

xeos AURA

Precisely where it matters



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The power of PET-CT in the operating room

In resective surgery, rapid verification of the excised specimen at the point of surgery is of great value. With the right information at their fingertips, surgeons can make well-informed decisions when it counts. The XEOS AURA 10 PET-CT specimen imager brings a wealth of information about the resected specimen into the operating room, that can help surgeons to enhance surgical outcomes.

The first intraoperative specimen PET-CT imager

Molecular imaging has been the gold standard in oncology for years. Whole-body PET-CT scanners have proven to be invaluable for the diagnosis and follow up of cancer, because they provide **unparalleled sensitivity for the detection and localization of malignant cells.**

Imagine you could obtain this level of precision within minutes after excision, right at the point of surgery, without having to transport your specimen to the radiology or pathology department. Imagine how this could boost your surgical confidence and improve the wellbeing of your patients. The **XEOS AURA 10** is the first-ever specimen PET-CT for the OR, offering surgeons and imaging specialists the sensitivity of PET imaging at submillimeter spatial resolution - right at the point of surgery.

With the AURA 10 you can:

- ✘ **Visualize low dose radiotracer uptake in specimens with submillimeter spatial resolution**
- ✘ **Obtain imaging results within minutes after excision**
- ✘ **Seamlessly integrate a compact and mobile specimen PET-CT in your OR**

Intraoperative high-resolution PET-CT Workflow



Step 01

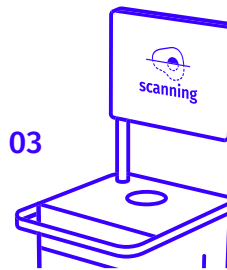
Low-dose radiotracer injection

→ Step 02



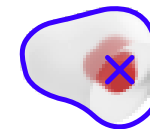
Resective surgery procedure

→ Step 03



Intraoperative specimen PET-CT imaging

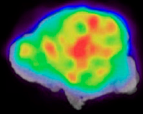
→ Step 04



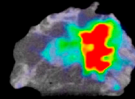
Immediate visualization of resected specimen



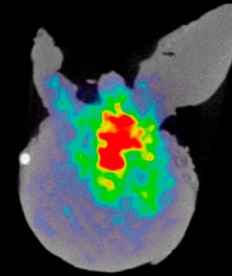
Watch a demo video of the workflow.



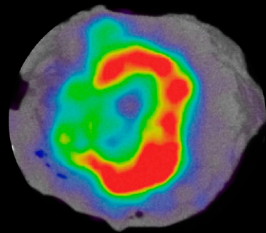
Thyroid
Papillary carcinoma
 ^{18}F -FDG



Breast
Invasive ductal carcinoma
 ^{18}F -FDG



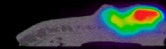
Prostate
Adenocarcinoma
 ^{68}Ga -PSMA



Pancreas
Adenocarcinoma
 ^{18}F -FDG



Neuroendocrine tumor
GEP-NET
 ^{68}Ga -DOTATOC



Head & neck
Squamous cell carcinoma
 ^{18}F -FDG

A myriad of possibilities

The AURA 10 can image any PET radiotracer. The images shown above are examples of the many tumor types that can be visualized with high precision at the point of surgery.

Scan the QR code to visit our website and explore more clinical case examples.



XEOS AURA I 6

Clinical case examples





Breast Cancer

Invasive Ductal Carcinoma

During breast-conserving surgery it is common practice to perform intraoperative assessment of the resected tumor specimen to assess if the resection was successful.

In this clinical case, which is part of the multi-center prospective BrIMA study (NCT04999917), we highlight how intraoperative specimen PET-CT imaging can bring more confidence into the operating room. This gives the surgeon a clear view of what was resected – and the ability to act upon this information at the point of surgery.

Patient history

A 63-year-old woman with invasive ductal carcinoma underwent breast-conserving surgery followed by sentinel node resection. The tumor size on preoperative imaging was 14mm, biopsy showed a grade 1 tumor with receptor status ER+/PR+/HER2-. Preoperative staging was cT1cN0M0.

