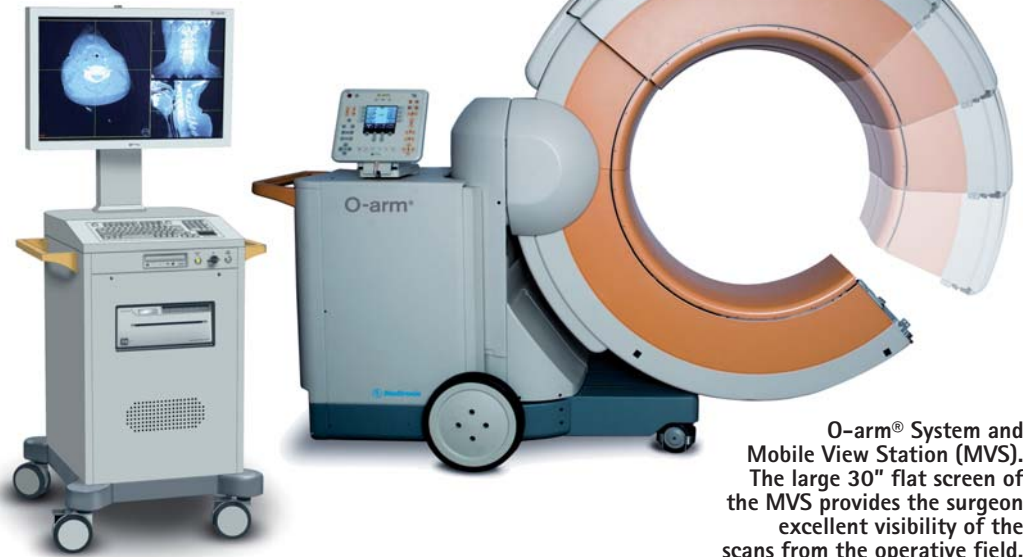


The future of mobile 2 and 3 dimensional intraoperative X-ray imaging today



O-arm® System and Mobile View Station (MVS). The large 30" flat screen of the MVS provides the surgeon excellent visibility of the scans from the operative field.

The O-arm® System - Changing Surgery

In the modern OR, two dimensional (2D) and three dimensional (3D) imaging is increasingly important for the surgical team striving for the best patient outcomes. The O-arm® System from Medtronic is a new innovative solution that offers both, full 3D volumetric scans and simple 2D fluoroscopic images.

The fully motorized system brings intra-operative X-ray imaging to a new level by providing excellent image quality, a large field of view and unparalleled ease of use to optimally support the surgical workflow.

Beyond imaging, the seamless interface with the StealthStation® navigation system makes surgical navigation easier than ever before. The unique combination of the O-arm® System with the StealthStation® navigation allows the surgical team to simplify their workflow and to treat complicated cases with confidence while reducing X-ray dose for surgeons and staff.

2D-fluoroscopy using C-arms has been the standard work horse for intra-operative spinal and orthopedic imaging for decades. Today, most hospitals are still limited to 2D fluoroscopy using standard C-arms, leaving it to the surgical team to figure out the true 3D anatomy of the patient. Recently, 3D C-arms and intra-operative CTs have been utilized to provide 3D imaging in the OR. While

these systems have some drawbacks in terms of usability in the OR, the O-arm® System is designed to take advantage of modern flat panel imaging technology and to optimally support the surgical workflow allowing the OR-team to fully concentrate on the patient.

"The clinical need for intra-operative imaging is driven by surgeons' desire to take advantage of minimally invasive procedures performed in critical areas provided that conditions of maximum safety are guaranteed. The O-arm® System satisfies entirely these requirements in spinal surgery," says Dr. D. Boscherini, Vice-Primario Neurochirurgia, Servizio Cantonale di Neurochirurgia, Lugano, Switzerland.

State-of-the-art Digital Imaging

The system's 2D and 3D imaging is based on the use of distortion free state-of-the-art digital flat panel technology. The 30cm x 40cm, 3 Megapixel (1.5k x 2k) detector enables an enhanced dynamic range and high spatial resolution. It provides high image quality and a large field of view.

