

SpineGuard obtains regulatory clearance to sell PediGuard® Curved and Curved XS in Mexico

PARIS and SAN FRANCISCO, Oct. 28, 2013 – SpineGuard (FR0011464452 – ALSGD) announced today that it has obtained additional regulatory clearance from COFEPRIS (the Mexican healthcare regulatory authority) to sell its Curved and Curved XS PediGuard® devices in Mexico. SpineGuard has previously received clearances for its Classic and Cannulated PediGuard devices.

"This additional regulatory approval completes our offering into the substantial market of Mexico. Mexico's spine surgeons will now benefit from all of the PediGuard features, including directionality and miniaturization, thus minimizing complications due to cortical breaches and reducing their exposure to radiation as a result of less dependence on fluoroscopy," said Pierre Jérôme, CEO and co-founder of SpineGuard.

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 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-times fewer pedicle perforations than with free-hand technique and a 3-fold reduction in neuromonitoring 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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