Specimen PET-CT images

The patient received a periareolar injection with 158 MBq of ^{99m}Tc and an intravenous injection with 53 MBq (0.80 MBq/kg) of ^{18}F -FDG at the nuclear medicine department. The patient was then transferred to the operating theatre and breast-conserving surgery was performed per standard protocol.

The resected breast specimen was imaged immediately after resection and the images were interpreted by the surgeon in the operating room. This was approximately 90 min after ^{18}F -FDG injection.

The CT (figure 1) visualizes the entire specimen in 3D and shows a dense lump in the specimen, localized slightly towards the inferolateral side of the specimen. This already provides an indication of where the tumor is located in the specimen. Several microcalcifications can be observed due to the high spatial resolution (100 μm) of the CT image.

Adding the PET overlay to the CT images demonstrates how specimen PET-CT leverages to power of molecular imaging to bring more clarity into the operating room (figure 2). The colored overlay highlights the ^{18}F -FDG uptake, which indicates metabolically more active regions such as invasive ductal carcinoma cells.

In this case, ^{18}F -FDG uptake reaches the antero-infero-lateral border of the imaged specimen. Based on this image, the surgeon decided to take a cavity shave in this area. Postoperative final pathology showed that there was indeed a positive margin in this area

After tumorectomy the sentinel lymph node was localized using a gamma probe and resected. A specimen PET-CT image was also acquired of the sentinel node (figure 3). The CT images visualize a circular dense structure allowing confirmation that a lymph node was resected. The PET images show increased ^{18}F -FDG uptake in the node, leading to the suspicion of malignant invasion of the sentinel node. A metastatic deposit of 12mm was shown by postoperative final pathology.

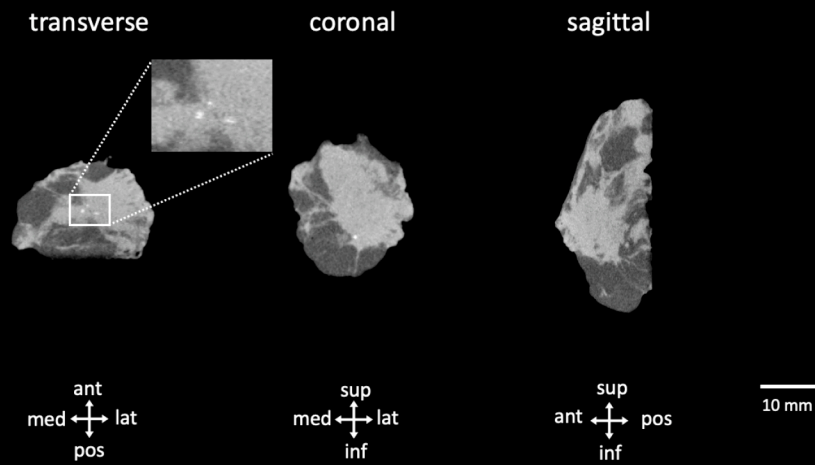


Figure 1. Transverse, coronal and sagittal slices of the CT specimen images of an invasive ductal carcinoma. A dense lump is visualized slightly excentric in the specimen towards the antero-infero-lateral border of the specimen. Microcalcifications can be seen (inset). Abbreviations: med, medial; lat, lateral; sup, superior; inf, inferior.

