Accelerating Minimally Invasive Spine Surgery

A Revolution in Robotics: As we look to the future of spine care, new advancements in technology are changing the way surgeons treat patients, while enabling technologies are providing more cost-effective solutions that optimize surgical workflow and elevate the standard of patient care. Included in these technologies is the Accelus Robotic Navigation System that offers a cost effective, compact, portable design, with advanced computational software to lead the way in the next generation of navigated robotics.

Indications for Use: The Accelus Robotic Navigation System received 510(k) clearance by the U.S. FDA on February 24, 2021. It is intended for use as an aid for precisely locating anatomical structures and for the spatial positioning and orientation of a tool guide (tool holder or guide tube) to be used by surgeons for navigating and/or guiding compatible surgical instruments in open or percutaneous spinal procedures in reference to rigid patient anatomy and fiducials that can be identified on an O-arm scan. The Accelus Robotic Navigation System is indicated for assisting the surgeon in placing pedicle screws in vertebrae in the posterior lumbar region (Ll-S1). The system is designed for lumbar pedicle screw placement with the patient in the prone position and is compatible with the LineSider Pedicle Spinal System.

Accelus Robotic Navigation System Technical Characteristics: The Accelus Robotic Navigation System uses optical tracking of navigated surgical instruments, while trajectory software provides real time visualization relative to the registered model of the patient's anatomy. This ability to preplan the surgical workflow, partnered with advanced computational software,[1,2] allows the surgeon to practice the art of surgery, while the navigation system performs the computational tasks of pedicle screw placement.

A registration array is placed during image acquisition to ensure images are relative to the location of the patient's anatomy. This is achieved using a camera affixed to the patient's pelvis to ensure that the registration remains accurate even in the event that the patient's position shifts.[1-5] The controller component of the system allows for both manual macro adjustments and force-controlled movement of the systems targeting platform, to align the tool guide with the preplanned surgical trajectory.

Figure 1. Accelus Robotic Navigation System including nearfield camera (200 g) and robotic arm (2.2 kg) affixed in the storage position to the display monitor and cart.

The Accelus Robotic Navigation System is cost effective, compact, and portable compared to other leading robotics navigation systems currently on the market, affixing to the OR surgical bed, while meeting industry standards for navigation accuracy within <2mm under worst-case simulated use conditions.[1-5]

Advanced Line of Sight: The Accelus Robotic Navigation System utilizes a monocular camera mounted on the patient's pelvis to track navigated instrumentation using dynamic referencing for precise placement of LineSider pedicle screws.[1-3]

The Accelus Robotic Navigation System provides the surgeon with freedom to manually locate the robotics module (Targeting Platform) in the general area of the planned surgical location.[1-4] After, the Targeting Platform automatically micro adjusts the location and trajectory, allowing for fine tune alignment prior to pedicle screw placement.[1-4] These macro and micro adjustments can all be made by the surgeon, while maintaining registration and conserving space within the OR.[1-5]

Note: The Accelus Robotic Navigation System is currently intended to be used with intraoperative 3D imaging (O-arm) only for producing the most accurate model of the patient anatomy, while 2D fluoroscopic imaging capabilities are under development.

Accuracy: Performance testing for the Accelus Robotic Navigation System, demonstrated accuracy of pedicle screw placement to within less than 2.0 mm using the LineSider Spinal System. These performance results are consistent with those reported by other leading spine navigation systems (<2.0 mm tracking accuracy).[1-4]

Surgical Efficiency: The compact design of the Accelus Robotic Navigation System, coupled with advanced computational software, has resulted in surgical efficiencies in the operating room when compared to leading robotic navigation systems.[5]

A recent study of the Accelus Robotic Navigation System against a leading competitor demonstrated statistically significant reduction in operative time, with a statistical reduction (increase surgical efficiency) in system set-up time ($p<0.05$), operative planning to in-position time ($p<0.05$), and total procedure time ($p<0.05$).[5]

Per the Iampreechakul et al grading system, all pedicle screws placed in the study for both groups were determined to be grade A on the post-placement images with no significant difference between the systems.[5,6] In addition, all placed pedicle screws were accurate compared to the surgical plan with both systems. However, the Accelus System performed with a statistically significant reduction in workflow time. This study demonstrated an increase workflow efficiency while maintaining the pedicle screw placement accuracy for the Accelus system that surgeons demand.[5]

