

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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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: GP/PT/EE

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®



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^[9]**
- **51% reduction in thyroid radiation exposure to the surgeon^[9]**
- **25% - 30% reduction in Fluoroscopy shots during pedicle screw placement^[2,6]**



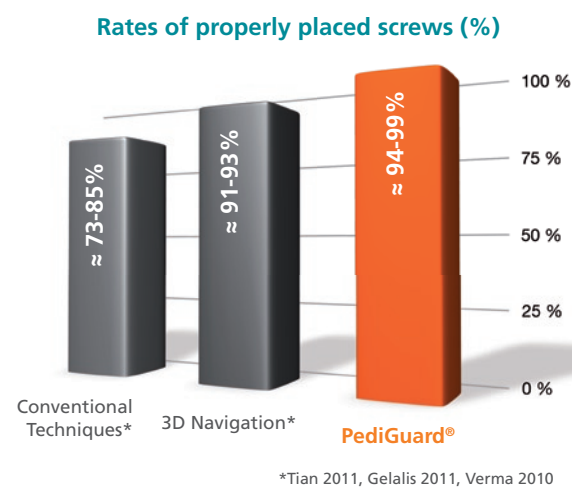
Delivered sterile, ready to use.

Now you have a choice

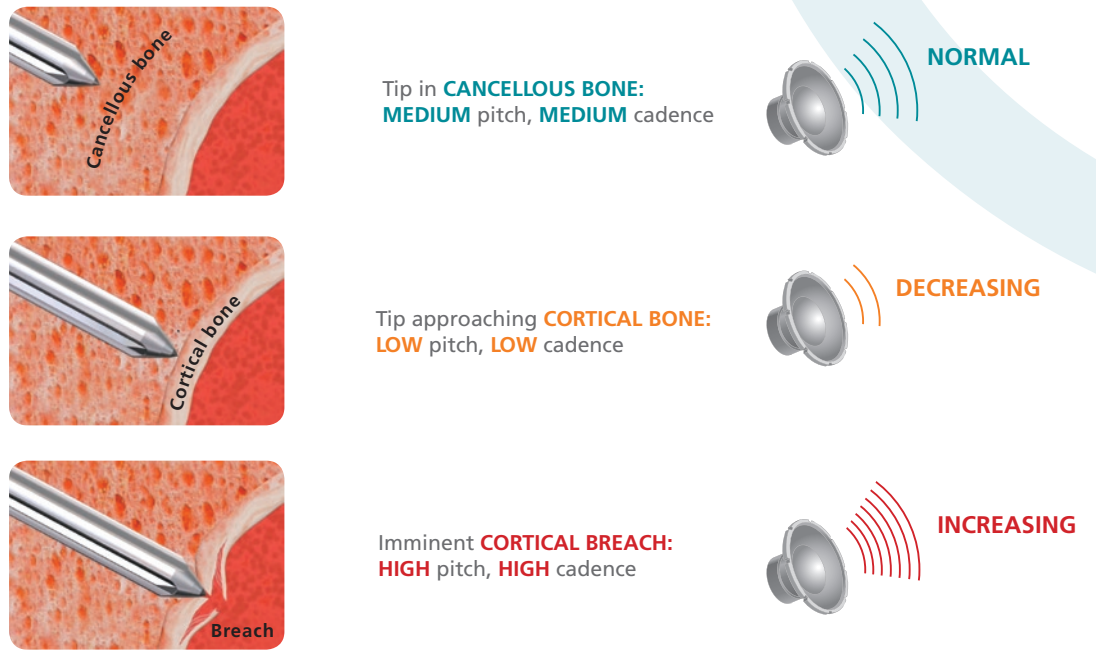
Surgeons who prefer a curved gearshift will appreciate the tactile feel of the Curved PediGuard:

- **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.

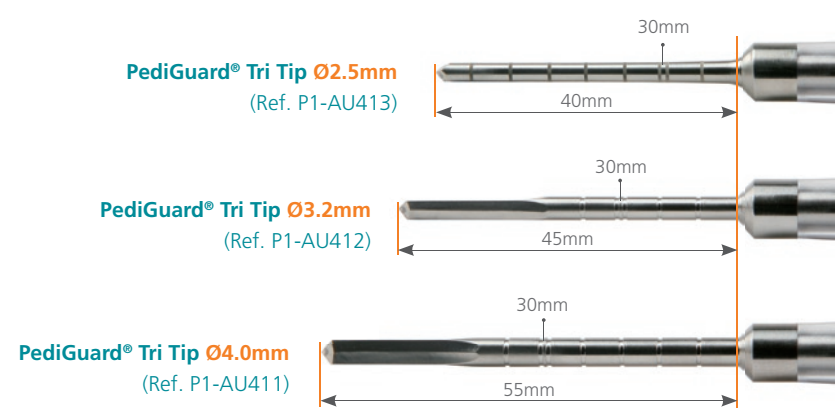
Proven Efficiency



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



Classic Curved Cannulated PediGuard®



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