

## SpineGuard to launch two new products from its PediGuard® platform at North American Spine Society (NASS) annual meeting

### XS Classic PediGuard and XS Curved PediGuard feature miniaturized sensor

PARIS and SAN FRANCISCO (Oct. 7, 2013) – SpineGuard (FR0011464452 – ALSGD) announced today that it will launch two new products from its PediGuard platform at this week's annual scientific meeting of the North American Spine Society (NASS), to be held in New Orleans on Oct. 9-12.

The new products, XS Classic PediGuard and XS Curved PediGuard, expand the Company's platform of single-use drilling instruments that are designed to secure a pedicle screw pilot hole for optimal placement by spine surgeons.

"The expansion of the PediGuard platform is an integral part of our company's mission to help surgeons meet the highest safety standards for the most challenging clinical situations in spine," said Pierre Jérôme, co-founder and Chief Executive Officer.

"The XS Classic PediGuard penetrates bone more easily with a great tactile feel," said PD Dr Heiko Koller, Werner Wicker Klinik, Bad Wildungen, Germany, a reviewer for *European Spine Journal* and *Spine*. "This new feature of the XS Classic PediGuard allows for easier access to the intended cervical pedicle direction, particularly in patients with challenging cervical anatomy and deformities."

"The new miniaturized sensor of the XS Curved PediGuard allows us to access the smallest and most difficult pedicles encountered in our deformity cases. Like for the precedent design, the new curve gives us precious directional information as well as the ability to redirect. In a teaching context, it is very reassuring to receive the instant auditory feedback when the resident or any other trainee is creating the trajectory for the screw within the pedicle," said Sergey Neckrysh, M.D., Chief of Spine Surgery, Assistant Professor, Department of Neurosurgery, University of Illinois – Chicago.

Pedicle screw-based stabilization is the gold standard for treating spine instabilities and deformities. This market is growing due to an increasing number of patients requiring surgical treatment and a larger number of surgeons being trained in pedicle screw-based technologies. Technological advancements such as minimally invasive surgery, bone substitutes, dynamic stabilization and thoracic screws further reiterate the importance of pedicle screw placement.

However, 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 is approximately 20% (Tian 2011, Gelalis 2011, Verma 2010) with 2-7% of patients presenting neurologic complications (Amato 2010, Amiot 2000, Waschke 2012) and 4-5% of patients having vascular complications (Sarlak 2009, Samdani 2009, Belmont 2002) due to misplaced screws.

#### About the PediGuard® Platform

Co-invented by Maurice Boursion, 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. Over 27,000 procedures have been performed with

PediGuard on all continents. Several studies published in peer-reviewed medical and scientific journals have demonstrated that PediGuard detects 98% of pedicle breaches, presents an average screw placement accuracy of 97% (vs. 92% on average for navigation), provides 3-fold less pedicle perforations than with free-hand technique and a 3-fold reduction in neuro-monitoring alarms. It also limits radiation exposure by 25-30% and decreases by 15% the time for pedicle screw placement.

#### **About SpineGuard®**

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 screw placement in spine surgery. 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](http://www.spineguard.com).

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