Magnetic lesion and lymph node localisation

Sentimag® – Magseed®

Small seed.
Big impact.

www.sysmex-europe.com/magseed
Clinical results

Since its launch in 2016, Magseed® alongside the Sentimag® system has been used to safely and effectively localise lesions and lymph nodes in over 50,000 patients. Clinical studies involving over 3,000 patients worldwide have demonstrated that Magseed® can be accurately placed and successfully removed and stays securely in place without migrating.

The Magseed® magnetic marker is preferred over wire localisation due to lower positive margin rates and higher surgeon satisfaction. [1] High accuracy of the method is shown by an averaged re-excision rate of only 11% over a multitude of studies. [2] Placement and retrieval is feasible across a wide range of localisation depths and breast sizes without complications. [3] Results from two independent studies demonstrated the ease and accuracy of marking positive lymph nodes with Magseed® and 100% retrieval success. [4, 5]

Magseed® is more convenient, can reduce scheduling delays and improve efficiency in the OR [2, 6-9]. Patients reported no pain during breathing and movement, resulting in overall higher comfort. [10, 11] In addition to its clinical benefits, Magseed® has the potential to drive cost savings when adopting it as a standard of care.

The results below represent feedback from over 400 surgeons and radiologists who used Magseed® in over 1,000 procedures [12].

Feedback from 140+ radiologists

- 98% Placed where intended
- 97% Placement was simple
- Magseed® improves patient comfort
- Magseed® is easier than wire localisation*

Feedback from 300+ radiologists and surgeons

- 95% Magseed® improves workflow efficiency
- 99% Clinicians want to use Magseed® again

Feedback from 170+ surgeons

- 98% Seeds detected pre-incision**
- 7% Positive margins on initial dissection
- Magseed® improves workflow efficiency
- Magseed® is easier than wire localisation*

References

[12] Data from the Sysmex Magseed® Xperience Survey 2017/2018

For further clinical results, please visit www.sysmex-europe.com

* 98% of clinicians rated the easiness of Magseed®-guided lesion localisation ‘easier’ or ‘same’ as wire-guided localisation.
** 100% of seeds located post-incision

Confidence meets convenience – for clinicians and patients

In recent years, advancements in medical practices have offered more women diagnosed with breast cancer the opportunity to receive breast-conserving and lymph node-sparing surgery. At any stage, the target is to de-escalate the surgical radicality.

To ensure both oncologic safety and patient comfort, reliable marking of lesions and target lymph nodes is a prerequisite. However, many tissue markers encounter significant challenges, including:

- unreliable detectability due to migration or low visibility in imaging
- radiation exposure
- not always suitable for long-term placement
- not always suitable for each tissue type

As a result, patients can experience discomfort, such as unnecessary anxiety, physical pain and a suboptimal cosmetic outcome.

The Magseed® marker has been specifically designed to overcome the challenges of other clip, reflector, tag, radioseed and wire markers. It enables a flexible patient treatment pathway – from placement of the marker until the day of surgery. Magseed® promotes high oncologic safety, accurate tissue localisations and improved patient satisfaction, preventing unnecessary surgery and helping to reduce the extent of the required ones.

Magseed® is used alongside the Sentimag® system, a sensitive magnetic detector that locates the seed. The marker is deployed under ultrasound or X-ray guidance any time before surgery. Once in the operating room, the surgeon then uses the Sentimag® system’s probe to precisely locate the Magseed®, and thereby the lesion or lymph node in which the Magseed® has been placed.

Magseed® – benefits for all

✔ Designed with the patient in mind – no radioactivity, reduced stress, less pain
✔ Placed in any soft tissue – breast lesion, lymph node, etc.
✔ Can be implanted for as long as needed – always reliably detectable by Sentimag®
✔ Smallest non-radioactive seed – ideal for lymph node placement
✔ Decoupling of OR and radiology scheduling
✔ Stays securely in place without migration from soft tissue
✔ Very low re-excision rate for lesions (11% averaged over multiple studies)
✔ Magseed® has been used in over 50,000 tissue localisations
✔ Sentimag® and Magseed® are CE-marked and FDA-cleared for soft tissue
**Sentimag®** – one system, with multiple flexible applications

Together with the Magseed® marker, the Sentimag® system offers a complete solution for various types of magnetic soft-tissue localisation.

