January 2015

vascularnews

EDUCATIONAL SUPPLEMENT

Hybrid Suite

State-of-the-art imaging in a sterile environment

This educational supplement has been sponsored by Philips Healthcare

The use of Hybrid Suites—state-of-the-art imaging in an operative environment—is changing the way endovascular procedures are performed. Combined with a range of advanced tools developed by Philips, these sophisticated systems expand the treatment options for complex disease and have the potential to manage radiation dose and enhance patient care.

In this supplement:

Introduction

Interventional medicine and surgery meet each other in the Hybrid Suite

Vascular surgery has evolved immensely over the past decades, with a vast number of open repair procedures being replaced by endovascular interventions. Until recently, these endovascular interventions were performed in the angiography suite and open surgery took place exclusively in operating theatres. With the advent of hybrid suites—sterile suites equipped with top-end imaging—interventional procedures are becoming more complex, open repair is becoming less invasive, and intervention and surgery are being combined in hybrid procedures. The Philips Hybrid Suite offers state-of-the-art imaging in an operative environment and is at the forefront of high-quality imaging with managed radiation dose in vascular and endovascular procedures.

The Hybrid Suite is the result of a trend in which interventional medicine and surgery are growing towards each other. It combines aspects of an angiosuite environment, such as a high-quality X-ray system, with aspects of an operating room, including surgical light, high sterility and access to anaesthesia and other surgical resources. This hybrid environment is eminently suitable for a large variety of procedures, ranging from minimally invasive and hybrid to open surgery procedures.

Typical procedures performed with a hybrid suite include endovascular repair of aortic aneurysms (abdominal and thoracic), fenestrated procedures, lower limb stenting, carotid stenting, visceral reconstruction, and other vascular procedures.

"From the beginning I was convinced we needed to have a Hybrid Suite as I wanted to perform complex vascular procedures and be able to deliver enhanced patient care," says Frank Vermassen, Ghent University Hospital, Ghent, Belgium. "Now that we have had the Hybrid Suite for two and a half years, our team prefers to use the system for all procedures. It is far easier and comfortable to use than a conventional system, and the quality of the images and, therefore, the quality of the work that we can deliver is much higher."

With the growth in endovascular interventions and combined open and endovascular procedures, alongside the need for better image quality and more radiation safety, there has been an exponential growth in the number of Hybrid Suites being used, with Philips alone having installed more than 600 systems worldwide. Angelique Balguid, Global Marketing Manager Hybrid OR from Philips, explains that the design of the company's Hybrid Suite offering is focused around seamless performance across three levels: Hybrid operating room design (involving all stakeholders), user-optimised products, and easy-to-use advanced imaging to support clinical workflow.

Vermassen notes that the Hybrid Suite allows his team to perform a wide range of procedures, including those where a conversion to open repair was necessary, and exemplifies with a recent case of mesenteric ischaemia that was started

endovascularly in which there was still stenosis after stent placement. "It was not possible to recanalise the mesenteric artery and we converted the procedure to an open bypass. That was very convenient in the Hybrid Suite—in a conventional radiology room, you would have to stop the procedure to go to the conventional operating theatre," he explains.

Another example where the Hybrid Suite makes a difference, Vermassen says, are complex fenestrated procedures that demand a long time to recanalise all branches. "We had a difficult case like this recently and we could not have done it without the Hybrid Suite."

He adds that his group is also performing several visceral and arch hybrid procedures, and "this is a great advantage of the Hybrid Suite because you are able to do the open part of the procedure in the same setting".

Jan Brunkwall

Vermassen says that even for simpler procedures such as embolectomies, it is important to assess with imaging what you have achieved and this can be done very conveniently in the Hybrid Suite.

Jan Brunkwall, Department of Vascular Surgery, University Clinic, Cologne, Germany, states that with the Hybrid Suite and advanced imaging tools such as 3D live image guidance, he can work faster and more precisely, which leads to fewer complications: "You can use the Hybrid Suite for all cases, even if you perform only iliac, renal or lower limb stenting. Of course you are able to perform these procedures with a C-arm only but the quality is much better with the hybrid system."

