

Revealing the whole picture

OSNA



Accurate nodal staging for
personalised cancer treatment

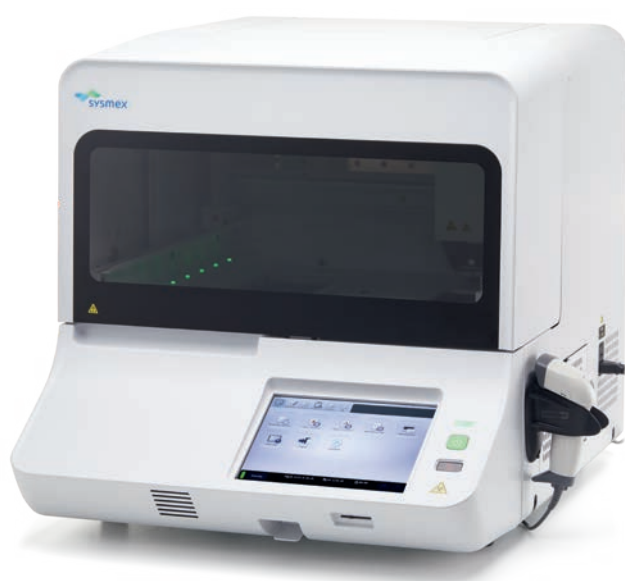
A unique multi-application molecular platform for fast and accurate nodal staging

Metastatic spread to lymph nodes is one of the most important prognostic factors in most cancers. The nodal status is a significant parameter guiding clinicians' decisions on the most appropriate surgical procedure and subsequent therapy steps.

Precise assessment of lymph node tissue and determination of the metastatic burden is decisive for providing high diagnostic quality and enabling reliable disease staging. Often, exhaustive nodal analysis is not common practice, not standardised as well as labour intensive for both the laboratory and the reporting pathologist.

With OSNA we aim to change this.

OSNA – or one step nucleic acid amplification – is a unique molecular diagnostic test facilitating standardised, accurate and rapid lymph node examination. The possibility to assess the entire tissue in combination with fast availability of results, offers clinicians a tool that fits perfectly with their clinical needs and the diagnostic requirements in managing patients with different cancer types. OSNA enables accurate nodal staging at any time, independent of whether the result is required intraoperatively or postoperatively.



Key benefits at a glance

- ✓ Whole node analysis
- ✓ Quantification of metastatic burden
- ✓ Standardised protocol
- ✓ Intraop results within 20 min
- ✓ 14 samples in 30 min
- ✓ Mix and match of different applications
- ✓ One kit for all
- ✓ Reduced pathology workload



Having two RD-210 systems based at the RSCH allows us to provide the benefits of OSNA to our breast cancer patients within our Surrey and Berkshire Pathology Network in a responsive and flexible manner. It gives us the capacity to analyse from multiple sources at a given time and also to investigate the potential of multiple OSNA applications such as for gynaecological cancers.

James Woodland CSci FIBMS,
Lead Biomedical Scientist,
Berkshire and Surrey Pathology Services, UK



Breast cancer



- Accurate sentinel node assessment
 - risk determination of non-sentinel node involvement^{1,2}
 - supports de-escalation of axillary surgery
- Added value for treatment decision-making due to predictive and prognostic capabilities^{1,3}
- Relevant staging information even if no axillary dissection is performed³
- Applicable for patients having received neoadjuvant therapy
- Reduced psychological anxiety for both negative and positive patients
- Included in European and several national guidelines



The high accuracy and quantitative capabilities of OSNA make it a useful tool in intraoperative gastric cancer diagnostics. The possibility of examining the entire nodes provides robust results, avoiding sampling bias.

Prof. Dr Wojciech Polkowski,
Chairman of the Department of Surgical Oncology
at SPSK1, Lublin, Poland



Gastric cancer



- Fast, fully informed diagnosis during surgery
 - supports de-escalation of surgical radicality of stomach tissue and associated post-surgical morbidities, improving patient's QoL
- Reduces pathology workload and TAT to report
- Accurate nodal staging
 - prevents false negative results supporting prognosis assessment⁴



In endometrial cancer, OSNA could be considered as an alternative to ultra-staging for the definitive pathology, with a consequent cost reduction. Conversely, in cervical cancer the OSNA analysis could be adopted for intraoperative analysis for a more accurate diagnosis of macro- and low-volume metastasis.

