Press Release

SpineGuard receives FDA clearance to market its PediGuard products for Minimally Invasive Surgery (MIS)

PARIS and SAN FRANCISCO (Feb. 3, 2015) – SpineGuard (FR0011464452 – ALSGD) announced today that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) to market its PediGuard products for Minimally Invasive Surgery (MIS).

"This is an especially important regulatory milestone for SpineGuard, as it will allow us to promote the use of PediGuard in the United States for minimally invasive pedicle screw placement, one of the fastest growing market segments in spine surgery. It also further strengthens our US regulatory position as we prepare the submission for dynamically guided screws," said **Pierre Jérôme**, CEO and co-founder of SpineGuard.

Minimally Invasive Surgery was developed to treat disorders of the spine with less disruption to the muscles, allowing patients a significantly more rapid recovery and return to normal function post operation. Notwithstanding its benefits, the challenge for surgeons of correctly placing pedicle screws is greater in MIS procedures versus standard conventional open procedures given surgeons have less visual landmarks and tactile feel. The current solution to this issue in the MIS field is extensive use of fluoroscopy which results in radiation exposure to the surgeon and OR team as well as increased procedural time. As a result, in addition to unacceptably high rates of *misplacements* that can lead to numerous serious complications for patients, pedicle screws placed with conventional techniques mean high radiation exposure for surgeons and staff to radiation. In fact, the average spine surgeon receives the maximum allowable lifetime exposure of radiation for workers within just 10 years of practice (*Ul Haque, Shufflebarger et al, 2006*).

Cannulated PediGuard expands the applicability of pedicle screw placement with real-time feedback by allowing spine surgeons to benefit from the Dynamic Surgical Guidance technology value proposition in the small, confined spaces of MIS. This represents a branch of spine surgery where SpineGuard's PediGuard technology delivers unparalleled benefits for the patient, surgeon and hospital.

Nearly one million spine procedures using pedicle screws are performed annually worldwide (I-Data). We estimate that 15 to 20% of these procedures are performed via a minimally invasive approach; this percentage is rapidly growing driven by surgical technique improvements and surgeon training.

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 also focuses on exploring other applications for its Dynamic Surgical Guidance technology platform. SpineGuard has offices in San Francisco and Paris. For further information, visit www.spineguard.com.

About PediGuard®

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 35,000 procedures have been performed with PediGuard worldwide. 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% for surgical 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.

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