PHILIPS

Image guided therapy

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Spine suite

Hybrid OR

Spine Suite Perform spine procedures with confidence and precision

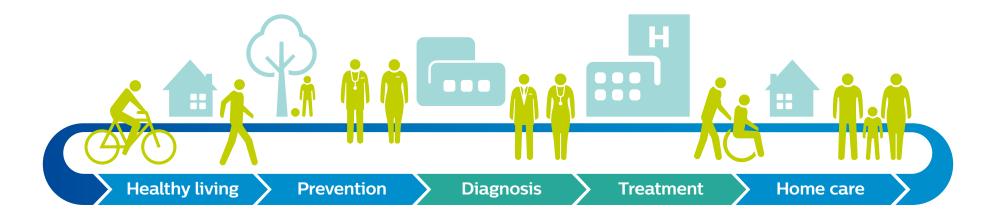
LAO

Defining the future of Image Guided Therapy

Defining the future of Image Guided Therapy

At Philips, we look beyond technology to the experiences of patients, providers and caregivers across the health continuum, from healthy living to prevention, diagnosis, treatment and home care. We unlock insights leading to meaningful innovations from hospital to home.

Our integrated solutions – packaged suites of systems, smart devices, software and services – combine broad and deep clinical expertise, technology and services, actionable data, consultative new business models and partnerships. Together, with our customers, we can transform how care is delivered and experienced. to deliver upon the Quadruple Aim: improved patient experience, better health outcomes, improved staff experience, and lower cost of care.

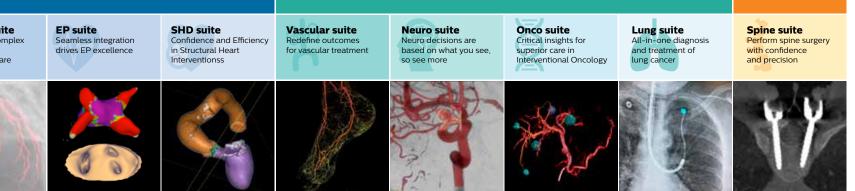


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At Philips Image Guided Therapy, we have played a pioneering role in image-guided minimally invasive therapy for cardiovascular disease since the inception of the field back in the 1950s, thanks to our expertise in X-ray imaging systems. We aim to both improve existing procedures and introduce new procedures so that more patients can benefit from image-guided

therapy. We also develop new business models to cater for new care settings, such as ambulatory surgery centers and office-based labs, and drive improved lab performance. Today our clinical partners benefit from complete procedural solutions to treat a wide range of diseases – from cardiovascular disease to stroke. cancer, and spine conditions.



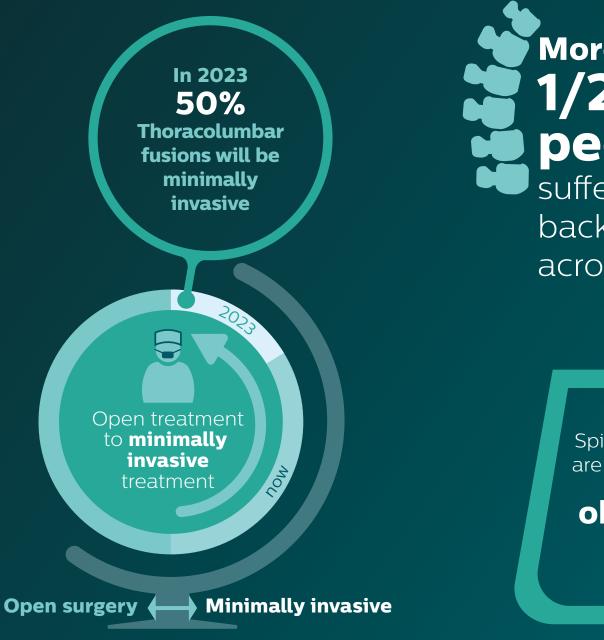
Trends in spine procedures

The spine surgery landscape has changed dramatically in recent years. More and more spine surgeries are moving from "open surgery" procedures, where you can see and touch the patient's spine while working - to minimally invasive techniques, performed through small incisions. Minimally invasive surgery has the advantage of reducing blood loss, soft tissue damage, and hospital acquired infection. As a result, it can reduce post-operative pain and promote faster recovery, which can shorten hospital stays.

Minimially invasive surgeries come with challenges. However, due to reduced visibility of the spine during these procedures, you have to rely on real-time imaging solutions to guide your surgical tools and implants.

66 The structural solution possibilities to provide a Hybrid OR enable us to carry out minimally invasive interventions, which, for the patients in turn, generally means shorter lengths of stay in the hospital.??

