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Localizing non-palpable breast lesions with Sirius Pintuition®

A value case for patients and professionals

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Editorial contributors:

Prof. Dr. Fred van Eenennaam - Chairman Value-Based Healthcare (VBHC) Center Europe.
"Many breast cancer patients will benefit from Sirius Pintuition, so will doctors, their teams and the health care system. I encourage adopters to go beyond the direct Sirius Pintuition benefits to strengthen the team processes."

Michele van der Kemp – Value-Based Healthcare (VBHC), Clinical Leadership & Care-Redesign consultant at VDKMP
"Technology such as Sirius Pintuition and programmes like SiriusLink deliver much more than a novel device or a way to advise. It shows the true value of system integration between providers and industry, and its positive effects on outcomes, cost and experiences."

Moving from localization to Surgical Marker Navigation

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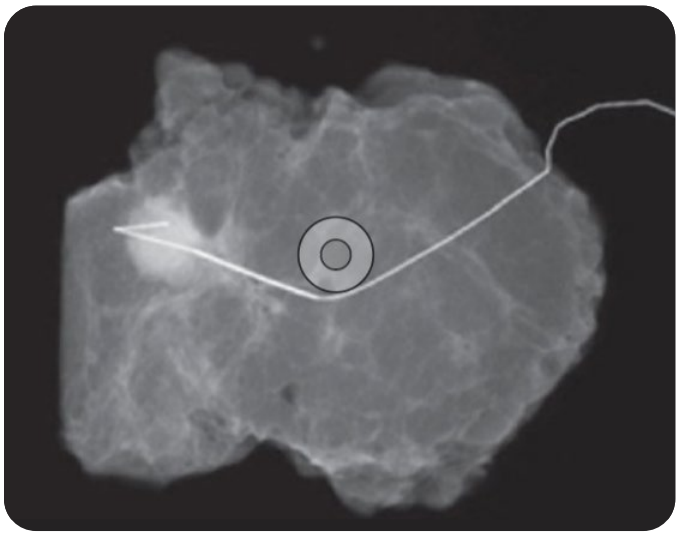
Advances in breast cancer localization technology

Breast cancer is one of the most commonly occurring types of cancer among women with over 2 million new cases every year.[13] When detected and treated early, the chances for cure are generally high.[14] Screening programs and optimised diagnostics help detect abnormal lesions early, even before an abnormality can be felt. The majority of breast cancers are non-palpable.[1] In most of these cases, breast conserving surgery is indicated.[2] But how does a surgeon know what tissue to remove with breast cancer that cannot be felt by hand and is not visible in situ? To localize non-palpable breast cancer, several techniques can be used among which are wire guided localization, radioactive seed localization or Surgical Marker Navigation.

Breast cancer **1st** most common disease in the world[1].

Wire guided localization: gold or old standard?

Wired guided localization has long been considered the gold standard localization technique for breast conserving surgery. During this procedure, the radiologist places a wire with a hooked tip in the breast at the target site. Although wire guided localization is a commonly used technique, it has disadvantages for patients, healthcare professionals and hospitals (see Table 1).