One limitation of the study is the comparative assessment of system breakdown. This metric was collected for the Accelus Robotic Navigation System but was not available for the leading competitor from the cited literature.[5] The breakdown time for the Accelus Robotic Navigation System was 2.4 ± 0.3 minutes.[5]

System Design: With its ultra-lightweight nearfield camera (200 g) and robotic arm (2.2 kg) attached the surgical bed, the Accelus Robotic Navigation System has a minimal footprint of 30” x 30”. This positioning minimizes common line-of-sight and dynamic referencing challenges of competitive systems. When not in use, the portable system components can be disassembled for cleaning and stored within the cart maximizing space within the operating room.

LineSider Spinal System: The LineSider Spinal System is designed to accommodate a variety of surgical options with the use of the Accelus Robotic Navigation System. The proprietary screw tip design offers unique thread geometry, in an array of configurations, while a mandible tip facilitates engagement of bony anatomy, to ensure surgeons have the right tools for the highest standard of patient care.

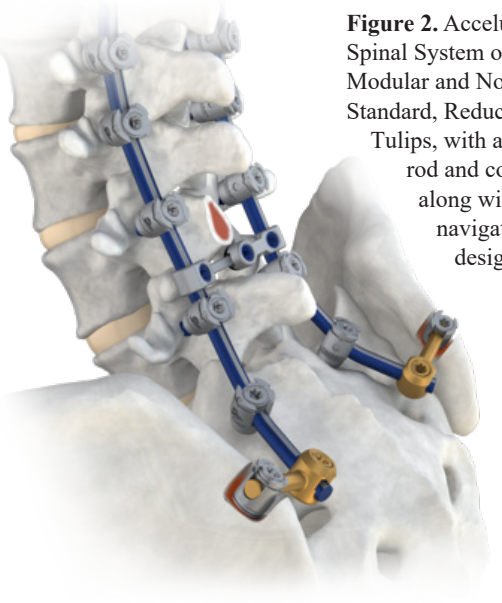

Figure 2. Accelus LineSider Spinal System offers both Modular and Non-Modular Standard, Reduction, and MIS Tulips, with an assortment of rod and connector options along with thoughtful navigated instrument design

References: 1. Surgical Usability Testing on file at Accelus: A simulated operating room environment controls variables to evaluate clinical viability, utility and ease-of-use for surgeons and surgical staff. Acceptance Criteria: Full completion of simulated-use tasks. Results: All test cases were successfully performed, screw placements were confirmed by surgeons and staff using O-arm and fluoroscopic imaging modalities.
2. CT Imaging Validation on file at Accelus: Independent surgeon review of pedicle screws placed with the Accelus Robotic Navigation System to validate that the final placement matches the surgical plan with clinical efficacy. Acceptance Criteria: 100% clinical efficacy. Results: 100% confirmation of clinical efficacy relative to the surgical plan.
3. ASTM F2554-10 Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems. A test fixture calibrated to accuracy testing software evaluated deviations in the positional accuracy of instruments tracked by the camera. Acceptance Criteria: Accuracy of <2.0 mm with 95% confidence by all measures.
4. Cadaveric Accuracy Validation on file at Accelus: Evaluation of pedicle screw positional accuracy using a formulated cadaveric ground truth, PSIS pin and dynamic referencing. Acceptance Criteria: Accuracy of <2.0 mm with 95% confidence by all measures. Results (mm): Dynamic Referencing: 0.985; PSIS Pin and Arm: 0.845.
5. Soliman M A, Khan A, O’Connor T E, et al. Accuracy and efficiency of Fusion Robotics™ versus Mazor-X™ in single-level lumbar pedicle screw placement. Cureus. 2021;13(6): e15939. doi:10.7759/cureus.15939.
6. Iampreechakul P, Chongchokdee C, Tirakotai W. The Accuracy of Computer-Assisted Pedicle Screw Placement in Degenerative Lumbrosacral Spine Using Single-Time, Paired Point Registration Alone Technique Combined with the Surgeon’s Experience. J Med Assoc Thai 2011;94:337.