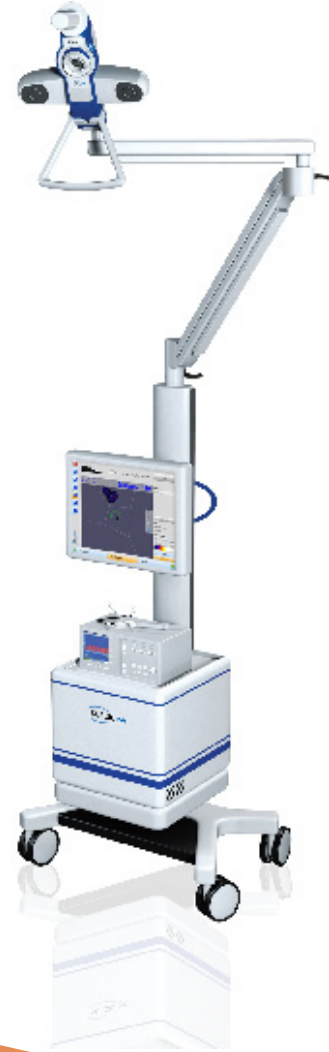


declipse[®]SPECT Laparoscopy

Worldwide first intraoperative 3D
imaging and navigation system for
laparoscopic surgery



Highlights of declipse®SPECT Laparoscopy:

- The declipse®SPECT Laparoscopy is an intraoperative 3D imaging system for precise, minimally invasive sentinel lymph node biopsy (SLNB)
- It generates 3D images of radioactively marked structures using freehand SPECT technology¹ for easy and intuitive SLNB mapping
- The intraoperative declipse®SPECT Laparoscopy supports precise navigation and localization of SLNB
- The declipse®SPECT Viewer helps to analyze pre-operative images, such as SPECT/CT and PET/CT, in situ, during the intervention



Advantages of declipse®SPECT Technology:

- SLNs can be visualized and localized easily, even close to the injection site
- SLNs seen in lymphoscintigraphy can be found again reducing 24% of discrepancy between imaging and surgical findings²
- 3D SPECT images can be acquired intraoperatively at any time during surgery enabling to control complete resection of all SLNs and instant detection of residual labeled SLNs
- Preoperative images can be navigated virtually and co-registered with the patient in the OR to simplify the localization and mapping of SLNs

Advantages of abdominal SLNB:

- The standard pelvic and paraaortic lymph node dissection (PPLND) can be spared in up to 30% of the patients with an equivalent prognostic value^{2,3,5,6}
- Sentinel lymph node biopsy (SLNB) can find positive lymph nodes outside PPLND region in up to 7% of the cases lowering potentially regional recurrence rate^{2,4,7}
- Pelvic and paraaortic SLNB can be performed minimally invasive and provide together with fertility sparing procedures excellent success rates^{3,5,8}
- Complication rate and morbidity can be lowered compared to standard PPLND from 35% to 1%³

Urologic application

Clinical indication

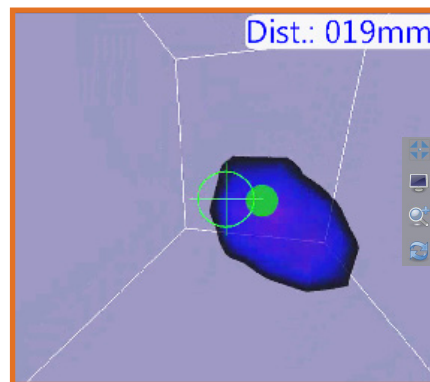
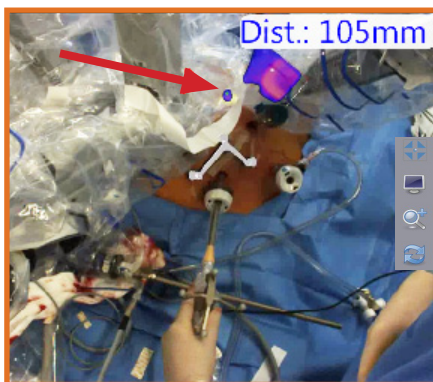
Patients with prostatic cancer with Gleason scores 6, 3+4 and 4+3 as well as clinically negative regional lymph nodes².

Recommended injection protocol:

- preoperative transrectal ultrasound guided injection
- 80-320 MBq (depending on expected time before surgery) in 1-3 aliquots of 0.1-0.5ml pro prostate lobe
- use of saline solution for flushing activity in injection needle

Selected case prostatic carcinoma

Below, the red arrow in the left image points at the sentinel node next to the injection site in the prostate overlaid on a realtime video image. The right image shows the same node from the perspective of the gamma probe (3D view) including the exact distance from the tip of the probe to the labeled hotspot. Images courtesy of Dr. Henk van der Poel, The Netherlands Cancer Institute, Amsterdam, the Netherlands.