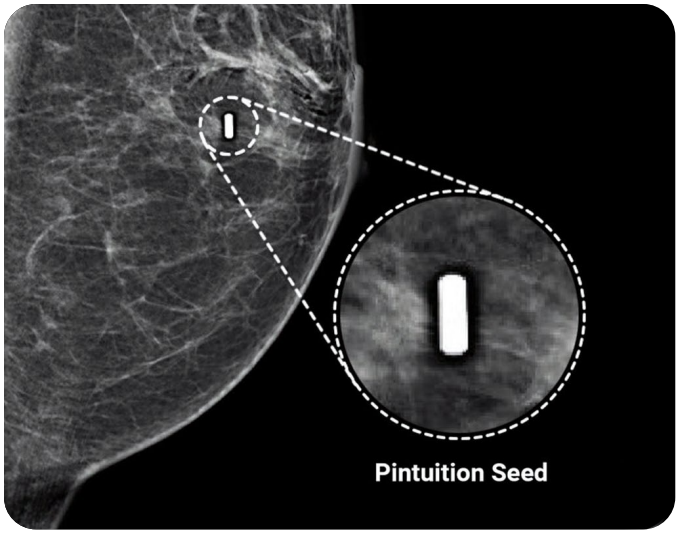


Jennifer Rusby, consultant oncoplastic breast surgeon DM FRCS at The Royal Marsden, has ample experience with this technique: "It had to be done relatively close to the time of the operation so the patient didn't have the wires sticking out of her breast for too long but that's fraught with complexities of scheduling. We need the radiologist available at the right time, close enough to the time of surgery and if we do it on the day of surgery the patient is starved, fragile and emotional. It's not nice being put into a mammogram machine and having a wire stuck in your breast when you're in that situation."

The hassle of radioactive seeds

To counter the disadvantages of wire guided localization, wire-free techniques were introduced. One of these is radioactive seed localization. Although frequently used, there are several disadvantages related to the use of radioactive seeds (see Table 1).

Jennifer Rusby: "We were in conversation with our nuclear medicine department who were reluctant about radioactive seeds. They had concerns about tracing the seeds and all of the bureaucracy".



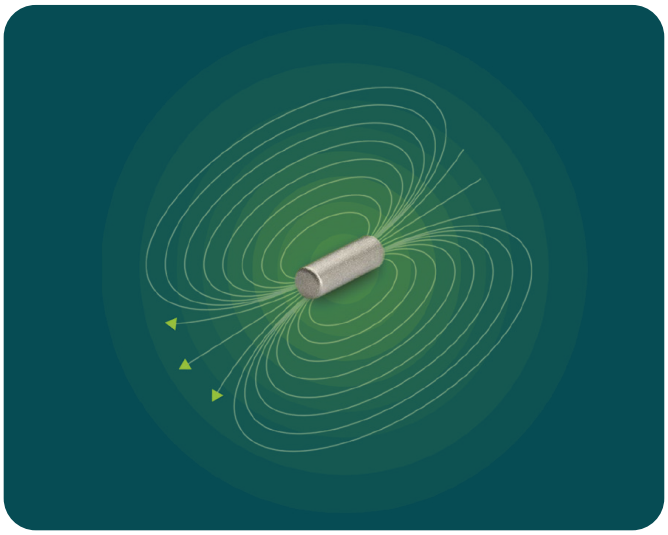
Starting with radioactive seed localization takes about nine months[1] The use of radioactive seeds is a complex process involving many departments[15] and the technique is not without risk. In the Netherlands, each year on average one or two incidents occur per hospital.[16] These incidents include seed loss or transection, which can result in minimally two days of additional (paper)work. [16]

	Wire guided localization	Radioactive seed localization
Disadvantages for patients	• Pain during wire localization[17] • Pre-procedure anxiety[17] • Extended hospital stay at day of surgery[18]	• Not suitable in case of pregnancy or lactation • Advise not to hold a baby or young animal longer than 30 minutes until the seed is removed
Disadvantages for healthcare professionals	• The ideal wire entry site may be different from the ideal surgical incision site[19,20] • Potential removal of healthy tissue when retrieving the wire[20,21]	• Need to take extreme caution when handling radioactive materials • Administrative burden due to radiation safety handling procedures and precautions[22]
Disadvantages for hospitals	• Coupling of radiology and surgery schedules[11] • Disruptions to theatre and radiology flows[16] • Costly operating room delays[16]	• Requires access to a Nuclear Medicine Department[21] • Radiation safety handling procedures and precautions[1] • Risk of having incidents with radioactive material[16]

Table 1. Disadvantages of wire guided localization and radioactive seed localization

Surgical Marker Navigation: the new gold standard?