Flexibility and enhanced access to patients

Another important aspect of the Hybrid Suite is the flexibility and ease of access to patients that the system provides. With the Philips system, the ceiling mounted X-ray solution (FlexMove) allows operators to increase the image coverage and provides enhanced access to the patient because there is no fixed foot mount standing between operator and patient. In addition, the anaesthesia area is not blocked by the X-ray system.

"You can easily move the system to reduce interference with the medical team, and you do not have to worry about driving over cables on the floor with your equipment. A ceiling mounted system is also easy to clean," says Angelique Balguid. "You can move the X-ray system laterally and longitudinally on both sides of the table, so you can examine the patient without panning the table and becoming entangled with wires and tubes from other equipment. This full range of movement frees up the operating area so physicians and staff can work in their normal positions and easily access the patient. It provides full body coverage to support a variety of different procedures."

Frank Vermassen

Vermassen comments: "With the FlexMove system, now it is not an issue to bring the C-arm and do an angiogram while doing an open procedure. As you can move the C-arm in two directions, it is not in your way when you are doing the open part of the procedure as you just put it on the side and at the same time it is easy to bring it back in."

What is a Hybrid Suite?

The Hybrid Suite is a state-of-the-art environment where high definition imaging and surgical tools are available. The room consists of an operation table with a radiolucent top, a C-arm, anaesthesia equipment, screens, lighting for open procedures, injector, ultrasound machine and many other devices. Two options of tables are available for the Hybrid Suite: the Philip Xper table for endovascular procedures and the Maquet Magnus OR table for open and minimally invasive procedures. The Hybrid Suite is supported by a technical room, a control room and a storage room.

Drivers for Hybrid Suites

- Growth in endovascular procedures
- Combined open and endovascular procedures
- Need for angiographic control after open procedures
- Increased complexity of the procedures
- Need for better image quality
- Radiation management
- Sterile environment (implants)
- Use by different specialities (trauma, spine, cardiac and neurosurgery)

Source: Frank Vermassen

Key advantages

- With the Hybrid Suite, you can perform a full range of procedures—from endovascular to hybrid to minimally invasive or open surgery—in a single room, virtually without compromise
- Increased use by performing a wide range of procedures in one room
- Hybrid procedures may reduce the number of separate procedures
- New treatment options have the potential to enhance patient care
- The entire team can work smoothly together and quickly adapt the room to different setups required for diverse procedures. This allows hospitals to use their rooms to their fullest extent and enhance patient care

Consultancy and planning

A strong partnership to achieve total room solutions

The number of Hybrid Suites has risen dramatically in the past few years and has become a well-recognised hospital infrastructure. Within the next five years, it is expected that most hospitals with comprehensive cardiovascular services will be planning to or will have implemented at least one Hybrid Suite.

To justify this investment, organisations considering the installation of a Hybrid Suite need to build a solid business case. Philips works with the concept of Total Room Solutions—where all the equipment for a procedure is available in a single, unique space—and offer a comprehensive consultancy programme from conception to planning and implementation in order to create a Hybrid Suite that meets physicians' needs and their institution's financial resources.

Frank Vermassen, who worked with Philips for the creation of Hybrid Suites in Ghent, comments: "When you want to build a Hybrid Suite, you need to contact the company at a very early stage. In the conception of such a room, a lot has to be decided upon, for instance where to place the lights, the C-arm, the panels and all the rest of the material. This is very important. They have experience in building these rooms and can certainly help you to create a room where the workflow can be organised for your hospital."

Because the Hybrid Suite can be used for a broad range of procedures, it allows efficient use of people and technical resources. It also has the potential to improve care for patients, by allowing multiple procedures that would otherwise be performed in separate rooms, to be performed in the same room in one session.

With a long history of partnership with Philips and decades of experience integrating endovascular and surgical procedures, the Miami Cardiac & Vascular Institute, Miami, USA, has recently expanded its facilities and invested in new, high-end hybrid endovascular suites from Philips. Carol Mascioli, chief operating officer of the Miami Cardiac & Vascular Institute, explains that integration between specialities has always been part of the institution's philosophy and that the endovascular suites follow the same ethos. In the organisation, the rooms were designed with a red line area within the procedural areas allowing the combined procedures to be performed within the red line and the procedures that do not require all OR equipment to be performed outside the red line area but still in a sterile environment.

