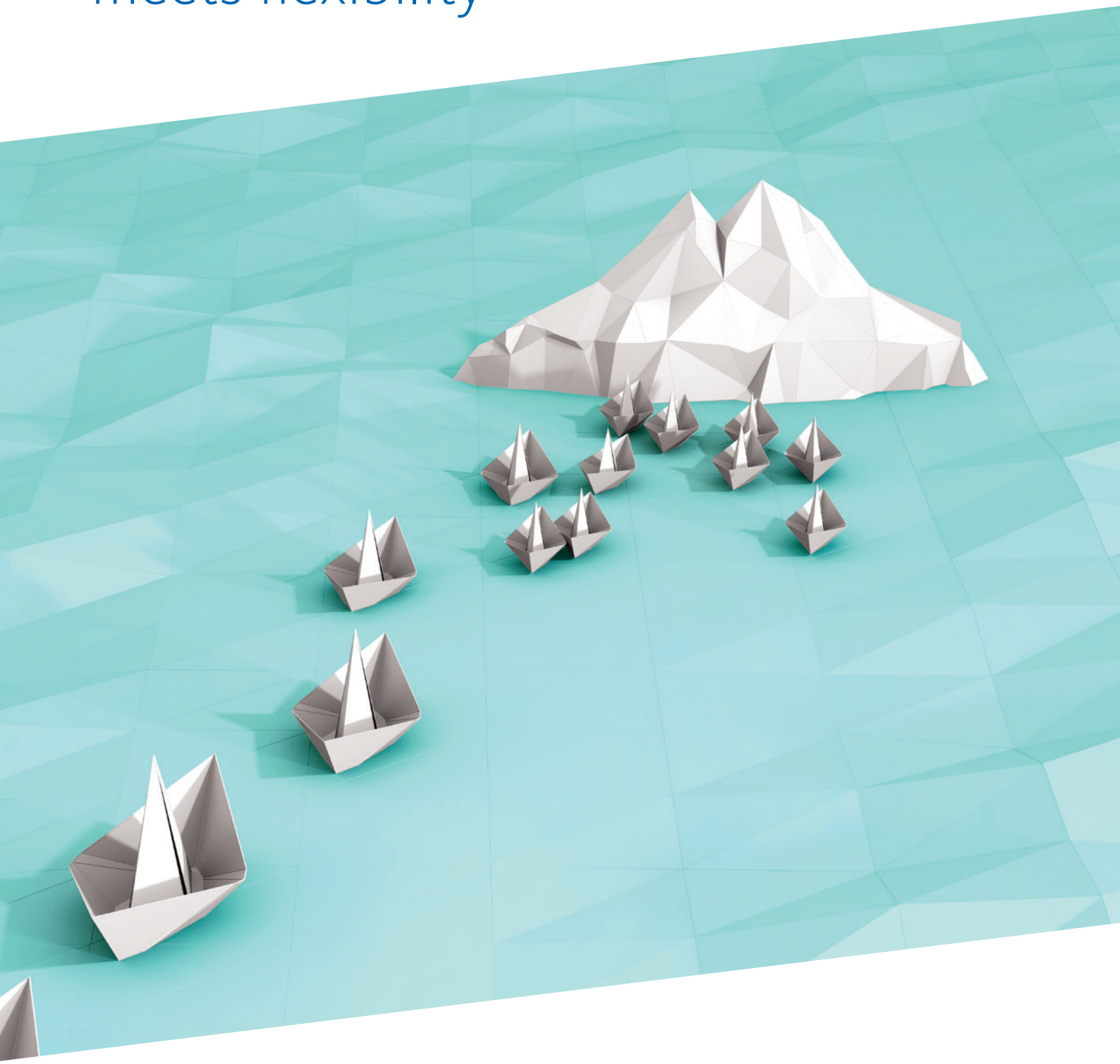
Sentimag®– Magtrace®: lymph node localisation