Gynecologic application



„The 3D declipse®SPECT Laparoscopy technology opens new horizons to minimal-invasive surgery in gynecologic oncology. Sentinel lymph node biopsy during laparoscopic procedures seems to be easily feasible and may in the nearer future become standard of care for cervical and endometrial cancers.“

Prof. Dr. René Hornung
Head of Department of Gynecology
Kantonsspital St. Gallen, Switzerland

Clinical indications:

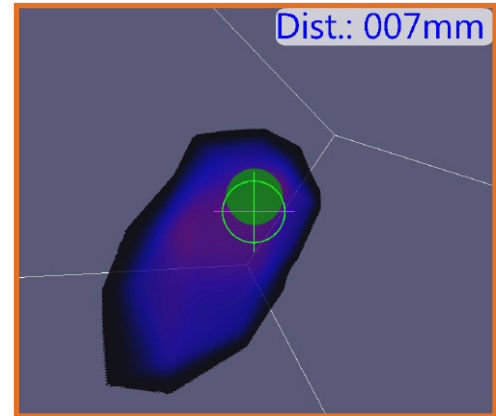
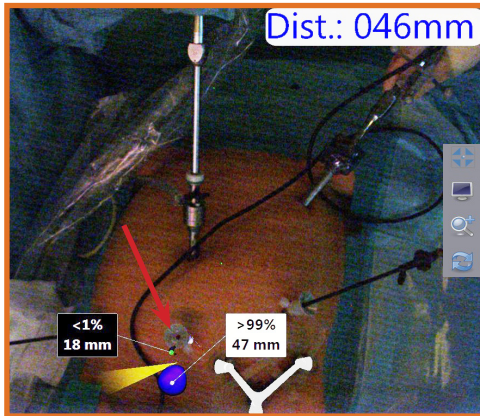
- Patients with cervical cancer in FIGO stages Ia, Ib1 and IIa (<4 cm diameter) and clinically negative regional lymph nodes⁵
- Patients with endometrial cancer in FIGO stage I and clinically negative regional lymph nodes⁶

Recommended injection protocol:

- Cervical cancer:
 - direct injection in cervix, either preoperatively or intraoperatively injection
 - 40-320 MBq (depending on expected time before surgery) in 4 aliquots of 0.1-0.5 ml
 - use of saline solution for flushing activity in needle
- Endometrial cancer:
 - three options for injection location:
 - 1.preoperative transvaginal ultrasound guided myometrial
 - 2.preoperative cervical
 - 3.preoperative or intraoperative hysteroscopic injection
 - 40-320 MBq (depending of expected time before surgery) in 2-4 aliquots of 0.2-1.0 ml
 - use of saline solution for flushing activity in needle

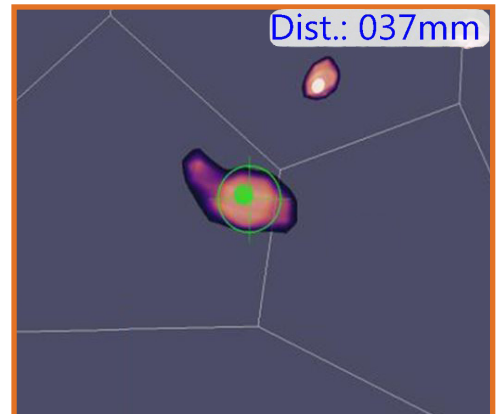
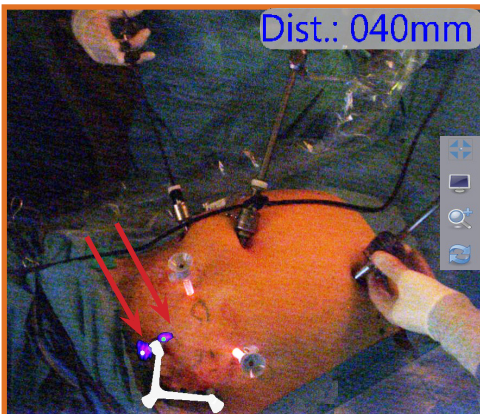
Selected case endometrial carcinoma

Below, the left image shows one reconstructed SLN (red arrow) in the left pelvic region next to the injection site overlaid onto a realtime video image of its exact location. The right image shows the same node from the perspective of the gamma probe (3D view) including the distance in mm from the tip of the probe. Images courtesy of Prof. René Hornung, Kantonsspital Sankt Gallen, St. Gallen, Switzerland.



Selected case cervical carcinoma

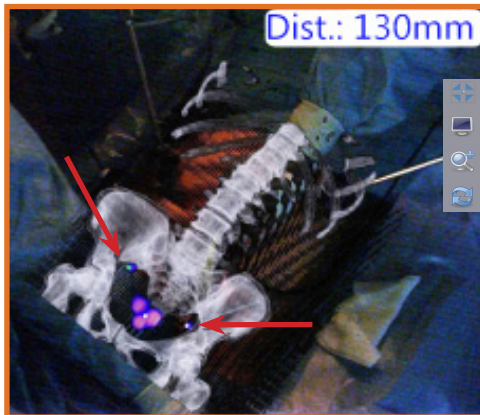
Below, the left image shows two reconstructed SLN in the right pelvic region overlaid on a realtime video at its exact location. The right image shows the same nodes from the perspective of the gamma probe (3D view) including the distance in mm from the tip of the probe. Images courtesy of Prof. René Hornung, Kantonsspital Sankt Gallen, St. Gallen, Switzerland.