More recently, Surgical Marker Navigation without radioactivity was introduced to overcome some of the disadvantages of both wire guided localization and radioactive seeds. Sirius Pintuition is a safe and feasible[8,23-25] technique. It is powered by a state of the art navigation software, GPS*Detect*™ and hereby providing real-time, directional guidance using audio and visual feedback to precisely locate a tumor. During surgery, the Pintuition marker can be detected quickly and safely regardless of breast size.[25] The transcutaneous marker detection rate is close to 100%.[8,9]



Janneke Berlage, MD, oncology surgeon at Maasziekenhuis Pantein: "With a probe the size of a thick felt-tip pen, we can see exactly where the Sirius Pintuition marker and therefore the tumor is during surgery. This allows us to operate much more accurately and remove less of the healthy breast."[26]

In our previous whitepaper you can learn more about Sirius Pintuition with respect to its technique and clinical performance.[27] On our website you can find demonstration videos: https://www.sirius-medical.com/clinical.

Top 5 Frequently Asked Questions about Sirius Pintuition®

1. What are the main advantages of Sirius Pintuition?

It is a radioactivity- and wire-free Surgial Marker Navigation technique for use during localization surgery. The system has intuitive and directional, millimeter accurate detection with a range of 50mm. The probe is fully reusable and compatible with conventional surgical tools (see Figure 1).

2. How does Sirius Pintuition work?

Before surgery, the Radiologist uses ultrasound or X-ray to precisely image the area of the tumor. With a needle, the radiologist injects the Pintuition marker into the tumor to mark the target tissue.

3. How long in advance can the marker be placed?

In the EU the Pintuition marker may be placed up to 180 days in advance of surgery. In the US this is 30 days before to surgery.

4. Is the Sirius Pintuition marker compatible with MRI-imaging?

The Pintuition marker is labelled as MR conditionally safe; this means patients with a Pintuition marker in situ can safely undergo an MR scan (under certain conditions), but this will lead to image artefacts around the marker.

5. Is the Pintuition marker approved for use during neoadjuvant therapy?

There is no contra indication for the use of Pintuition during neoadjuvant therapy.

"Surgical Marker Navigation is better for the surgical team because we don't have to wait for that wire process to happen before we can do the surgery so it makes scheduling easier. It's better for the radiology team because they can have a much more calm, controlled and predictable workflow as to when they're going to do those seed insertions and therefore it's better for the overall running of the unit. It wins all around."

Jennifer Rusby, consultant oncoplastic breast surgeon DM FRCS at The Royal Marsden

Sirius Pintuition® powered by GPSDetect™

- It cannot be deactivated
- It can be detected in fluid
- Excellent visibility on major imaging technologies
- 50 mm of directional detection range
- Reusable and compatible with metal instruments
- One time calibration before each procedure
- Software updates without hardware changes
- Unique smart detection algorithm
- TargetLOC™, perfect alignment of probe and marker

Figure 1. Sirius Pintuition system components

	Before day of surgery		Day of surgery		Post-surgery
	Radiology		Radiology	Surgery	Pathology
Wire guided localization	-	-	Wire placement	Sparing surgery	-
Radioactive seed localization	Pick up radioactive seed by authorized individual personnel	Radioactive seed placement and measure radiation	-		Processing of radioactive materials
Sirius Pintuition	-	Pintuition marker placement	-		-

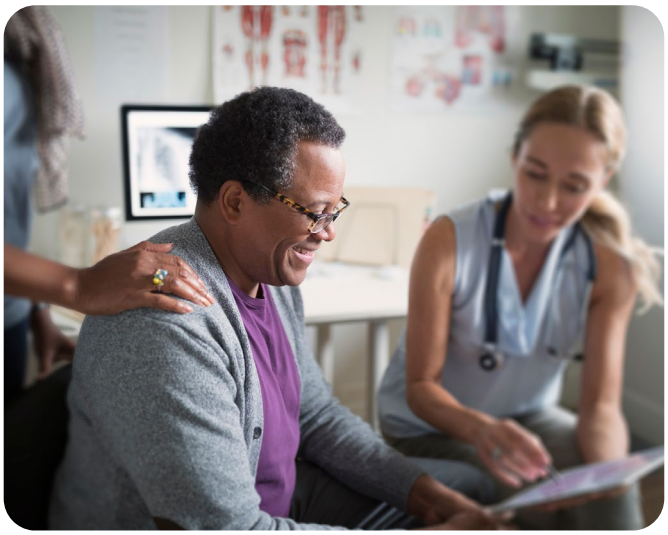
Figure 2. Examples of patient journeys when using a wire, radioactive seed or the Sirius Pintuition surgical marker

Improving outcomes and experiences

Key elements of the value case are patient-reported outcomes and experiences of patients and professionals. These helps forming a more hollistic picture of the effects of a localization method beyond clinical outcomes.

