

SpineGuard receives U.S. patent for PediGuard® pedicle screw

PARIS, SAN FRANCISCO (June 18, 2013) – SpineGuard (FR0011464452 – ALSGD), announced today that it has been issued a U.S. patent for the integration of its PediGuard sensor technology directly onto the tip of a pedicle screw.

In SpineGuard's 'smart screw' concept, the sensor of the PediGuard technology is embedded in the implantable pedicle screw itself, and the electronic is located in the screwdriver handle. "This patented design allows for appealing benefits: surgical work flow with time savings and ultimate assurance about the correct placement of the pedicle screw," said Stéphane Bette, CTO and co-founder of SpineGuard.

"There is a well-documented safety issue associated with pedicle screw placement and a striking need for differentiation among the existing 200 or so pedicle screw systems in an ultra-competitive arena. The PediGuard screw is a potentially game-changing technology in a global annual market of one million pedicle screw-based procedures," added Pierre Jérôme, CEO and the other co-founder of SpineGuard.

The PediGuard screw is one of the latest innovations from SpineGuard, which is commercializing Classic, Curved, and Cannulated PediGuard, all being FDA-cleared and CE-marked, single-use drilling instruments to secure the pilot hole in which to place a pedicle screw.

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.

Furthermore, surgeons' greater reliance on fluoroscopy during those procedures exposes the OR team to dangerous radiation:

- The average spine surgeon will receive the maximum allowable lifetime exposure of radiation for workers within 10 years of practice (Ul Haque, Shufflebarger et al, 2006);
- The radiation exposure in spine surgery has been found to be 10 to 12 times greater than the radiation exposure during other fluoroscopically assisted non-spinal musculoskeletal procedures (Rampersaud, 2000)

About the PediGuard® Platform

Co-invented by Maurice Bournion, 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 25,000 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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