Arrive where effectiveness meets flexibility



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

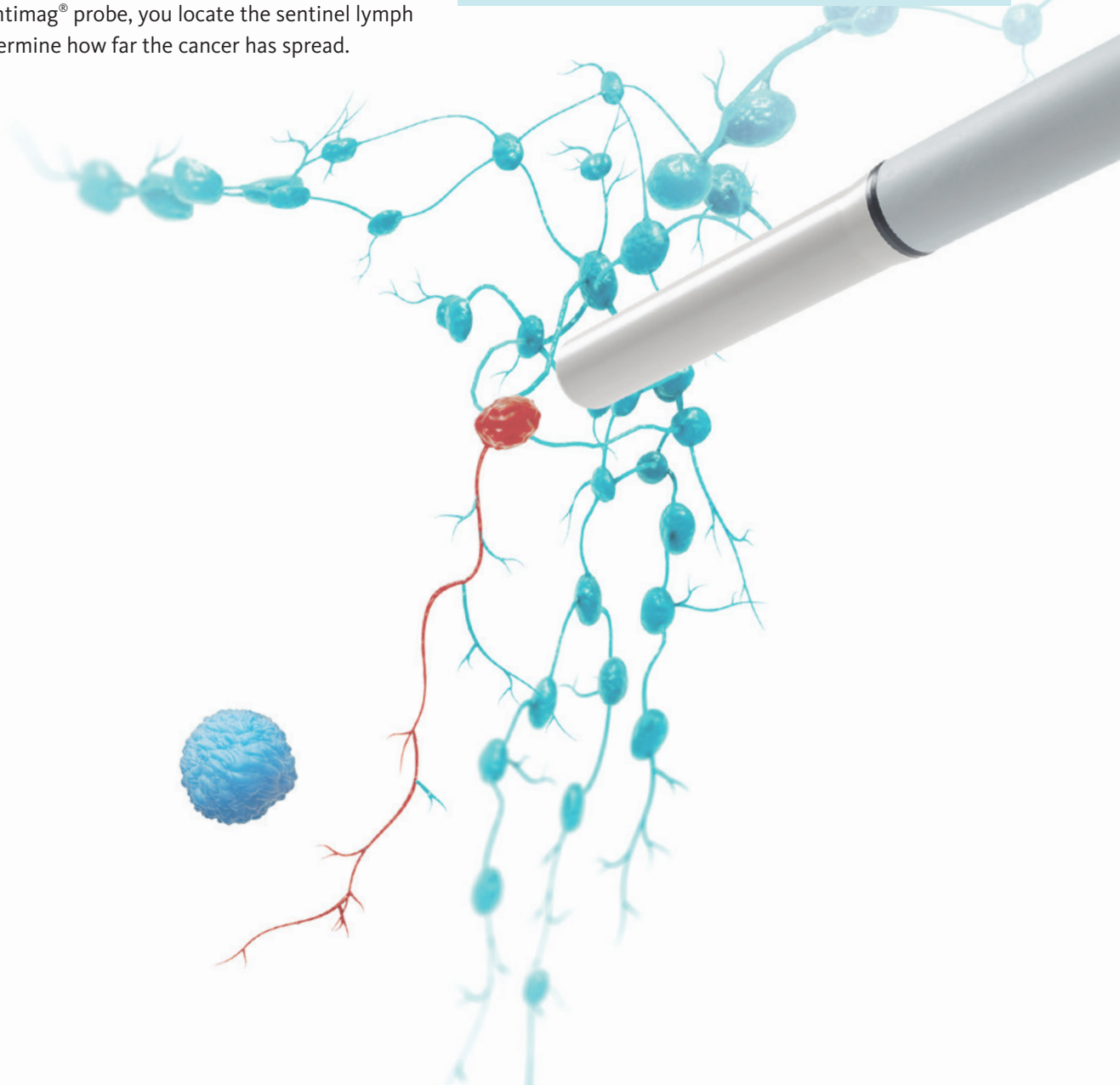
Many treatments for early-stage cancer involve ‘sentinel lymph node biopsy’, or SLNB. This method, which identifies the lymph nodes with the highest potential for harbouring metastases, helps to determine the nodal stage of the cancer and make informed decisions for surgery and subsequent treatment.