Prof. Francesco Fanfani,
and Prof. Gian Franco Zannoni,
University Hospital Agostino Gemelli IRCCS, Rome, Italy



Gynaecological cancer



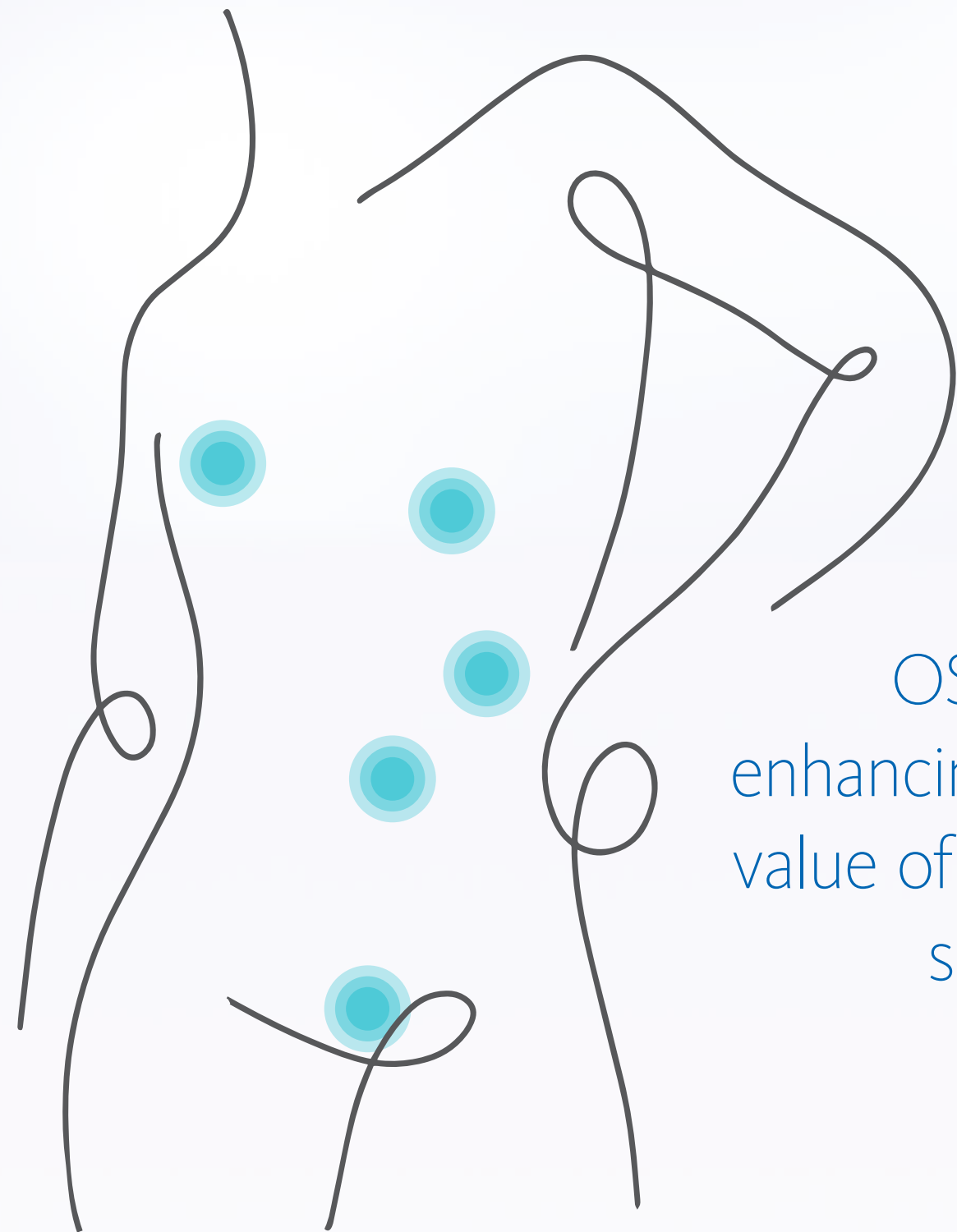
- SLNB + OSNA whole node analysis offers a less invasive alternative for nodal staging instead of pelvic lymph node dissection (PLND)

Cervical cancer

- Intraoperative information comparable to ultra-staging not missing low-volume disease
- Avoid false negative intraoperative results and potential overtreatment
- Reliable basis for appropriate surgical approach, considering the patient's wish

Endometrial cancer

- Avoid unnecessary PLNDs and surgical morbidities not compromising staging accuracy
- Information beyond ultra-staging, supporting adequate therapy choice and avoiding the risk of over- or undertreatment



OSNA –
enhancing the
value of nodal
staging



The OSNA lung application is a quantitative and highly reproducible method that standardises diagnosis, improves nodal staging and increases prognostic accuracy, helping clinical decision-making in the context of personalised medicine.

