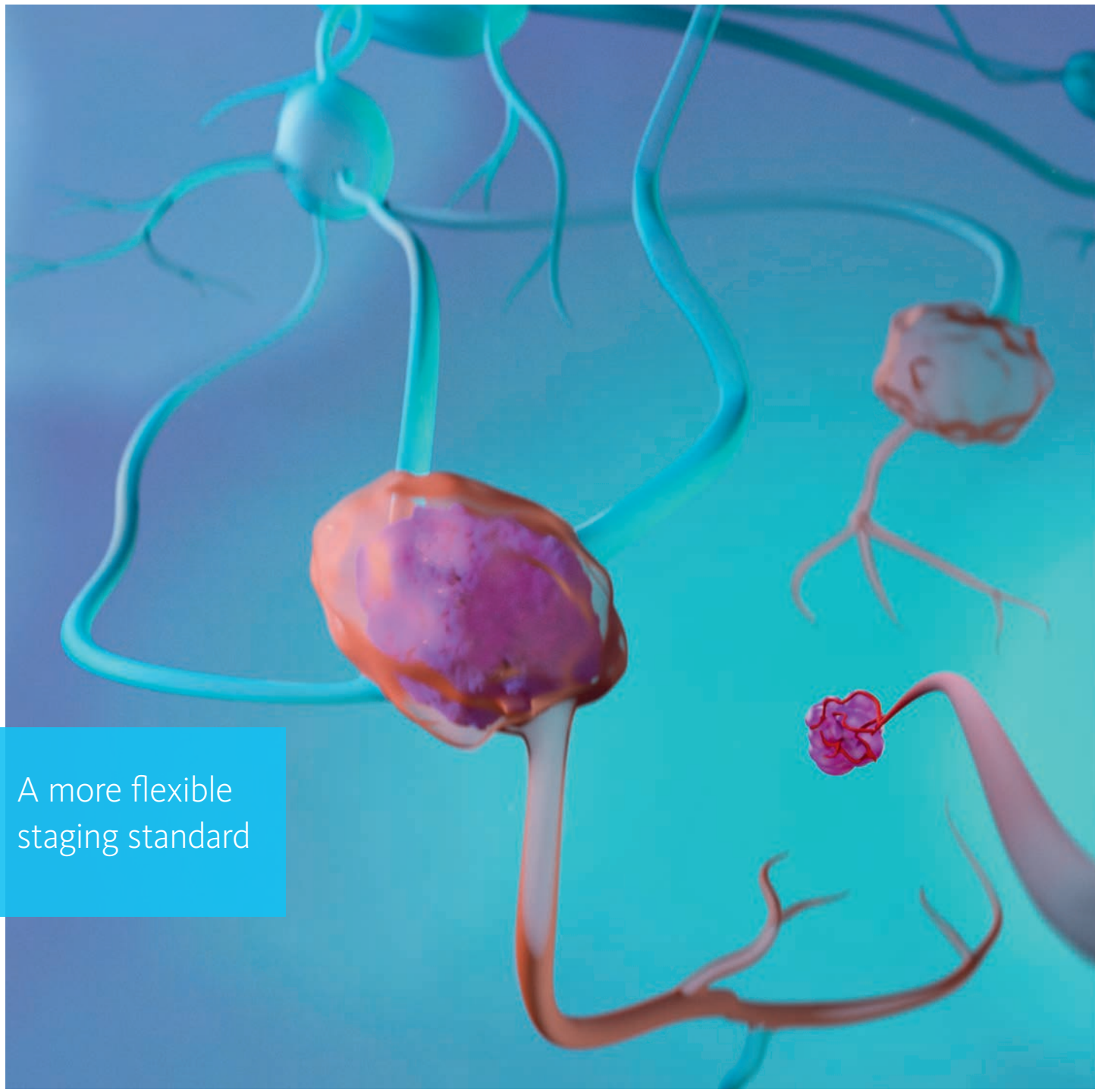
sysmex | Lighting the way with diagnostics

