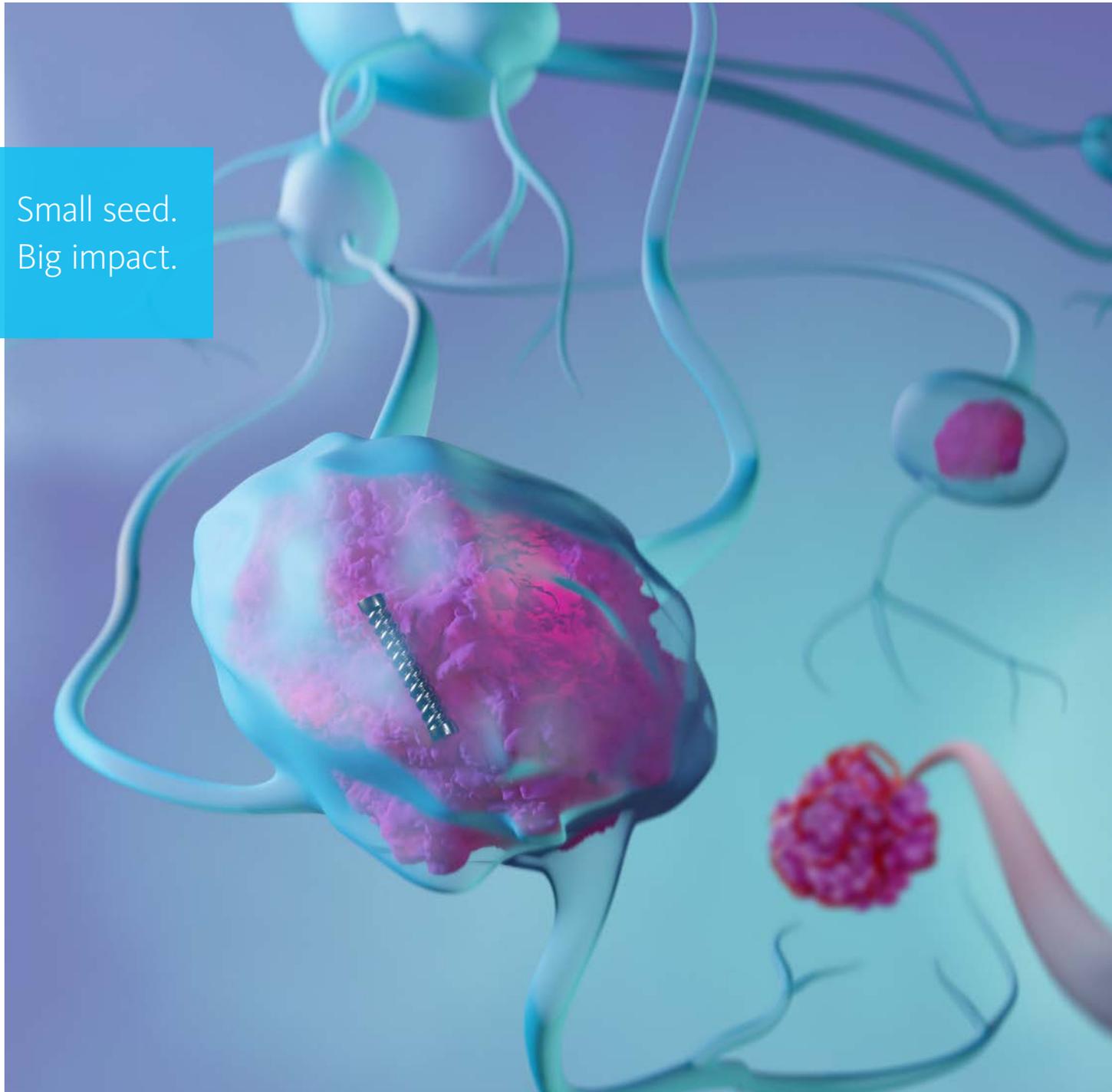


Magnetic lesion and lymph node localisation

Sentimag[®] – Magseed[®]

Small seed.
Big impact.



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

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]

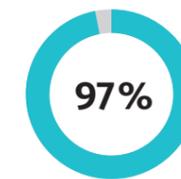
Magseed® is more convenient, can reduce scheduling delays and improve efficiency in the OR [2, 6-9]. Patients reported no pain during breathing and movement, resulting in overall higher comfort. [10, 11] In addition to its clinical benefits, Magseed® has the potential to drive cost savings when adopting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



Placed where intended



Placement was simple

Feedback from 300+ radiologists and surgeons



Magseed® improves patient comfort



Magseed® is easier than wire localisation*

75%

Feedback from 170+ surgeons



Seeds detected pre-incision**



Positive margins on initial dissection



Magseed® improves workflow efficiency



99%



Clinicians want to use Magseed® again

* 98% of clinicians rated the easiness of Magseed®-guided lesion localisation 'easier' or 'same' as wire-guided localisation.

** 100% of seeds located post-incision

References

- [1] Dehaene A et al. (2019): Poster, SABCS 42
- [2] Gera et al. (2020) Antic. Res. 40(4): 1809-15
- [3] Benn C et al. (2020): Poster, EBCC 12
- [4] Greenwood H et al. (2019): AJR 213, 355-6
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- [6] Malherbe F et al. (2019): Poster, ESSO 39
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- [8] Harvey JR et al. (2018): Breast Cancer Res Treat 169(3), 531-6
- [9] Price ER et al. (2018): Am J Roentgenol 210, W1-W5
- [10] Kühn et al. (2020): In Vivo 34: 1159-64
- [11] Lake B et al. (2018): EJSO 44(11), 1839.
- [12] Data from the Sysmex Magseed® Xperience Survey 2017/2018

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

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 any time 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).

No wire. No radioactivity. Just magnetism.

Magseed® – at a glance



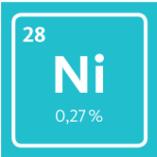
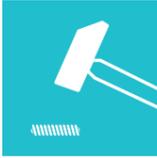
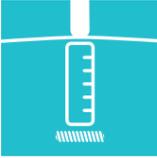
- 1 x 5 mm, smaller than a grain of rice
- Surgical steel marker, very low nickel content
- 18-gauge, sharp needle – precise and easy placement also in dense breast tissue, no skin incision needed, high patient comfort
- Firmly implanted, no migration from soft tissue
- Spiral shape optimises tissue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

 Impalpable lesion localisation	 Bracketing of lesions	 Target lymph node biopsy	 Sentinel lymph node biopsy*	 X-ray visibility
 Long-term placement	 Improved scheduling	 Minimal hospital oversight	 X-ray/US visible	

 Non-radioactive	 Small size	 Firmly implanted	 Medical grade stainless steel/low nickel content
 Robust	 No risk of deactivation	 360° sensing	 Depth sensing

* Using Sentimag® in combination with Magtrace® magnetic tracer

The world's only system for magnetic lesion and lymph node localisation



*Magseed®
magnetic marker*

*Sentimag®
magnetometer*

*Magtrace®
magnetic tracer*

For more information, visit
www.sysmex-europe.com/sentimag

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