

## Making Spine Surgery Safer for Patients and Doctors

PediGuard®, from SpineGuard, is the world's first and only wireless, handheld 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. "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."

## What Surgeons are Saying

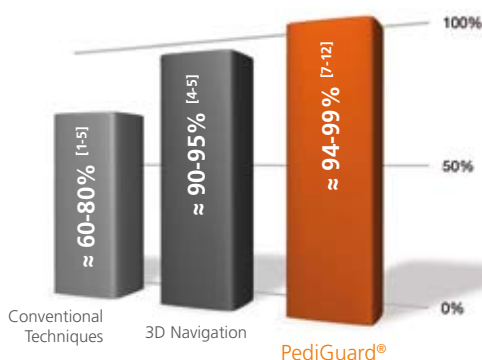
"PediGuard can reduce radiation risk for surgeons, who get twice the acceptable level of exposure to radiation per year when they use fluoroscopy without PediGuard to place pedicle screws."

*- 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.*

(continued on back)



# Proven Efficiency



- **99% probability of detection** if there is a breach
- **Provides a 3 fold reduction** in neuro-monitoring events
- **Doubles the detection rate;** even small breaches can be detected
- **Time saving technique** reduces screw placement time
- **Decreases radiation exposure** by up to 30%



## 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 Benefits

- 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
- Effective in Minimally Invasive Surgery (MIS)

## Ease of Use

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

## SpineGuard

Product Profile 2011

Privately Held

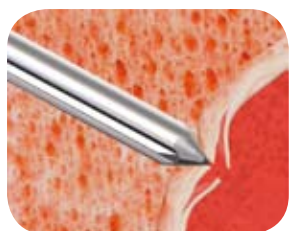
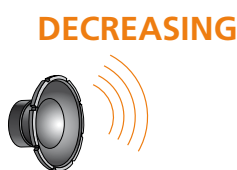
Sector: Medical Device/Spine



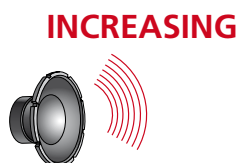
Tip in **CANCELLOUS BONE:**  
**MEDIUM** pitch, **MEDIUM** cadence



Tip approaching **CORTICAL BONE:**  
**LOW** pitch, **LOW** cadence



Imminent **CORTICAL BREACH:**  
**HIGH** pitch, **HIGH** cadence



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