Carol Mascioli

"Challenging Philips to provide us with support and designing that kind of environment was very instrumental. Designing an OR is very straightforward but coming up with something that is unique, with high-end imaging equipment and flexibility that addresses all the needs that our physicians have takes real expertise," Mascioli says.

In vascular and endovascular surgery, the endovascular suites—as they are called in the Miami Cardiac & Vascular Institute—are being used mainly for complex EVAR and TEVAR procedures. The suites are also used by cardiovascular specialists for TAVI procedures, MitraClip, and combined cardiac surgery and interventional procedures.

On the planning of the new endovascular suites, Mascioli highlights the close relationship between the Miami Cardiac & Vascular Institute and Philips to pursue what was best for the physicians' clinical needs.

"What we have with Philips is a partnership in looking at not only what is the best type of equipment, but how we can utilise that equipment in the best type of environment. When we combined the scientific and technical background from the company that relates to the equipment with our physicians' expertise, it was a great synergy," Mascioli notes. "We had several meetings with everyone in the room—individuals from Philips and all the physicians, interventional cardiologists, anaesthetists, vascular surgeons, cardiac surgeons, interventional radiologists, electrophysiologists, and staff members—and everyone worked together to design the room and decide on what was going to be the best environment for our goals with the expansion project. It was important to have Philips there at the table working with the key customers' needs and assisting us with designing what was going to be best suited for our project."

Philips helps to create the project plan for your Hybrid Suite

Discover the Hybrid Suite – Because each specialty has its own workflow, set of equipment, and team, it is important to first define the case mix that makes sense for your facility.

Define the business case – Hospital management calculates the investment required and compares it against the expected returns to evaluate feasibility. When you are assessing the feasibility of investing in a Hybrid Suite, it is important to create a financial overview of both the costs that will be expended and the revenues that will be generated.

Define the requirements – All stakeholders provide their requirements and key decisions about equipment are made.

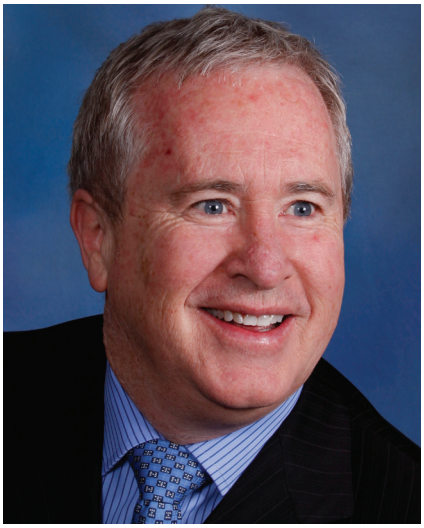
Design the room layout – The layout of the room can be designed around users' needs using 3D simulation tools to facilitate smooth procedures.

Organise for the Hybrid Suite – To ensure full utilisation, the organisation should set up a process for acquiring patients and referrals and prepare and train staff for the new facility.

Imaging and multidisciplinary approach

“Integration with the Hybrid Suite has brought a renewed energy to our staff”

The benefits of interventional procedures in cardiovascular medicine—less invasive access, reduced bleeding and faster recovery—are beyond dispute. However, increasingly complex endovascular and hybrid procedures require ever more high-quality imaging to avoid complications, thus exposing patients and medical staff to higher radiation doses. The Philips FlexMove Hybrid Suite with AlluraClarity provides an environment where cross-disciplinary support has the potential to overcome some of these challenges.



Mark Goodwin

Catherine Smith

The Edward Heart Hospital in Naperville, USA, is an example of where integrated teams conduct cutting-edge procedures in a room designed for a multidisciplinary approach.

For cardiologist Mark Goodwin, having multiple functional utilities available to deliver care in both an open and endovascular situation, helps cultivate a sense of safety and security. “We can never identify the person who may need all of our resources,” he says, “but I would just as soon have everything at my fingertips ready to go.

