

## SpineGuard reports early adoption of its PediGuard® platform by KOL spine surgeons at a leading university school of medicine in Japan

*“We are pleased by the enthusiastic response of key opinion leaders who wish to make spine surgery safer throughout Japan.”*

**Pierre Jérôme, CEO**

PARIS and SAN FRANCISCO (Nov. 19, 2013) – **SpineGuard** (FR0011464452 – ALSGD) announced today that its **PediGuard** platform has been adopted by leading spine surgeons in the department of orthopaedic surgery at **Kobe University Graduate School of Medicine**. This early adoption of PediGuard at one of the oldest and largest national universities in Japan, which is also consistently one of the highest-ranking national universities in the country, comes on the heels of SpineGuard recently receiving product certification ("Ninsho") to market its Classic and Curved PediGuard® products in Japan.

“We are very pleased with the early adoption of our technology by leading surgeons at a renowned school of medicine in Japan,” said **Pierre Jérôme**, Co-founder and Chief Executive Officer of SpineGuard. “With Surgical Spine, Inc., our Japanese partner, we consider it as a requisite step and significant milestone in penetrating the significant Japanese market with our PediGuard devices, whose value in boosting the accuracy of pedicle screw placement has been unequivocally validated in several peer-reviewed medical journals.”

“PediGuard worked well in my operation,” said **Dr. Kotaro. Nishida, M.D., Ph.D.**, Associate Professor, Department of Orthopaedic Surgery, Kobe University Graduate School of Medicine. “It will give Japanese spine surgeons a sense of security in making a reliable pedicle screw pathway.”

“PediGuard was even more helpful than I had expected before the operation,” said **Dr. Koichiro Maeno, M.D., Ph.D.**, Assistant Professor, Department of Orthopaedic Surgery, Kobe University Graduate School of Medicine. “I am eager to use PediGuard on patients with different bone properties and in cases where the point of insertion varies.”

Japan is the second-largest market in spine after the USA and as reported in an article by David Cassak in the July/August 2013 issue of *IN VIVO* magazine entitled “Taming of the Screw”, “Japan is a particularly promising market [for PediGuard] because surgeons there implant a lot of pedicle screws in the upper part of the spinal column as a result of specific problems that affect Asian patients.”

### 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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### **About the PediGuard® Platform**

Co-invented by Maurice Bournion, 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 28,000 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 pedicle screw-based stabilization**

Pedicle screw-based stabilization has become the gold standard for treating spine instabilities and deformities. This market is growing due to the 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.

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