

SURGIVISIO: Unified Surgical Platform

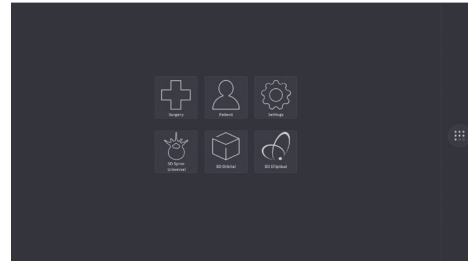
2D Fluoroscopy • 3D Imaging • Navigation



Benefits:

- **Automatic registration of the 3D volume**
- **Real-time compensation of respiratory movements**
- **3D Low dose technology***
- **Pediatric mode**
- **Open platform compatible with all MIS spinal fusion system**

*Rousseau J, Dreuil S, Bassinet C, Cao S, Elleaume H. Surgivisio® and O-arm® 02 cone beam CT mobile systems for guidance of lumbar spine surgery: Comparison of patient radiation dose. Phys Medica Eur J Med Phys. 1 mai 2021;85:192-9.



Intuitive user interface

- The "home" button provides direct access to the home screen and patient files at any time during the procedure.
- The system is controlled by icons that provide direct access to the various functions and steps of the surgical protocol.

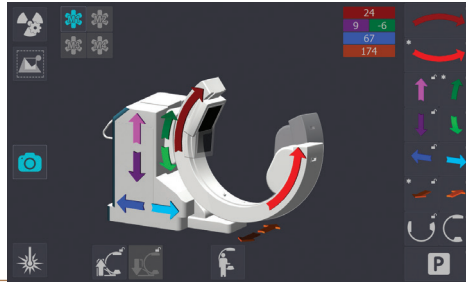


Total control at the fingertips

- Two 16:9 22" displays allow access to a full menu of options. The left screen shows X-ray sequences and last image hold (LIH), while the right one gives you access to 3D image visualization and navigation functions, as well as patient files.
- Two duplicated displays control the operation of the C-arm, including one on a remote panel for easy use in sterile areas.
- The remote panel controls the movements and position of the C-arm, and the preset of up to four positions, screenshots and X-ray exposure parameters.

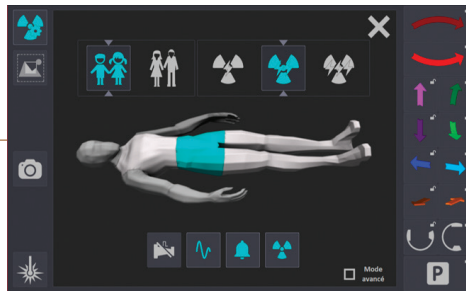
Universal Surgical Platform 2D Fluoroscopy - 3D Imaging - Navigation





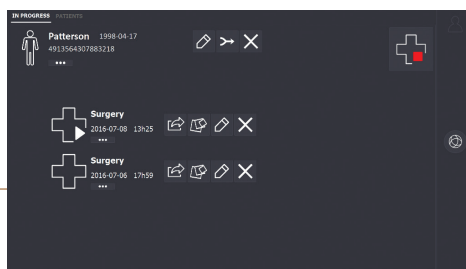
Robotic C-arm

- 5 motorized axes, including unlimited translation along the table, guarantee total accessibility to the operating field.
- Optimized trajectory of the C-arm increasing the reconstructed 3D volume.
- Anti-collision system allowing the C-arm to automatically stop at 1 cm from the detected obstacle, protect against any risk of collision with the patient.
- 2D or 3D intraoperative control.
- 3D Elliptical App allowing a 3D acquisition for intraoperative control with or without metallic material.