Goodwin’s team is now using a Philips Hybrid Suite with FlexMove, which has the AlluraClarity Xper FD20 interventional X-ray system at the centre of the Philips technology. It combines a large field of view and high-resolution flat detector with advanced diagnostic and 3D interventional tools. The Edward Heart FlexMove Hybrid Suite configuration consists of these specific elements:

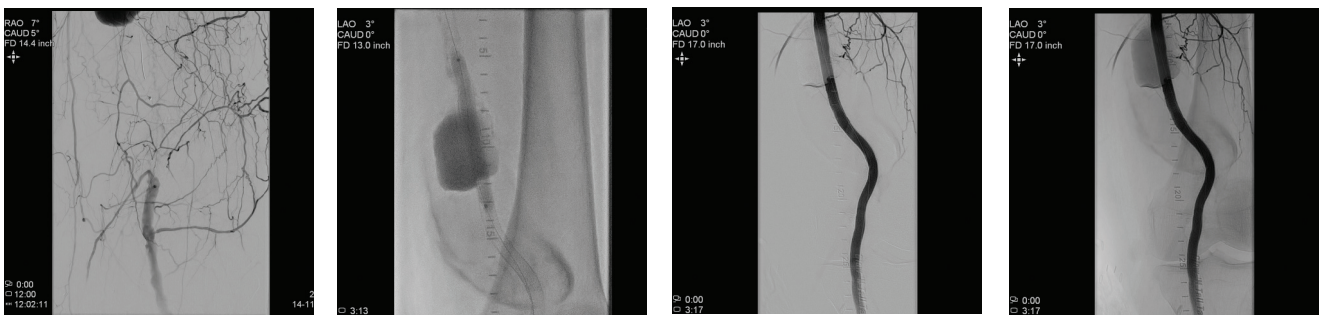
- AlluraClarity Xper FD20 interventional X-ray system
- FlexMove ceiling rails for wide C-arm movement
- FlexVision 56” medical display
- Maquet Magnus table system
- 3DRA, XperCT, and HeartNavigator interventional tools
- Stryker lights, booms, and video integration

The FlexMove Hybrid Suite design allocates a wider footprint for complex procedures, introduces state-of-the-art imaging technology, and maintains the sterility of an operating room.

“We are getting excellent high-quality images,” says Goodwin, “which is important when we are doing high-end complex procedures. However, it is the ability of the room to handle all the staff plus supportive equipment that is equally critical.”

The FlexMove Hybrid Suite is designed to provide enhanced access to the patient. With FlexMove, the ceiling mounted C-arm can be quickly moved anywhere it is required around the table, or completely out of the way if necessary. This gives the team more room to work around the patient and frees up the head area so the anaesthesiologist and/or echocardiologist can work with ease. “In a hybrid environment, the higher the flexibility of the room, the higher the utility,” says Goodwin.

Preparing the room between distinctly different procedures is a simple task,” says Catherine Smith, director of Interventional Suites and Cardiovascular Surgery with Edward Heart Hospital. “We have put all inventories on specialty carts. We have the ability to switch between procedures very easily. We move the carts in, we move the carts out. This allows for the flexibility of having inventory for virtually every type of procedure. In addition, when not used



the carts can be moved out and the Hybrid Suite maintains a clean non-cluttered environment."

Edward Heart's Hybrid Suite

Managing dose

Managing dose for both patients and staff is an important consideration for the Edward Heart team during lengthy procedures in the new hybrid suite. The AlluraClarity Xper FD20 interventional X-ray is part of the Philips AlluraClarity family of X-ray systems with ClarityIQ technology, capable of maintaining equivalent image quality at a low dose level.

According to Goodwin, "Despite more fluoroscopy time during some of our more complex cases, we are recording very low radiation dose levels for both our endovascular aneurysm repair (EVAR) and transcatheter aortic valve implantation (TAVI) cases and yet we still maintain a great image."

Staff members track their exposure using Philips DoseAware dose measuring system. Personal dose meters provide real-time feedback, showing when and where dose was acquired. "Before AlluraClarity the badge of the doctor standing closest to the tube would be red and the staff badges right next to him would be yellow. Now everybody in the room is green," says Goodwin.

A true multipurpose room

Goodwin and Smith knew their hybrid suite would be useful for TAVI procedures, but had initial concerns as to whether they would use the room much beyond that. "What we have learnt," says Goodwin, "is that the Philips Hybrid Suite has given us more flexibility to manage the operating room schedule. It has made endograft procedures quick, fast, and it has been a key factor in giving us the ability to grow our volumes."

