

SAFER
Personalized
cancer
surgery



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 **Sentinella 102**
your new eyes

REAL-TIME MULTIMODAL CANCER DETECTION SUITE

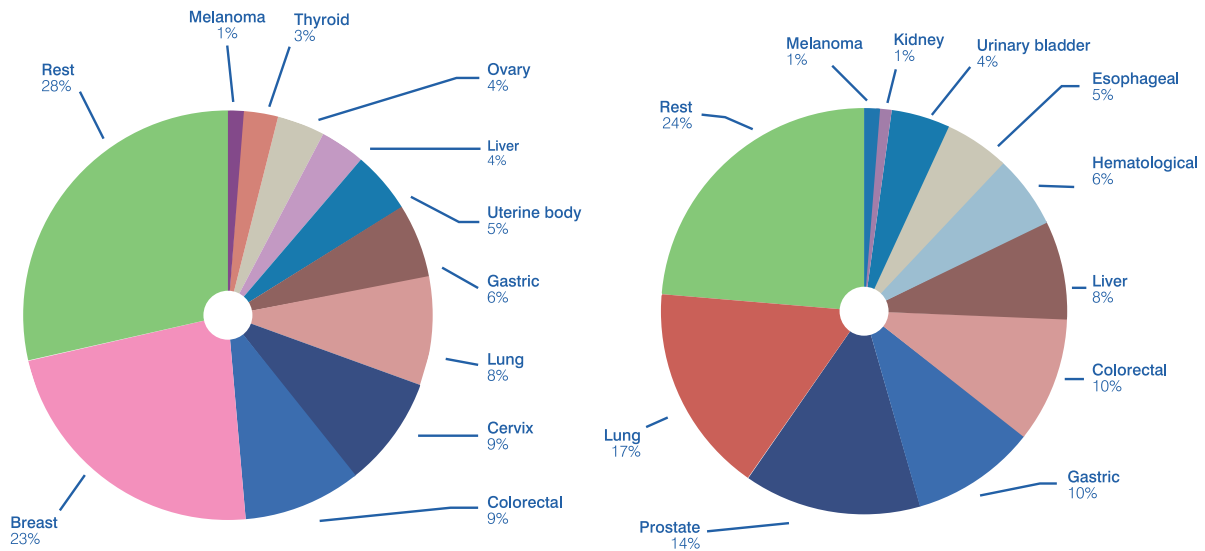
 **ONCO
VISION**
GEM-IMAGING SA

Defeating Cancer: growing success, but still far from a definitive solution

A critical pathology

Cancer is a broad term encompassing 200+ types of malignant tumors, with growing incidence. It figures among the leading causes of death all over the world, and has a major social and psychological impact.

A vast majority of tumors expand through the lymphatic system, affecting progressively an increasing number of lymph nodes. The first direct-drainage nodes are denominated “Sentinel” nodes, and their status with regard to cancer cell invasion is critical in staging and in determining patient treatment, as is evidenced by multiple studies, including ACOSOG’s Z0011.



New Cancer cases worldwide, women, 2013

Source: Globocan 2012, FCAECC, internal assessment

New Cancer cases worldwide, men, 2013

Source: Globocan 2012, FCAECC, internal assessment

The condition of regional lymph nodes is the most important prognostic factor in the clinical evolution of cancer patients

Recent developments in the “sentinel node” concept have resulted in the application of this revolutionary technique in a growing number of tumors, both the ones that drain superficially and now, using Sentinella, the ones that have complex, deep drainage.

Medical and Surgical cross-specialty teams, with the decisive role of **surgeons** from different specialties, **nuclear medicine physicians, pathologists and oncologists**, are using new image-guided techniques and improved oncological treatments based on solid clinical evidence to win the battle against cancer and give new hope to patients.