Magseed® is a wire-free, non-radioactive marker which can be placed anytime before surgery. It is the smallest available device continuously detectable with a probe. Distance-based measurement enables precise localisation.

**Impalpable lesions – confident localisation at low positive margin rates**

By using an alternative to the wire, radiology and OR scheduling can be decoupled, reducing stress for the patient and improving the clinical workflow. Magseed® enables highly accurate lesion localisations at a very low re-excision rate. It minimises infection risk and offers flexible scar placement. For an effective localisation, elongated lesions can be bracketed with two or more seeds placed at least 20 mm apart.

**Long-term lesion localisation – on the safe side at any time**

The seed’s spiral shape optimises tissue in-growth ensuring that it stays securely in place, even if neoadjuvant treatment is subsequently applied. Whilst it offers high echogenicity under ultrasound and excellent X-ray visibility, Magseed® surgery can be performed completely independent of an imaging system thanks to the reliable and accurate detection with the Sentimag® probe.

**Targeted axillary dissection (TAD) – optimising nodal staging post-NAST**

Its small size and design makes Magseed® an excellent fit for the localisation of initially positive lymph nodes, through target lymph node biopsy (TLNB), and no migration has been reported during long-term placement. It can always be confidently located without any further imaging technique beyond the Sentimag®. Magseed® offers full flexibility in placement time, any time prior to or on the day of surgery. In combination with the Magtrace® lymphatic tracer – an ideal tracer for SLNB treatment – and Magseed®, the Sentimag® is the world’s only system for radiation-free, wire-free targeted axillary dissection (TAD).

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**Magseed® – at a glance**

- 1 x 5 mm, smaller than a grain of rice
- Surgical steel marker, very low nickel content
- 18-gauge, sharp needle – precise and easy placement also in dense breast tissue, no skin incision needed, high patient comfort
- Firmly implanted, no migration from soft tissue
- Spiral shape optimises tissue in-growth and visibility under imaging
- No risk of deactivation
- Permanently detectable with Sentimag®

**Sentimag® – at a glance**

- Highly sensitive magnetic detector
- Temporarily magnetises Magseed® during detection
- Real-time audio and visual feedback
- 360-degree detection with millimetre accuracy
- Distance guidance
- OR lights do not influence the performance
- 90,000 patients successfully treated worldwide, using Magtrace® and/or Magseed®

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**Key features**

- Impalpable lesion localisation
- Bracketing of lesions
- Target lymph node biopsy
- Sentinel lymph node biopsy*
- X-ray visibility
- Robust
- Medical grade stainless steel/low nickel content
- No risk of deactivation
- Ultrasound visibility
- Non-radioactive
- Small size
- Firmly implanted
- 360° sensing
- Depth sensing

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*Using Sentimag® in combination with Magtrace® magnetic tracer
The world’s only system for magnetic lesion and lymph node localisation

For more information, visit www.sysmex-europe.com/sentimag
Sentimag® – Magseed®

Magnetic lesion localisation for breast cancer – clinical results from 2000+ seed placements

Since the Sentimag®– Magseed® system was launched at the end of 2016, it has been used to safely and effectively localise benign and cancerous lesions as well as lymph nodes in over 40,000 cancer patients. Magseed® can now be implanted into any soft tissue with no restriction on implantation time. Clinical studies involving over 2,000 patients globally have demonstrated that Magseed® can be accurately placed, successfully removed and stays securely in place without any migration. It promotes seamless operating room scheduling, accurate localisation at low positive margin rates and high patient comfort.