Smith agrees, "The room offers a lot of scheduling flexibility—we use it for TAVI, along with abdominal aortic aneurysms, vascular procedures, and coronary artery bypass graft procedures. It has also helped as an additional suite for implant procedures—implantable cardiac defibrillators and permanent pacemaker insertions."

By adding a room of such multi-use capacity, Edward Heart has seen tangible growth. Their EVAR and TAVI volume is up, and their total valve work is up by 100%.

For Edward Heart Hospital, the Philips FlexMove Hybrid Suite has helped to establish a new era in interdisciplinary cooperation with the ultimate goal of providing high quality services and patients care.

"One of the unspoken advantages of a hybrid environment," suggests Goodwin, "is that it creates a different energy—with everyone working together. We all learn collectively because we are able to ask questions and share ideas that we would not normally share. This room allows everyone to broaden their viewpoint."

"Integration," says Smith, "has brought a renewed energy to our staff. Each group fully appreciates what the other does. We have a very strong, united team."

Performing complex hybrid procedures is a critical part of Edward Heart Hospital's commitment to remain a healthcare leader. "This is an area you do not want to be last in," Goodwin states. "Early adopters are going to carve out a niche that will become a self-fulfilling prophecy, demonstrating their ability to stay busy and grow their volumes." And concludes: "Having a room where we can do complex high-end procedures is a much larger piece of the pie than I would have originally thought."

Advanced imaging

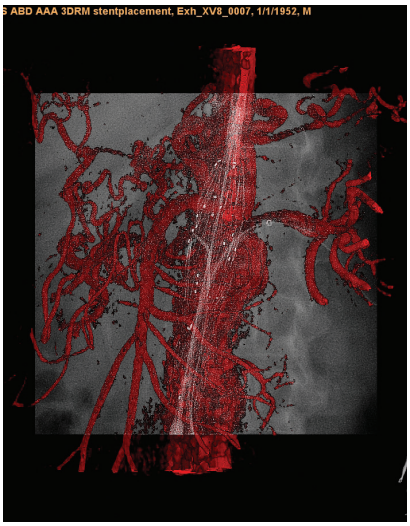
Novel, high-end technologies enhance visualisation and have the potential to impact patient care

In recent years, the use of dynamic 3D roadmap techniques with the fusion of preoperative CT scans and live fluoroscopy has become a reality during endovascular procedures. Techniques such as real-time 2D perfusion, cone-beam CT with XperCT and live navigation with XperGuide enhance the capabilities of a Hybrid Suite and have the potential to deliver enhanced patient care.

Live 3D image guidance

With the increasing complexity of interventional procedures, there is a growing need for 3D image overlay (or fusion) to assist operators with device guidance and precise placement. The fusion of preprocedural CT scans with 2D fluoroscopy has shown positive outcomes in the treatment of complex aneurysms of the aorta. Live 3D image guidance can also be performed with intraprocedural 3D rotational angiography or cone beam CT.

Hicham Kobeiter



MR/CT RoadMap

In a study conducted in the Maastricht University Medical Centre (*Eur J Vasc Endovasc Surg*. 2014 Apr;47(4):349–56) comparing CT angiography with fluoroscopy image fusion roadmapping in patients who underwent fenestrated and/or branched endovascular repair with a control group, contrast volume and procedure time were significantly lower in the fusion group. There was no significant difference in fluoroscopy time. The authors concluded that "image fusion guidance provides value in complex endovascular interventions".

In Créteil, France, Hicham Kobeiter and colleagues from Henri Mondor University Hospital have shown that image fusion-based roadmapping is a feasible technique for TEVAR (*Circulation*. 2011;124:e280–e282) and complex EVAR procedures (*J Vasc Interv Radiol*. 2013 Nov;24(11):1698–706). Also, they showed it is associated with significant reduction of injected contrast agent volume and similar X-ray exposure and procedure time. Henri Mondor University Hospital was one of the first centres worldwide using imaging fusion.

Kobeiter told *Vascular News*: "At our institution, fusion has become standard practice in many types of procedures. We have adopted the technique not only for complex cases but for all cases in which we wanted to have high-quality imaging coming from the CT or MR. It is used mainly for aneurysms and embolisation procedures in approximately 30–40% of the cases."