Magnetic sentinel lymph node biopsy

Sentimag® – Magtrace®



A more flexible staging standard

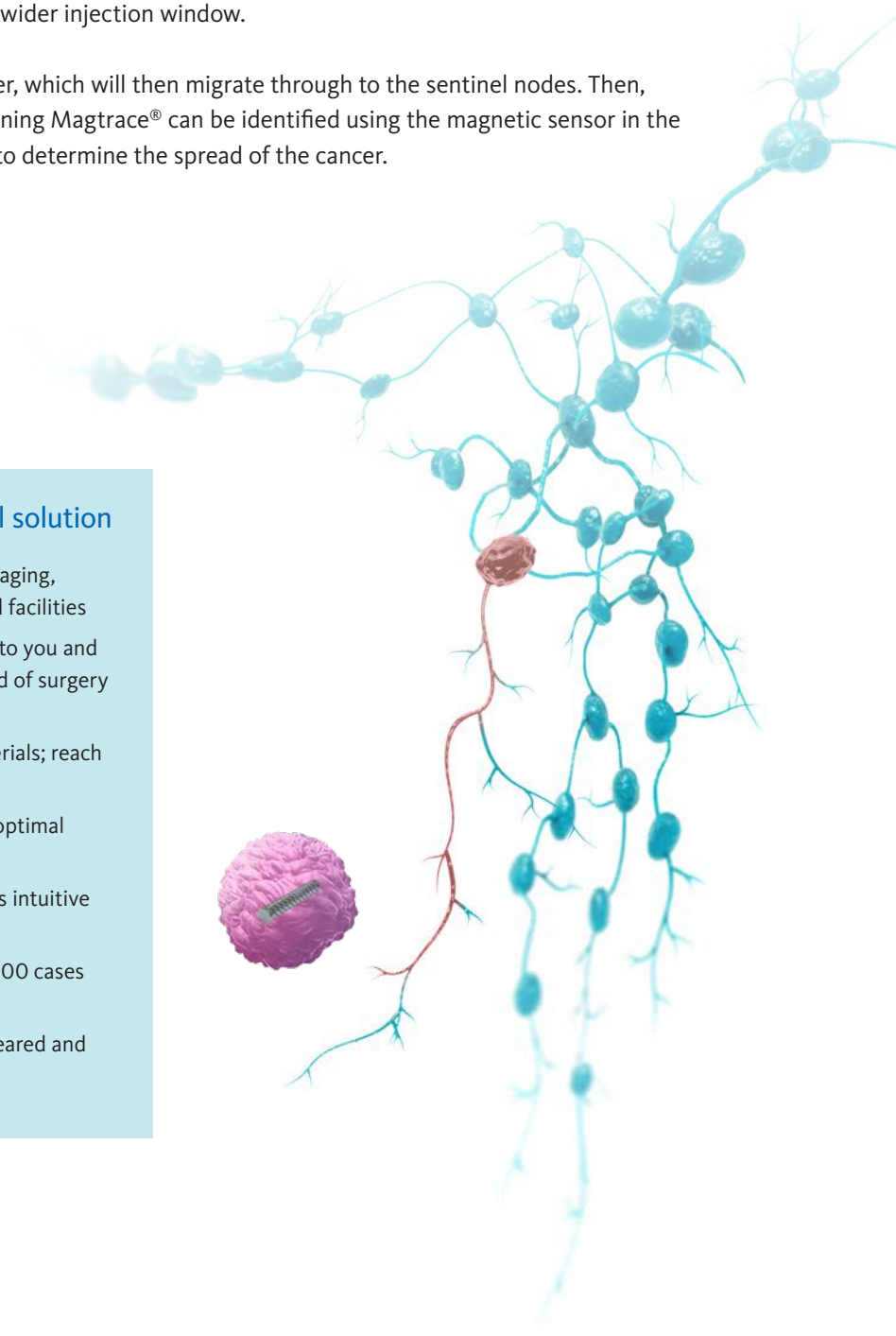
www.sysmex-europe.com/magtrace

Radiation-free, flexible cancer staging

Many cancer treatments involve 'sentinel lymph node biopsy', or SLNB – both in the adjuvant and neo-adjuvant setting. Identifying the lymph nodes with the highest potential for harbouring metastases and determining the nodal stage of the cancer allows for informed decisions for both surgery and subsequent treatment.

Standard SLNB uses radioisotopes for sentinel node localisation. The Magtrace® lymphatic tracer offers an effective clinical solution that uses safe magnetic fields instead. This eliminates concerns related to the safety, workflow and availability associated with ionising radiation, whilst providing more flexibility for when you inject. With Magtrace®, SLNB is now possible everywhere, with a wider injection window.

First, the patient is injected with the tracer, which will then migrate through to the sentinel nodes. Then, with its traceable signal, the nodes containing Magtrace® can be identified using the magnetic sensor in the Sentimag® probe, before being removed to determine the spread of the cancer.



