



Pierre Jérôme, CEO

*“The primary focus of SpineGuard is to establish **PediGuard** as the standard of care for safer pedicle screw placement in spine surgery.”*

LEADERSHIP

Pierre Jérôme
Chief Executive Officer

Stéphane Bette
CTO; GM, U.S. Operations

Maurice Bourlion, PhD
Co-Inventor of PediGuard

Ciaran Bolger, MD, PhD
Co-Inventor of PediGuard

Randall R. Betz, MD
Chief Medical Officer, SpineGuard;
Editorial Board, *Journal of Pediatric Orthopaedics*;
Associate Editor, *Spinal Frontiers*;
Reviewer, *Journal of Bone and Joint Surgery*,
Journal of Pediatric Orthopaedics, and *Spine*.

Edie Evers
Chief Financial Officer

James Coyle
Vice President, U.S. Sales

Lysiane Cobo Peña
Director, International Sales

Accuracy of pedicle screw placement is a critically important issue in spine surgery: published rates of intraoperatively ‘misplaced’ screws range from 10 to 40 percent, some of which result in pathological consequences such as spinal cord damage. Consequently, liability risks for spine surgeons are high.

So, Dr. Randy Betz is on a mission: To make spine surgery as safe as possible for both patients and surgeons. He is the principal investigator for an ongoing, postmarketing clinical study of **PediGuard®**, the world’s *first and only* handheld device capable of 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. “Our early data are in line with published European data about PediGuard,” says Dr. Betz, a member of the editorial board of the *Journal of Pediatric Orthopaedics* and associate editor of *Spinal Frontiers*. “If the trend continues, I see no reason why the PediGuard technology platform can’t become standard of care in any kind of spine surgery. 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.”

Safer for Surgeons, Too “PediGuard has changed my practice tremendously,” says Luis F. Vasquez, MD, a Texas neurosurgeon. “It has greatly simplified the accuracy of pedicle screw placement, making spine surgery safer for my patients. Also, the use of PediGuard has drastically reduced radiation exposure for me and my staff.”

Without PediGuard, fluoroscopy must be used to continuously monitor the correct placement of pedicle screws into the pedicles of the spine. 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, a form of ionizing radiation; while the 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 about 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 of the spine surgeries that require placement of pedicle screws.”

PediGuard®: Making Spine Surgery Safer

Challenge



Pedicle screw placement is too lateral and can damage soft tissue or nerves.



Pedicle screw placement is too medial and can damage spinal cord.



Pedicle screw is correctly placed within the pedicle.

Solution



- Rationale: Safe pedicle screw placement can be a major hurdle in spine surgery, as published rates of misplaced pedicle screws range from 10%-40%. Perforations can lead to complications such as dural tear, nerve root injury, paraplegia or vascular injury.
- PediGuard is the *first and only* free-hand drilling instrument with the capability to *anticipate and detect* iatrogenic breaches in the pedicle (before they occur), enabling surgeons to better and more safely place pedicle screws in the vertebra while consistently avoiding critical structures (i.e. nerve roots, spinal cord and major blood vessels).
- In addition, PediGuard serves to shorten overall operating time, as well as limit physician exposure to X-rays, given the reduced need for fluoroscopy imaging.