Personalized Oncological Surgery, The Next Revolution, NOW

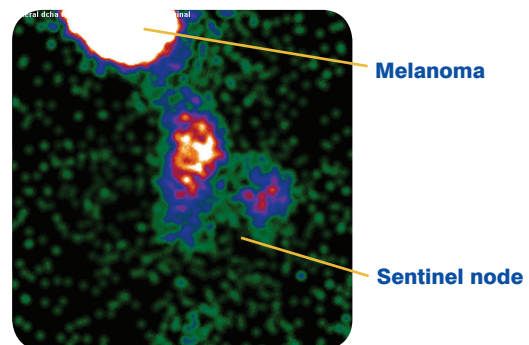
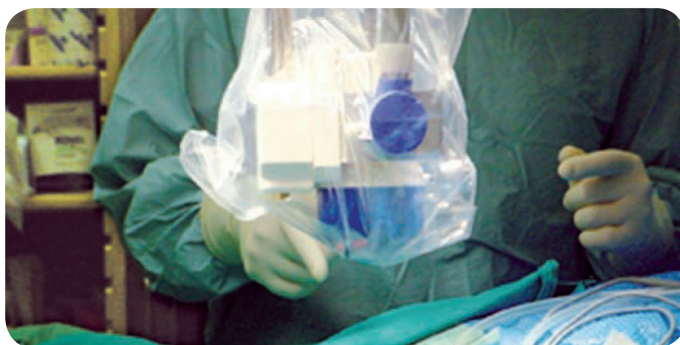
Molecular vision for surgery

More than 30 years after the original innovative papers by Dr. R. Cabañas in Urology, and more than 15 from the revolutionary publication of Dr. D. Morton on melanoma, Sentinel Node Navigation has been performed successfully in millions of patients, becoming “best practice” in superficially draining tumors. Its proven clinical results and hundreds of clinical papers from the most advanced oncological centres support its efficacy and effectiveness.

The safety of this technique for patients and surgical staff alike has been fully documented by clinical studies and assessed by radiophysicists and radioprotection specialists.

Limited use of the procedure due to shortcomings of dyes and gamma probes

The difficulty to visualize structures stained by dyes and the technical limitations of gamma probes—low depth of detection, subjective acoustic signal, etc.—have been factors that have limited the use of Sentinel Node Technique to certain types of tumors.



It's time for **personalized cancer surgery in every patient and every tumor**

Sentinella's integrated gamma camera + gamma probes + pointers + dedicated software are making real time molecular imaging of each patient's personal lymphatic drainage possible, before and during surgery. Sentinella tracks and documents each step of the procedure, and finally confirms the “Clean Field”, with clinical and legal validity. This is critical in every tumor, but even more decisive in deep draining and complex tumors, and in small, low captation, next to tumor lymph nodes.

Strong Evidence, Improved Survival and Quality of Life

“Gold standard” Indications / Superficial Draining Tumors

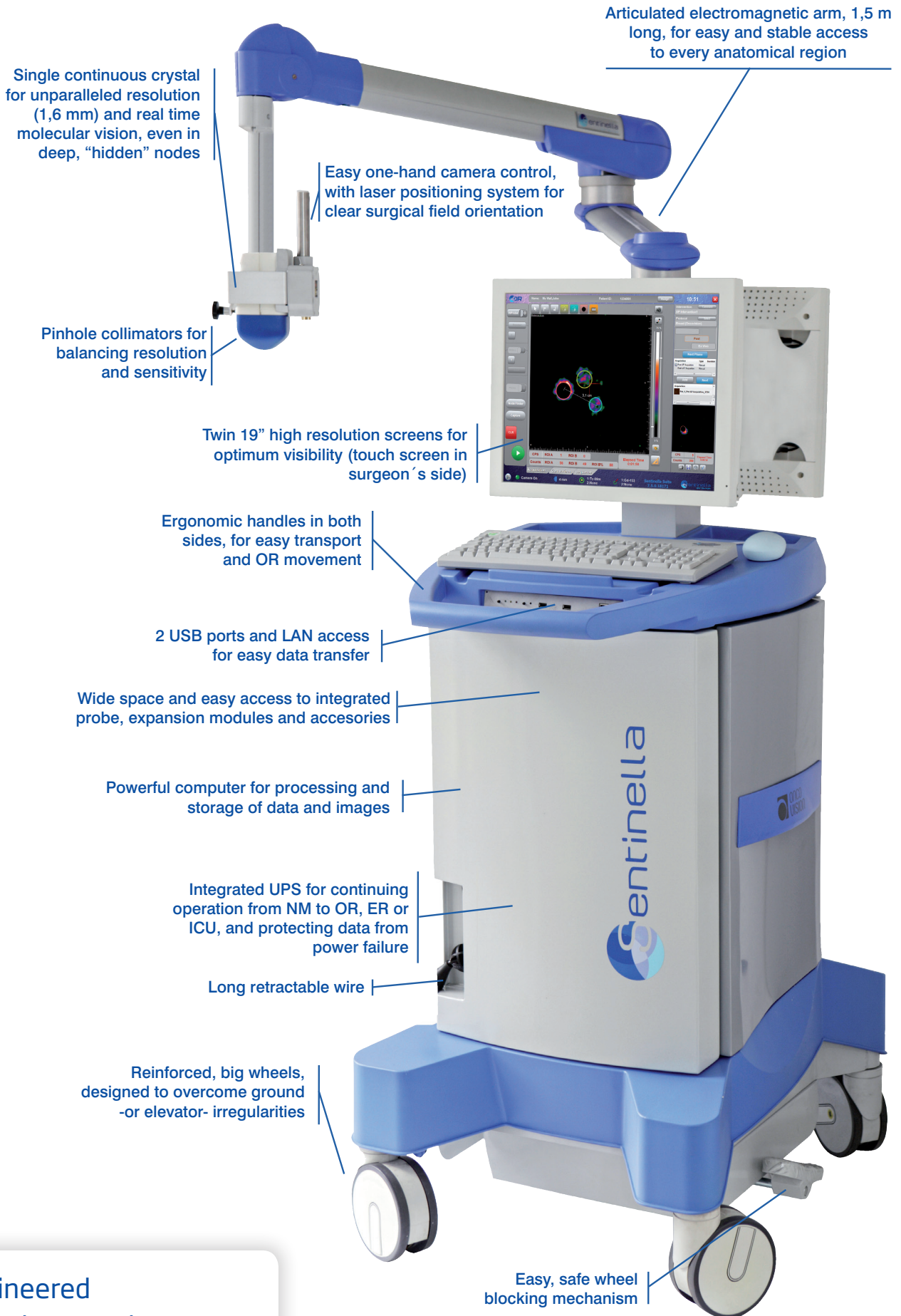
Proven outcomes with highly reliable evidence in sentinel node mapping in breast cancer, ROLL, SNOLL, melanoma and head and neck (thyroid-parathyroid pathologies, squamous tumors), gynaecological (vulva) and urological (penis, testicle) tumors.