Clinical outcomes remain strong

To date, over 7500 procedures across 125 hospitals have been performed with Sirius Pintuition worldwide. When switching from wire guided surgery to Surgical Marker Navigation, clinical outcomes remain strong in terms of reoperation rate for positive margins and post-operative complications.[23,24]



Better patient-reported outcomes

The clinical experience so far suggests that compared to wire guided patients, ratings of pain[5,6] and preoperative anxiety[3,4] is lower for patients with a surgical marker. “A few days before surgery, the radiologist placed the surgical marker in the middle of the tumor. You don't feel a thing, just a little sting. This way I could have surgery right away on the day of surgery. No extra stress beforehand, because all kinds of preparations are needed”, said a patient who received a Sirius Pintuition marker.[26]

Good experiences of patients and professionals

Patient satisfaction ratings were more favourable in case of using a surgical marker compared to a wire, both regarding the implant and the overall procedure.[7] Surgeons and radiologists consider Sirius Pintuition as an improvement over wire guided localization[3] and are highly satisfied with the system.[8,9]

Lowering costs while increasing efficiency

Besides outcomes and experiences, another key element of the value case are costs. The Pintuition technology may reduce costs while maintaining strong outcomes. This is enhanced by the SiriusLink programme which was designed to drive efficiencies within the surgical care pathway.

Lowering costs

A cost reduction can be achieved when using wire-free techniques due to efficient theatre utilisation and more effective allocating of personnel.[10] Ottawa Hospital (Canada) found that the cost per patient was $1,130 for wire, and $250 for a radioactive seed, an overall cost reduction of 78% per patient.[11] Surgical Marker Navigation without radioactivity can further reduce costs as radiation rules and regulations (e.g., nuclear medicine audit/quality control, radiation survey) are no longer needed.[28]

Increasing efficiency of the surgical care pathway

The SiriusLink program is an opportunity for process optimisation along the complete surgical care pathway. It challenges a team to find better, more efficient ways to work together. At OLVG (Amsterdam, The Netherlands) and The Royal Marsden Hospital (London, United Kingdom), SiriusLink showed that it is feasible to use administrative data and process mining software to get relevant insights for optimization along the complete surgical breast cancer pathway.[12]
Besides demonstrating process optimisation potentials, SiriusLink also provides insight into the potential benefits of Sirius Pintuition. At the Royal Marsden, it showed that switching from wire to a surgical marker reduced pre-surgery preparation time with one hour due to not having to insert a wire. Also, patients with a surgical marker were less likely to stay overnight (7.9%) compared to wire guided patients (10.2%) which can have a positive effect on total costs (see Figure 3).