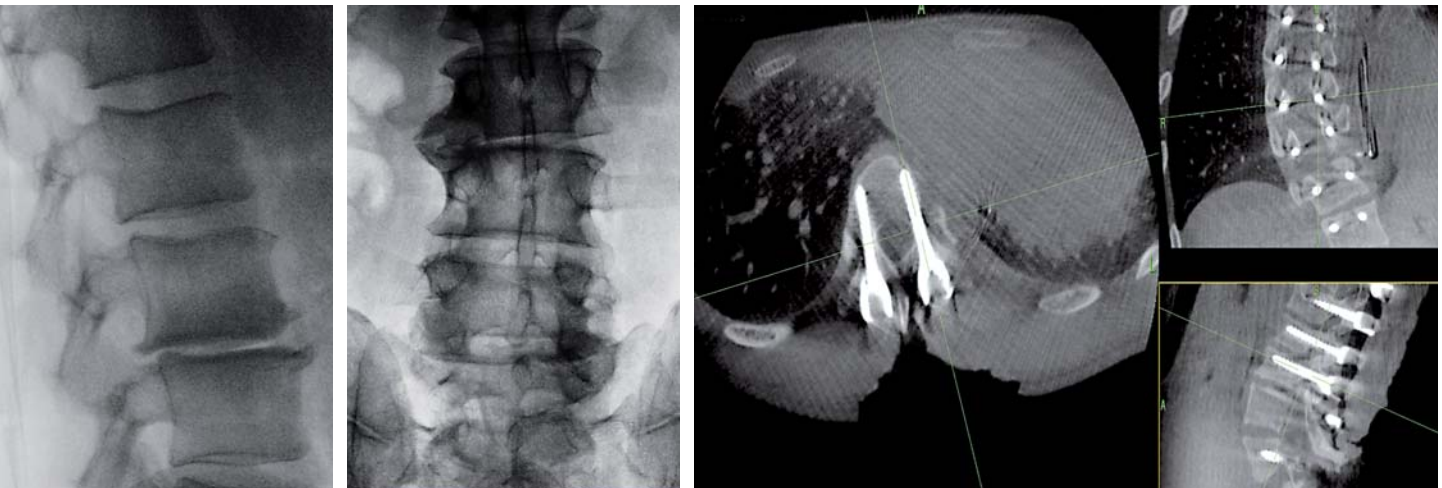
The O-arm® System combines the flat panel detector with a powerful 32kW X-ray generator to enable imaging of heavier patients or of hard to image regions like the cervical-thoracic junction.

Depending on the information needed, the surgical team can decide to obtain a full 3D scan or a simple fluoroscopic image.

In 2D-mode the imaged region is approximately three times bigger than the one shown by a classic 9" C-arm, simplifying the treatment of larger fractures and complicated trauma cases.

A 3D volumetric scan takes only 13 seconds. The closed O-arm® gantry allows the tube and detector to quickly rotate a full 360° without the risk of collision with the patient or OR equipment. A few seconds later the surgeon is presented with a multi-planar (axial, coronal & sagittal) 3D volume, similar to data from computed tomography (CT). This allows the user to see the scanned volume under any angle and provides precise information to the surgeon while the patient is still in the OR.

"We had the opportunity to clinically test different 3D intra-operative imaging devices before opting for the O-arm® Sys-



2 D Fluoroscopic image of the lumbar spine and 3D oblique view of a thoracic deformity case.

tem. Among other advantages, the fast acquisition time of 13 sec made a major difference for us. For example, imaging in the thoracic spine, which is a critical area for surgeon and more susceptible to respiratory movements, is explorable without compromise on image quality” says Dr. Boscherini.

The system’s large 3D scan volume reduces the need for image re-centering and allows surgeons to comfortably treat cases where a large image volume is needed. For example, a 13 second scan can typically capture the entire cervical spine. The O-arm® system supports the surgeon in critical cases or in hard to image regions like the thoracic spine where previously little or no imaging information was available. Surgeons can now evaluate the outcome of the surgery with a 3D volumetric scan before closing the patient and potentially avoid revision surgery.

In addition, the use of the O-arm® System can simplify the workflow and free up the Hospital’s CT for other patients by reducing the need for additional CT imaging before, during, and after surgery.

Designed to support the surgical workflow

When designing the O-arm® System, special care was taken to offer ease of use and to optimally support the surgical workflow to overcome the hurdles that today still limit 3D imaging in the OR.

All motions of the unit are motor driven and can be controlled by the touch of a button on the simple central control

panel. This allows every staff member to handle it easily, and to maneuver it in the crowded OR setting.

The O-shaped gantry can be opened and allows lateral access to the operating table, which is crucial to fit into the OR workflow. Once opened, the gantry can be draped in seconds to optimize the sterile environment during the entire surgery.

During surgery, the system allows storage of 4 user determined optimal im-

age positions and a Park position. By simply pushing one button, these positions can be recalled whenever needed during surgery. When a new acquisition is required, the gantry is quickly recalled to the exact same imaging position as the earlier acquisition. This capability can eliminate the need for additional scout shots thereby limiting x-ray exposure and time loss to get back to the previous position.

O-arm System® used in combination with navigation during surgery.