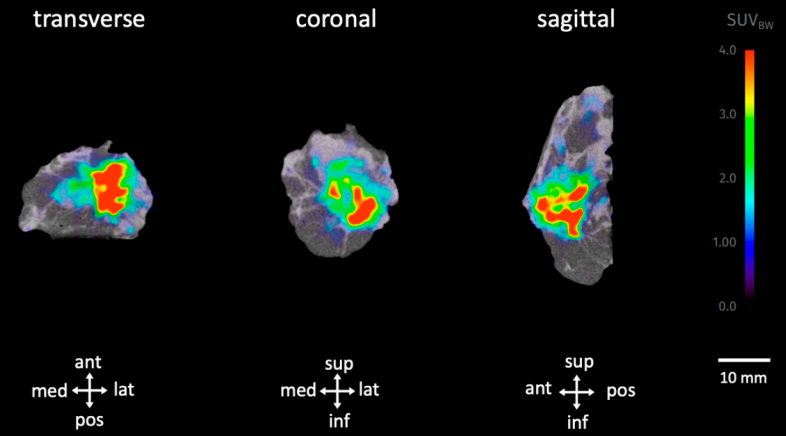


Figure 2. Transverse, coronal and sagittal slices of the PET-CT specimen images of an invasive ductal carcinoma. The ¹⁸F-FDG uptake is visible in the color overlay and reaches the antero-infero-lateral border of the specimen. Final histopathology confirmed a positive surgical margin inferolateral. Specimen orientation is as indicated. Abbreviations: med, medial; lat, lateral; sup, superior; inf, inferior.

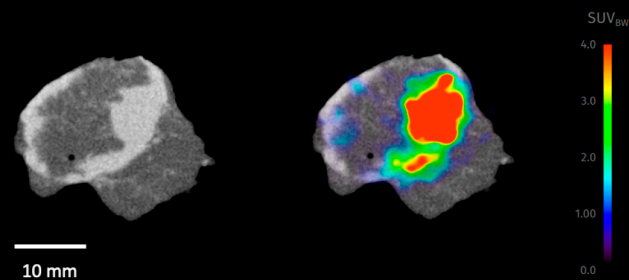


Figure 3. CT (left) and PET-CT (right) image of the sentinel lymph node. The dense (light grey) circular structure represents the resected lymph node. On the PET image a clear region of ^{18}F -FDG uptake is visualized in the lymph node. Final histopathology confirmed metastatic invasion of the node.

Histopathological evaluation

After specimen imaging, the resected specimens were sent to the pathology department for routine histopathological evaluation. The final histopathological results are presented in Table 1. The final margin status – after the additional cavity shave – was negative. No reoperation was required and the patient could immediately move on to postoperative therapy.

Discussion and conclusion

This case highlights the power of bringing specimen PET-CT imaging into the operating room. The surgeon decided intraoperatively to perform an additional cavity shave as imaging indicated ^{18}F -FDG uptake was reaching the border of the specimen. Final histopathology confirmed that tumor cells reached the border of the specimen in this area. Taking the extra cavity shave possibly avoided the need for reoperation and the associated burden in this patient.

Tumor characteristics

Subtype

Invasive ductal carcinoma with in situ component

TNM stage

pT1c pN1a(sn)

Specimen size

45 × 30 × 20 mm

Tumor size

14 × 16 × 13 mm

Grade

2

Receptor status

ER positive, PR positive

Margin status (main specimen)

Positive margin antero-infero-lateral on main tumorectomy specimen

Margin status (final)

Negative after additional cavity shave

Lymph nodes

Macrometastasis of 12mm in sentinel lymph node



Prostate cancer Adenocarcinoma

Nerve-sparing radical prostatectomy aims to reduce postoperative impotence, but this comes at the cost of a higher probability of incomplete resection. In this case, we illustrate how intraoperative specimen PET-CT imaging with ^{18}F -PSMA can visualize the tumor in the resected tissue specimen. This could aid the surgeon in deciding whether it is necessary to remove more tissue intraoperatively.

This clinical case is courtesy of PD Dr. C. Darr and Prof. B. Hadaschik, Department of Urology, Universitätsmedizin Essen and is part of a case series published in *European Urology Open Science* in 2023.

Patient history

A patient diagnosed with an anterior high-risk prostate cancer (Gleason score 9) underwent bilateral nerve-sparing radical robot-assisted prostatectomy, followed by excision of the pelvic lymph nodes. The patient was injected with 268 MBq ^{18}F -labelled prostate specific membrane antigen (^{18}F -PSMA) on the morning of surgery. After exclusion of metastases by whole-body PSMA PET-CT, surgery was performed on the same

day.

