PHILIPS

Image guided therapy

Azurion Hybrid OR

ClarifEye

Step into **the new dimension** of spine surgery

with ClarifEye Augmented Reality Surgical Navigation

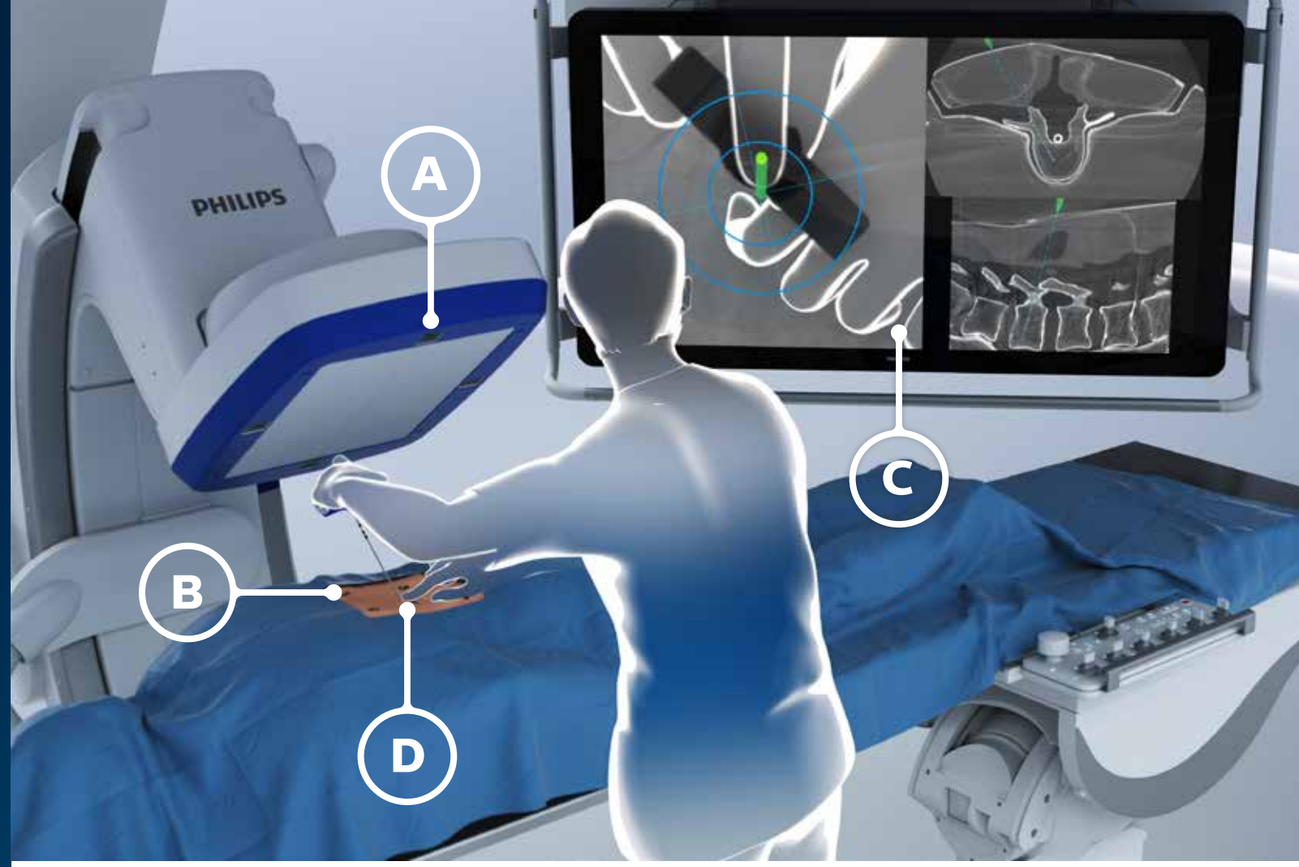
Introducing **ClarifEye Augmented Reality Surgical Navigation**

Adds a new dimension to help you improve surgical precision for your spine patients

When you are performing delicate tasks in the spine, accuracy is paramount to achieving the best outcome for your patients. Our new ClarifEye solution can show you the way forward. It brings your views of the outside world and the inside world together – to add a new dimension in your ability to improve surgical precision for patients.

ClarifEye is an industry-first solution that combines imaging and augmented reality (AR) navigation into one system, to support precise planning and effective device guidance for accurate[1] placement of pedicle screws. By integrating ClarifEye with Philips Azurion image guided therapy system, we provide insightful visualizations that help you keep your attention on the patient and task at hand, while improving surgical workflow, compared to many conventional surgical navigation systems.