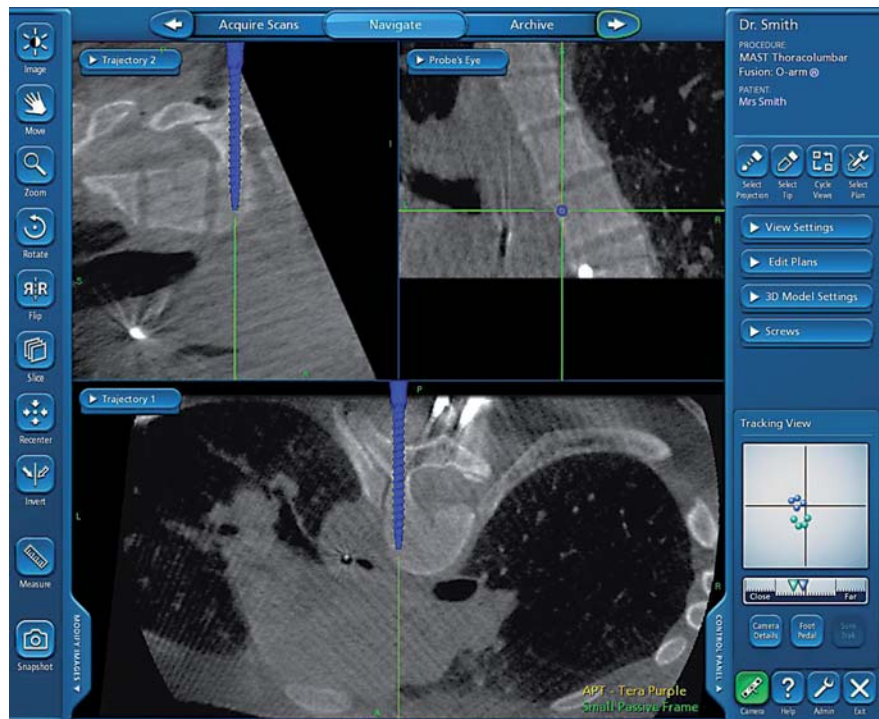
The ability to store multiple positions normally eliminates the need for multiple C-arms and allows the surgeon to within seconds 'park' the gantry out of his/her way. Motorization and position memory are time effective solutions that reduce the risk of errors due to manual movements and that help create a controlled environment for the surgery.

In my OR, the scrub nurses prefer to use the O-arm® System, rather than the 2D fluoroscopy, because of its robotic functions. With one touch on a button, the O-arm® System slides carefully into the correct position. It therefore is time-saving and limits X-Ray exposure to the personnel to the minimum." says Dr. E. Van de Kelft, Neurosurgeon, AZ Nikolaas, Sint-Niklaas, Belgium.

O-arm® and Navigation – Enabling Advanced Surgery

Radiation free surgical navigation tracking technology provides the surgeon with full 3D information about the position of surgical instruments in relationship to the patient's anatomy, thereby, reducing the X-ray exposure to patient, surgeon and staff.

The O-arm® System seamlessly interfaces with the StealthStation® navigation



Full 3D information available on the screen of the StealthStation navigation system guides the surgeon. If needed updated image information is imported automatically from the O-arm® System.

system. This solution provides automatic data transfer of the patient's 3D data as well as of the AP and lateral images. Automatic patient registration eliminates the need for lengthy manual patient registration and allows the surgeon to navigate on 3D images of their patient in the actual operative position, taken less than a minute earlier. If needed, updated image information can be easily obtained from the O-arm® System at any time. This fully empowers the use of navigation. The combined use of the O-arm® System with StealthStation® navigation enables advanced surgery. It is an ideal tool to support the surgeon in the treatment of difficult cases like complex deformities or fractures, while increasing patient security and reducing X-ray exposure of surgeon, staff and patient.

"The combination of 3D intra-operative imaging and surgical navigation with reduced radiation exposure guarantees the highest possible level of excellence in surgical treatment of complex spine patients", says Dr. M. Oertel, Neurosur-

geon, University Clinic in Giessen, Germany. This combination is also an ideal tool for hospitals interested in minimally invasive surgery (MIS). MIS has the potential to reduce patient trauma, hospital stay and to speed up return to work.

"O-arm® System assisted navigation technique during minimal invasive TLIF increases safety of the procedure because of high quality 3D images delivered during surgery. In 20 consecutive cases, all screws were correctly placed as confirmed by the intra-operative as well as post-operative CT-scan." says Dr. E. Van de Kelft.

Conclusion

In conclusion, the O-arm® System is an outstanding imaging tool for the modern OR that will allow a hospital to stand out in its health community and to attract patients and surgeons.

Its intra-operative 3D image capabilities and the combination with surgical navigation allow the surgical team to approach their cases in new ways and to treat complicated cases with confidence. The additional image information and the better controlled environment will potentially improve patient security and outcome of the surgery.

Features and Benefits of the O-arm® System

Motion Control of gantry

- Linear x,y,z
- Rotational Wag
- Iso -Wag
- Tilt
- including detector position and x-ray settings

Screen control with wireless sterile mouse

3D Scan

- Volume 15cm (height) x 20cm (diameter)
- 0.83mm axial slice thickness, 0.415 coronal and sagittal slice thickness

Digital Data Transfer

- fully DICOM 3 compatible
- USB stick, CD/DVD-ROM