Specimen PET-CT images

Once the prostate specimen was resected, it was immediately imaged inside the operating room with the XEOS AURA 10 PET-CT specimen imager. This was approximately 5 hours after injection of the radiotracer. Two orthogonal views of the specimen PET-CT images are depicted in Figure 1. The PET images are represented in color scale, superimposed on the CT images in greyscale.

The tumor is visualized inside the specimen as the bright colored region. At the right ventral side of the specimen, F-PSMA uptake is seen that reaches the border of the specimen. Tumor localization is far away from the dorsolateral neurovascular bundles. Within this feasibility study surgery was not adapted based on intraoperative imaging.

Findings and diagnosis

After finalization of surgery, the resected tumor was sent to the pathology department for

histopathological examination. The histopathological results are listed in Table 1, and demonstrate a positive surgical margin at the right ventral border of the specimen.

Discussion and conclusion

The specimen PET-CT images show a promising correlation with histopathology. The images specifically highlight radiotracer uptake at the right ventral border of the specimen where histopathological analysis finds a positive surgical margin. Availability of this information at the point of surgery could possibly help the surgeon enhance surgical outcomes.

REFERENCES

Darr C et al. (2023). Intraoperative Molecular Positron Emission Tomography Imaging for Intraoperative Assessment of Radical Prostatectomy Specimens. *European Urology Open Science* 54:28-32

Figure 1. Transverse (A), sagittal (B) and coronal (C) slices of the specimen PET-CT images. The tumor is represented by a bright colorful region in the specimen. Surgical orientation of the specimen images is shown in each image. The PET tracer scale bar is depicted on the right hand side. The ellipse highlights a region of radiotracer uptake reaching the border of the specimen.

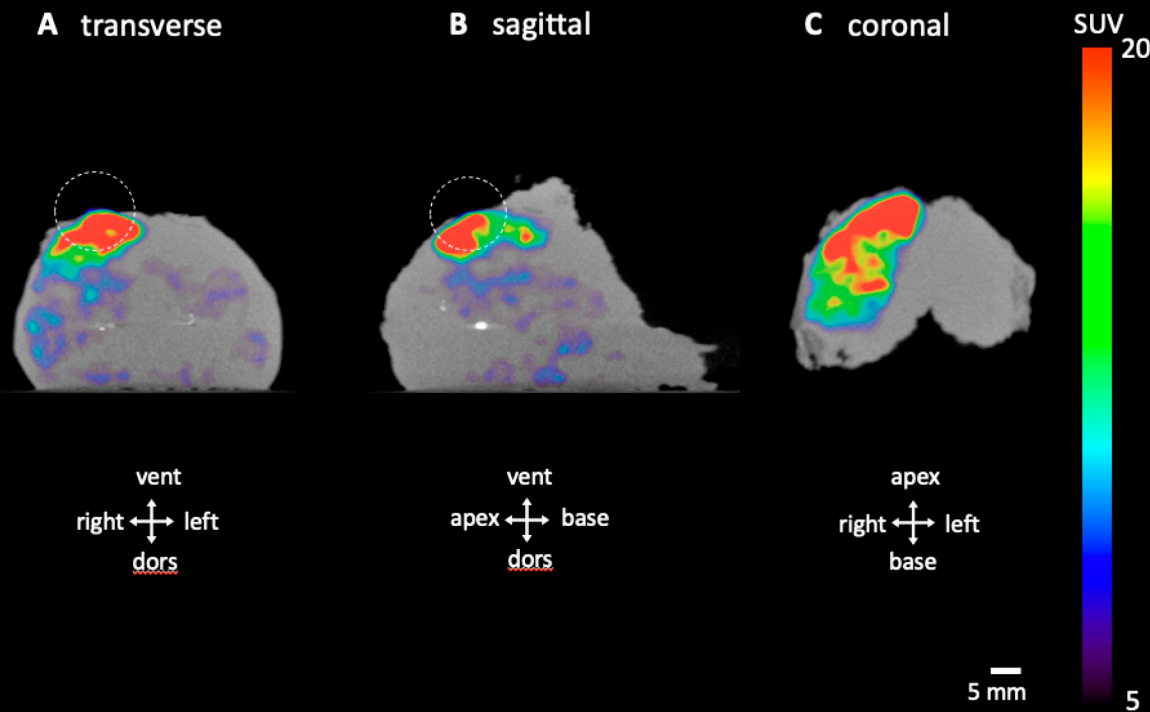
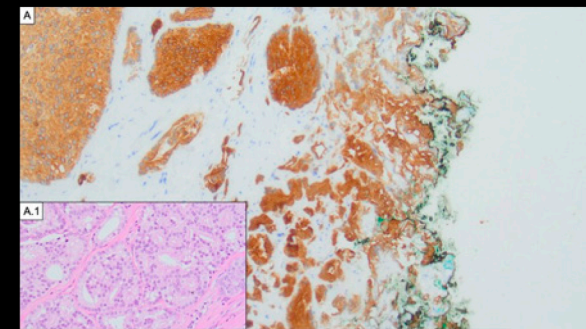


