SpineGuard®

SpineGuard receives E.U. patent for its "smart screw"

PARIS, SAN FRANCISCO (January 29, 2015) – SpineGuard (FR0011464452 – ALSGD), announced today that it has been granted a patent by the European Patent Office under the number *1781198* for the integration of its Dynamic Surgical Guidance technology directly into a pedicle screw, by far the most frequently used implant in spine surgery.

SpineGuard's proprietary technology platform, already used in its marketed PediGuard product, enables surgeons to more safely and accurately place pedicle screws delivering significant benefits for patients, surgeons and hospitals. The 'smart screw' product represents the next generation of the technology, migrating the sensory technology into the screw itself thereby delivering further clinical workflow, economic and patient outcome benefits. In SpineGuard's 'smart screw' concept, the sensor is embedded at the tip of the screw with the electronic component located in the screwdriver handle.

"This grant follows previous patent grants in the USA and China and, combined, means we now have an exceptionally strong and broad IP position relating to the 'Smart Screw' technology platform." said **Stéphane Bette**, CTO and co-founder of SpineGuard.

"There is a well-documented safety issue associated with pedicle screw placement and a striking unmet need for differentiation among the numerous pedicle screw systems in an ultra-competitive arena. This new block in our IP portfolio brings us incremental value and confidence as we complete development and prepare the roll-out of our dynamically guided screw products." added **Pierre Jérôme**, CEO and cofounder of SpineGuard.

Pedicle screw-based stabilization has become the gold standard for treating spine instabilities and deformities. This one million procedure market is experiencing robust growth driven by the increasing number of patients requiring surgical treatment and increasing 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 increase 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% (*Verma 2010, Tian 2011, Gelalis 2011, Mason 2013*) with 2-11% of patients presenting neurologic complications (*Amiot 2000, Amato 2010, Waschke 2012, Oh 2013, Koktekir 2014, Nevzati 2014*) and 2-6% of patients having risk of vascular complications (*Sarlak 2009, Sarwahi 2014, Parker 2014*) due to misplaced screws.

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 developing other applications for its Dynamic Surgical Guidance technology platform. SpineGuard has offices in San Francisco and Paris. For further information, visit <u>www.spineguard.com</u>.

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. Realtime 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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