

# PediGuard®



Electrical Circuit Board

Provides audio / visual feedback which can alert the surgeon prior to a breach

## The Challenge

### Accuracy of pedicle screw placement remains a critical issue in spine surgery.

In recently published papers studying screw placement accuracy:

- The average rate of misplaced screws using conventional techniques is around **20%** (Tian 2011, Gelalis 2011, Verma 2010)
- The average rate of misplaced screws using navigation is around **8%** (Tian 2011, Gelalis 2011, Verma 2010)
- Up to **40%** of patients have screws of concern (106 patients / 2,229 screws). Screws of concern are qualified as: adjacent to aorta, viscera or 2-4mm breach OR impinging on aorta, viscera medial displacement greater than or equal to 4mm (Wollowick, 2011)

### Consequences of misplaced pedicle screws are not to be underestimated.

Literature reviews and clinical studies recently published suggest that:

- **2.3%** of patients (29/1,254) presented neurologic complications due to misplaced screws placed free hand with or without fluoroscopy (Gelalis 2011, Verma 2010)
- **4.7%** of patients (7/148) showed screw proximity (7/1,797 screws) to the aorta requiring a revision surgery (Sarлак 2009)

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SpineGuard®  
Make spine surgery safer

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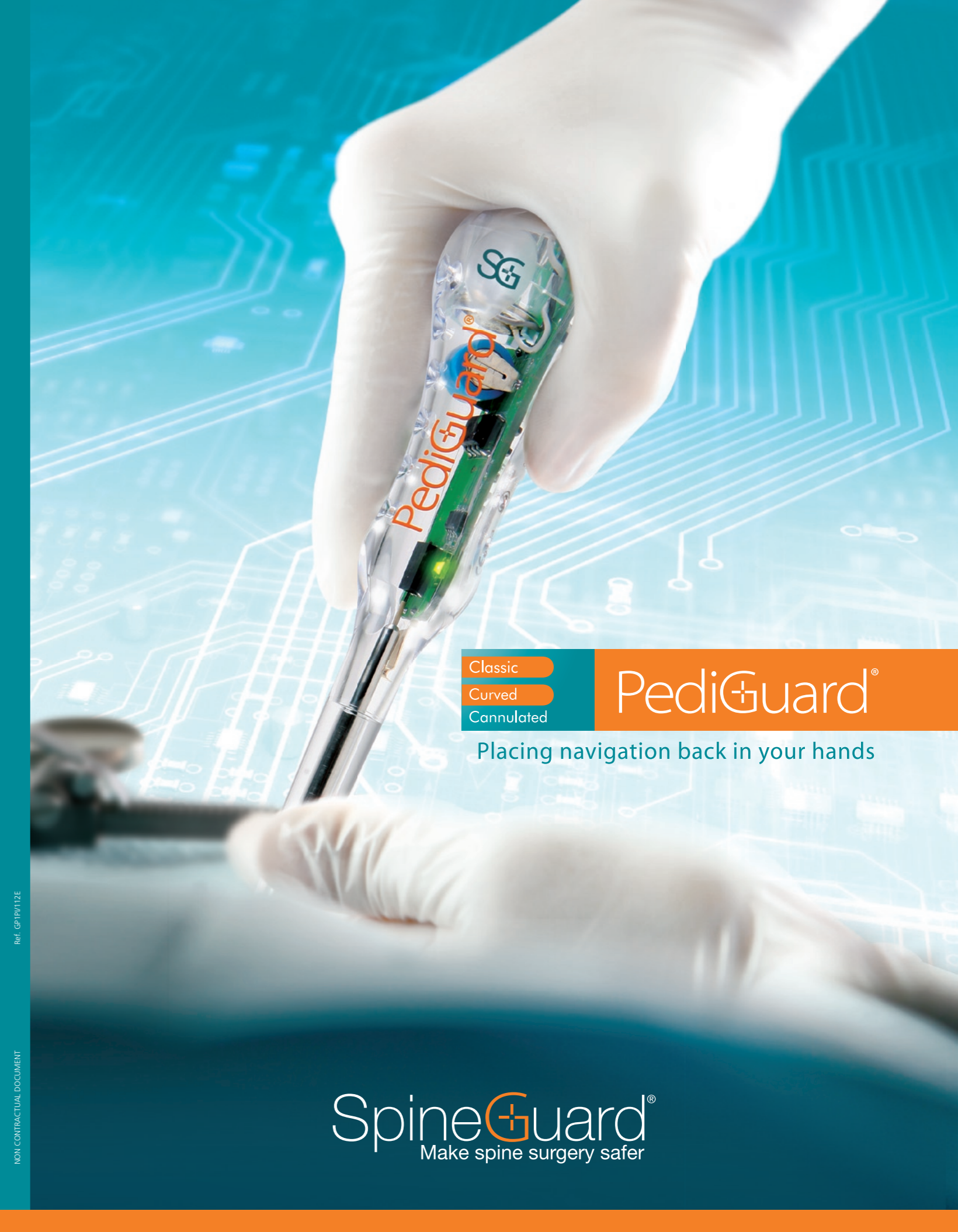
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Caution: See package insert for labeling limitations, intended uses, relevant warnings, precautions, side effects and contraindications. Federal (USA) law restricts the sale and use of this device to a prescription of a physician

Bibliography



Classic  
Curved  
Cannulated

PediGuard®

Placing navigation back in your hands

SpineGuard®  
Make spine surgery safer

Ref: GP1717E

NON CONTRACTUAL DOCUMENT

Simple.  
Innovative.  
Smart.

