# Surgeon-Controlled, Robotically Navigated Spine Surgery with Remi™

The Remi™ Robotic Navigation System has changed the way spinal robotics and navigation have traditionally been approached by offering a cost-effective, efficient, and compact solution. Remi's surgeon-centric software, coupled with innovative hardware, streamlines the image acquisition, trajectory planning, and navigation workflow while allowing the surgeon to be fully engaged in the surgical process.

## SURGEON-CONTROLLED, ROBOTICALLY NAVIGATED SURGERY

The Remi system allows for real-time positioning of the trajectory platform and navigated instruments utilizing optical marker arrays mounted to the targeting platform and instruments. The system allows surgeons to optionally position the Remi targeting platform within the general area of the planned surgical location before it automatically micro-adjusts trajectory to match the surgeon's pre-determined surgical plan.[1-4]

Utilizing a proprietary end effector, not available in other robotic systems, the targeting platform allows the surgeon to make any necessary micro-adjustments to the trajectory while displaying the instrumentation live on the navigation screen. These surgeon-controlled adjustments, combined with the system's automatic robotic navigation and positioning, provide surgeons a new level of control with demonstrated accuracy of less than 2mm.[1-5]

## ADVANCED LINE OF SIGHT

The system's near field, monocular camera detects the markers, determines their spatial positions, and reports the information to the workstation continuously throughout the procedure. The "fisheye" camera is draped and affixed to the surgical bed and connected to the patient's pelvis with a PSIS pin, providing a wide field of view with unmatched visualization for accurate pedicle screw placement. Its close proximity to the surgical field vastly reduces the line-of-sight issues commonly seen with competitor systems that require their camera be placed six feet away from the patient.

## SURGICAL EFFICIENCY

The thoughtful design of the Remi system has resulted in surgical efficiencies in the operating room when compared to leading robotic navigation systems.[5] A recent study pairing Remi (Fusion Robotics) against a leading competitor demonstrated a statistically significant reduction in operative time, with a sttistically significant reduction 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]

| Procedure Time (in minutes) | Remi™ (Fusion Robotics) group, mean ± SD | Competitive System group, mean ± SD | P-value |
|---|---|---|---|
| System set-up | 2.4 ± 0.2 | 7.8 ± 1.2 | <0.05* |
| Create sterile barrier "ready for scan" | 4.3 ± 1.5 | 5.1 ± 1.8 | 0.5 |
| Scan and import | 7.9 ± 2.8 | 7.7 ± 3.1 | 0.9 |
| Create plan | 2.6 ± 0.5 | 2.5 ± 0.5 | 0.8 |
| Plan to in-position for screw 1 | 3.8 ± 0.5 | 12.7 ± 5 | 0.05* |
| Pre-placement of screw | 21 ± 2.1 | 35.8 ± 14.9 | 0.1 |
| Screw 1 placed | 2.9 ± 0.7 | 4 ± 1.6 | 0.3 |
| Screw 2 placed | 4.7 ± 1.4 | 3.8 ± 2 | 0.5 |
| Screw 3 placed | 4 ± 0.5 | 4.3 ± 2.9 | 0.9 |
| Screw 4 placed | 3.8 ± 0.3 | 3 ± 0.7 | 0.1 |
| Time/screw | 3.9 ± 1.1 | 3.8 ± 2 | 0.9 |
| PSIS pin placement | 0.3 ± 0.1 | 0.3 ± 0.1 | 1 |
| Total time | 36.6 ± 4.4 | 55 ± 1.9 | 0.05* |

**Statistically significant*

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


## LINESIDER SPINAL SYSTEM

The Remi system has been cleared for use with the LineSider Spinal System. The LineSider Spinal System offers surgeons a variety of approach options to use in conjunction with the Remi Robotic Navigation System. The Remi system's screw tip offers unique thread geometry, while a mandible tip facilitates purchase upon first engagement of bone. These features, available in an array of thread configurations, facilitate quick bite of the pedicle upon engagement of the anatomy.

## INDICATIONS FOR USE

The Remi 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 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 Remi 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 Accelus LineSider Spinal System.

*Note: The Remi Robotic Navigation System is currently intended to be used with intraoperative 3D imaging (O-arm) although 2D fluoroscopic imaging capabilities are under development.*

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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, and 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 sc rews placed with the Remi 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 Accuracy Verification Testing on file at Accelus: A test fixture calibrated to accuracy testing software evaluated deviations in the positional accuracy of instruments tracked by the camera. Acceptance Criteria: Accuracy of <2.0mm 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 <2.0mm 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. (June 26, 2021) Accuracy and Efficiency of Fusion Robotics™ Versus Mazor-X™ in Single-Level Lumbar Pedicle Screw Placement. Cureus 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 techniquecombined with the surgeon's experience. J Med Assoc Thai. 2011, 94:337-45.