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Methods for Localization of Different Types of Breast Lesions

A prospective non-interventional multicenter cohort study to evaluate different imaging-guided methods for localization of malignant breast lesions (EUBREAST-4/iBRA-NET, NCT05559411)

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Study Lead: EUBREAST / iBRA-NET (Intergroup Study)

Study design
Prospective non-interventional multicenter cohort study (IIT)

Enrollment begin: January 2023

Current status (Oct 2025):
215 open study sites in 27 countries (8358 patients)

Financial support
Endomag, Merit Medical, Sirius Pintuition, Hologic and Korean Breast Cancer Society

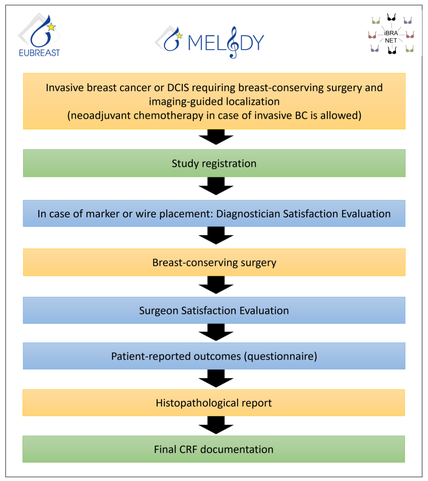


Fig. 1 MELODY Flow chart.

Why do we need the MELODY study?

In the last two decades, the proportion of patients with breast cancer receiving breast-conserving surgery has increased, reaching 70-80% in developed countries. In case of non-palpable lesions, surgical excision requires some form of breast localization. While wire-guided localization has long been considered gold standard, it carries several limitations, including logistical difficulties, the potential for displacement and patient discomfort, and re-excision rates reaching 21%. Other techniques have been developed with the aim of overcoming these disadvantages (Fig. 2). However, comparative data on the rates of successful lesion removal, negative margins and re-operations are limited. In most studies, patients' perspective with regard to discomfort and pain level has not been evaluated. The aim of MELODY is to compare different localization methods with regard to oncological safety, patient-reported outcomes, and surgeon and radiologist satisfaction.

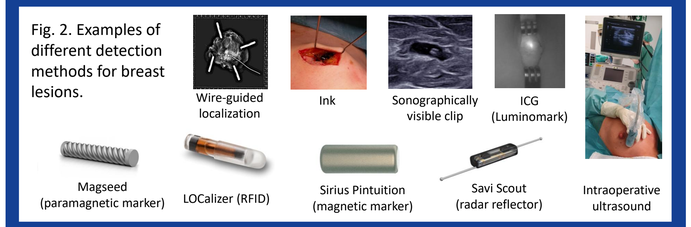


Fig. 2. Examples of different detection methods for breast lesions.

Primary outcomes
- Intended target lesion and/or marker removal
- Negative resection margin rates (defined as lesion removal with no invasive or non-invasive carcinoma on ink) at first surgery

Secondary outcomes
Second surgery – Secondary mastectomy – Resection Ratio – Duration of surgery – Marker dislocation – Marker placement failure – Localization failure – Patient-reported outcomes (e.g., patient discomfort, pain level, and impairment of breathing) – Diagnostician/radiologist's satisfaction – Surgeon's satisfaction – "Lost markers" – Volume and weight of resected tissue – Learning curve – Impact of self-reported ethnicity on other outcome measures – Economic resources – Economic impact (cost-benefit analysis) – MRI artifacts – Complication rates

Inclusion criteria
- Malignant breast lesion requiring breast-conserving surgery and imaging-guided localization (DCIS or invasive; multiple or bilateral lesions and the use of neoadjuvant chemotherapy are allowed)
- Planned surgical removal of the lesion using one or more of the following imaging-guided localization techniques:
  - ✓ Wire-guided localization
  - ✓ Intraoperative ultrasound
  - ✓ Magnetic localization
  - ✓ Radioactive seed localization
  - ✓ Radioguided Occult Lesion Localization (ROLL)
  - ✓ Radar localization
  - ✓ Radiofrequency identification (RFID) tag localization
  - ✓ Ink/carbon localization
  - ✓ ICG localization (Luminomark)

For more information, visit:
http://eubreast.org/melody

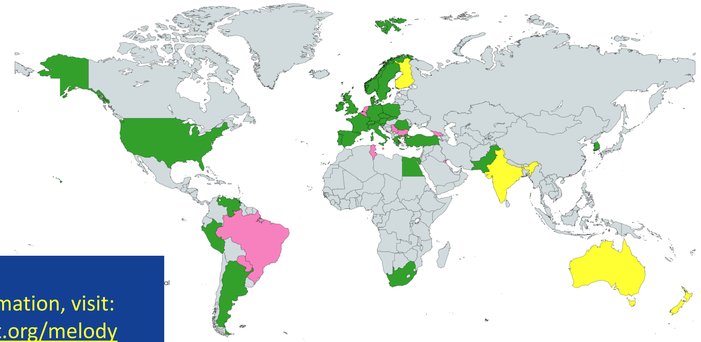


Fig. 3. Current status of international participation.
Recruting
Applying for ethical approval
Planning to join

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