

Classic
Curved
Cannulated

PediGuard®

Hear what you cannot see

SpineGuard®
Make spine surgery safer



Simple. Innovative. *Smart.*

Classic
Curved

Cannulated

PediGuard®

Introducing the Cannulated PediGuard® for Minimally Invasive Spine Surgery (MIS): a handheld device that can detect possible vertebral cortex perforation during pedicle preparation for screw placement.

Featuring a detachable electronic handle and cannulated shaft, the Cannulated PediGuard provides you with real-time feedback for smart navigation of the pedicle while significantly reducing the need for intraoperative fluoroscopy^[2,6].

- **Hear and feel** what you cannot see
- **Be reassured** that your trajectory is sound
- **Reduce your radiation** exposure by relying on PediGuard feedback
- **Anticipate possible breaches** of the pedicular wall or vertebral body^[7]
- **Redirect with complete confidence**
- **Safely cannulate deeper into the vertebral body** than with traditional MIS techniques, then introduce the k-wire

Minimally Invasive Spine Surgery: Benefits and Risks

Minimally Invasive Spine surgery has been developed to treat disorders of the spine with less blood loss and soft tissue destruction, allowing quicker recovery and faster patient return to normal function. However the pedicle screw placement challenge is even greater in these less invasive procedures due to the lack of visual landmarks and tactile feel, resulting in excessive use of fluoroscopy.

The new Cannulated PediGuard can help you take advantage of the benefits of MISS while addressing the challenges in pedicle screw placement.

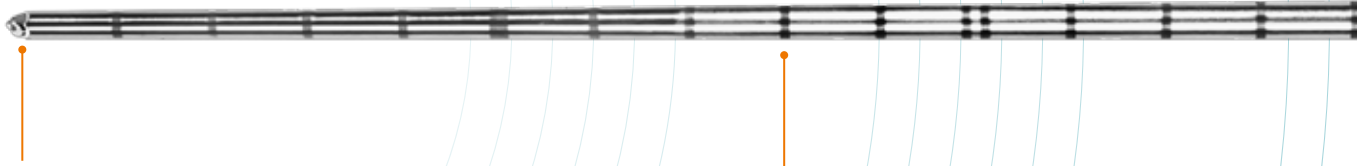
The one-of-a-kind **PediGuard** technology is
placing navigation back in your hands.

Classic
Curved
Cannulated

PediGuard®

Make your first pass the right pass

The PediGuard technology provides valuable feedback unmatched by fluoroscopy and other technologies without interrupting your surgical procedure. The result is continuous real-time navigation in a simple, handheld device.

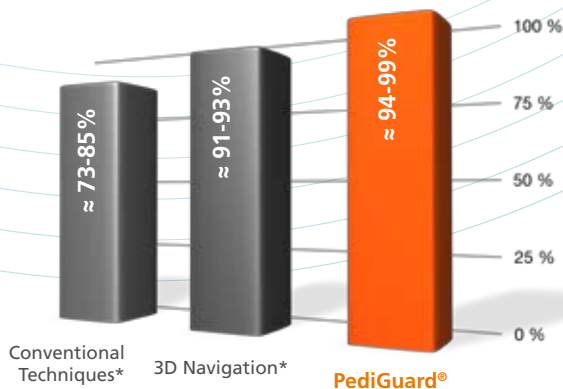


Electromagnetic bipolar sensor
Monitors real-time changes
in electrical conductivity
5 times per second