Emerging major clinical options / Deep Draining Tumors

Colon and rectal, upper GI, urological (prostate, kidney, bladder), gynaecological (cervix, endometrium...), lung cancer, neuroendocrine tumors...

Laparoscopic, diagnostic and interventional approaches beyond Sentinel node biopsy

Gammacameras are being used in endocrinology, osteoarticular, nephrological pathologies, therapy efficacy follow-up, donor and organ assessment in transplants, perfusion in limb tumors...



Engineered
with the experience
of World Leading
Cancer Centers

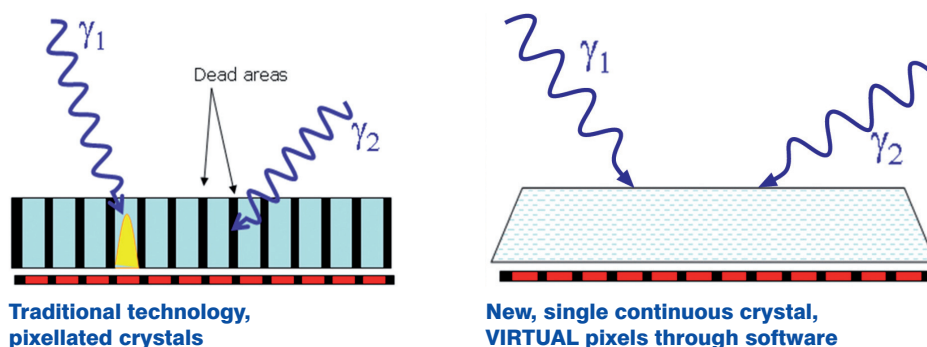
Sentinella: Five + 1 **critical advantages**

- 1 Preoperative, Intraoperative and Postoperative portable integrated cancer detection unit**
 - Gamma camera + gamma probes + pointers + dedicated software.
- 2 Real-time vision, making a major clinical difference in “difficult” cases in breast cancer, melanoma and head & neck tumors**
 - Consistently finds -and generates image and objective quantification- of nodes that gamma probes do not find, due to depth, low activity or closeness to tumor.
 - Breakthrough in ROLL and SNOLL with faster and safer procedures.
 - Proven corellation with lymphoscintigraphic NM preoperative explorations.
- 3 Growing published experience in radioguided surgery for deep draining tumors**
 - Clinical studies underway in Urological (prostate, testicle, penis, kidney, bladder...), Colorectal, Gastric, Gynaecological (cervix, endometrium, vulva...), neuroendocrine...
 - Dedicated software tools for unprecedented location of hidden deep nodes.
 - Optimum complement to SPECT CT and other state of the art imaging techniques.
- 4 Guarantees and documents complete resection of identified tumors and lymph nodes**
 - “Clean field” after completion of surgery, comparative images and ex-vivo quantification of node (or tumor) activity are generating objective, legal documentation.
 - Automatic image re-scale after resection of tumor and high activity nodes monitors and can detect additional hidden, low activity primary nodes.
 - Patient data and image integration in Hospital information systems (generates DICOM files, it is PACS compatible, wireless, 2 USB ports and LAN access for easy data transfer...).
- 5 Opens the new clinical option of personalized, limited lymphadenectomy**

