



News Release

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SpineGuard reports 10,000th spine procedure using PediGuard® for safer pedicle screw placement



“PediGuard®”

SAN FRANCISCO and PARIS, Jan. 4, 2010 — [SpineGuard](#) announced today that the **10,000th** case has been performed using its *PediGuard®* device for safer pedicle screw placement in spine surgery.

Nearly one million¹ spine procedures using pedicle screws were performed in 2008. According to published studies, pedicle screws show high rates of *misplacements* that can lead to a number of serious complications for patients, including quadriplegia. Consequently, liability risks for spine surgeons are high.

“PediGuard will probably become a standard tool in any spine surgery requiring instrumentation,” said **Randal Betz, M.D.**, Chief of Staff, Shriners Hospitals for Children, Philadelphia. “Anything we can do to help us get a safer screw insertion is certainly worthwhile, given that published rates of pedicle screw misplacements are as high as 20 percent. PediGuard makes spine surgery safer for surgeons also. Fluoroscopy (a type of X-ray) is an imaging technique commonly used by physicians to obtain real-time images of the spine during surgery. While the exposure to a patient during one surgery is minimal, spine surgeons may perform 140 or more cases per year. Studies are showing that the use of PediGuard reduces fluoroscopy time by one-third in some surgeons’ cases. Less use of fluoroscopy per case means significantly less accumulated radiation exposure over the course of a typical year’s worth of cases.”

(more)

“As a PediGuard user for over eight years, I have enjoyed using this device for pedicle screw insertion,” added **André Kaelin, M.D.**, Chief, Department of Paediatric Orthopaedics, Children’s Hospital, Geneva, Switzerland. “After training and a brief learning curve, you add a third sense—the auditory—as an additional help for pedicle preparation. With time, the sound frequency and tone becomes a preeminent part of your technique. For a University Hospital, PediGuard is an invaluable teaching tool: you can assist your residents *and* ensure safe control of their actions.”

Tom Barton, a U.S. agent for SpineGuard, commented: “The PediGuard allows me, as a salesperson, to represent a truly unique and non-threatening product that puts patient safety and optimal outcomes first, while seamlessly complementing my surgeons’ technique.”

“Safe placement of pedicle screws continues to be *the number-one* challenge in spine surgery,” said **Pierre Jérôme**, CEO of SpineGuard. “Now, with **10,000** spine procedures performed on all continents, PediGuard is on its way to becoming an irresistible solution to the well-documented clinical need for safer pedicle screw placement in spine surgery.”

“Several peer-reviewed publications now validate the value proposition of PediGuard for spine professionals and their patients: pedicle breach anticipation, plus reduction of radiation exposure and surgery time,” added **Stéphane Bette**, Chief Technology Officer and General Manager of U.S. Operations for SpineGuard.

Co-founded this year by **Pierre Jérôme** and **Stéphane Bette**, former executives at Medtronic Sofamor-Danek and SpineVision, SpineGuard’s primary objective is to establish its FDA-cleared and CE Marked **PediGuard®** device as the global standard of care for safer pedicle screw placement in spine surgery.

About *PediGuard®*

Co-invented by **Maurice Bourlion, Ph.D.**, and **Ciaran Bolger, M.D., Ph.D.**, PediGuard is the world’s *first* and *only* handheld device capable of alerting surgeons to potential pedicular or vertebral breaches. Real-time feedback is provided via audio and visual signals. Two multi-center clinical studies about PediGuard have been published: one by Ciaran Bolger, M.D., Ph.D. et al., in the *European Spine Journal*, and the other by Randy Betz, M.D. et al., in the *Temple University Journal of Orthopaedic Surgery & Sports Medicine*. These two studies demonstrated that PediGuard doubles the pedicle breach detection rate, reduces radiation exposure by 30 percent, and decreases by up to 10 percent the average time for pedicle screw placement.

SpineGuard’s mission is to make spine surgery safer. The company has offices in San Francisco and Paris. For further information, visit www.spineguard.com.

¹ Source: I-Data Research.