audio and visual feedback
Bracketing:	Seeds 20mm apart or greater



Ultrasound visibility of Magseed®



X-Ray visibility of Magseed®

About Endomag

Endomag is dedicated to improving the global standard cancer care for everyone, everywhere, by developing a unique clinical platform that uses magnetic fields to power diagnostic and therapeutic devices. Endomag's first approved products form a minimally-invasive surgical guidance system to address unmet needs in work flow efficiency, availability and affordability for surgical oncology.

Sentimag® is the foundation of this system, and is the world's most sensitive handheld magnetic probe. Given its sensitivity, it can detect minute quantities of magnetic material in the body to guide surgeons in a lumpectomy using Magseed®, or to the lymph nodes first in line to drain from a tumor in a sentinel lymph node biopsy using Sienna+®.

Clinical references:

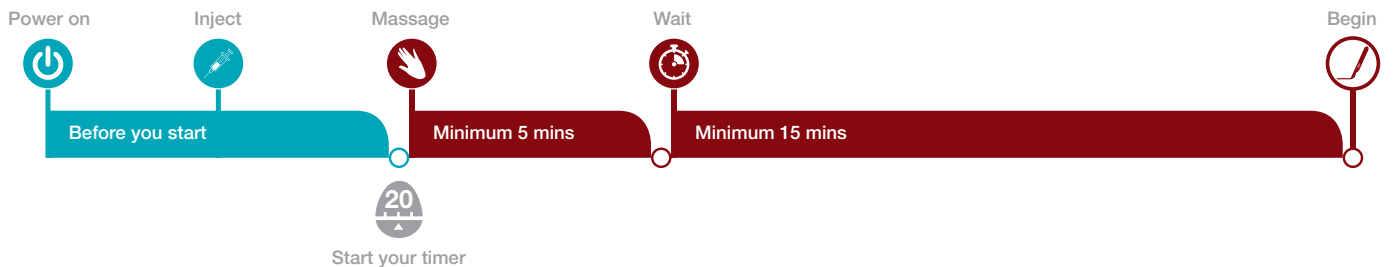
1. Teshome M, Wei C, Hunt KK, et al., Use of a Magnetic Tracer for Sentinel Lymph Node Detection in Early-Stage Breast Cancer Patients: A Meta-analysis. *Ann Surg Oncol.* 2016; 23(5): 1508-14.
2. Price eta (2018) Initial Clinical Experience with an inducible Magnetic Seed System for Preoperative Breast Lesion Localization. *AJR AM J Roestgengol W1-W5. Arch Pathol Lab Med.* 2017 Oct;141(10):1324-1329. doi: 10.5858/arpa.2017-0214-RA.Jeffries DO et al Localization for Breast Surgery The next Generation.
3. James R. Harvey1 ·et al (2018) Safety and feasibility of breast lesion localization using magnetic seeds (Magseed): a multi-centre, open-label cohort study *Breast Cancer Research and Treatment* (2018) 169:531–536.

Sentimag® launched in 2013 and, along with Sienna+®, has been used in over 12,000 sentinel lymph node biopsies in Europe and Australasia. In that time a number of multi-center clinical trials across Europe have completed. The most recent publication, a meta-analysis, concluded that Sienna+® is “non-inferior to the standard method [Tc99 + Blue Dye] for SLN detection in patients with clinically node-negative breast cancer”¹.

Sentimag® and Magseed® have FDA 510(k) clearance and are available in the United States. Sienna+® is limited to investigational use only under an FDA-approved IDE.