Key advantages

- High-definition image fusion of CT or MR with fluoroscopy for device guidance and precise placement
- 3D view for real-time, motion compensated navigation through vessels and soft tissue
- Reduction in contrast volume and procedure time in complex cases

2D Perfusion

Performing perfusion imaging during endovascular procedures helps clinicians identify the severity of a patient's condition before the intervention. Real-time 2D Perfusion imaging also gives clinicians a deeper insight into tissue perfusion and can be of great value while trying to restore vessel patency and overcome ischaemia.

"2D Perfusion is a new tool that provides functional information about tissue perfusion based on a digital subtraction angiography and allows us to assess how good the quality of revascularisation will be. It has been validated by neuroradiologists in the brain and it has also been used in peripheral vessels. In complex EVAR and TEVAR procedures, it can give important information on the perfusion of renal arteries and other branches," says Mario Lachat, Department of Cardiovascular Surgery, University of Zurich, Zurich, Switzerland.

The 2D Perfusion software enables high-definition visualisation of flow of contrast through vessels and the organ parenchymal enhancement over time in a single colour image. By comparing pre and post procedural images, clinicians can identify perfusion differences in the colour images. The phases and parameters that can be analysed with 2D perfusion include arrival time, mean transit time, width, area under curve, time to peak, and wash-in rate.

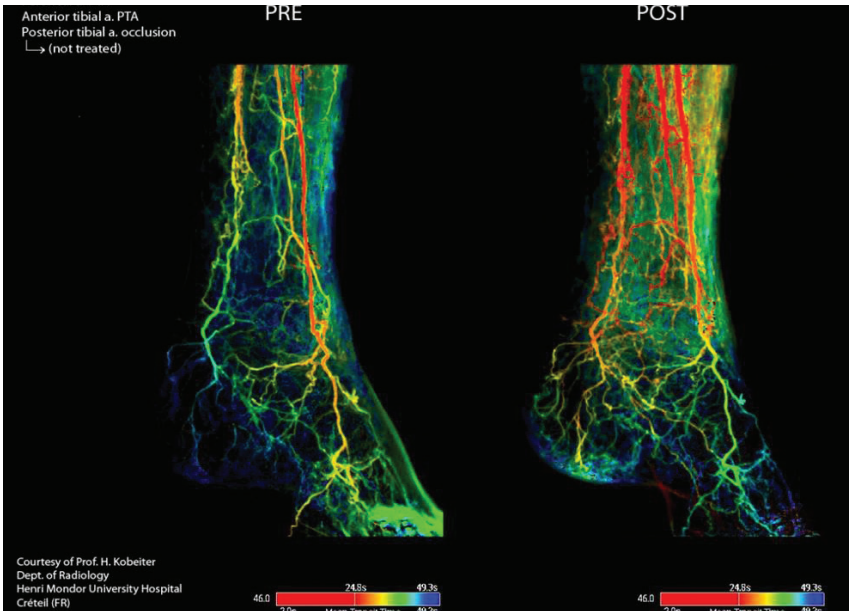
"This gives you different sets of information that will be very valuable in complex patients. 2D Perfusion is a very attractive tool and I think it will be of great value in the abdominal area," Lachat notes.

Key advantages

- High-definition perfusion imaging with comprehensive data analysis tools
- Instant perfusion feedback during procedures
- Dedicated image acquisition protocols for different anatomical regions

XperCT

The XperCT is a new generation cone-beam CT imaging that enhances insight for challenging cases. It is used to create 3D high-definition images and can be used as



2D Perfusion

a check-up tool to assess device placement.

Michiel de Haan, Maastricht, The Netherlands, employs XperCT for complex cases—branched and fenestrated EVAR and TEVARs—on a regular basis during and after procedures. He adds that the Ethics Committee of the institution is currently analysing a protocol for co-registration using XperCT in peripheral interventions. "We believe the main benefit of using XperCT is that fluoroscopy time and amount of contrast will go down. Radiation can be an issue, because you have to do a CT scan before the procedure, but with reduced fluoroscopy time it almost balances it out."

