

SpineGuard is sponsoring a multicenter U.S. *postmarketing* study of its FDA-cleared device, *PediGuard*®...

Making Spine Surgery Safer for Patients *and* Doctors.

PediGuard®, from SpineGuard, is the world's first and only wireless, hand-held instrument capable of accurately detecting changes in tissue type, thus alerting surgeons to potential pedicular or vertebral breaches during pedicle screw site preparation. **Real-time feedback** is provided to surgeons via audio and visual signals, giving them new additional information. Equally important, the use of PediGuard requires no change in surgical technique.

"Anything we can do to help us get a safer screw insertion is certainly worthwhile, given that published rates of pedicle screw misplacements can be as high as 40 percent," says Dr. Randy Betz, a member of the editorial board of the *Journal of Pediatric Orthopaedics*.

Safer for Surgeons, Too
Without the use of PediGuard, *fluoroscopy* is used to continuously monitor correct placement of pedicle screws. Fluoroscopy is an imaging technique commonly used to obtain real-time images of the internal structures of a patient through the use of a fluoroscope (C-Arm). Fluoroscopy involves use of x-rays; while exposure to a patient during one surgery is minimal, spine surgeons may perform 140 or more cases per year. On the other hand, surgeons who use PediGuard do not have to use continuous fluoroscopic guidance. Indeed, use of PediGuard may reduce surgeons' radiation exposure by 30 percent.



Randal R. Betz, MD
Editorial board, *Journal of Pediatric Orthopaedics*, and associate editor, *Spinal Frontiers*; principal investigator in the ongoing clinical study of PediGuard.



Luis F. Vasquez, MD
Ass't Prof., Texas Tech Univ. Health Science Center (TTUHSC) School of Medicine at El Paso, Neurosurgery Division, and has been using PediGuard as standard of care in his spine practice for several years.

"PediGuard is used in many spine surgeries that require the placement of pedicle screws. It can clearly detect more breaches that are blind to the surgeon, thus making surgery safer."

"PediGuard can reduce radiation risk for surgeons, who get twice the acceptable level of exposure to radiation per year when they use fluoroscopy without PediGuard to place pedicle screws."



Rx Only! See package insert for labeling limitations, intended uses, relevant warnings, precautions, side effects and contraindications.

"Less use of fluoroscopy per case means significantly less accumulated radiation exposure over the course of a typical year's worth of cases," says Dr. Betz. "PediGuard is used in many spine surgeries that require placement of pedicle screws." ■

How PediGuard Works

The scientific principle underlying PediGuard® is based on the electrical conductivity (property of a material to allow current flow) of tissues. When electrical conductivity changes, the surgeon is alerted by changes of:

- Sound pitch and cadence
- Flashing LED cadence

Powerful Detection

- Cortical, cancellous bones & soft tissues are differentiated
- Even small breaches can be detected (99% of accuracy)
- True real-time monitoring: immediate alert of vertebral pedicle breach
- Works on all spine levels (lumbar, thoracic & cervical)

Key Benefits¹

- Reduction of pedicle breach risk and revision rate
- Less radiation exposure (up to 30% less)
- Time and cost savings
- Decrease the residents' surgical learning curve

Ease of Use

- No change in surgical procedure
- Brief learning curve
- No capital equipment required
- No additional personnel needed

The PediGuard® technology is effective in Minimally Invasive Surgery (MIS).

PediGuard® is currently marketed in more than 20 countries. To date, more than 7,000² procedures have been performed with PediGuard.

¹ *PediGuard™: A Solution for the Challenges of Pedicle Screw Placement*, Randal R. Betz, MD, Amer F. Samdani, MD, Mladen Djurasovic, MD, Stewart I. Bailey, MD, Courtney Brown, MD, JahanGir Asghar, MD, Linda P. D'Andrea, MD, John Dimar, MD, Harry L. Shufflebarger, MD, John Gaughan, PhD, Temple University Journal. Volume 3. Spring 2008. ² Data on file.