Figure 2. Histopathological image of the cancer and positive surgical margin. (A) Histopathological positive surgical margin R1 (2.5 mm, ventral right; 100x) with a Gleason grade 4 pattern. For better illustration, a pan-cytokeratin immunostain is shown. (A.1) A detailed microphotograph of the cancer (200x) is shown in hematoxylin and eosin staining exhibiting Gleason grade 4 pattern architecture. Reproduced from Darr C. et al. European Urology Open Science 54:28-32.



Tumor characteristics assessed by histopathological evaluation.

TNM stage
p3aN0M0 R1
Tumor size
20% of prostate volume invaded by tumor
Gleason score
9
ISUP Grade
5
Margin status
Positive right ventral surgical margin over a length of 2.5 mm



Head & Neck

Squamous Cell Carcinoma of the Scalp

Cutaneous squamous cell carcinoma (cSCC) is the second most common non-melanoma skin cancer. They arise commonly in the head and neck region, especially on the scalp. For most patients complete tumor resection with an adequate margin of healthy tissue (> 5mm) is the first line of treatment. This case illustrates how specimen PET-CT images could help the surgeon intraoperatively remove the target lesion. It was published as part of a pilot study in cancer of the head and neck region.

Patient History

A 78-year-old man was scheduled for a resection of a squamous cell carcinoma (SCC) of the scalp.

Specimen PET-CT images

On the day of surgery, ^{18}F -FDG was intravenously administered to the patient right before the patient was put under anesthesia to start the surgery. The tumor was surgically removed and a PET-CT image

of the surgical specimen was acquired immediately after resection of the specimen. The specimen was cut by a pathologist in two halves before performing the PET-CT scan.

Figure 1 shows three orthogonal views of the PET-CT specimen images. The PET images are represented in color scale superimposed on the CT images in greyscale. A circular hotspot of ^{18}F -FDG uptake is visible in the centre of the specimen.

Findings

After PET-CT imaging, the surgical specimen was sent to the pathology department for routine histopathological evaluation. A pathological close margin between the invasive tumor and the resection margin of 145 μm was found. When correlating the PET-CT images with the pathology whole-slide images, this close margin could be located on the PET-CT images as a small region where the deep margin shows an increased ^{18}F -FDG uptake. This is visualized in Figure 2.

Discussion and conclusion

A good correspondence was found between ^{18}F -FDG activity close to the resection margin in the PET-CT images and the position of a close margin as confirmed after histopathological examination. Having this information at hand during surgery could help the surgeon decide to extend the resection to ensure an adequate free margin.

REFERENCES

Debacker JM et al. High-Resolution ^{18}F -FDG PET/CT for Assessing Three-Dimensional Intraoperative Margins Status in Malignancies of the Head and Neck, a Proof-of-Concept. *J Clin Med* 2021; 10:3737.