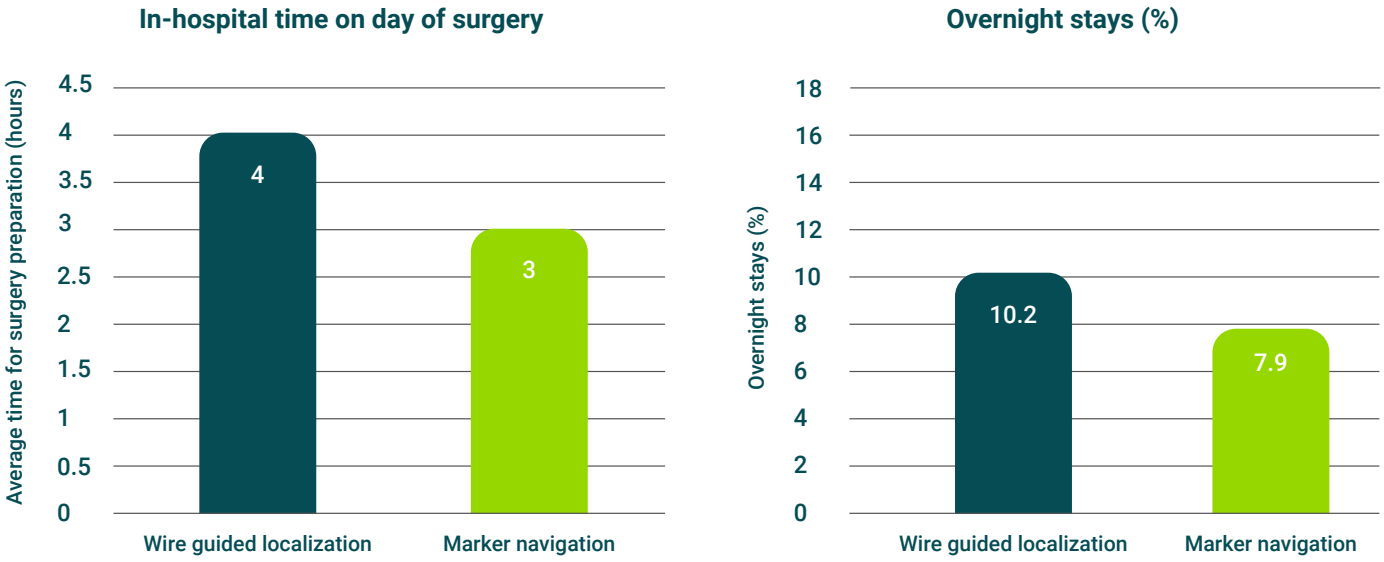
