----- THE CHALLENGES

Accuracy for screw placement is one of the key factors that determines the success of spinal fusion surgeries.

Teaching residents how to place pedicle screws accurately can be a challenge.

Current monitoring modalities provide information of nerve damage after the fact.

Radiation exposure in spine surgery can be excessive, protection is underutilized and the long-term biological effects can be deadly.

Current navigation techniques require extensive pre-operative preparation and reliance on cumbersome equipment

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Ce o123 Caution: See package insert for labeling limitations, intended uses, relevant warnings, precautions, side effects and contraindications. Federal (USA) law restricts the sale and use of this device to a prescription of a physician.



PediGuard[®] **devices** with DSG[®] Technology (Dynamic Surgical Guidance)

ACCURACY - - -

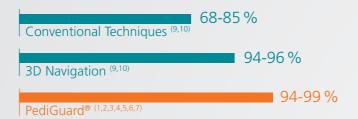
Continuous monitoring of electrical conductivity of the tissue at the tip of the PediGuard device allows for pedicle preparation with a high degree of accuracy:

97% screw placement accuracy (1,2,3,4,5,6,7)

98% probability of breach detection ⁽⁸⁾

3-times fewer pedicle perforations than with free-hand technique ⁽⁴⁾

Rates of properly placed screws (%)



REDUCED RADIATION -

Usage of the PediGuard probe can significantly reduce reliance on intraoperative fluoroscopic imaging:

Less X-ray exposure, particularly in MIS

73 % Radiation time reduction in MIS⁽¹¹⁾ Reduction in thyroid radiation exposure to surgeon in MIS⁽¹¹⁾ Reduction in fluoroscopy shots during pedicle screw placement in open^(1,3,4)

The bipolar sensor measures real-time changes in electrical conductivity of the tissue five times a second.

ALLOWS REDIRECTION TO AVOID NEURAL OR VASCULAR DAMAGES (12)

- 87% breach anticipation: 100% anticipation into the pedicle, 72% in the anterior vertebral body and 79% in the lateral vertebral body
- 100% successful redirection without a breach after anticipation of an impending pedicle wall breach

MINIMIZES RATE OF BREACH AND AVOID COMPLETE BREACH

- 58% breach rate reduction among residents (13)
- 3 times reduction in neuro-monitoring alarms⁽¹⁴⁾
- · 98% probability of breach detection in clinical study⁽⁸⁾
- 100% breach detection in cadaveric study⁽¹²⁾

REDUCES SURGICAL TIME (4)

· 15% surgical-time savings during screw placement

- - SIMPLICITY

The self-contained PediGuard probe provides significant and relevant information without additional equipment, pre-operative preparation or change in the surgical technique.

The PediGuard probe is a simple, yet effective, teaching tool. The audio signals from the PediGuard probe help the supervising surgeon to comprehend the trajectory of the device when used by a resident or fellow. This allows the supervising surgeon to advise any redirection without the use of excessive radiographic imaging.

DSG[®] Technology: Simple. Accurate. Smart.