With ClarifEye, a video-based navigation system is built into the Philips Azurion Hybrid OR.
The C-arm offers high quality 2D and 3D cone-beam CT intraoperative imaging. Four high-resolution optical cameras are used to augment the surgical field with 3D cone-beam CT imaging, without the need for additional X-ray. Patient tracking is ensured by video tracking of non-invasive markers placed on the skin. No external reference frame is used.
The systems visualizes the tip of the ClarifEye Needle as it is navigated along the planned path on the spinal anatomy.



Four high-resolution cameras in the C-arm Flat Detector (A) automatically detect the non-invasive patient markers (B) to augment the surgical field. The live video images provided by the cameras are overlaid on 3D cone-beam CT (C) The systems visualizes the tip of the ClarifEye Needle as it is navigated along the planned path on the spinal anatomy (D).

Augment precision and patient safety

94% Navigated vs **89.6%** Freehand improvement in clinical accuracy of pedicle screw placement.[1]

Excellent image quality at lower dose

Up to **3.7** times higher contrast-to noise-ratio and up to **83%** lower X-ray dose compared to mobile Cone-beam CT.[2]

Perform procedures **simply and easily**

100% of the users found the system user-friendly.[3]

Streamlined workflow with **all-in-one-imaging** and **navigation solution**

High quality cone-beam CT

In just 10 seconds, you can make an intraoperative cone-beam CT scan with **superb image quality at low dose**. After you have made this cone-beam CT, ClarifEye creates a high-resolution 3D model of the spine with automatic spine segmentation.

Easy planning

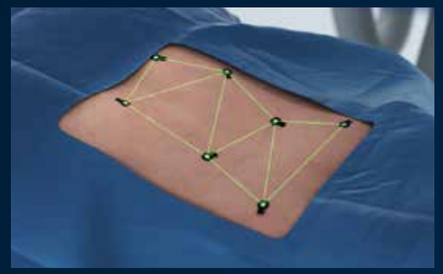
The 3D spine model assists planning for each pedicle. When you click on the highlighted pedicle, a screw is **automatically positioned** in various views, and you can fine-tune the length and direction of the screw as needed. After you have planned a screw, you select the level you want to treat.

Live augmented reality guidance

ClarifEye provides **live augmented reality guidance** so you can see the underlying vertebrae of your patient without the need of additional X-ray. This provides better insight into the anatomical structures and supports you in carrying out optimal treatment. ClarifEye comes with a trackable needle that enables automatic detection and navigation without X-ray.

Intraoperative verifcation

After you have placed the screws, you can verify the screw positions with a **intraoperative cone-beam CT**. This allows you to assess screw placement when it is still easy to do so, before placing rods or closing the wound and revise intraoperatively if necessary.[4]



Non-invasive patient tracking

During navigated procedures, ClarifEye skin markers are used to provide non-invasive patient tracking. The system automatically tracks the position of the markers in relation to the anatomy and corrects the 3D image to support accuracy.

An additional invasive step is avoided and multiple levels can be treated without repositioning the reference frame and without compromising accuracy. No manual registration steps are required. Line-of-sight issues and risk of hitting the external reference frame are minimized.

Experiences in spinal deformity and minimally invasive surgery procedures

Spinal deformity/ open procedures

Dr. A. Elmi-Terander, neurosurgeon from Karolinska University Hospital, Stockholm, Sweden.

The clinical trial is part of the innovation partnership between Philips and Karolinska University Hospital. The aim is to combine clinical insights and innovative image guidance technologies to jointly develop new navigation concepts to enable more precise surgery.

Courtesy of Karolinska University Hospital, Stockholm, Sweden

"The augmented reality surgical navigation helps us to place pedicle screws in positions where we actually couldn't or wouldn't do that otherwise."

Dr. A. Elmi-Terander from Karolinska University Hospital, Sweden

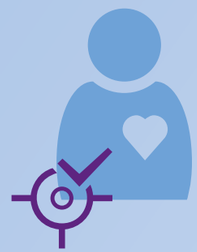
"The surgeon is dominating the technology around him and is not dominated by the technologies. Navigation becomes simpler with this imaging technology."

Dr. P. Scarone from Ente Ospedaliero Cantonale (EOC) Lugano, Switzerland

Clinical investigation results

Study objective: estimation of accuracy for pedicle screw placement using Augmented Reality Surgical Navigation (ClarifEye)[5]

Study set-up: 20 patients treated, of which 13 with scoliosis and 253 screws were placed.