Key advantages

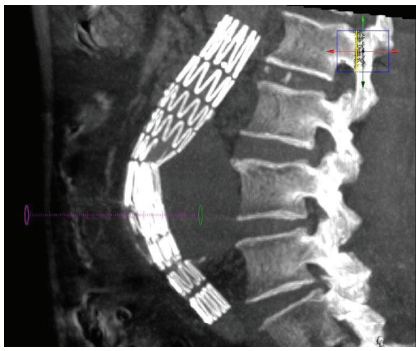
- Very fast imaging protocols for excellent image quality and fewer breathing and motion artefacts
- The image quality of XperCT enhances the visualisation of pathologies, such as endoleaks
- High-quality image for large and bariatric patients without requiring additional radiation dose

XperGuide

The XperGuide tool provides live 3D image needle guidance by overlaying 3D soft tissue imaging data from XperCT with live fluoroscopy, allowing operators to bring percutaneous needle procedures into the Hybrid OR. XperGuide overlays live fluoroscopy and 3D soft tissue imaging data from previously acquired CT or MR scans or from XperCT, providing information on the needle path and target.

In Maastricht, Michiel de Haan, Department of Radiology, Maastricht University Medical Centre, has used the system for tumour ablation in the liver and lungs, and more recently used the software for the treatment of abdominal endoleaks.

"Years ago we tended to go for the technique of stop the supplying vessels of the endoleaks; nowadays we tend to treat the aneurysm sac by embolisation with direct puncture and that is when you can use the XperGuide, as it is very convenient to use," de Haan says.



XperGuide

Key advantages

- Supports procedures from biopsy and drainage to radiofrequency ablation and embolisation
- Real-time feedback on needle location during diagnosis, planning and intervention
- Ideal patient access at every step of the process

Integrated solutions

New collaboration expands Philips' integration solutions for minimally invasive therapies

The trend towards image-guided minimally invasive therapies continues to grow, requiring integrated solutions that enable physicians to optimally perform their procedures. With the objective of further expanding solutions for its hybrid suite with integrated video and live streaming capabilities, Philips has partnered with Image Stream Medical (ISM), a leading provider of advanced solutions for the control, routing, capturing and management of data and images utilised in various procedural environments, including hybrid suites and interventional labs.

Through this partnership, Philips will be able to offer complete integration solutions and associated consultancy services, complementing its offering of live-image guided solutions, clinical informatics and services. The combined Philips and ISM offering will be available in the USA from January 2015 onwards.

"Integrated video and live streaming capabilities have become increasingly critical to connecting clinicians and enabling remote collaboration in both interventional and hybrid environments," said Bert van Meurs, general manager, Image-Guided Therapy at Philips. "With a similar consultative approach to customer engagements, the partnership with Image Stream Medical is a natural extension of our current image-guided minimally invasive therapy offering, and this addition further reinforces our commitment to connecting care across the health continuum."

For the past 15 years, ISM's platform, including audio/video integration, informatics integration, recording, streaming and conferencing solutions, has enabled more effective collaborative environments for conducting minimally invasive surgical procedures. EasySuite, ISM's latest integrated solution is designed to enhance operating room, hybrid suite and interventional lab flexibility, staff satisfaction, patient safety and to enable secure and easy sharing and archiving of data inside and outside the lab—including data for the electronic medical record (EMR).

"Image Stream Medical is very pleased to enter into this partnership with Philips in the image-guided therapy field, a natural extension of our perioperative solution," said Eddie Mitchell, CEO of Image Stream Medical. "ISM provides a workflow-centred platform for integrating surgical and procedural video information across the hospital enterprise, facilitating efficiency, teamwork, collaboration and learning. The complexity of the hybrid suite demands these capabilities. By partnering with Philips, ISM solutions will bring value not only to Philips' hybrid suite customers, but also to its interventional lab customers."

With the combined Philips and IMS offering, physicians will have access to real-time information from a range of technologies at their fingertips—inside or out of the procedure room—making interventional X-ray and other procedures more efficient and easier to perform. The result is a connected, collaborative environment, enabled by secure and easy data sharing both in the hospital and remotely. Paired with Philips' consultancy and clinical informatics solutions, these enhancements to Philips' live-image guidance offering reflect the company's ongoing commitment to improving care at every step of the health continuum.