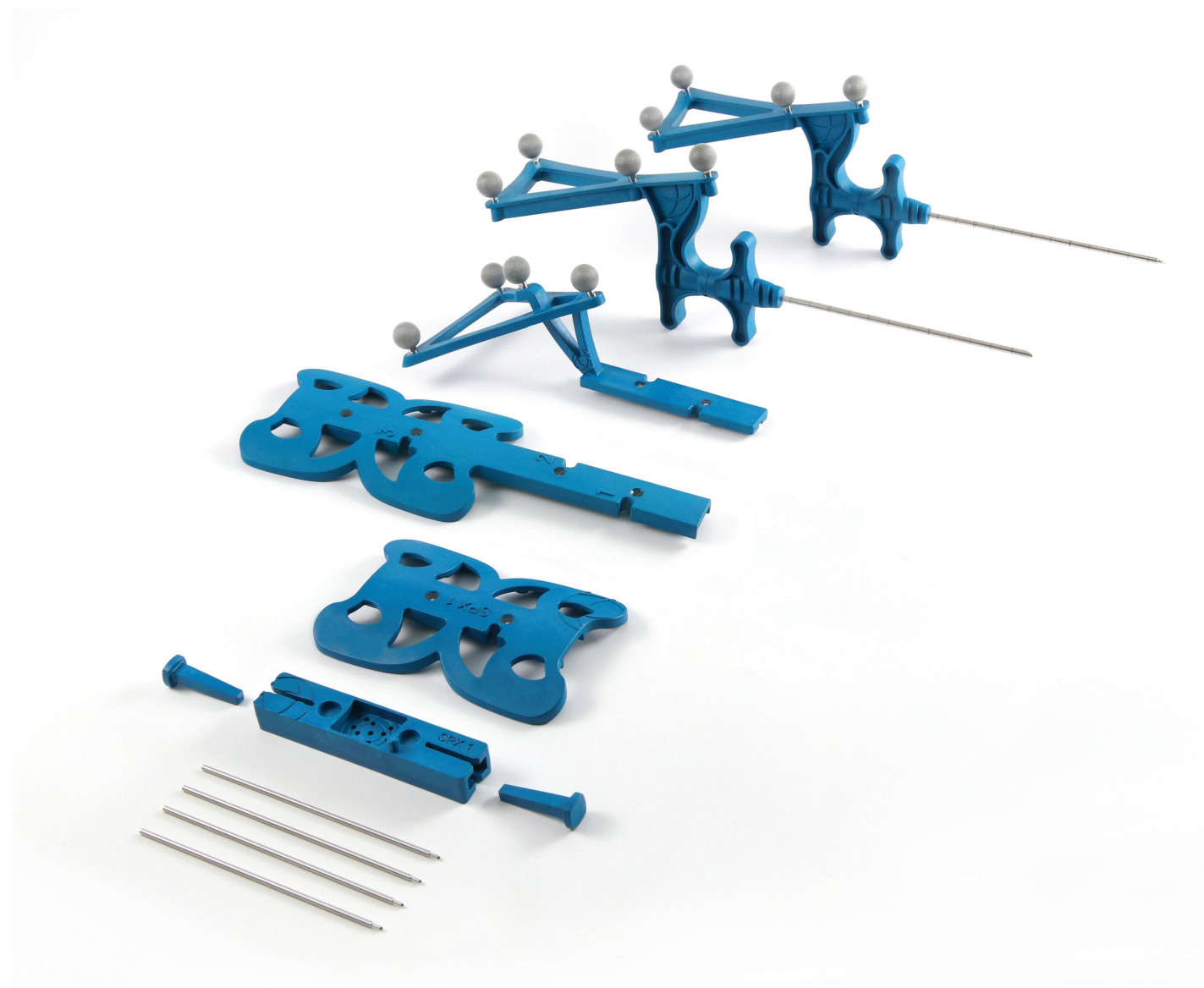


● Pre-calibrated single-use instrumentation



Plug & Play

- Identification card for each component of the single use kit to upload individual pre-calibration data to the system.

