Double Detection of Sentinel Lymph Nodes by Gamma and Fluorescence
Corporate Profile

• EuroMedical Instruments has been a major player in the field of intraoperative detection for almost 20 years.

• As the global distributor of the Europrobe system for surgeons and doctors, we have been forerunners in the detection of sentinel lymph nodes.

• Since 2014, we offer a unique system that allows bimodal gamma and fluorescence detection.
In terms of SLN detection the Gold Standard is the **dual detection** with gamma (Technetium $^{99m}$Tc) detection combined to a colorimetric detection, with methylene blue.

The radiolabelled colloids allow preoperative mapping and intraoperative SLN detection thanks to a **portable gamma probe**.

Preoperative administration of the **blue dye** provides the surgeon with an additional visual identification of the SLN.
Drawbacks with the Blue Dye

- A blue lymphatic vessel deeply located will be **difficult to find**, and its removal may be difficult.

- Methylene blue causes a significant level of **anaphylactic shocks**, making its usage somewhat tricky.

- It **stains** the injection site for months.

- SLN’s do **not always absorb** dye, for example in the neck.

- The detection rate of **false negatives** in patients with melanoma is high: 9% - 21%.
To circumvent usage of methylene blue a new colorimetric method is emerging: **Fluorescence-based** detection.

- The injection of indocyanine green (ICG), shortly before the operation is **simple and its diffusion is fast**.
- The occurrence of **side effects**, such as anaphylactic shocks, with ICG is **significantly lower** than with the blue dye, and estimated to be less than 1 in 10,000.
- However, the visualization of fluorescence required the use of a camera and therefore the introduction into the operating field of additional **bulky and expensive equipment**.
IndoCyanine Green

- Indocyanine green is a dye widely **used in medical diagnostics**. ICG absorbs mainly between 600 nm and 900 nm and emits fluorescence between 750 nm and 950 nm.

- Side-effects such as anaphylactic shock, hypotension, tachycardia are rare, and **rate of severe side-effects is <0.05%**.

- It is a **non radioactive** molecule.

- The product may directly be injected by the surgeon, and SNL detection becomes **no longer reliant on nuclear medicine**.
Detection Methods

Up until now, different tracers required different methods of detection and distinct separate devices.

Gamma signal detection + Fluorescence

1) Excitation wavelength
2) Collection of the emission signal

Europrobe 3.2
ICG as a Hybrid or Stand-Alone Tracer

- ICG can be combined with the radioisotope for a simultaneous injection to the patient.

- The two tracers, ICG and the radioisotope, may also be administered separately.
A complete modular system combining:

- Gamma detection
- Fluorescence dye detection

The Opto-Nuclear Probe is the first modality tailored for the detection of hybrid tracers.

Fluorescence tracing works in ambient light.

The Opto-Nuclear Probe is the only device in the world that allows to detect SNL via fluorescence without the need for cumbersome imaging systems.
Clinically Established

- ICG – 99mTc-nanocolloid enables both preoperative SLN mapping and intraoperative SLN identification in patients with melanoma.¹
- Optical identification of the SLNs through the fluorescent signature of the hybrid tracer is superior compared with SLN identification with blue dye.¹
- ICG - 99mTc-NanoColloid improve the SLN detection accuracy up to 98.2%²
- Fluorescence imaging enabled intraoperative identification of the SLNs in the areas where acoustic gamma tracing is inefficient.²
- In the other areas fluorescence helped identify the exact location of the SLNs with a higher precision.²
- Higher rate of SLN identification: 99.8%.³
- A sharp decrease of the rate of False Negatives³:
  - 2.8 % for bi-modal detection
  - 10 % for radioisotope only
  - 6.7 % for ICG Only
63% of SLN detected by both modalities

35% detection by ICG only

For Metastatic patients, 15% of M+ SLN detected by ICG only

123 patient study in Charleroi Hospital (Belgium) and San Carlo Hospital (Milano), by Dr. Luciano Mazzeo Cicchetti.
   Nynke S. van den Berg et al, Radiology 2014

2. Intraoperative Laparoscopic Fluorescence Guidance to the Sentinel Lymph Node in Prostate Cancer Patients: Clinical Proof of Concept of an Integrated Functional Imaging Approach Using a Multimodal Tracer
   Vav der Poel et al, Europ Urol 2011

3. Détection du ganglion sentinel dans le cancer du sein par sonde opto-nucléaire après injection de vert indocyanine et de technétium 99 m
   E. Barranger, M.-A.Poumellec et al., Gynecologie Obstétrique & Fertilité (2016)

4. First-in-human evaluation of a hybrid modality that allows combined radio-and (near infrared) fluorescence tracing during surgery

5. Accuracy and prognostic value of sentinel lymph node biopsy in head and neck melanomas
   R. Patuzzo et el, JSR 2014


7. The indocyanine green method is equivalent to the 99mTC-labeled radiotracer method for identifying the sentinel node in breast cancer : a concordance and validation study
   B.Ballardini et al. / EJSO 39 (2013) 1332-1336

8. Evaluation of sentinel node biopsy by combined fluorescent and dye method ans lymph flow for breast cancer
   T.Hojo et al. / The Breast (2010)

9. Impact of indocyanine green for sentinel lymph node mapping in early stage endometrial and cervical cancer : comparison with conventional radiotracer (99m)Tc and/or blue dye
   A.Buda et al. - Annals of surgical oncology- December 2015

10. Fluorescence imaging after indocyanine green injection for detection of peritoneal metastases in patients undergoing cytoreductive surgery for peritoneal carcinomatosis from colorectal cancer
Main Features:
• Optional module placed underneath the Europrobe.
• Allows dual Gamma and Fluorescence detection.
• Selection of detection modality via a footswitch.
• Simple and identical use to Gamma gesture.
• Usable in ambient lighting conditions.
• Requires no specific set-up.
• Improved discrimination and sensitivity.

Technical specifications:
• Module height: 55mm.
• Weight: 1 Kg.
• Width / Depth: 233 mm / 270 mm.
• Suitable for Indocyanine Green (ICG) detection.
Sales contacts

EUROMEDICAL INSTRUMENTS
13 rue Raymond Loesserand
75014 Paris - France
+33 9 83 62 63 17
+33 9 83 82 63 17
www.em-instruments.com
sales@em-instruments.com

Nathalie Feuillâtre
Sales Administration Manager
Nathalie.Feuillatre@em-instruments.com

Rodolphe Rodriguez
Sales Director
Rodolphe.Rodriguez@em-instruments.com

Manufacturer

EURORAD SA
2 rue Ettore Bugatti
67201 Eckbolsheim - France
+33 88 26 81 30
+33 3 88 28 45 48
www.eurorad.com
info@eurorad.com

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