Sentimag Quick Guide

Pre-incision checklist



Sentimag probe – proximity sensing



Sweep the probe around the axilla until a hotspot is located



Pivot the probe around the hotspot to maximise the signal

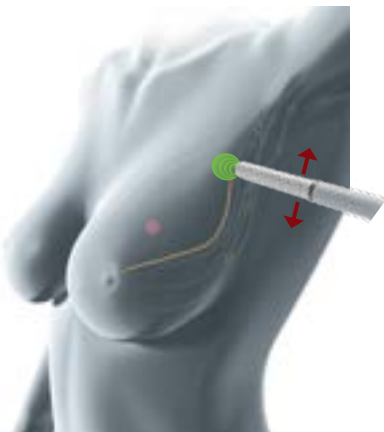


Palpation of the hotspot should result in a rise and fall in the signal

Finding a node

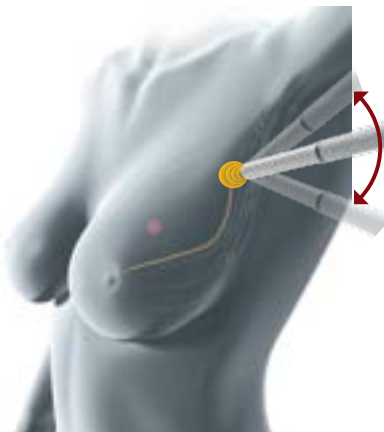
Detect

Sweep the probe around the cavity until a hotspot is located



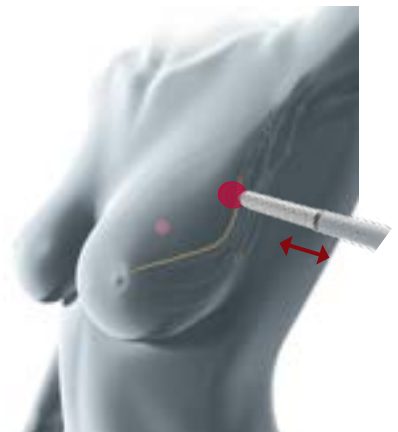
Pinpoint

Pivot the probe around the hotspot to find the highest signal



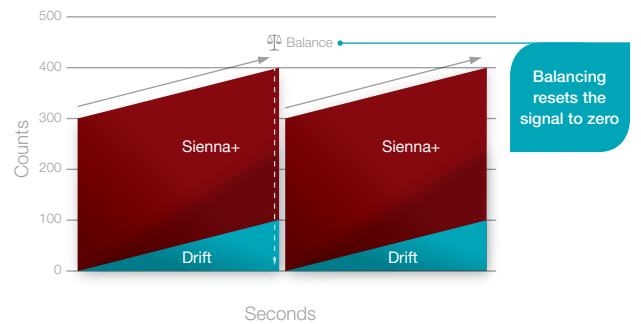
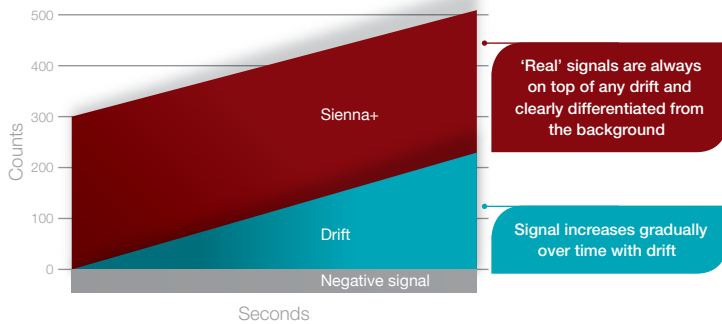
Confirm

Gentle palpation of the hotspot should result in a rise in signal



Understanding drift

Sentimag probes are highly sensitive and therefore respond to thermal changes in their environment. When inserted into the axilla, all probes will experience some thermal drift which causes the Sentimag count to rise.

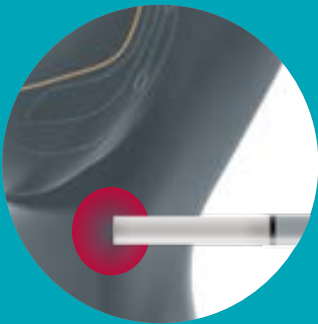


Balancing

How to use the balance function:

Body balance

to locate transcutaneous signal



Air balance

locating lymph nodes
(*in vivo* and *ex vivo*)



How to confirm a Sienna+ node

Listen

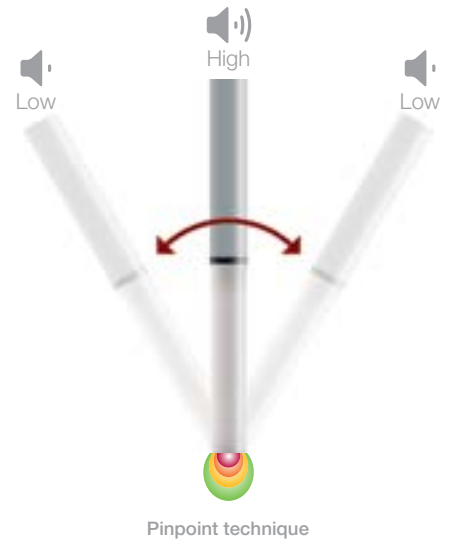
The signal will increase when the probe is pointing directly at a Sienna+ node, and decrease when angled away. This is known as the 'pinpoint' technique.

Balance in air

Remove the probe from the incision, balance in the air and recheck the suspect node.

Balance *in vivo*

From within the incision, withdraw 2-3cm from the suspect node and re-balance. A clear positive signal should be seen when you examine the node again.



Additional tips



Hold behind the black ring



Always keep the probe moving



Navigate using the sound of the base unit



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