Press Release

SpineGuard receives FDA 510(k) clearance for miniaturized and directional versions of its PediGuard® platform

New products designed to enhance pedicle screw penetration of small and/or difficult-to-access pedicles

PARIS and SAN FRANCISCO (Aug. 28, 2013**)** – SpineGuard (FR0011464452 – ALSGD) announced today that it has received FDA 510(k) clearance of three new products that complete its PediGuard platform of single-use drilling instruments which secure the pedicle screw pilot hole: Two miniaturized versions of its classic and curved range, and a directional version of its cannulated series.

"This new product-development milestone now empowers SpineGuard to assist surgeons in the most challenging clinical situations in spine, and fortifies our potentially game-changing technology in the US market," said **Pierre Jérôme**, co-founder and Chief Executive Officer. "The addition of a miniaturized PediGuard sensor opens the door to multiple new potential small-size applications of our platform, such as drill bits, guide wires or implants," added Stephane Bette, co-founder and CTO.

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.

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. 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.

Disclaimer

The SpineGuard securities may not be offered or sold in the United States as they have not been and wíll not be registered under the Securities Act or any United States state securities laws, and SpineGuard does not intend to make a public offer of its securities in the United States. This is an announcement and not a prospectus, and the information contained herein does and shall not constitute an offer to sell or the solicitation of an offer to buy, nor shall there be any sale of the securities referred to herein in the United States in which such offer, solicitation or sale would be unlawful prior to registration or exemption from registration.

Contacts

Ronald Trahan, APR, Ronald Trahan Associates Inc.
+1-508-359-4005, x108

ALSGD
LISTED
NYSE
ALTERNEXT