A high performance portable gammacamera
(in resolution, speed, reliability and ease of use)
for advanced Nuclear Medicine indications

A VERY special gammacamera, with breakthrough single continuous crystal technology

Sentinella´s patented single continuous crystal and PSPM technologies are bringing a major improvement in resolution, quantification and image quality vs previous pixellated crystal gammacameras and gamma probes, finding formerly undetectable nodes, and paving the way for additional major improvements in combined localization, of tumors and lymph nodes with camera + probes + pointers + dedicated software at the OR and in the NM suite. Future further performance improvements possible through software.



Powerful Computer Aided

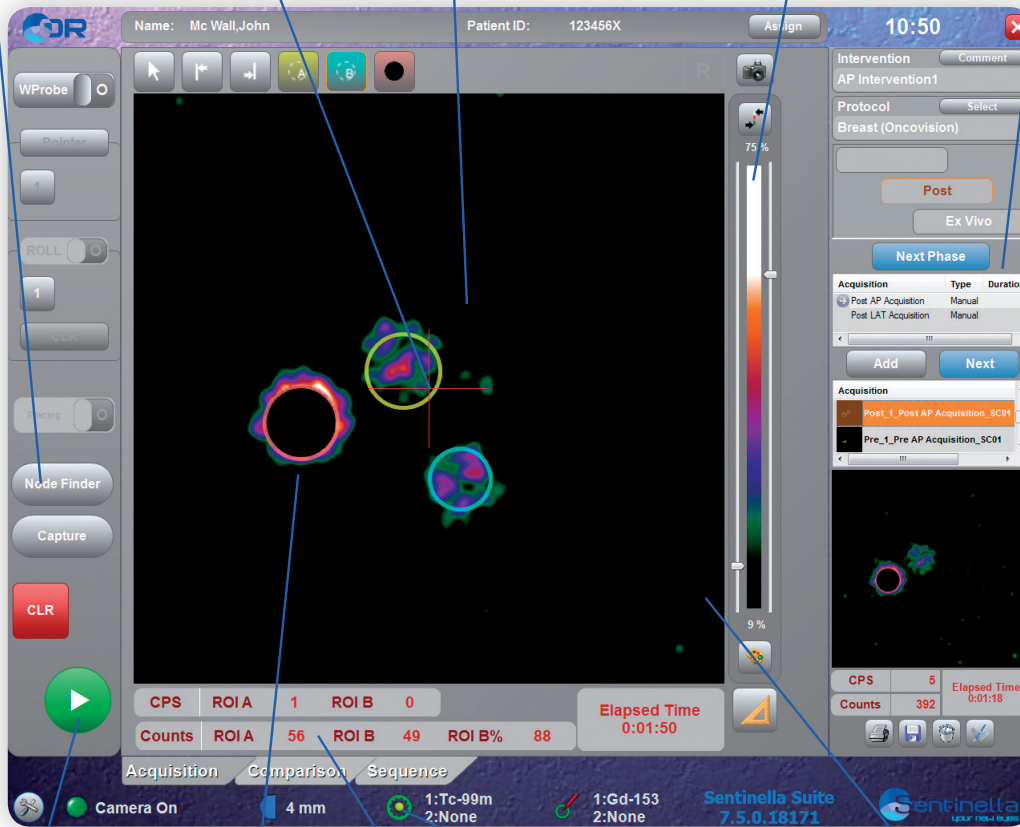
Identifies and highlights "hottest" spots in the field

Up to two regions of interest, of variable customer-selected diameter with precise comparative quantification

Automatic scale correction, to highlight points of activity, also adjustable by the side bar

Laser Pointer for clear orientation and alignment center of image surgical field

Fully customizable protocols by procedure, NM Doctor, surgeon, unit...