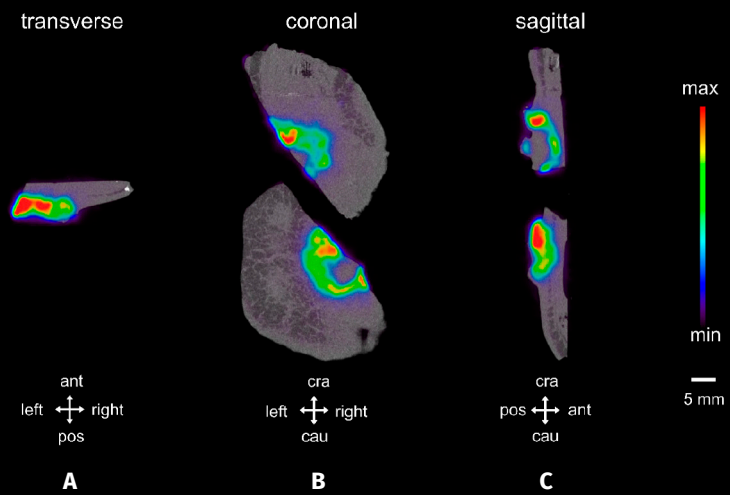


Figure 1. Transverse (A), coronal (B) and sagittal (C) slices of the specimen PET-CT images. The tumor is represented by a bright colorful region in the specimen. Surgical orientation of the specimen images is shown at the bottom of each section. The PET tracer scale bar is depicted on the right hand side. Abbreviations: ant, anterior; pos, posterior.

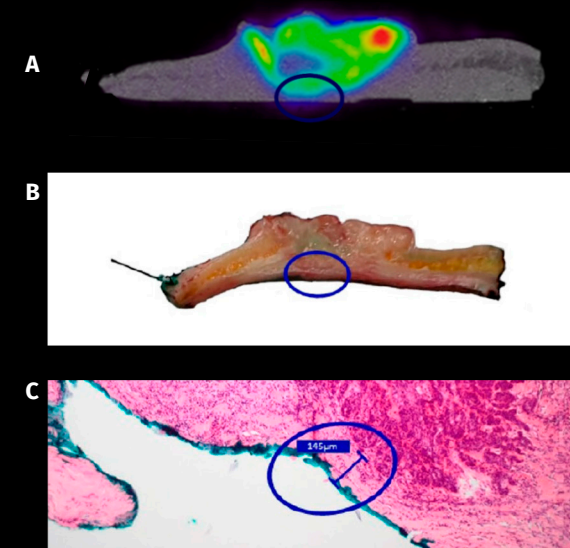


Figure 2: correlation between the close margin as seen on a transverse view of the PET-CT images (A), on a slice of the resected tissue (B) and on a close-up of a whole-slide pathology image (C). The region of interest with the close margin is indicated with a blue circle..

Smarter workflow, better results

The AURA 10 is the imaging technology surgeons and imaging experts have been waiting for. Now it's available for the OR at a fraction of the cost of a conventional whole-body PET-CT scanner. The benefits the AURA 10 brings, make this technology a must-have for every medical facility that is serious about improving surgical outcomes.

Save procedure time

Transporting your specimen to the radiology or pathology department during surgery and receiving diagnostic results takes time. Meanwhile, you need to wait and lose valuable minutes before closing your patient with more confidence. With the **AURA 10** specimen imager, there is no transport required. Just **obtain reference image quality at the point of surgery and upload the images to your PACS**, so your imaging specialist can view them right away. This saves valuable procedure time.

See more of what matters with more clarity

2D images obtained with conventional specimen radiography are valuable, but the limited sensitivity of this technology still makes it hard to accurately localize tumor cells in the specimen. The **AURA 10** offers more clarity and confidence, because it provides high-precision 3D data that allows you and your imaging experts to visualize what was resected with more certainty. The **AURA 10** clearly highlights the radiotracer uptake of the tissue and indicates its location, shape, size and extent inside the specimen.

Integrate seamlessly into your OR

The compact **AURA 10** imager has a high-quality finish and will seamlessly integrate into your OR environment. It's very mobile, so you are free to give it the most suited place in your procedure room or to share it with other surgeons. The **AURA 10** starts up in minutes and the solid shielding of the x-ray source will offer your surgical staff the highest protection during use.