Clinical study results – selection

<table>
<thead>
<tr>
<th>First author</th>
<th>Patients</th>
<th>Seeds placed</th>
<th>Placement success</th>
<th>Retrieval rate</th>
<th>Migration rate</th>
<th>Positive margin rate</th>
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<tbody>
<tr>
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</tbody>
</table>

Ultrasound: 64%  Mammography: 36%

Mean placement to surgery time

Range = 0 – 248 days

Placement method

Positive margin rate

0%
Magnetic lesion localisation for breast cancer – clinical results

Publications


Last update December 2019
Sentimag® – Magseed®
Targeted Axillary Dissection (TAD) – results from 200+ target node localisations

Breast cancer patients diagnosed with clinically positive lymph nodes often receive neoadjuvant systemic therapy (NAST) with the aim to downstage or eradicate the disease. To accurately assess the response in the breast and the axilla, it is important that both the positive lymph node/s and the breast lesion are marked before NAST to be able to locate them later on. Systemic therapy can negatively impact lymphatic drainage and hence reduce the accuracy of the sentinel lymph node biopsy (SLNB). However, when SLNB is paired with removal of the previously positive target lymph node, a technique called Targeted Axillary Dissection (TAD), the operation becomes a lot more accurate. Studies of TAD have demonstrated a false negative rate of < 2 % compared to SLNB alone. (Caudle et al. JCO 2016)

The Magseed® marker has already been used to safely and effectively localise over 40,000 breast lesions and axillary lymph nodes. Its small size makes it the ideal marker for TAD and can now be implanted in any soft tissue for as long as required. Clinical studies involving over 200 patients globally have demonstrated accurate placement, no migration once implanted and accurate removal. In addition to improving clinical outcomes, it also offers a better patient experience and promotes seamless radiology and OR scheduling. When the Magseed® marker is used in combination with the lymphatic tracer Magtrace®, they offer the world’s only wire-free, radiation-free solution for TAD in one platform.

Clinical study results – selection

<table>
<thead>
<tr>
<th>First author</th>
<th>Patients</th>
<th>Seeds placed</th>
<th>Placement success</th>
<th>Longest placement to surgery time</th>
<th>Retrieval rate</th>
<th>Nodal identity</th>
<th>TLN = SLN</th>
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<td>ND</td>
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<tr>
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<td>100 %</td>
<td>30 days</td>
<td>100 %</td>
<td>80 %</td>
<td></td>
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</table>
Target lymph node localisation – clinical results

Publications

[1] Salazar Gomez et al. (2019): Utilidad de la semilla magnética para la localización de los ganglios mercado tras tratamiento neoadjuvante. 4th Spanish Breast Congress. [open access]


Ongoing studies


[8] NCT03718455 - Evaluation of Magseed as Localization Device for Biopsy Proven Metastatic Axillary Lymph Nodes. 20 patients, recruiting. Sponsor and site: Mayo Clinic, Rochester

Last update December 2019
Clinical results
Results for breast cancer SLNB
Detection rate per patient
Malignancy detection rate per patient
Concordance Malignancy concordance
Mean no. SLNs

98 %
2.0
97 %

Standard

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Manufacturer: Endomagnetics Ltd
The Jeffreys Building, St John’s Innovation Park, Cowley Road, Cambridge CB4 0WS, United Kingdom

You will find your local Sysmex representative’s address under www.sysmex-europe.com/contacts

The Sentimag® and Sienna+®/ Magtrace® magnetic tracers were developed in the clinic with direct input and feedback from surgeons. Since the system was launched at the end of 2012, it has been used to treat over 30,000 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 1,300 breast cancer patients across 12 European countries and the United States have demonstrated non-inferiority to the standard of care for SLNB – either Technetium (99mTc) alone or the combination technique (99mTc and blue dye) [1 – 3]. 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, melanoma, vulva and endometrial cancer, suggesting that the magnetic SLNB method is suitable for an increasingly wide range of cancer indications [3 – 7].

Sienna+® / Magtrace®

References:

For further clinical results, please visit www.sysmex-europe.com
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 Magtrace® 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 [1–3]
- 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 Magtrace® are FDA-cleared and CE-marked for SLN localisation

Clinical studies involving over 1,300 breast cancer patients across 12 European countries and the United States have demonstrated non-inferiority to the standard of care for SLNB – either Technetium (99mTc) alone or the combination technique (99mTc and blue dye) [1–3]. 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, melanoma, vulva and endometrial cancer, suggesting that the magnetic SLNB method is suitable for an increasingly wide range of cancer indications [3–7].

