SpineGuard Receives FDA 510(k) Clearance for Miniaturized and Directional Versions of Its Pediguard® Platform

Business Wire

SpineGuard announced today that it has received FDA 510(k) clearance of three new products that complete its PediGuard platform of single-use drilling instruments which secure the pedicle screw pilot hole: Two miniaturized versions of its classic and curved range, and a directional version of its cannulated series.

New PediGuard(R) products designed to enhance pedicle screw penetration of small and/or difficult-to-access pedicles (Photo: Business Wire) “This new product-development milestone now empowers SpineGuard to assist surgeons in the most challenging clinical situations in spine, and fortifies our potentially game-changing technology in the US market,” said Pierre Jérôme, co-founder and Chief Executive Officer. “The addition of a miniaturized PediGuard sensor opens the door to multiple new potential small-size applications of our platform, such as drill bits, guide wires or implants,” added Stephane Bette, co-founder and CTO.

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.

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