94% screw placement accuracy in difficult Spine deformity surgeries

- 64% grade 0: Screws perfectly in pedicle
- 30% grade 1: 0-1 mm breach of cortical wall
- 6% grade 2: 13/15 screws were larger than pedicle
- No screws severely misplaced (grade 3)

5 min
Average screw placement time
50% below 4 minutes

Zero
Device-related adverse events

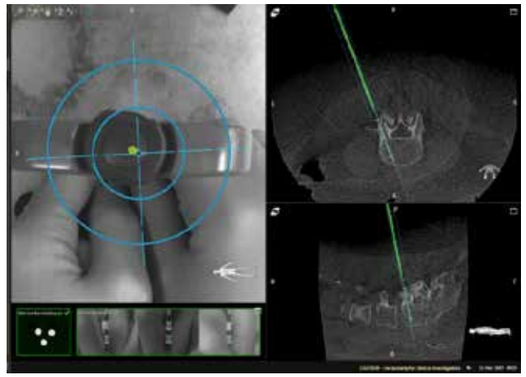
Zero
X-ray during navigation

- Radiation dose exposure for full procedure ranged from 0 to 1.1 µSv for operating surgeon
- No postoperative CT, as intraoperative cone-beam CT was used for clinical evaluation.

Minimally invasive procedures

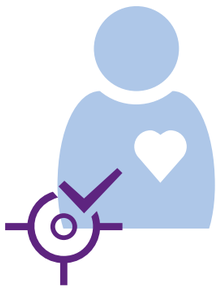
Dr. P. Scarone, neurosurgeon from Ente Ospedaliero Cantonale (EOC) Lugano, Switzerland is using ClarifEye to support minimally invasive transforaminal lumbar interbody fusion procedures.

The clinical research collaboration between Lugano Hospital and Philips focuses on enhancing image guidance during minimally invasive spinal procedures.



Courtesy of Ente Ospedaliero Cantonale (EOC) Lugano, Switzerland

How does **ClarifEye** improve your procedures



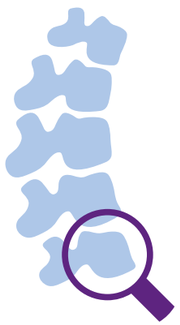
Augment precision and patient safety

In a matched-control study of pedicle screw placement in open spine surgeries, the Gertzbein scale[6] was used to evaluate clinical accuracy. Screws assessed as Gertzbein grade 0 and 1 were considered accurately placed (grade 0: no cortical breach, grade 1: 0–2 mm breach, minor perforation including cortical encroachment). This study found:

94% vs **89.6%**

improvement in clinical accuracy of pedicle screw placement by navigated open surgery compared to conventional fluoro-guided method based on matched control data[1]

Studies show that this relates to better long-term biomechanical stability and lower revision surgery rates[6]

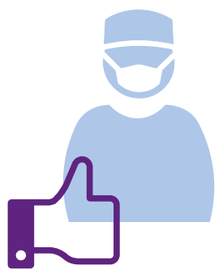


Excellent image quality at **lower X-ray dose**

With ClarifEye you can reduce the cone-beam CT radiation dose for both patient and staff, while still visualizing small and narrow pedicles in challenging anatomies. A study found that this system provides up to:

- **3.7 times higher** contrast-to-noise-ratio and
- **83% lower X-ray dose** compared to mobile Cone-beam CT (in industry-standard phantoms)[2]

Nachabe et al. Radiation dose and image qualitycomparison during spine surgery with two different intraoperative 3D imaging navigation systems. - Medical Imaging 2018. [2]



Perform procedures **simply and easily**

ClarifEye offers Philips intuitive user experience and simplicity of control to make it easy to learn and use. A usability evaluation was carried out for the ClarifEye system and the key findings included:

100%

- found the system user-friendly
- of participants believed that the full integration of imaging and navigation into one system will improve the workflow of navigated cases
- of participants (surgeons and technicians) agreed that elimination of steps that are required using conventional navigation systems (registration, placing reference frame, positioning of separate camera systems), will save them time
- **86%** of participants believed the procedure time will be shorter compared to other navigation systems
- Scored in the top **10%** of usability with a score of 83 on the System Usability Score (SUS) scale.[3]

Results obtained during a Usability Evaluation with clinical users (neurosurgeons, orthopedic surgeons, x-ray technologists and OR nurses) in a simulated use environment.[3]