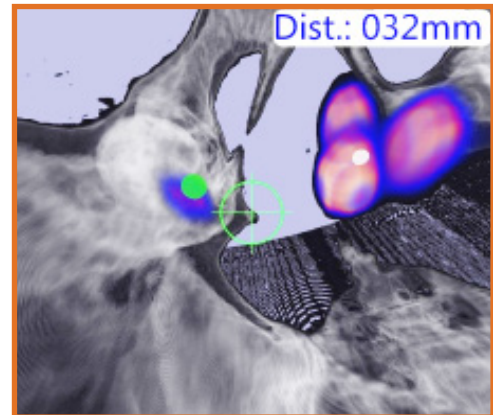
declipse®SPECT Viewer

The declipse®SPECT Viewer brings preoperative diagnostic images into the operating room. The use of 3D images such as SPECT/CT and PET/CT is extended from its pure diagnostic purpose to intuitive image based orientation during the intervention.

- The preoperative data can be virtually overlaid on the patient for intuitive image viewing and easy orientation
- The preoperative information can be used either in precise slice view or in intuitive direct navigation during the operation, for the first time in-situ and in correlation with the patient in order to plan and validate the intervention
- The intuitive anatomical correlation has potential to support the surgeon for safer and faster resections of labeled structures



Video overlay of cervix cancer lymphatic drain (red arrows) on a realtime video image co-registered in the operating room



3D view used for surgical navigation towards sentinel lymph nodes in correlation with the patient's anatomy

References and citations:

¹Wendler, T., Herrmann, K., Schnelzer, A., Lasser, T., Traub, J., Kutter, O., Ehlerding, A., Scheidhauer, K., Schuster, T., Kiechle, M., Schwaiger, M., Navab, N., Ziegler, S.I. and Buck, A.K. First demonstration of 3-D lymphatic mapping in breast cancer using freehand SPECT. *Eur J Nucl Med Mol Imaging*. 2010 Aug;37(8):1452-61.

²Holl, G., Dorn, R., Wengenmair, H., Weckermann, D. and Sciuk, J. Validation of sentinel lymph node dissection in prostate cancer: experience in more than 2,000 patients. *Eur J Nucl Med Mol Imaging*. 2009 Sep;36(9):1377-82.

³Meinhardt, W., Valdés Olmos, R. A., Van Der Poel, H. G., Bex, A., & Horenblas, S. (2008). Laparoscopic sentinel node dissection for prostate carcinoma: technical and anatomical observations. *BJU international*, 102(6), 714-717.

⁴Vermeeren, L., Valdés Olmos, R.A., Meinhardt, W., Bex, A., van der Poel, H.G., Vogel, W.V., Sivo, F., Hoefnagel, C.A., Horenblas, S. Value of SPECT/CT for detection and anatomic localization of sentinel lymph nodes before laparoscopic sentinel node lymphadenectomy in prostate carcinoma. *J Nucl Med*. 2009 Jun;50(6):865-70.

⁵Levenback, C.F. Status of sentinel lymph nodes in cervical cancer. *Gynecol Oncol*. 2007 Oct;107(1 Suppl 1):S18-9.

⁶Vidal-Sicart, S., Doménech, B., Luján, B., Pahisa, J., Torné, A., Martínez-Román, S., Antonio Lejárcegui, J., Fusté, P., Ordi, J., Paredes, P., Pons, F. Sentinel node in gynaecological cancers. Our experience. *Rev Esp Med Nucl*. 2009 Sep-Oct;28(5):221-8.

⁷Bats, A.S., Mathevet, P., Buenerd, A., Orliaguet, I., Mery, E., Zerdoud, S., Le Frère-Belda, M.A., Froissart, M., Querleu, D., Martinez, A., Leblanc, E., Morice, P., Daraï, E., Marret, H., Gillaizeau, F., Lécuru, F.. The sentinel node technique detects unexpected drainage pathways and allows nodal ultrastaging in early cervical cancer: insights from the multicenter prospective SENTICOL study. *Ann Surg Oncol*. 2013 Feb;20(2):413-22.

⁸Torné, A., Pahisa, J., Vidal-Sicart, S., Martínez-Roman, S., Paredes, P., Puerto, B., Albela, S., Fusté, P., Perisinotti, A., Ordi, J. Transvaginal ultrasound-guided myometrial injection of radiotracer (TUMIR): a new method for sentinel lymph node detection in endometrial cancer. *Gynecol Oncol*. 2013 Jan;128(1):88-94.



Vision for Tomorrow's Surgery

declipse®SPECT Laparoscopy

is developed and manufactured

in Munich, Germany

by **SurgicEye GmbH**

www.surgiceye.com

SurgicEye, declipse and declipseSPECT

are registered trademarks of **SurgicEye**

GmbH in the EU and US

Recommendations of this flyer are subject to
be validated by the user with your national
guidelines

SurgicEye GmbH

Friedenstrasse 18a

81671 Munich

Germany

info@surgiceye.com

Phone +49 89 549 9890 00

Fax +49 89 549 9890 90