Low dose technology

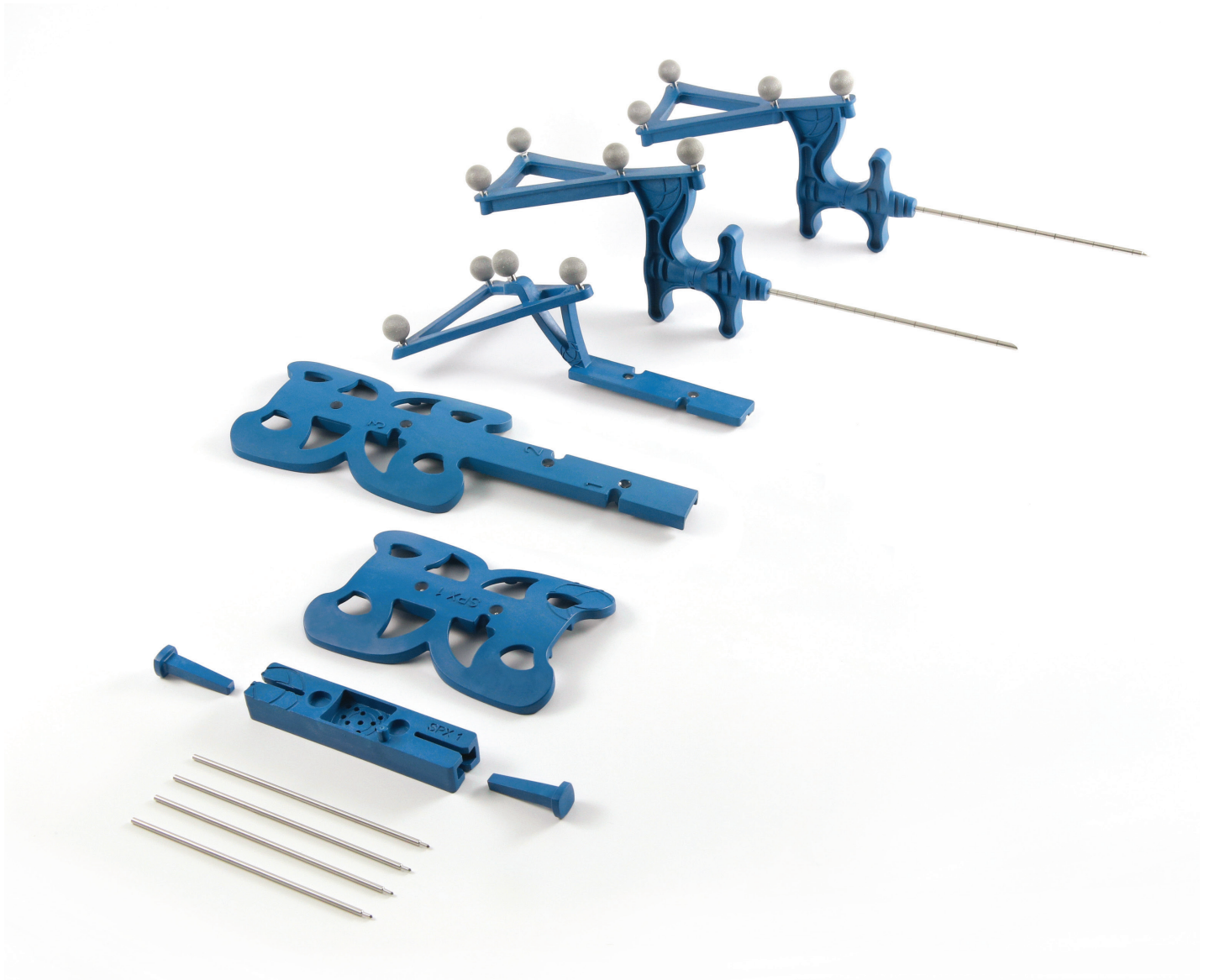
- 3D acquisition from 90 or 180 images.
- Radiation source located at the furthest distance from the patient in accordance with the ALARA principle (As Low As Reasonably Achievable).
- Easy selection of the Area of interest on the 2D image using the collimator in order to reduce radiation exposure of the adjacent areas.
- Pulsed 2D fluoroscopic or fluorographic imaging with automatic regulation: X-ray parameters automatically adapted to the area of interest for optimum brightness.



Automatic backup

- Automatic backup of all images generated on the system's hard drive.
- Platform compatible with the DICOM 3.0 standard to facilitate export of images and dosimetry reports to the PACS or to a USB drive.

● Pre-calibrated single-use instrumentation



Plug & Play

- Each component of the kit is matched with an identification card which is simply inserted into the system for automatic identification.



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LEGAL MANUFACTURER:

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Simplified joint stock company with share capital of €46,415.16

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Intended use: intraoperative x-ray imaging and surgical spine navigation medical device.
SURGIVISIO Class IIb medical device CE0459.

- 3D Imaging Set SPX1 - 3D Offset Imaging Set SPX1 > classe I.
- Broach Set SPX1 - Navigated Targeting Needles SPX1 - Navigation Sets SPX1 > classe IIa.

Carefully read the instructions in the user manual.

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ECENTIAL ROBOTICS SAS is the manufacturer of the X-ray imaging device and associated software and sterile instruments.

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