Single button control for image capture and image refreshing for fully intuitive use

Clear identification of collimator, pointer and isotope used

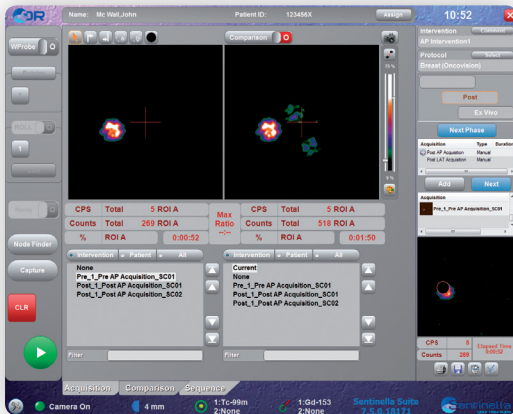
File format for storage, with complete molecular information for each image, which you can process and study also after surgery

NEW

Virtual Lead to hide the tumor or injection point to enhance hidden nodes

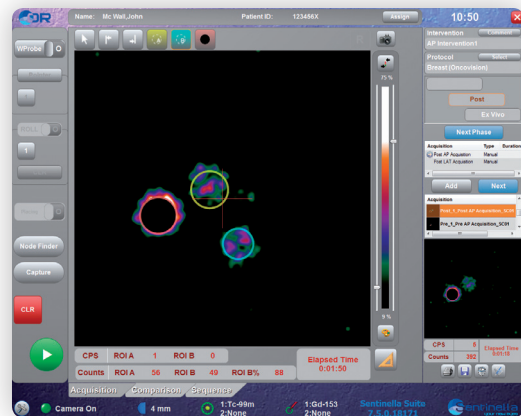
Objective quantification of full field of view and regions of interest

Diagnosis for the OR and NM Suite

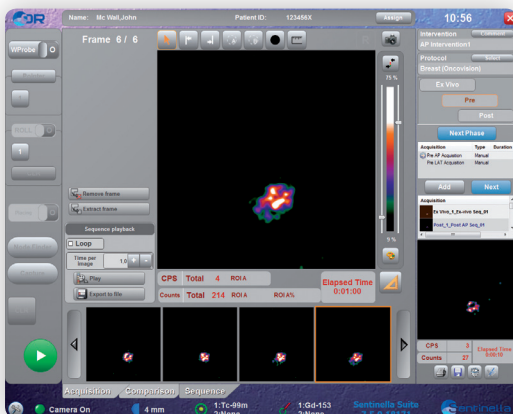


This tool allows comparisons between two acquisitions whatsoever, displayed in a practical and simple result of the biopsy, activity difference between two images or simultaneously viewing from two points of view.

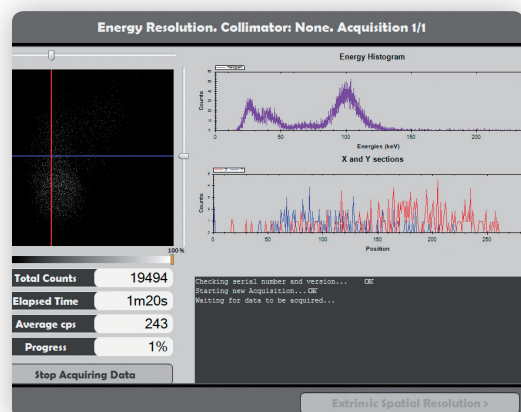
The various diagnostic support tools that software enables to take distances references between clusters of activity i.e. **injection point-sentinel nodes**, calculate activities of different regions or block those areas of the image that may be hiding nearby activity points.



The tab sequence allows scheduling acquisitions in number and variable duration to record changes in activity in the area of interest, allowing dynamic studies to be done. The acquired sequence can be exported in video format.



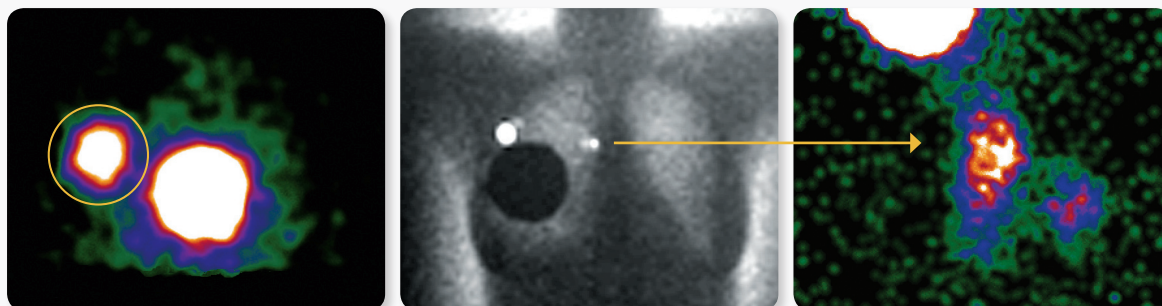
The software suite includes various tools to meet in a comfortable and easy way validation tasks and periodic verification of the equipment, as well as generating self-status reports.