Magtrace® – an accurate clinical solution

- ✔ Provide the best standard of cancer staging, regardless of your hospital setting and facilities
- ✔ Inject the tracer when it's convenient to you and your patients – from 20 minutes ahead of surgery up to 30 days in advance
- ✔ Eliminate issues with radioactive materials; reach equivalent clinical outcomes [1–3]
- ✔ Designed for effective migration and optimal retention in sentinel nodes
- ✔ Provides visual confirmation, as well as intuitive magnetic identification
- ✔ No reports of anaphylaxis in over 65,000 cases per date
- ✔ Sentimag® and Magtrace® are FDA-cleared and CE-marked

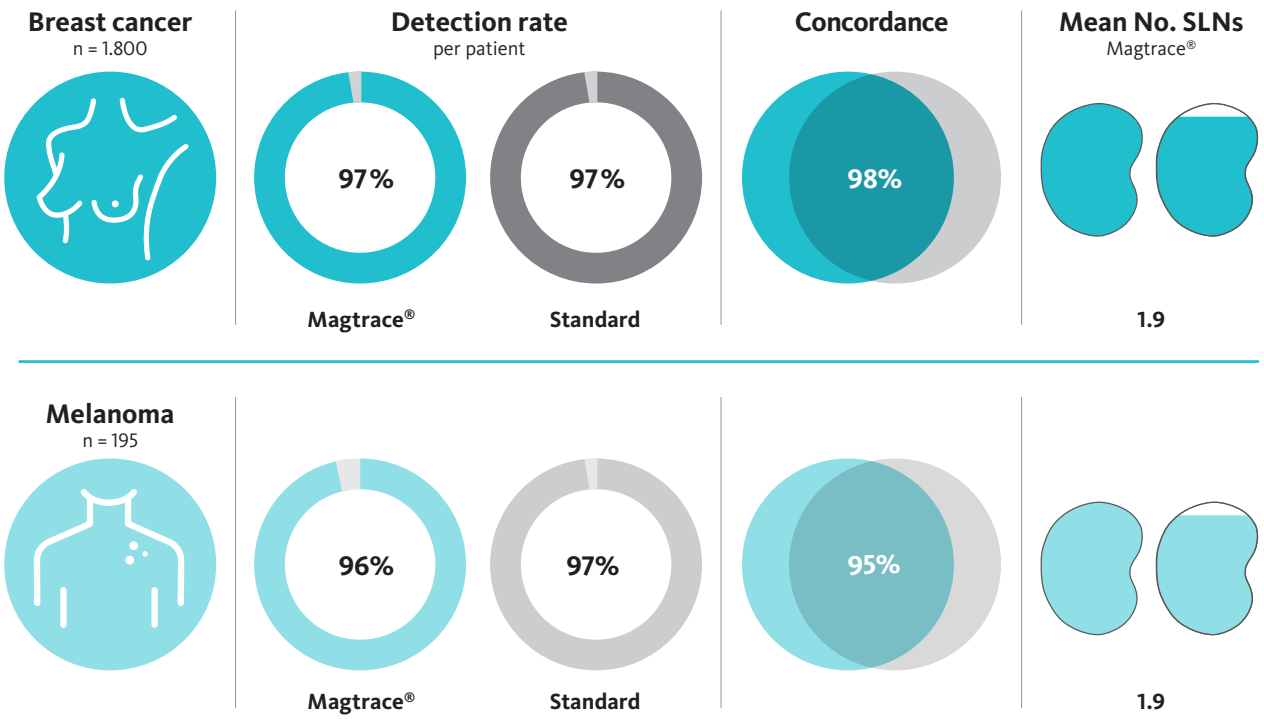
Supporting clinical evidence

The Sentimag® and Magtrace® magnetic tracer were developed with direct input and feedback from surgeons. The system has now been used to treat over 90,000 breast cancer patients worldwide and has produced a strong base of clinical results that confirms its safety and efficacy in sentinel node localisation, a vital element of nodal cancer staging.

Clinical studies involving over 1,800 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 dual-tracer technique (99mTc and blue dye) [1–3].

Other cancer entities besides breast cancer are currently being evaluated. Initial clinical data has been collected for magnetic SLNB in melanoma, prostate, penile, endometrial, vulvar, thyroid, and oral cancer, suggesting that the magnetic SLNB method is suitable for an increasingly wide range of cancer indications [4–10].

Results for breast cancer and melanoma SLNB



Selected references

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[2] Karakatsanis et al. (2016): *Breast Cancer Res Treat. 157(2):281–94. – Meta-analysis of 7 clinical studies of magnetic SLNB in breast cancer.*
[3] Teshome et al. (2016): *Ann Surg Oncol. 23(5):1508–14. – Meta-analysis of 6 clinical studies of magnetic SLNB in breast cancer*
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[8] Jedryka et al. (2020): *Int J Gynecol Cancer. 2020;1–5*
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[10] Fustegueras et al. (2019): *EJSO. 45(7):1175–81*

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

Magtrace® – a tracer like no other

Similar to the radioactive method, Magtrace® has been optimised to stay in the sentinel nodes and does not migrate to higher echelon nodes, regardless of when it is injected. However, Magtrace® allows neither you nor your patients to have to be exposed to radiation in the process.

Inject when it's convenient

A unique benefit of the Magtrace® tracer is that it can be injected at any time, from 20 minutes prior to surgery up to 30 days before. With this flexibility, you can use it in a way that suits your hospital set up.