**Stainless steel shaft and cannula
(160mm total length)**
Stiff tapered tip for smooth
insertion and removal

Safety is our primary concern

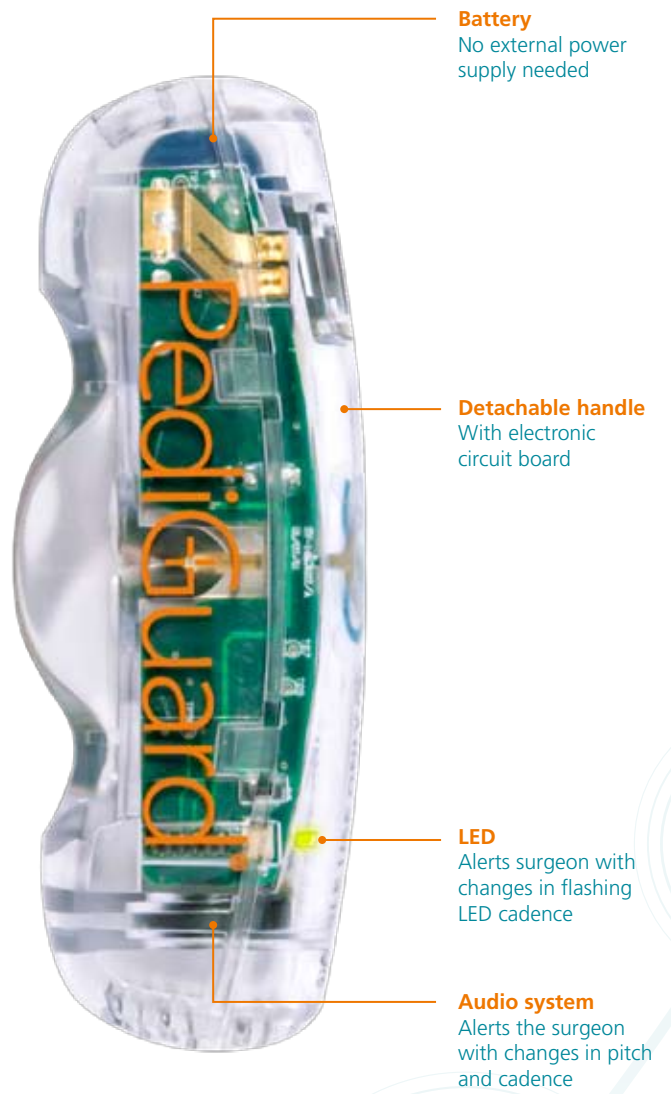
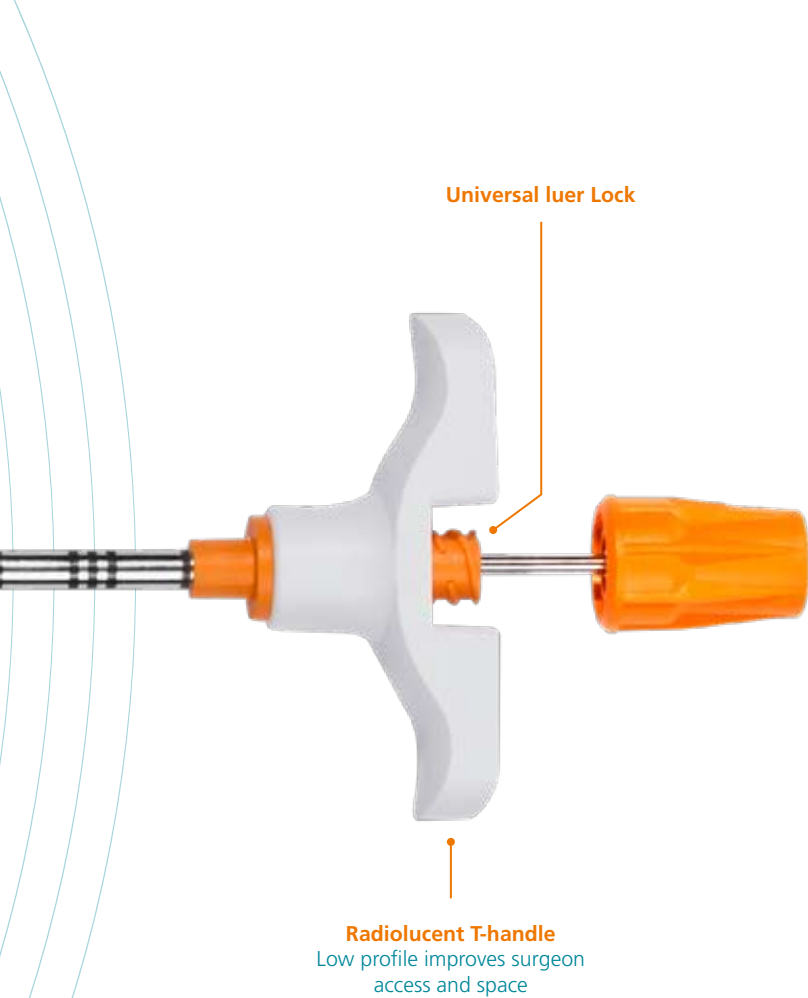
Rates of properly placed screws (%)



*Tian 2011, Gelalis 2011, Verma 2010

The PediGuard technology has demonstrated strong results in a wide number of clinical studies with more studies forthcoming:

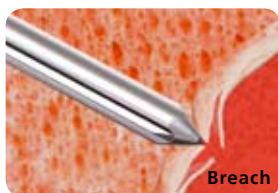
- **97% screw placement accuracy**^[2, 3, 4, 5, 6]
- **98% probability of breach detection**^[1]
- **87% breach anticipation**^[7]
- **3-fold reduction in neuro-monitoring alarms**^[8]
- **15% time saving during screw placement**^[6]



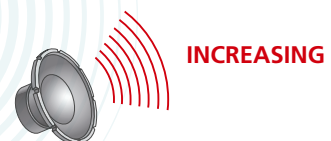
Tip in **CANCELLOUS BONE**:
MEDIUM pitch, **MEDIUM** cadence



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



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



Protect yourself from the dangers of radiation exposure

Research suggests that the average spine surgeon will receive the maximum allowable lifetime exposure of radiation for classified workers within 8 years of practice*.