The need for a smart pedicle probe is real - and the solution is here. Introducing **PediGuard, the smart gearshift.**

- **Hear and feel** what you cannot see
- **Be reassured** your trajectory is precise
- **Anticipate possible breaches** of the pedicular wall or vertebral body and
- **Redirect with complete confidence**

PediGuard has assisted orthopedic spine surgeons and neurosurgeons throughout the world in **over 20,000 surgeries** - experience the difference today.

# PediGuard®



**Electromagnetic Bipolar Sensor**  
Monitors real-time changes in electrical conductivity five times per second

**LED**  
Alerts surgeon with changes in flashing LED cadence

**Audio System**  
Alerts surgeon with changes in sound pitch and cadence

**Battery**  
No external power supply needed

## Reduce Radiation Exposure

Surgeons' greater reliance on fluoroscopy during procedures exposes the OR team to dangerous radiation

- The average spine surgeon will receive the maximum allowable lifetime exposure of radiation for classified workers within 10 years of practice (Ul Haque 2006)
- The radiation exposure in spine surgery has been found to be 10 to 12 times greater than the radiation exposure during other fluoroscopically assisted non-spinal musculoskeletal procedures (Rampersaud 2000)

Studies show that the use of PediGuard can significantly reduce the radiation exposure to you and your staff:

- **73% radiation time reduction<sup>[9]</sup>**
- **51% reduction in thyroid radiation exposure to the surgeon<sup>[9]</sup>**
- **25% - 30% reduction in Fluoroscopy shots during pedicle screw placement<sup>[2,6]</sup>**



Delivered sterile, ready to use.

## Now you have a choice

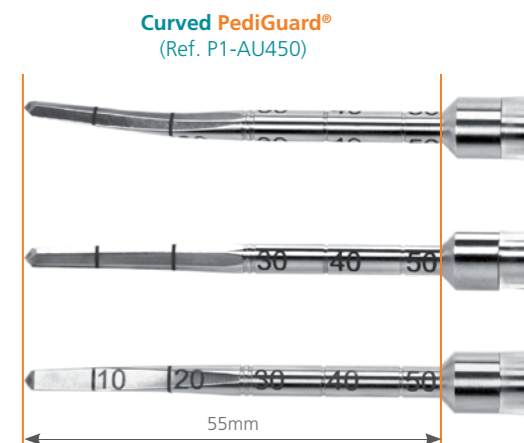
Surgeons who prefer a curved gearshift will appreciate the tactile feel of the Curved PediGuard:

- **A tapered tip to ease penetration** through the pedicle and removal from the pedicle when drilling is complete.
- **A sense of directionality.** As surgeons become comfortable with the direction of the curve, we anticipate enhanced awareness of the location of a possible breach for proper redirection.

### Classic Curved Cannulated PediGuard®

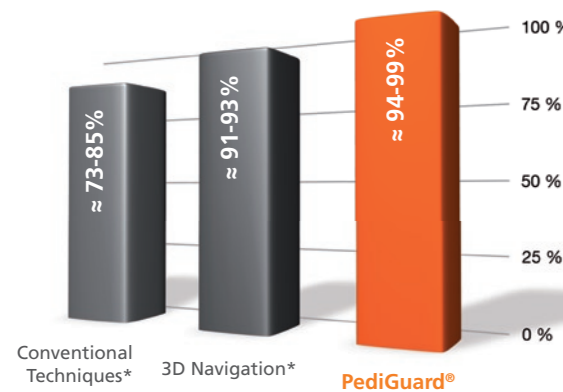


### Classic Curved Cannulated PediGuard®



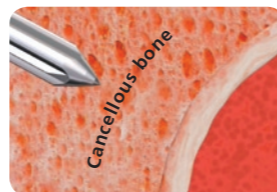
## Proven Efficiency

Rates of properly placed screws (%)

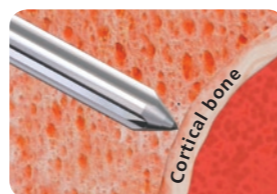


\*Tian 2011, Gelalis 2011, Verma 2010

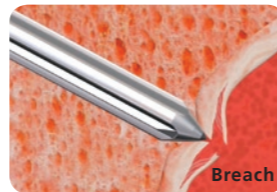
- **97% screw placement accuracy<sup>[2, 3, 4, 5, 6]</sup>**
- **98% probability of breach detection<sup>[7]</sup>**
- **87% breach anticipation<sup>[7]</sup>**
- **3-fold reduction in neuro-monitoring alarms<sup>[8]</sup>**
- **15% time saving during screw placement<sup>[6]</sup>**



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



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



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

