



News Release

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SpineGuard expands its PediGuard[®] franchise



PediGuard[®] Curv (top), PediGuard[®] Classic (bottom)

SAN FRANCISCO and PARIS, Jan. 31, 2011 — **SpineGuard** announced today that it has expanded its **PediGuard** platform for enhanced pedicle screw placement by successfully introducing **PediGuard Curv** in a limited release among key opinion leaders (KOLs) in spine surgery. The full-scale launch of the new product, *PediGuard Curv*, will commence at the upcoming annual meeting of the **American Association of Neurological Surgeons (AANS)** in Denver, April 9-13, 2011.

The introduction of the “smart” *PediGuard Curv* pedicle screw placement device is expected to enable SpineGuard to further penetrate the spine surgery market, as about 30% of spine surgeons prefer a “curved”-tipped probe.

Regardless of whether spine surgeons use a straight- or curved-tip pedicle placement probe, pedicle screws placed with conventional probes show high rates of *misplacements* that can lead to a number of serious complications for patients, including nerve injury and even quadriplegia. Consequently, risks for patients and spine surgeons are high. *PediGuard Classic* has been adopted by nearly 200 spine surgeons for more than 14,000 procedures across 30 countries. Now, *PediGuard Curv* expands the applicability of pedicle screw placement by allowing spine surgeons who prefer a curved-tip probe to benefit from the *PediGuard* technology value proposition while keeping the tactile feel with which they are familiar.

The three diameters of the straight-tipped *PediGuard Classic* and the curved-tipped *PediGuard Curv* allow for addressing *all* spine levels for pedicle screw placement.

“PediGuard *Curv* is the first new product coming out of SpineGuard’s pipeline, and we are actively working on many other very exciting projects,” said **Stéphane Bette**, Chief Technology Officer and General Manager of U.S. Operations for SpineGuard. “The PediGuard technology platform has outstanding potential, and we are committed to materializing that potential through a series of new-product introductions.”

Thirty (30) spine surgeries have been performed to date in the limited-release program for PediGuard *Curv* since mid-December 2010, and the surgeon feedback has been very encouraging.

“The PediGuard *Curv* improves my ability to navigate the most difficult pedicles, especially in patients with spinal deformity. The curved tip allows for redirection and precise control of direction in three planes. The overall effect is a significant improvement in safety,” said **Sigurd Berven, M.D.**, Associate Professor in Residence, Director of Spine Fellowship and Resident Education, Department of Orthopaedic Surgery, University of California, San Francisco (UCSF).*

“Because of the off-set axis of PediGuard *Curv*, it alerts me if there is a breach and where that breach is,” said **Ciaran Bolger, M.D.**, Head of Department for Clinical Neuroscience, Royal College of Surgeons in Ireland, Director of Research & Development, National Neurosurgical Unit, Beaumont Hospital, Ireland, Current President of the EuroSpine Society.*

“We are very encouraged by the initial feedback on PediGuard *Curv*,” said **Pierre Jérôme**, CEO of SpineGuard. “This new product is strongly expected to be adopted quickly, especially in the U.S., where a large group of spine surgeons have learned to place pedicle screws via a curved-tip instrument. With the addition of PediGuard *Curv*, our PediGuard franchise is on its way to becoming a ‘must-have’ solution to the well-documented clinical need for safer pedicle screw placement—the number one challenge in spine surgery.”

Co-founded in 2009 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 the *PediGuard*[®] platform

Co-invented by **Maurice Bourlion, Ph.D.**, **Ciaran Bolger, M.D., Ph.D.**, and **Alain Vanquaethem**, Biomedical Engineer, 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. Nearly 14,000 procedures have been performed with PediGuard on all continents. 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.

* Statements made by surgeons are based upon their own experiences with the PediGuard products and may not comply with the specifics of the U.S. FDA-approved indications for use. These statements are opinions and are provided for information only.

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