Results for breast cancer SLNB

The Sentimag® and Sienna+®/Magtrace® magnetic tracers were developed in the clinic with direct input and feedback from surgeons. Since the system was launched at the end of 2012, it has been used to treat over 30,000 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 results

- Detection rate per patient
  - Sentimag®/Magtrace®: 97%
  - Standard: 97%

- Malignancy detection rate per patient
  - Sentimag®/Magtrace®: 95%
  - Standard: 94%

- Malignancy concordance
  - Sentimag®/Magtrace®: 98%
  - Standard: 98%

- Mean no. SLNs
  - Sienna+/Magtrace®: 2.0
  - Standard: 1.9

<table>
<thead>
<tr>
<th>References:</th>
</tr>
</thead>
</table>

For further clinical results, please visit www.sysmex-europe.com
As effective as the radiotracer, as easy as blue dye

With the Sentimag®/Magtrace® 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 radiotracer method. With Magtrace®, however, neither you nor your patients are exposed to radiation at any stage.

A unique benefit of the Magtrace® 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.

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 Magtrace®. The Sentimag® probe then detects the tiny magnetic signature generated by the Magtrace® 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.

Magtrace®

Magtrace® 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, Magtrace® is traceable both magnetically and visually.

<table>
<thead>
<tr>
<th>Technique/ Benefit</th>
<th>Sentimag®</th>
<th>Gamma system</th>
<th>Fluorescent system</th>
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</thead>
<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>7-day injection window</td>
<td>✓</td>
<td>x</td>
<td>x</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>
</tr>
</tbody>
</table>

Highlights 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

Highlights of Magtrace®
- 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

* Age-related liver can increase with patient age, weight or breast size
Clinical results

Results for breast cancer SLNB

Malignancy detection rate per patient

Concordance

Malignancy concordance

Mean no. SLNs

98 %

97 %

95 %

Clinical studies involving over 1,300 breast cancer patients across 12 European countries and the United States have demonstrated non-inferiority to the standard of care for SLNB – either Technetium (99mTc) alone or the combination technique (99mTc and blue dye) [1–3]. 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, melanoma, vulva and endometrial cancer, suggesting that the magnetic SLNB method is suitable for an increasingly wide range of cancer indications [3–7].

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Sentimag® – Sienna+®/Magtrace®

Magnetic lymph node localisation for breast cancer – clinical results

Since the Sentimag® system was launched for lymph node localisation at the end of 2012, it has been used to treat over 30,000 patients and has produced a strong base of clinical results that confirms its safety and efficacy in the nodal staging of breast cancer. Clinical studies involving over 1,300 patients across 12 European countries and the United States 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).

Detection rate per patient
- Sienna+®/Magtrace®: 97%
- Standard: 97%

Concordance
- Sienna+®/Magtrace®: 98%
- Standard: 98%

Malignancy detection rate per patient
- Sienna+®/Magtrace®: 95%
- Standard: 94%

Malignancy concordance
- Sienna+®/Magtrace®: 98%
- Standard: 98%

Average nodes
- Sienna+®/Magtrace®: 2.0
- Standard: 1.9

Clinical study results

<table>
<thead>
<tr>
<th>First author</th>
<th>Patients</th>
<th>Detection rate standard</th>
<th>Detection rate Sentimag®</th>
<th>Concordance</th>
<th>Malignancy concordance</th>
<th>Av SLNs standard</th>
<th>Av SLNs Sentimag®</th>
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<tr>
<td>Thill</td>
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<td>98.0%</td>
<td>99.3%</td>
<td>100%</td>
<td>1.8</td>
<td>1.9</td>
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www.sysmex-europe.com/Magtrace
Magnetic lymph node localisation for breast cancer – clinical results

Publication


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