Dr Ángel Concha,
Head of the Pathology Department at CHUAC,
A Coruña, Spain



Lung cancer



- Accurate nodal staging⁵
 - prevents false negative results
 - high negative predictive value (NPV)
- Fast, fully informed diagnosis during surgery
- Supports adequate therapy choice avoiding undertreatment
- Supports intraop decision-making and surgical de-escalation

Colorectal cancer



- Accurate nodal staging
 - prevents false negative results
 - high negative predictive value (NPV)
- Correlates with prognosis and classical CRC high-risk factors⁶
- Supports patient's selection for adjuvant therapy and assists patient management⁶, avoiding over- and undertreatment
- Reduces pathology workload and improves cost-effectiveness⁷
- Fast, fully informed diagnosis
- OSNA CRC included in Spanish recommendations⁶



OSNA allows the identification of colorectal cancer patients with positive lymph nodes not detected by conventional histopathology diagnosis who would benefit from adjuvant therapy. It's an opportunity to save their lives.

Dr Miriam Cuatrecasas,
Senior Pathologist at Hospital Clinic,
Barcelona, Spain



Prostate cancer



- Fast, fully informed diagnosis during surgery
 - supporting de-escalation of surgical radicality of pelvic lymph nodes and associated post-surgical morbidities, improving patient's QoL⁸
- Reduces pathology workload and TAT to report
- Accurate nodal staging
- Prevents false negative results⁸
 - supporting selection of patients, with two or more positive LNs, for adjuvant therapy
 - reduces patient's anxiety



OSNA analysis offers us for the first time the possibility to integrate molecular lymph node diagnostics into clinical routine. The possibility of intraoperative application in combination with minimally invasive sentinel-guided lymphadenectomy opens up new ways for risk-adjusted lymphadenectomy in prostate cancer. Our patients can thus benefit not only from high diagnostic safety but also from a lower morbidity.

Dr med. Alexander Winter,
Director of the Uro-oncological Centre at University
Hospital for Urology, Oldenburg, Germany



References

- [1] **Peg V et al. (2013):** *Intraoperative molecular analysis of total tumour load in sentinel lymph node: a new predictor of axillary status in early breast cancer patients. Breast Cancer Res and Treatment. 139(1):87–93.*
- [2] **Di Filippo F et al. (2016):** *Elaboration of a nomogram to predict non-sentinel node status in breast cancer patients with positive sentinel node, intraoperatively assessed with one step nucleic amplification: Retrospective and validation phase. J Exp Clin Cancer Res. 2016 Dec 8. 35(1):193.*
- [3] **Peg V et al. (2017):** *Role of total tumour load of sentinel lymph node on survival in early breast cancer patients. Breast. 2017 Feb 27. 33:8–13.*
- [4] **Märkl B et al. (2021):** *Ultrastaging using ex-vivo sentinel lymph node mapping and one-step nucleic acid amplification (OSNA) in gastric cancer: Experiences of a European Center. Cancers 2021 May 29;13(11):2683.*
- [5] **Escalante Pérez M. et al. (2019):** *Detection of lymph node metastasis in lung cancer patients using a one-step nucleic acid amplification assay: a single-centre prospective study. J Transl Med. 2019 Jul 22; 17(1):233.*
- [6] **García-Alfonso P. et al. (2019):** *Update of the recommendations for the determination of biomarkers in colorectal carcinoma: National Consensus of the Spanish Society of Medical Oncology and the Spanish Society of Pathology. Clin Transl Oncol. 2020; 22, 1976–1991.*
- [7] **Diaz-Mercedes S et al. (2019):** *Budget Impact Analysis of Molecular Lymph Node Staging Versus Conventional Histopathology Staging in Colorectal Carcinoma. Appl Health Econ Health Policy. 2019 May 17, 655–66.*
- [8] **Engels S et al. (2021):** *Evaluation of Fast Molecular Detection of Lymph Node Metastases in Prostate Cancer Patients Using One-Step Nucleic Acid Amplification (OSNA). Cancers 2021 Mar 13(5), 1117*

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