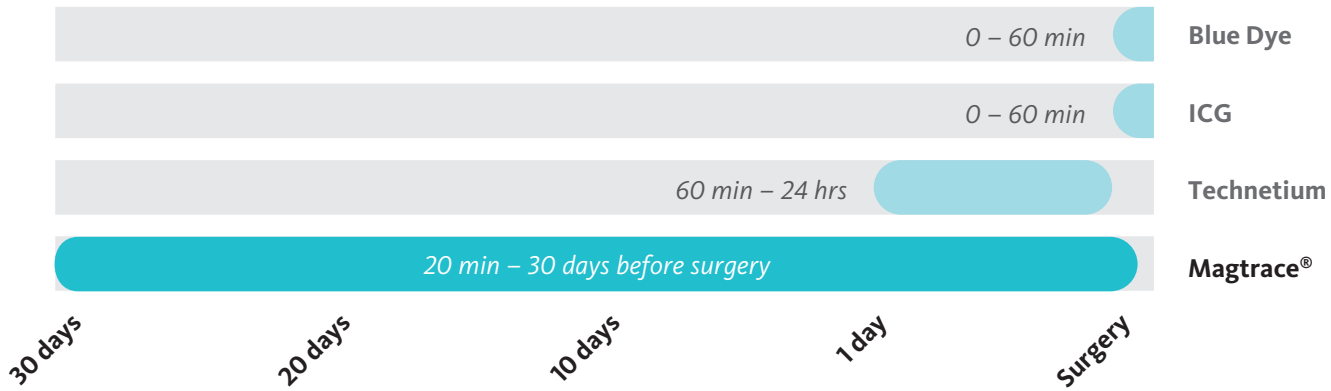
- Improve scheduling between departments
- Reduce pre-operative preparation
- Arrange more SLNB procedures per day
- Help those who need treatment sooner

Intuitive detection

It takes little training to adapt to using the Sentimag® with Magtrace®, with the probe handling remarkably similar to those of gamma systems. No special procedural alterations are necessary either, such as for fluorescent localisation systems where darkening the room is required.

Technique/ Benefit	Sentimag® system	Gamma system	Blue Dye or ICG
Quantifiable SLNs	✔	✔	✘
Avoids radiation	✔	✘	✔
30-day injection window	✔	✘	✘
Surgeon-controlled	✔	✘	✔

Injection time window



Magnetic SLNB – how does it work?

Sentimag® probe

The Sentimag® system applies the principles of para-magnetism, generating a magnetic field that temporarily magnetises the iron oxide particles in Magtrace®. The Sentimag® probe then detects the tiny magnetic signature generated by the particles.

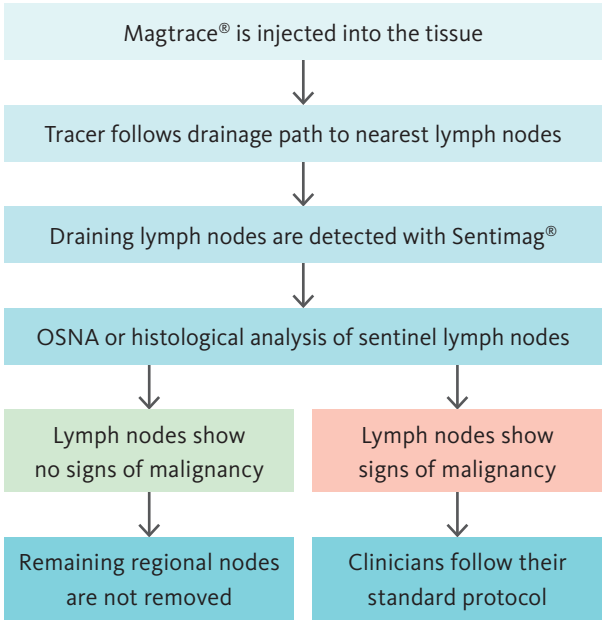
Since Sentimag® sensing is proximity-based, localising nodes is particularly intuitive. You can use the system both before and after incision and adjust its sensitivity as required according to tracer accumulation in the nodes.

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 into the tissue, the lymphatic system's natural filtration ensures the particles flow to the sentinel nodes, where they are retained.

The magnetic tracer has a good safety profile and a long shelf life. It is also compatible with standard histo-logical techniques, as well as the OSNA assay. Due to its brownish colour, Magtrace® is easy to identify, both magnetically and visually.

Magnetic SLNB procedure



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 – 30-day window from injection to surgery
- ✔ Compatible with OSNA assay

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

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

Magseed®
magnetic marker

Magtrace®
magnetic tracer

Sentimag®
magnetometer

For more information, visit

www.sysmex-europe.com/sentimag

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