Personalized Open and Laparoscopic

A SAFE Clinical Option in Breast Cancer Surgery

SENTINEL NODE BIOPSY as proven critical staging and treatment tool in most patients, its role reinforced by recent studies such as ACOSOG's Z0011. Sentinella, with thousands of patients diagnosed and treated successfully, has become the standard in many world class Institutions, with relevant clinical evidence:



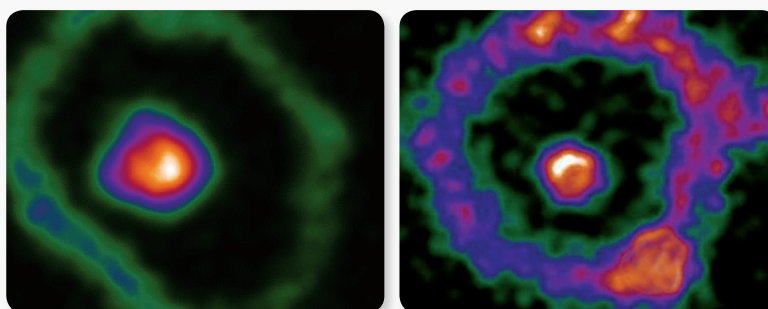
Courtesy of Dr. S. Vidal-Sicart - Nuclear Medicine Dpt. - Hospital Clínic. Barcelona. Spain.

- 1.- Demonstrated localization of additional histologically positive lymph nodes not detected with gamma probes or blue dye, in at least 5% of patients.
- 2.- Proven clinical improvement in localization of difficult lesions: extraaxillary nodes (IMA, intramammary, supra/infraclavicular, contralateral...) and nodes near to primary tumor, by combining gamma camera, probe, pointers and software.
- 3.- Guarantees and documents completeness of breast cancer surgery (post-op clean field confirmation that NO hidden lymph nodes with tracer drainage have been left, ex-vivo quantification of resected nodes...), with legal validity.
- 4.- Standardization of technique among different surgical teams.
- 5.- High resolution and fast OR lymphoscintigraphy, even more valuable in centers where this exploration is not viable before surgery.



ROLL & SNOLL

ROLL (Radioguided Ocult Lesion Localization) and SNOLL (Sentinel Node biopsy and ROLL in the same patient) have become two strong support tools for breast cancer assesment in the OR, with a corellation superior to 85% with final pathology results about safety of margins, allowing immediate action. Sentinella is providing precise and objective real-time visual information, has been successfully used in patients worldwide and is supported by relevant clinical papers, highlighting its significant advantages vs gamma probes:



Courtesy of Dr. P. Paredes Nuclear Medicine Dpt. Hospital de Sant Pau. Barcelona. Spain.

Courtesy of Dr. B. Ballester Univ. Hospital of Alzira. Valencia. Spain.

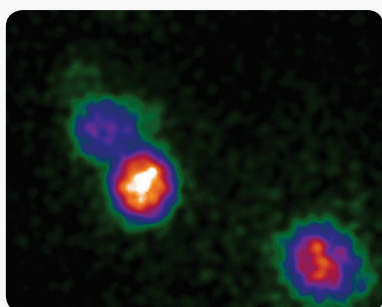
- 1.- Faster and better (visual) identification of resection margins.
- 2.- Reproducible, easy and intuitive technique.
- 3.- Quick and clear identification of lesion margins in controversial cases.
- 4.- Generates objective documents of quality of surgery performed.



