SpineGuard®

Press Release

PediGuard® Bone-Monitoring Device from SpineGuard demonstrates high accuracy for C2-screw fixation in treating 50 patients with cervical spine disease

Clinical data presented from the podium at 5th Annual Meeting of the Cervical Spine Research Society–Asia Pacific (CSRS-AP)

PARIS and SAN FRANCISCO (April 29, 2014) – **SpineGuard** (FR0011464452 – ALSGD), an innovative medical device company focused on improving spine surgery safety, announced today that the anticipation of pedicle breaches using its FDA-cleared and CE-marked PediGuard® device in a prospective clinical analysis of 50 patients with "rather rare and severe cervical spine disease" was 100% accurate in identifying an impassable cortical pedicle isthmus in 34 pedicles. The data was presented by principal investigator **Heiko Koller, MD, PhD**, at the 5th Annual Meeting of CSRS-AP in Ho Chi Minh City, Vietnam. In 34 pedicles a decision to stop pedicle screw tract preparation based on a signal from the PediGuard device that suggested an impassable cortical stimulus isthmus was later confirmed appropriate based on analysis of postoperative CT scans.

« We surgeons are constantly faced with difficult treatment planning for complex cervical deformities. By integrating the PediGuard device into surgery, we are able to provide our patients with greater construct stability, less neurological risk, and a better overall surgical outcome, » said **Dr. Koller**, Werner Wicker Klinik, Bad Wildungen - Germany.

By far, pedicle screws are the most common implant used in spinal surgery. Unfortunately, high rates of pedicle screw misplacements in the vertebra persist, which can lead to dramatic neurologic and vascular impairment. The scientific literature reveals that about 20% of pedicle screws are misplaced using conventional techniques, causing a 2% to 9% overall complication rate. Several published clinical studies in peer-reviewed medical journals have demonstrated the excellent pedicle screw placement accuracy of PediGuard®.

About the PediGuard® Bone-Monitoring 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 30,000 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

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