Prof Dr med M Synowitz, Director of the Clinic for Neurosurgery, University Medical Center Schleswig-Holstein, Kiel, Germany

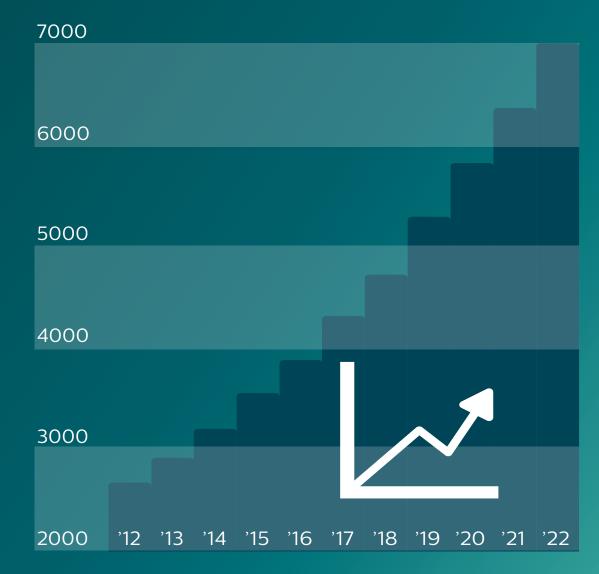


More than a 1/2 billion people

suffer from back pain across the globe

> Spine procedures are increasing with the rise in **obesity** and an aging population

Total **spine procedures** (k) globally



source of information: Medtech 2012 US image guided surgery; MRG, 2014, Global markets for MIVCF; MRG 2015, Surgical navigation systems; MRG 2013, US markets for minimal invasive spine technology.



Key benefits

- Provides exceptional, large field-of-view 2D and 3D images that boost confidence and enhance precision throughout the procedure
- Improves understanding of the spinal anatomy by providing exceptional 3D imaging
- · Cone-beam CT (SmartCT) can remove the need for post-op CT verification by providing excellent in-room cone-beam CT imaging
- Enhances the user experience thanks to greater movement flexibility through FlexMove and FlexArm intuitive positioning guidance, and enhanced patient access
- Improve accuracy using ClarifEye Augmented Reality Surgical Navigation.

and define the correct pathway for device placement. The tools provide remarkably detailed insights into anatomy, pathology, and clinical outcome during each phase of the procedure With the increasing complexity of spine surgeries and requirements as you decide, guide, treat, and confirm. Workflow innovations, for minimally invasive procedures, our Spine suite solution offers such as our FlexMove or FlexArm, can support medical teams in a state-of-the-art hybrid operating room that enables you to dramatically reducing overall procedure time and our technology perform fast, accurate, and simplified procedures. It supports the full enhances staff and patient safety by efficiently managing radiation spectrum of spine procedures – such as pedicle screw placement dose. and vertebroplasties to complex spinal fusions.

66 The Azurion has a large-area Flat Detector that provides exceptional 2D and 3D visualizations of complex spinal structures – providing far higher image quality than an image intensifier system – to enhance confidence, decision making and precision during spinal surgery.99

Prof Dr A Seekamp MD, Director of the Orthopedic and Emergency Surgery Clinic, University Medical Center Schleswig-Holstein, Kiel, Germany



Helping you focus on what's important - your patient

Today patients with spine disease have more treatment options, including minimally invasive spinal fusion procedures. During these procedures, advanced real-time image guidance is critically important in helping you get a better understanding of the anatomical structure

Based upon the Azurion platform. Spine suite supports increased confidence in decision-making and placement of devices through diverse surgical table options, workflow innovations, and dedicated 2D and 3D image guidance tools.

With the Spine suite, you have the innovations at hand that empower you to redefine outcomes for your spine patients.

Advanced flexibility in the Hybrid OR Workflow without compromise

Key benefits

• Workflow without compromise The anesthesiologist can stand at the head of the table, and team members can stand in their preferred working positions at both sides of the table, for diverse procedures

Positioning flexibility

All equipment is mounted on the ceiling to maximize use of OR space and allow easy positioning for different teams and procedures

• Easy full body patient coverage Provides full body coverage on both sides of the table to support complex open surgical and minimally invasive procedures Our ceiling-mounted gantry options FlexArm and FlexMove clear the room for free positioning of staff and facilitate full patient coverage with access on both sides of the table.

As with a mobile C-arm, the FlexMove or FlexArm system can be brought in from any side of the table for excellent patient access. All movements are fully motorized, and the system can be easily moved in and out without disrupting staff or equipment. Position memory brings the system automatically back to a previous position, such as a pedicle screw entry point, to save time. This positioning flexibility means you do not need to move the operating table during imaging or surgery, which can promote smooth and efficient spinal procedures.

"Our integrated Hybrid OR solution is an extremely movable device with the high quality of an angiography workplace. We use an adjustable table, a very large workspace, and a movable X-ray unit, which is much more modular and movable than a normal angiography workplace."