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www.encial-robotics.com

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LEGAL MANUFACTURER:

ECENTIAL ROBOTICS

2, avenue de Vignate
Zone de Mayencin II - Parc Equation - Bâtiment 1
38610 Gières - France

Intended use:

The SURGIVISIO Device through its freehand navigation feature is intended as an intraoperative guidance system to enable open or percutaneous computer-assisted surgery.
The SURGIVISIO Device through its robotic guidance feature is intended for the positioning of instrument holders or tool guides to be used by surgeons to guide the Spine CoBot instruments during general spinal surgery.

SURGIVISIO Device - Regulatory Class II.

FDA Cleared: K221028 Trade/Device name: SURGIVISIO Device.

Carefully read the instructions in the user manual.

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

Unified Surgical Platform

2D & 3D Imaging • Navigation • Robotics



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Unified Surgical Platform

2D & 3D Imaging - Navigation - Robotics

Benefits:

- Automatic registration of the 3D volume
- Real-time compensation of respiratory movements
- 3D Low dose technology*
- Open platform compatible with multiple spinal fusion systems
- Seamless and precise robotic guidance**



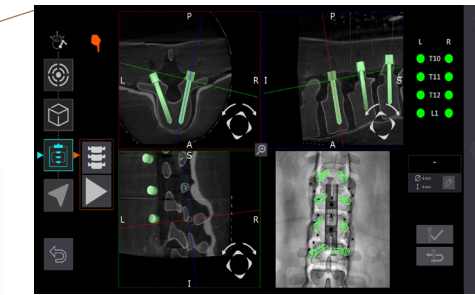
Unified User Interface

- Unified user interface to control all the system functionalities.



Robotic guidance

- Collaborative robot handling.
- Automatic instrument alignment for pedicle trajectory.
- Workflow control from the sterile area.



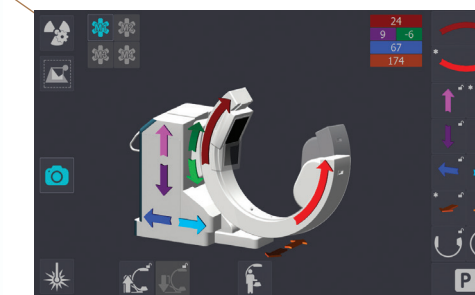
Planning

- Intraoperative planning on 3D image with patient in surgical position.
- Automatic pre-positioning of implants & intuitive interface for planning adjustment.



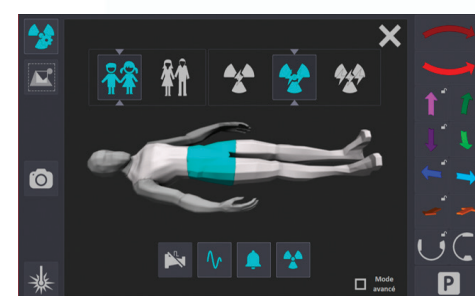
Navigation

- Automatic registration of the patient with 3D image.
- Single-use instrument, pre-calibrated and identified by QR code.
- Real-time visualization of trajectory on the 3D image.



Robotic C-arm

- 5 motorized axes, including unlimited translation along the table.
- Optimized trajectory of the C-arm enabling an increased reconstructed 3D volume.
- Sensor system detecting obstacles and preventing collisions.
- Compatible with a standalone 2D or 3D imaging usage.



Low dose technology

- 3D reconstruction from 90 or 180 images.
- Radiation source located at the furthest distance from the patient during 3D acquisition in accordance with ALARA principle (As Low As Reasonably Achievable).
- Pulsed 2D fluoroscopic or fluorographic imaging with automatic dose regulation.

*Julia Rousseau, Serge Dreuil, Céline Bassinet, Sophie Cao, Hélène Elleaume
DOI: <https://doi.org/10.1016/j.ejmp.2021.04.018>

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