Cancer Surgery in Superficial Draining Tumours

Making a Difference in Melanoma and Head & Neck Tumors

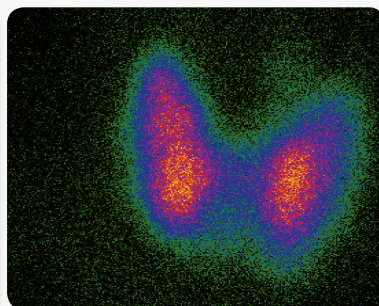
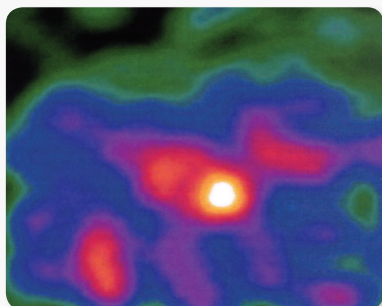
Growing fast in incidence, melanoma, a very aggressive tumor, is affecting younger patients every year. With documented evidence indicating that 10 to 30% of melanomas are draining out of the expected lymphatic areas, a detailed and accurate preop lymphoscintigraphy and true high precision surgery are a must. Sentinella's proven performance in both melanoma and head and neck tumors, often with very small and non-superficial lymph nodes, is extensively documented, with major international studies underway.



Courtesy of L. Vermeeren - W. M. C. Klop - NKI-AWL Amsterdam, the Netherlands.

- 1.- Excellent detection of "hidden" (deep, small or next-to-tumor -or injection-) nodes.
- 2.- Real-time guidance for node location.
- 3.- Quantification of nodes in-vivo vs ex-vivo.
- 4.- Possible constant monitoring of procedure and "clean field" assessment at its end.

Strong Evidence in Parathyroid Tumors



Courtesy of Drs. J. Ortega and J. Ferrer
 Department of Surgery, Hospital Clínic.
 Valencia, Spain
 Department of Nuclear Medicine, General
 University Hospital. Spain.

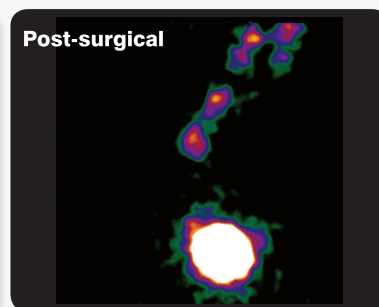
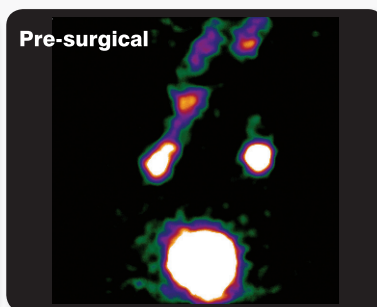
Courtesy of Dr. J. Ferrer
 Department of Nuclear Medicine, General
 University Hospital.
 Valencia, Spain.

The first Sentinella publications by Drs. J. Ortega and J. Ferrer, from Valencia, Spain, about parathyroid surgery in adenomas appeared during 2006. Since then, hundreds of patients have been successfully treated all over the World, demonstrating a precise, fast localization of the pathologic and healthy parathyroids, with only a small fraction of the tracer used before, eliminating any need for gamma probes.

Personalized Open and Laparoscopic

Breakthrough in Urological Cancer Surgery

Sentinel node biopsy is a controversial issue in some of the main urological indications due to some previous publications, while it is well accepted in penis cancer. There is, however, very strong positive evidence from The Netherlands and Austria, in Europe, and from some US centers about the excellent oncological results of Sentinel Node biopsy in prostate cancer, testicular cancer and even kidney and bladder cancer. Sentinella will become a powerful support tool in these pathologies, in laparoscopic and open surgery, with clinical studies underway, specially in prostate cancer.

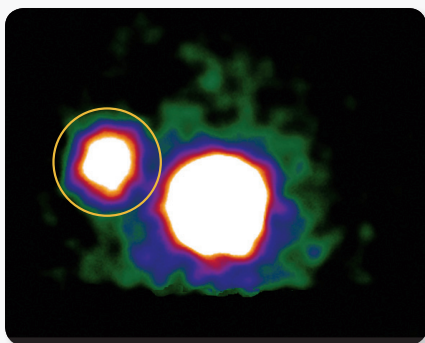


Courtesy of Drs. R. Valdés, A. Bex, S. Horemblas - NKI-AWL Amsterdam, The Netherlands.