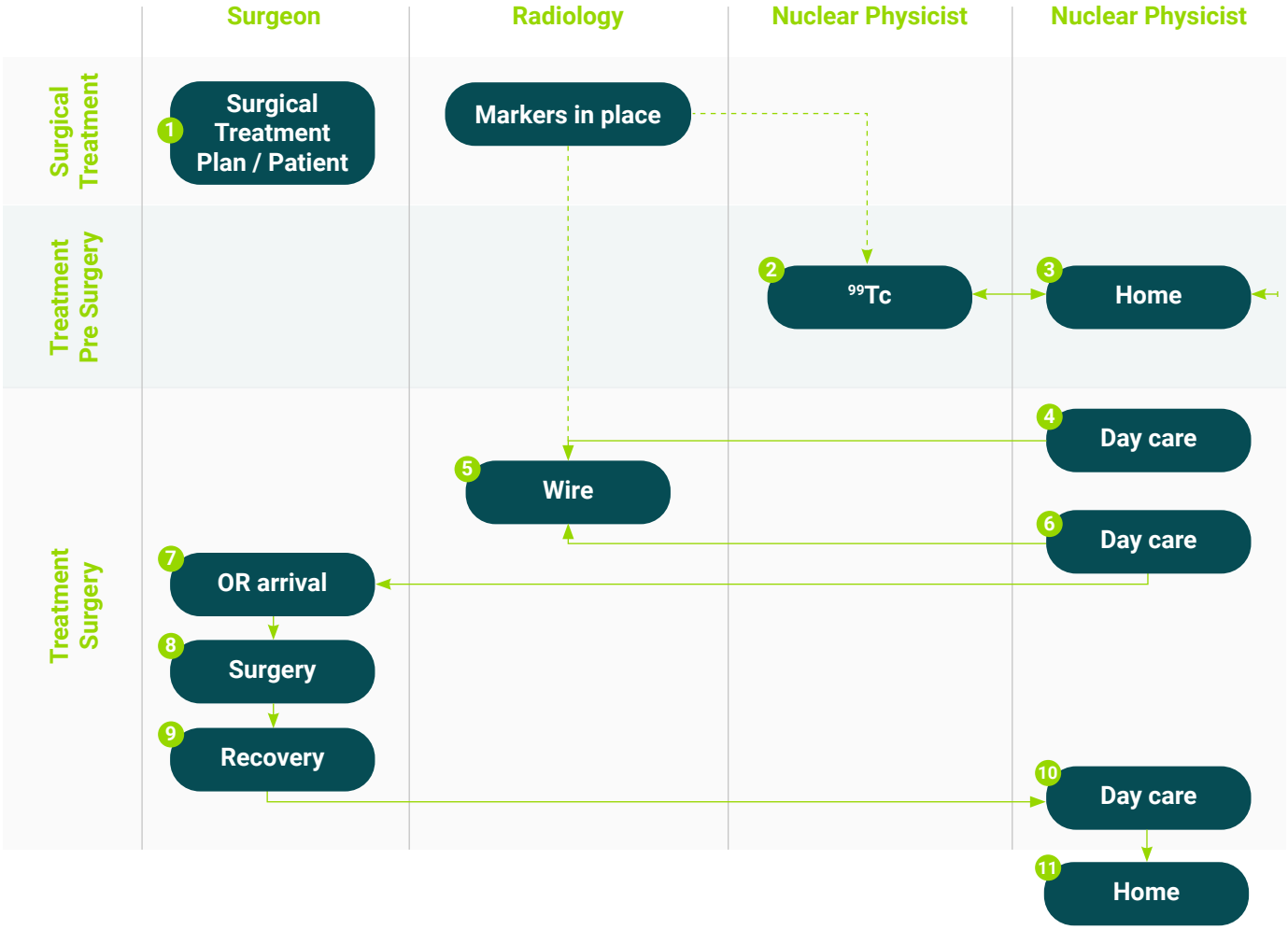