Studies show that 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]

*UI Haque 2006

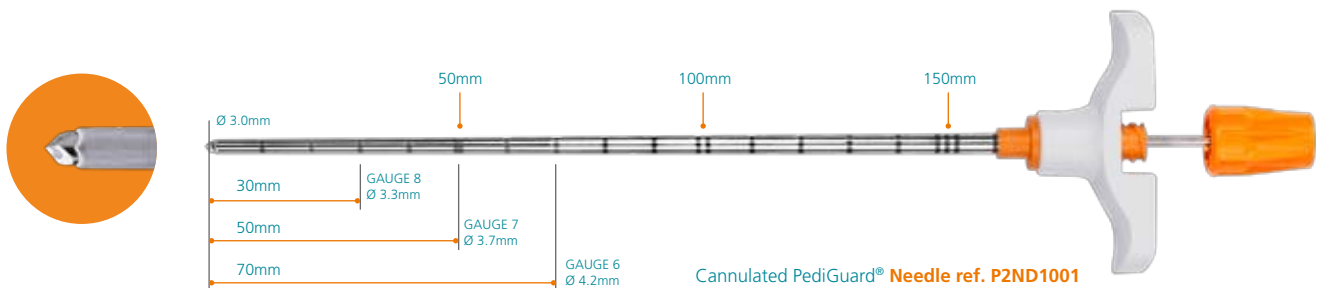
Classic
Curved
Cannulated

PediGuard®

Hear what you cannot see



Cannulated PediGuard® Handle ref. P2HE1000



Cannulated PediGuard® Needle ref. P2ND1001



Cannulated PediGuard® Starter Stylet - Bevel ref. P2ST1050



Cannulated PediGuard® Starter Stylet - Trocar ref. P2ST1060

Delivered sterile, ready to use.

Bibliography

1. Bolger C, Kelleher MO, McEvoy L, Brayda-Bruno M, Kaelin A, Lazennec JY, Le Huec JC, Logroscino C, Mata P, Moreta P, Saillant G, Zeller R. Electrical conductivity measurement: a new technique to detect iatrogenic initial pedicle perforation. Eur Spine J. 2007 Nov;16(11):1919-24
2. Chaput C, Williams JI, George K, Samdani AF, Gaughan JP, Betz RR Prospective, Randomized Trial of a New Pedicle Drilling Probe that Measures Electrical Conductivity and Reduces Radiation Exposure. IMAST 2011
3. Chang V, Patra S, Chedid M, Ford H. Clinical application of a specialized hand held pedicle drilling tool for pedicle screw placement in thoraco-lumbar fusions. Poster, AANS 2009
4. Lubansu A, Brotchi J, Dewitte O. Evaluation of a hand-held pedicle drilling tool for help in the posterior pedicle screw placement. Belgian Society of Neurosurgery annual meeting, Leuven, Belgium, March 2006
5. Bocquet J.F, Pedicle screw placement in spinal surgery at lumbar level : interest of guidance by conductivity measurement in the placement of 104 pedicle screws. PhD Thesis, University Hospital of Rennes, France, May2005
6. Bai YS, Niu YF, Chen ZQ, Zhu XD, Gabriel LK, Wong HK, Li M. Comparison of the Pedicle Screws Placement Between Electronic Conductivity Device and Normal Pedicle Finder in Posterior Surgery of Scoliosis. J Spinal Disord Tech. 2012 Feb 6
7. Betz RR, Williams JI, George K, Gaughan JP, Samdani AF. Can a New Pedicle Drilling Probe with Electrical Conductivity Measurement Capabilities Anticipate Pedicle Breach? A Cadaver Study. IMAST 2011
8. Ovadia D, Korn A, Fishkin M, Steinberg DM, Wientroub S, Ofiram E Ovadia D, Korn A, Fishkin M, Steinberg DM, Wientroub S, Ofiram E. The Contribution of an Electronic Conductivity Device to the Safety of Pedicle Screw Insertion in Scoliosis Surgery. Spine (Phila Pa 1976). 2011 Sep 15;36(20):E1314-E1321
9. Lubansu A, Dewitte O. Prospective Evaluation of a Free-Hand Electrical Conductivity Measuring Device to Reduce Radiation Exposure during Fluoroscopically Assisted Open or Minimally Invasive Pedicle Screw Arthrodesis. EurosSpine 2011
10. Lubansu A, Pirotte B, Rynkowski M, Zemmouchi A, Dewitte O. Prospective evaluation of the interest of a free-hand electrical conductivity measuring device to reduce radiation exposure during fluoroscopically assisted pedicle screw fixation. SFCR 2008.

Distributed by

www.spineguard.com

SpineGuard® S.A.
5-7, rue de l'Amiral Courbet
94160 Saint-Mandé - France
Phone: +33 1 45 18 45 19
Fax: +33 1 45 18 45 20

SpineGuard®
Make spine surgery safer

SpineGuard® Inc.
301 Howard Street, Suite 970
San Francisco, CA 94105 - USA
Phone: +1 415 512 2500
Fax: +1 415 512 8004