- 1.- Accurate localization of previously identified nodes and "hidden", deep nodes, guiding the gamma probe to difficult access regions
- 2.- Quantification of lymph node activity, both in-vivo (inside the patient) and ex-vivo
- 3.- Clean field confirmation, documenting completeness of surgery
- 4.- Clear identification of nodes very near injection point and/or tumor, and of "aberrant", unexpected drainage nodes



Major Impact in Gynecological Cancer Outcomes



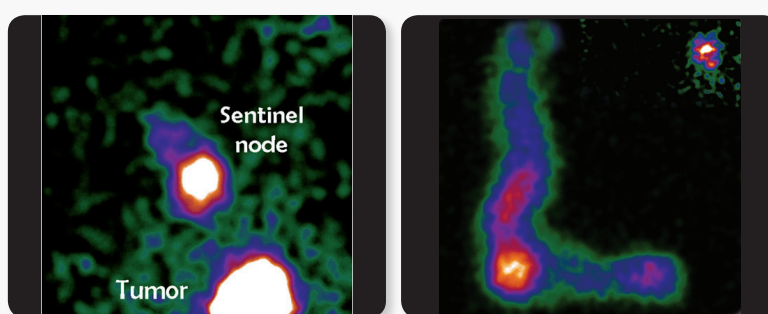
The high frequency and aggressiveness of uterine (and ovarian) cancers are a major clinical challenge, beyond the superficial draining vulvar cancer. These deep draining tumors can benefit from Sentinella's deep detection performance. Its main advantages are similar to the ones listed in Urology, and is also sharing with this Specialty the major benefits of a limited, personalized lymphadenectomy.

Courtesy of Dr. S.Vidal-Sicart, Nuclear Medicine Dpt. Hospital Clinic. Barcelona. Spain.

Cancer Surgery in Deep Draining Tumours

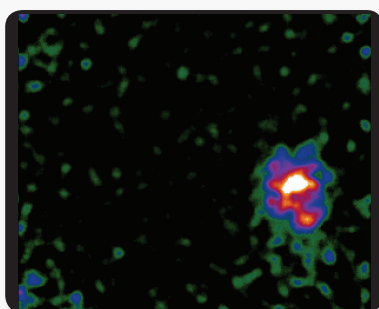
A New Era in Radioguided Colorectal Surgery?

With 9,1%+ of tumors draining beyond expected “classical” areas, specially in transverse and descending colon, the wide field and deep detection capabilities of Sentinella, proven clinically useful in colorectal pathologies, are relevant factors. Personalized limited lymphadenectomy, location of additional positive hidden and aberrant nodes, clear localization of nodes next to tumor or injection point... and guarantee of complete resection of identified nodes (clean field). The ex vivo assessment of the resected colon is an alternative opportunity for exploring the advantage of this technique.



Courtesy of Drs. J. Mayol and Dr. R. Delgado, Departments of Surgery I and Nuclear Medicine Hospital Clínico San Carlos. Madrid. Spain

A New Hope in Upper GI and Neuroendocrine Tumors



Courtesy of Dr. M. E. Rioja, Hospital Ramón y Cajal. Madrid. Spain.

The excellent results published by Japanese surgeons using sentinel node navigation are opening a new hope for patients with these complex pathologies. Sentinella´s experience in this field is still limited, but positive, along the lines of colon and urology.

In a different clinical area, there are very encouraging reports on the use of Sentinella for neuroendocrine tumors, of very complex localization. Deep detection capabilities and high resolution (1,6 mm) could allow accurate localization and confirmation of the non-existence of additional tumors after resection.

Sentinella 102

your new eyes

SAFER Personalized cancer surgery

Why surgeons use it?

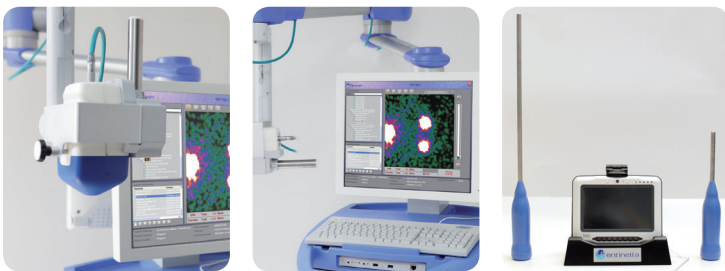
Proven
1.- Reduction in **false negatives** in sentinel node biopsy in superficial draining tumors (breast cancer, melanoma, head and neck, vulva, etc.)

Proven
2.- Helps in **personalized cancer surgery** in complex anatomical areas (head and neck, retroperitoneum, mesorectum) and small tumors

4.- Opening a new clinical way for personalized lymphadenectomy in **deep draining tumors** (advanced SNB indications)

5.- And tenths of thousands of patients worldwide, with strong multispecialty clinical evidence

EVERYTHING IS NOT WHAT IT SEEMS



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