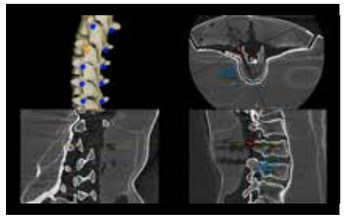
Solutions overview

System platform

Azurion 7 C20 Hybrid OR

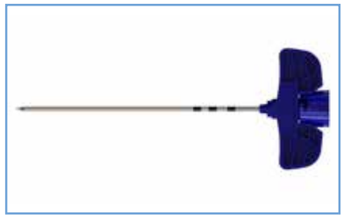
Azurion with ClarifEye

Software application and consumables



ClarifEye software

ClarifEye patient markers



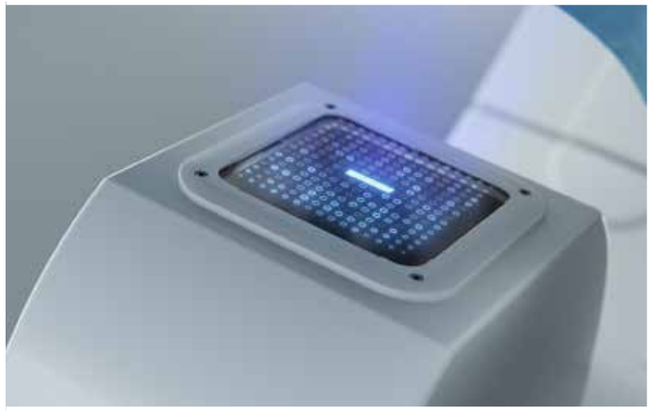
ClarifEye trackable needle

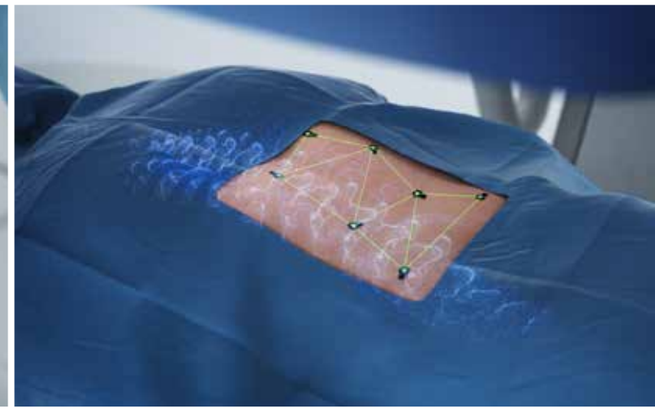
Integrated table options

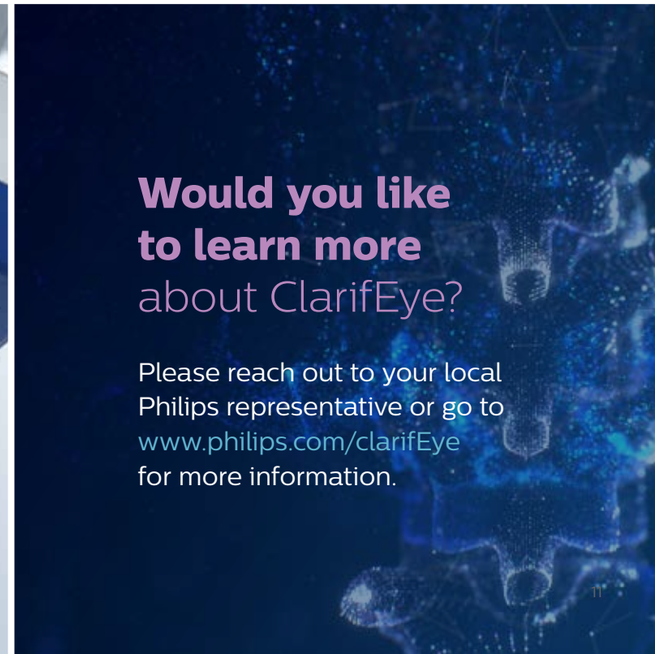
Getinge Maquet Magnus operating table

Trumpf Medical operating table

Philips patient table







References

1. Elmi-Terander A. at el. Augmented reality navigation with intraoperative 3D imaging vs fluoroscopyassisted free-hand surgery for spine fixation surgery: a matched-control study comparing accuracy
2. Nachabe et al. Radiation dose and image quality comparison during spine surgery with two different, intraoperative 3D imaging navigation systems. – Medical Imaging 2018. Single center pre-clinical study on industry standard phantoms comparing a Philips interventional X-ray system to mobile CBCT.
3. Results obtained during a Usability Evaluation with clinical users (neurosurgeons, orthopedic surgeons, x-ray technologists and OR nurses) in a simulated use environment.
4. Edström E, Burström G, Nachabe R, Gerdhem P, Elmi-Terander A. A novel augmented reality-based surgical navigation system for spine surgery in a hybrid operating room: design, workflow and clinical applications. Oper Neurosurgery. 2020 May 1;18(5):496-502. Doi: 10.1093/ons/opz236.
5. Elmi-Terander A. at el. Pedicle Screw Placement Using Augmented Reality Surgical Navigation With Intraoperative 3D Imaging: A First In-Human Prospective Cohort Study. The Spine Journal, SPINE Volume 44, Number 7 2008
6. Gertzbein SD & Robbins SE. Accuracy of pedicular screw placement in vivo. Spine. 1990;15(1):11–4.

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This medical device conforms with the applicable requirements set out by the European Union, as demonstrated in the Declaration of conformity.

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