

Press release

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Ziehm Imaging and BrainLAB improve trauma and spine surgery with X-ray based navigation

Nuremberg, Germany, 31. August 2009 – The two German medical technology companies Ziehm Imaging and BrainLAB have increased their cooperation to make trauma and spinal operations safer and more efficient for both surgeon and patient. Thanks to the Ziehm NaviPort interface, with immediate effect high-resolution 3D images from the mobile C-arm Ziehm Vision FD Vario 3D can be used for the surgical navigation of BrainLAB. The new flat-panel technology of Ziehm Vision FD Vario 3D reproduces more than 16,000 grayscales. The distortion-free, fully digital images can display the finest anatomical structures in three dimensions and make complex, navigated surgeries safer. Surgeons benefit from an improved overview - for example, when inserting screws and implants. Professor Josten MD and the Clinic and Outpatients' Department for Trauma, Reconstructive and Plastic Surgery at Leipzig University Clinic are the first in Germany to use this new technology.

The study proves: 3D images ensure a more precise placement of pedicle screws

In particular, 3D imaging is a crucial aid to surgeons operating on the spinal column. Studies prove that pedicle screws are positioned erroneously in 40 percent of all operations not employing X-ray monitoring. A study¹ by the Department for Trauma and Reconstructive Surgery at Rostock University Clinic shows, that pedicle screws can be positioned more precisely with the aid of the 3D C-arm from Ziehm Imaging. Monitoring during operations renders post-operative CT scans superfluous. Patients benefit from better operational results, reduced radiation exposure and a lower risk of revisions.

**High-resolution images for optimum orientation in the OR**

The three-dimensional X-ray images from Ziehm Vision FD Vario 3D offer surgeons the best possible view during an operation and are therefore particularly suitable for complicated procedures in which millimeter precision is essential. The fully digital flat-panel technology of the C-arm provides distortion-free images in more than 16,000 shades of gray – four times

¹ Markus Beck et al: "Monitoring of pedicle screw position by means of 3D image converter during operations", *Zeitschrift für Orthopädie und Unfallchirurgie* 2009: 147, 37-42.

more than conventional image converters. This enables doctors to make more precise diagnoses.

At the Clinic and Outpatients' Department for Trauma, Reconstructive and Plastic Surgery at Leipzig University Clinic, Professor Christoph Josten MD has already gathered clinical experience with Ziehm Vision FD Vario 3D. "3D imaging during operations provides us with a precise overview, ensuring to position pedicle screws more accurately", explains Professor Christoph Josten MD. "This applies particularly for the problematic cervical spine and the thoracic spine that are hard to spot with conventional X-rays. Especially the 3D function helps us to avoid injuring any sensitive structures such as the spinal cord. Therefore, it increases the safety of the surgery and can replace radiological follow-up scans. As a result, our patients are only exposed to low doses of X-rays and do not have to accept high radiation in post-operative control scans. Our clinic benefits from more efficient procedures and from the possibility of minimally invasive surgeries that help reduce the need for pain treatment, rehab phases and eventually the stationary stays."

X-ray based navigation with BrainLAB

Surgical navigation can also work more precisely thanks to the improved X-ray images. As a result of the new Ziehm NaviPort interface in combination with the latest Fluoro 3D navigation software from BrainLAB, 3D datasets taken during the operation can be used immediately for further interventions with the navigation system, without additional steps required for registration. This unique link between the two technologies saves both physician and patient valuable time in the operating room. The surgical navigation software Fluoro 3D from BrainLAB automatically and uniquely matches the C-arm dataset taken during the surgery with the anatomical structures of the patient within seconds. With the aid of BrainLAB Fluoro 3D software, the surgeon can follow the patient's anatomy and the movements of the surgical instruments on the monitor in real time during the operation. This provides surgeons with an improved overview of a minimally invasive procedure where they can, for example, plan for and position screws even more precisely than before. Patients benefit from increased OR safety and improved clinical results.

Flexibility during the surgery

In addition, the flat-panel detector is also unsusceptible to magnetic fields and can therefore be used in any operational environment, even in the vicinity of a magnetic resonance tomograph. The large amount of space saved by the flat-panel detector provides a unique size of C-arm opening at almost 90 cm which makes it easier for doctors to position the C-arm comfortably on the operating table. Optimum fluoroscopy is thus possible from any position – a crucial advantage, in particular, for operations on the spinal column. This is crucial to ensure best possible screw positioning in each direction.

"Ziehm Imaging has almost 40 years of experience in developing our high-tech C-arms", explains Martin Herzmann, Director of Global Marketing at Ziehm Imaging. "We cooperate

closely with more than 100 clinics in which we have installed our systems in order to continue development of X-ray based imaging with flat-panel technology. As a technology leader, we are expanding the range of clinical applications of our systems for the patients' benefit and for the benefit of joint customers of BrainLAB and Ziehm Imaging."

About flat-panel technology

Ziehm Imaging specializes in the development of mobile C-arms. The technology leader introduced the first C-arm with digital flat-panel technology onto the market in 2005. The introduction of digital flat-panel detectors in mobile fluoroscopy marks a quantum leap in the technological development of mobile x-ray imaging. C-arms with flat-panel can display images with more than 16.000 shades of grey. These high-end machines therefore improve soft tissue imaging along with visualization of bony anatomy and are suitable for a variety of clinical applications: from interventional radiology, through cardiology, to neurosurgery and vascular surgery. Apart from fully-digital, distortion-free imaging, the flat-panel improves the access to the patient due to the larger opening of the C-arm. The flat-panel detector is insensitive to magnetic fields which makes it possible to work close to MRI sites or places where strong magnetic fields are present.

About BrainLAB

BrainLAB develops, manufactures and markets software-driven medical technology that enables procedures that are more precise, less invasive, and also less expensive than traditional treatments.

Among the core products are image-guided systems that provide highly accurate real-time information used for navigation during surgical procedures. This utility has been further expanded to serve as a computer terminal for physicians to more effectively access and interpret diagnostic scans and other digital medical information for better informed decisions.

BrainLAB solutions allow expansion from a single system to operating suites to digitally integrated hospitals covering all subspecialties from neurosurgery, orthopedics, ENT, CMF to spine & trauma and oncology. With 3300 systems installed in over 75 countries, BrainLAB is a market leader in image-guided technology.

The privately held BrainLAB group, founded in 1989, is headquartered in Munich, Germany, and today employs 950 people in 16 offices across Europe, Asia, Australia, North and South America.

For more information, visit BrainLAB at www.brainlab.com

About Ziehm Imaging

Ziehm imaging specializes in the development, manufacturing and worldwide marketing of mobile x-ray-based imaging solutions. The company has been market leader in Germany for more than seven years as well as in many other European countries for two years. Today, Ziehm Imaging is a global systems provider, employing over 250 people worldwide. Extensive in-house development know-how is reflected in the Ziehm Imaging C-arms' high medical imaging performance, intelligent generator technology, significant dose savings and seamless digital network integration. Building on competence and creativity, as well as continuous dialog and close cooperation with renowned universities, research centers and hospitals, Ziehm Imaging has developed groundbreaking technologies that have made the company a global trendsetter in intelligent interventional imaging. Ziehm Imaging products are known for their outstanding versatility and their easy handling for a wide variety of medical applications. In addition, they offer seamless integration into existing IT environments for digital image data acquisition, image evaluation and image management. Please see www.ziehm.com for more information.