Prof Dr A Seekamp MD, Director of the Orthopedic and Emergency Surgery Clinic, University Medical Center Schleswig-Holstein, Kiel, Germany

Clarity IQ Excellent visibility at low X-ray dose levels for a comprehensive range of clinical procedures.

Zero Dose Positioning

Helps you manage dose by positioning the system or table on Last Image Hold so you can prepare your next run without using fluoroscopy.

Azurion with FlexArm or FlexMove

This innovative surgical environment offers unmatched procedural flexibility and ease of use, while meeting the highest standards for surgical infection control and hygiene.

Procedure cards

Set up the system the way you want with one click - exam settings, room set-up, required devices and materials, etc.

Integrated OR table

Seamlessly integrated OR table with controls that operate both the OR table and the C-Arm.

TSM and

FlexVision Pro View and control all system inputs including MRI data via the PACS at tableside to save time and unnecessary walking in and out of the sterile area.

Complex spine deformities and disorders

Effective guidance in treatment and decision making







Decide

Guide

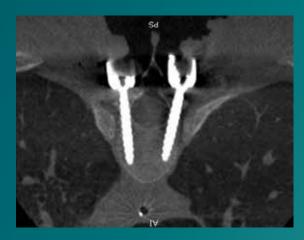
Live X-ray guidance

with ClarityIQ technology creates high definition images with exceptional detail to support precise treatment strategies, navigation, and follow-up.

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.





· Treat ······ Confirm

In-lab verification of screw placement

Cone-beam CT (SmartCT) enables you to obtain reliable information on the placement of the screws while the patient is still on the table, to access the efficacy of the treatment. By using cone-beam CT, you have extra assurance of device placement. The use of cone-beam CT during the surgery can also allow you to skip post-operative scans with conventional CT which can save time, money, and reduce the need for extra procedures.

Cone-beam CT (SmartCT)

For better insights

Superb image quality with fast imaging protocols, resulting in fewer breathing and motion artifacts

We developed dedicated acquisition protocols for spine procedures that deliver fast cone-beam CT scans to improve image quality.

Key benefits

- Fast and easy intra-operative 3D imaging
- Provides exceptional, large fieldof-view 3D images (up to 6 levels) that boost confidence and enhance precision throughout the procedure
- Cone-beam CT (SmartCT) can remove the need for post-op CT verification by providing excellent in-room cone-beam CT imaging

Reduced metal artifacts

Visualization around metal objects often poses challenges, making it difficult to assess anatomy in the vicinity of metal implants. For these cases cone-beam CT (SmartCT) provides a unique Metal Artifact Reduction filter, which significantly reduces the scattering artifacts in cone-beam CT.

"In our experience post-operative CT scans to check implant placements are no longer necessary, it is possible to verify whether a procedure has been successful immediately after treatment. As soon as surgery has been performed, we can be 100% sure that implants are in place, thanks to the high quality of the intra-operative cone-beam CT image and positioning flexibility of the system."

Prof Dr A Seekamp MD

Director of the Orthopedic and Emergency Surgery Clinic, University Medical Center Schleswig-Holstein, Kiel, Germany

Case:

Scheuermann's Kyphosis with 80 degrees preoperative thoracic Cobb angle

Patient:

- 18 year old male
- Underweighted patient (BMI=17.4)
- kyphosis deformity

 Hybrid hook/pedicle fixation from T4 to L2 (14 screws and 2 hooks)

 Hybrid OR used to perform intraoperative 3D cone-beam CT

Dr. A Elmi-Terander, MD, PhD. Senior Consultant Neurosurgery Karolinska University hospital, Stockholm, Sweden





3D cone-beam CT Courtesy of Dr A Elmi-Terander MD PhD Karolinska University Hospital, Stockholm, Sweden.

3D cone-beam CT Courtesy of Dr A Elmi-Terander MD PhD Karolinska University Hospital, Stockholm, Sweden,

66 When you are using this kind of system, you have the possibility to check your results immediately and then you have the possibility to correct that in the OR.99

ClarifEye Augmented Reality Surgical Navigation

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

Key benefits

- Imaging and navigation into one
- High quality Intra-operative conebeam-CT imaging at low dose
- Non-invasive patient tracking streamlines workflow
- Live augmented reality needle
 guidance to support precision

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 accurate² 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.

