SAFER, Personalized cancer surgery

Sentinella 102
your new eyes

GAMMA CAMERA + GAMMAPROBE + POINTERS + DEDICATED SOFTWARE

WORLDWIDE IN THOUSANDS OF PATIENTS CLINICAL SUCCESS

ONCOVISION
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) node(s) are denominated “Sentinel” nodes, and their status vs tumor invasion is critical to define patient treatment, as evidenced by multiple studies, including ACOSOG’s Z0011.

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 of superficial and (now with Sentinella) deep, complex drainage.

Medical and Surgical cross-specialty teams, with the decisive role of surgeons from different specialties, nuclear medicine physicians and pathologists, together with new image-guided techniques and improved oncological treatments, are creating a new hope, based on solid clinical evidence, in the victory of more patients over more types of cancer.
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 superficial drainage tumors. Its proven clinical results and hundreds of clinical papers from the most advanced oncological centres support its efficacy and effectiveness.

Its absolute safety for patients and healthcare professionals, has been demonstrated by clinical studies with high level of evidence, and assessed by radiophysicists and radioprotection specialists.

**Still limited procedure adoption due to clinical limitations of dyes and gamma probes**

Limited visibility of dyes, gamma probe need of directional, close contact with tissues and organs, limited depth of detection, subjective assessment of sound intensity, lack of integration in Hospital documentation systems, learning curve, lack of assurance about absence of deeper, low capation or next to tumor nodes.

**The hour of personalized cancer surgery in every patient and every tumor**

Sentinella’s **integrated gamma camera + gamma probes + pointers + dedicated software** are making possible real time molecular vision in the OR -and NM suite- of the personal lymphatic drainage of each patient, before and during surgery, supporting, tracking and documenting progress of the procedure, both open and laparoscopic, and confirming its completeness (“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 capation, next to tumor lymph nodes.

"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

Gammacamera are being used in endocrinology, osteoarticular, nephrologycal pathologies, therapy efficacy follow-up, donor and organ assessment in transplants, perfusion in limb tumors...
EXCLUSIVE Single continuous crystal for unparalleled resolution (1.6 mm) and real time molecular vision, even in deep, "hidden" nodes

Pinhole collimators for balancing resolution and sensitivity

EXCLUSIVE Articulated electromagnetic arm, 1.5 m long, for easy and stable access to every anatomical region

Easy one-hand camera control, with laser positioning system for clear surgical field orientation

Twin 19" high resolution screens for optimum visibility (touch screen in surgeon’s side)

Ergonomic handles in both sides, for easy transport and OR movement

2 USB ports, LAN and wireless access for easy data transfer

Wide space and easy access to integrated probe, expansion modules (multimodality...) and accessories (printers, portable storage solutions...)

Powerful, expandable computer for processing and storage of data and images

Integrated UPS for continuing operation from NM to OR, ER or ICU, and protecting data from power failure

Long retractable wire

Reinforced, big wheels, designed to overcome ground- or elevator- irregularities

Easy, safe wheel blocking mechanism

Reengineered with the experience of World Leading Cancer Centers
5 critical innovations for a safer, personalized cancer surgery

**EXCLUSIVE** Preoperative, Intraoperative and Postoperative portable integrated cancer detection unit
Gamma camera + gamma probes + pointers + dedicated software

**EXCLUSIVE** 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

**EXCLUSIVE** 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

**EXCLUSIVE** 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...)

**EXCLUSIVE** 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
What makes Sentinella different, and a strong clinical option in cancer surgery?

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

Proven superior to any gamma probe-based options

Why Sentinella has a higher Depth of detection?

Clinical limitation

Non detection beyond 2 cm (1)

Gamma probes are designed to pinpoint tracer counts, having no memory, and generating instantaneous sound from its tip crystal

Sentinella accumulates the counts detected with data coming from the same point, greatly increasing sensitivity

(1)...often lower, and variable according to tissue density

G-probes ~25 mm²

Sentinella 40mm x 40 mm, 1600 mm²

Detection surface at least 64 times bigger

Crystal size + photomultipliers, electronics... Sentinella's CLINICAL sensitivity is at least 75% superior to g-probes
A powerful, scalable, reliable and fully integrated software is the true heart of Sentinella. FOUR innovative and very user-friendly modules handle image acquisition and dedicated software (Sentinella OR module), patient data (Sentinella Manager), image gallery (Sentinella Viewer) and calibration, validation and system status (Sentinella Supervisor). Developed and regularly upgraded hand in hand with leading Surgeons and Nuclear Medicine Doctors from well respected World cancer centers, these software modules are as flexible as they are truly INTUITIVE and EASY TO USE.

**EXCLUSIVE**

- Identifies and highlights "hottest" spots in the field
- Up to two regions of interest, of variable customer-selected diameter with precise comparative quantification
- Laser Pointer for clear orientation and alignment center of image surgical field
- Automatic scale correction, to highlight points of activity, also adjustable by the side bar
- Single button control for image capture and image refreshing for fully intuitive use
- Clear identification of collimator, pointer and isotope used
- Objective quantification of full field of view and regions of Interest
- File format for storage, with complete molecular information for each image, which you can process and study also after surgery
- Fully customizable protocols by procedure, NM Doctor, surgeon, unit...

Powerful, interactive, intuitive software DESIGNED for the OR and NM suite
A SAFE clinical option in breast cancer surgery

Breast cancer, the most common malignant tumor in women, with growing incidence, up to 1 in 7 women in some regions, is impacting the lives of millions of women every year. Building on the pioneering work of leading surgeons such as Dr. U. Veronesi, and through the dedicated work of cross specialty teams, integrating also gynecologists, nuclear medicine doctors, oncologists, pathologists, nurses and other professionals, major improvements in prognosis are being gained, with the 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:

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: extramammary, 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 confirm negative lymph nodes with tracer drainage have been left), 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 Occlux Lesion Localization) and SNOLL (Sentinel Node biopsy and ROLL in the same patient) have become two strong support tools for breast cancer assessment in the OR, with a correlation 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:

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
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.

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

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.
A coming 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, especially in prostate cancer.

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.
surgery in deep draining tumors

A new Era in radioguided colorectal surgery?

Colorectal cancer is the third most frequent malignant tumor, and has significant mortality. With up to 27% recurrence rate, surgical oncology protocols are increasing the number of nodes excised for a ‘correct’ oncological treatment. Sentinel node biopsy in colon cancer is still controversial, with contradictory findings, but the landmark study presented at the ISNS Yokohama congress 2010 proved that cancer related survival improved in patients with SNB, with personalized upstaging and proper treatment.

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 potentially 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.

A new hope in Upper GI and neuroendocrine tumors

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.
Preoperative, intraoperative and Postoperative portable integrated cancer detection unit

Real-time vision, making a major clinical difference in "difficult" cases in breast cancer, melanoma and head & neck tumors

Growing published experience in radioguided surgery for deep draining tumors

Guarantees and documents complete resection of identified tumors and lymph nodes

Opens the new clinical option of personalized, limited lymphadenectomy