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

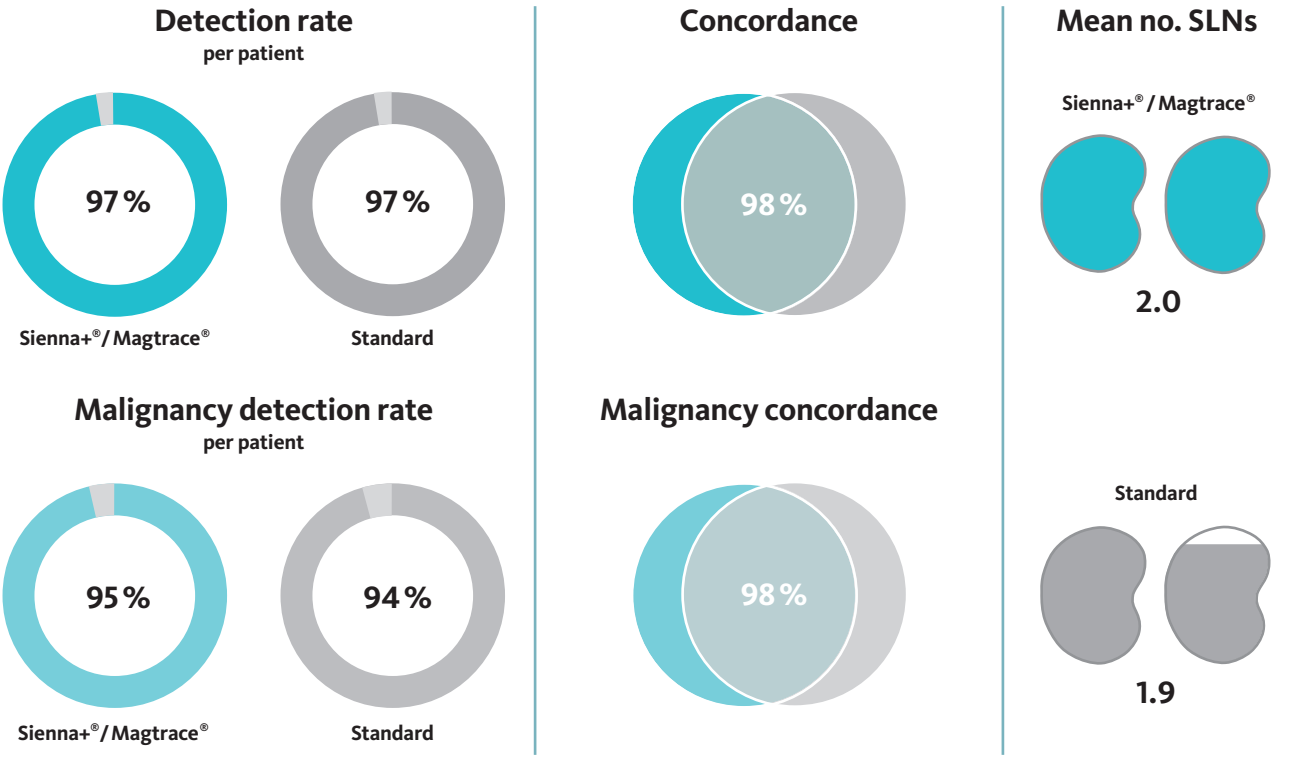


Clinical results

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 (^{99m}Tc) alone or the combination technique (^{99m}Tc 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, vulvar 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



References:

[1] ***Alvarado et al.*** *(2017). Cancer Res. 77 (4 suppl): P2-01-11.*

[2] ***Karakatsanis et al.*** *(2016). Breast Cancer Res Treat. 157(2): 281–294. – 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.*

[4] ***Winter et al.*** *(2017). Molecules. 22(12): E2192.*

[5] ***Piñero-Madrona et al.*** *(2018). Poster from abstract 533 presented on ESSO38.*

[6] ***Klimczak et al.*** *(2018). Poster from abstract 603 presented on ESSO38.*

[7] ***Rzepka et al.*** *(2014). J Clin Oncol. 32: (suppl; abstr E16550).*

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 radioactive 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.

Magnetic SLNB procedure

Magtrace® is injected into the interstitial tissue

↓

Tracer follows drainage path to nearest lymph nodes

↓

Draining lymph nodes are detected with Sentimag®

↓

OSNA or histological analysis of sentinel lymph nodes

Lymph nodes show no signs of malignancy	Lymph nodes show signs of malignancy
↓	↓
Remaining regional nodes are not removed	Clinicians follow their standard protocol

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

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.

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

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

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