Small format, big difference

The AURA 10 provides reliable imaging results time and again. The design is optimized for your staff's user comfort and viewing ergonomics.

Compact unit

The **AURA 10** offers high-performance PET-CT molecular imaging capabilities, all engineered into the smallest, most practical form factor. It's highly mobile for use in and out of your operating room, and while offering a similar level of precision, it only comes **at the fraction of the cost of a conventional, whole-body PET-CT scanner.**

Ergonomic design

The **AURA 10** is easy to use and allows you to fully focus on your patient. Your surgical staff

will appreciate the unit's compact design, curved transportation handle, easy brake system, and motorized top-load specimen receptacle. The medical-grade display monitor can be tilted and swiveled to give you more viewing comfort.

Safe for your staff

An LED ring around the top-load specimen receptacle will indicate proper tray insertion, specimen position and closure. A vertical LED bar on both sides of the unit shows when the X-ray acquisition is taking place and informs you about the progress of the image acquisition. The X-ray source is appropriately

shielded, which avoids exposure to the surgical staff. The PET scanner only requires a low radiotracer dose, and fully complies to Radiation protection standards.

Practical interface

The integrated touch-control display and trackpad enable you to instantly set up the image acquisition and obtain the required views with little image manipulation. Uploading the images to your PACS is easy and fast. **The intuitive user interface enables you to simply link the acquired images to the patient and procedure data within the PACS system.**

The AURA 10 offers sub-millimeter precision in the OR



Give your patients your best work

AURA 10 has made molecular imaging available in the OR for the first time. As a result, surgeons and imaging specialists have never been able to perform specimen imaging with so much confidence. Ultimately, your patients will be the ones who benefit.

Less chance of resurgery

The **AURA 10** combines the picomolar sensitivity of PET with high-precision 3D image reconstruction. This gives you all the capabilities you need to image the targeted tissue in a single procedure, to close your patient with more confidence, and to potentially reduce the probability of resurgery.

More peace of mind for your patients

Using the best available intraoperative imaging technology can significantly decrease the anxiety level of the patient. This stress reduction can contribute to your patient's recovery.

Reduced anesthesia time

A streamlined workflow and real-time collaboration with your radiology and nuclear medicine department shortens the procedure. This may also reduce anesthesia time for your patient and decrease the risk of postoperative complications.

Better cosmetic outcome

Intraoperative imaging can help you to remove less tissue in the initial surgery and to obtain a better cosmetic result.

Close your patient with more confidence.

Together, we make it happen

Being a partner

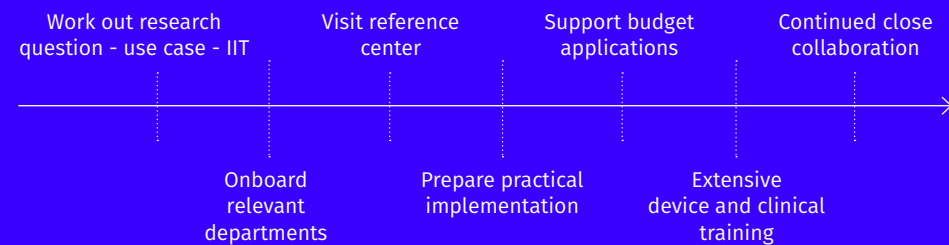
- ✕ Image data analysis
- ✕ Protocols
- ✕ Administrative support
- ✕ Hub in the specimen PET-CT community

Identifying and supporting route to budget

- ✕ Hospital budget
- ✕ innovation funds
- ✕ Grants

Device allocation & reservation

- ✕ For innovators & early adopters eager to implement specimen PET-CT in their field



	H1	H2	H3
IIT	Breast	Prostate	H&N
Budget	Innovation	Operational & Grant	Research
Reference center	Collaboration	Yes	Collaboration
Applications	New	Validation	Validation



*Precisely where
it matters*



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