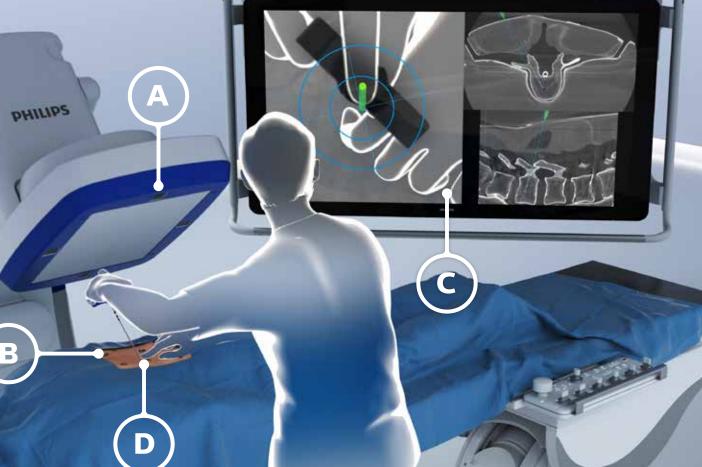
" The surgeon is dominating the technology around him and is not dominated by the technologies. Navigation becomes simpler with this imaging technology."

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

Learn more about ClarifEye Visit www.philips.com/ClarifEye



94% Navigated vs **89.6%** Freehand improvement in clinical accuracy of pedicle screw placement.²



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 video images are combined with intraoperative 3D conebeam CT images , to provide live augmentedreality feedback (C) The systems visualizes the tip of the ClarifEye needle in relation to the spinal anatomy (D).

Augment precision and patient safety

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.³

Perform procedures simply and easily

100% of the users found the system user-friendly.⁴

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Partners for spine surgery

Integration with OR table

The partnership between Philips and Getinge results in a seamless integrated OR table in the Hybrid room for a truly multifunctional room suitables for conventional surgery for a truly multifunctional room suitable for conventional surgery, hybrid surgery, or interventions. The Azurion image-guided system and Getinge OR table are completely synchronized, so you benefit from automatic position control (APC) and 3D software tools. The table can be outfitted with a radiotranslucent tabletop in different lengths. Tabletops can be easily exchanged using the transporter, allowing smooth transfer of patients between procedures.

Integration with third party navigation solutions

To support navigated procedures we can offer you real-time accurate data transfer, with the patient in the correct position based on high quality intra-operative conebeam CT. We are able to export 2D and 3D data via DICOM, including automatic image registration. You also have the possibility to merge pre-op CT and MR Datasets with in-room cone-beam CT.





Spine suite solutions

We offer a comprehensive range of options and support to help you realize a suite that fits your clinical and budgetary requirements. Our offerings also include advanced education, efficiency programs, and RightFit service agreements.

Our image guided therapy Spine suite is a combination of the Azurion platform, spine products, workflow options, accessories, education, and services. We also offer solutions to create a leading-edge Hybrid OR. Since all solutions are integrated, you have the flexibility to configure a multipurpose treatment environment that enables you to perform a wide and diverse range of clinical procedures, such as vascular and cardiac surgery.

Want to know more about the Spine suite solutions?

Please reach out to your local Philips sales representative for more information.

System platforms

- Azurion 7C20
- Azurion with FlexMove
 and FlexArm

Spine options

- Cone-beam CT (SmartCT)
- SmartCT Vaso
- XperGuide
- ClarifEye

Integrated solutions

Third party solutions

Consumables

- ClarifEye patient markers
- ClarifEye trackable needle

Table options

- Philips patient table
- Getinge Maquet
 operating table
- Hillrom operating table



Increase value throughout your Spine suite lifecycle

Stay clinically and operationally relevant with Technology Maximizer

Technology Maximizer secures all your eligible Philips imaging equipment with the same technology release level reducing maintenance complexity and simplifying lifecycle management across hospital departments. Maintain peace of mind with imaging equipment that is always up to date, and enhance patient care knowing you will always be among the first to take advantage of technology innovations.

Learn more about **Technology Maximizer**

To keep your Image Guided Therapy Suite state- of-art with regards to cyber security, clinical, and operational advancements, subscribe to IGT Technology Maximizer - Plus, Pro or Premium offer – for a standard duration of 4 years at point of sale.



Standard	l offer	Mid-level offer	Premium offer
Technology Maximizer Plus		Technology Maximizer Pro	Technology Maximizer Premium Cardiac/Vascular
-7			
2	Azurion system SW version upgrade		
110 101 010 010 1010	State-of-the-art security		
₽	Latest available Operation System		
Ę	Computer HW refresh to support software upgrade		
	Application training for new or enhanced functionality (days)		
PHILIPS	New version of existing iApps		
Petturs	Future iApps in one clinical suite (Coronary, EP, SHD, Vascular, Neuro, Onco, Spine or Lung)		
	Future iApps in one clinical domain (Cardiac or Vascular)		

- Medtech 2012 US image guided surgery; MRG, 2014, Global markets for MIVCF; MRG 2015, Surgical navigation systems; MRG 2013, US markets for minimal invasive spine technology
- 2. 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
- 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.
- Results obtained during a Usability Evaluation with clinical users (neurosurgeons, orthopedic surgeons, x-ray technologists and OR nurses) in a simulated use environment



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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