Figure 3. Comparison of wire guided localization and Surgical Marker Navigation at The Royal Marsden

At OLVG, a process model was developed for the envisioned care path for patients with nodal involvement and neoadjuvant therapy (see Figure 4). The intended workflow shows potential efficiency gains which may reduce costs. Post chemotherapy sentinel node biopsy and wire localization of the marked node are replaced by one targeted lymph node dissection (TLND), streamlining the workflow.

Current workflow



Intended workflow

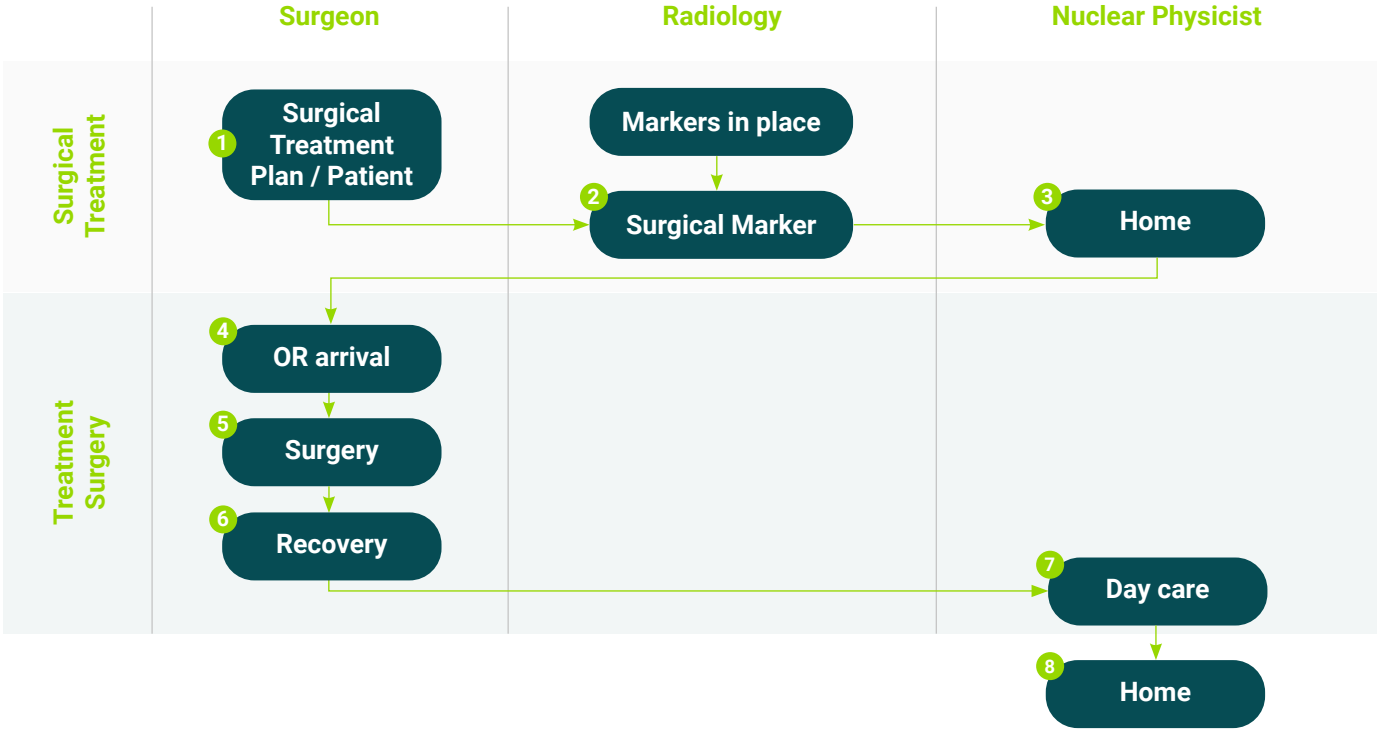


Figure 4. The current workflow and the intended workflow at OLVG

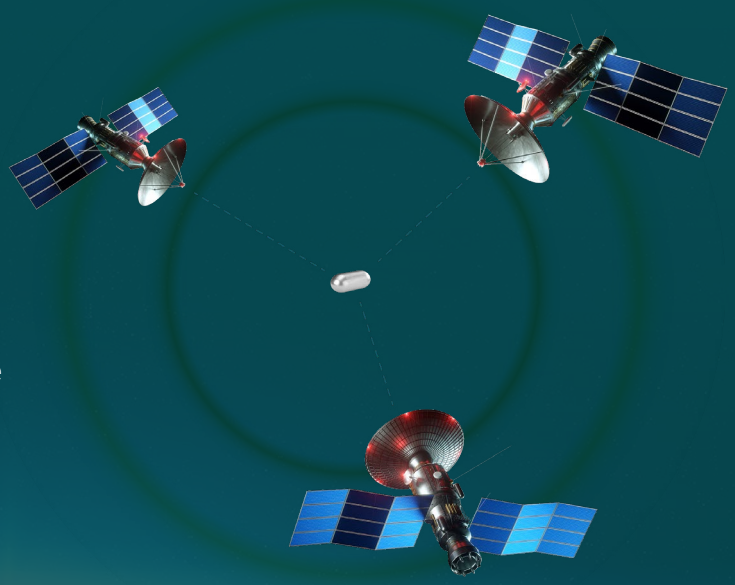
Implementation & future developments

Implementation is simple

Surgeons, radiologists and staff can easily learn and use Sirius Pintuition[25] and adopt it in their clinical workflow.[22] Radiologists and surgeons who used the Sirius Pintuition system described the technology as an intuitive system.[22,25] It can easily replace existing procedures.[25] “It is a very easy to understand localization technique. The learning curve is very short”, said Irma den Hoed MD, surgical oncologist at the door ETZ (Tilburg, The Netherlands). Implementation starts with a 2 hour training for the radiologist and surgeon and one hour training for the surgical team.

A glimpse into the future of Sirius Pintuition

We are continuously evaluating, developing and improving Sirius Pintuition in co-creation with end users. One of the innovations we are working on is 3D navigational guidance. This way surgeons not only get directional guidance, but also visual guidance to locate the tumor even more precisely. Besides technological innovations, we are also broadening the use of Pintuition for surgical indications as sarcoma, melanoma and other soft tissue lesions.[29]



Experience Sirius Pintuition

Want to know more about Sirius Pintuition?
Please visit our website www.sirius-medical.com to find more information or to book a demonstration.

Book a demo

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Colophon

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