SpineGuard®

Press Release

SpineGuard® introduces *Bevel-Cannulated* PediGuard®, the newest addition of its Dynamic Surgical Guidance platform

PARIS and SAN FRANCISCO, June 11, 2014 — **SpineGuard** announced today that it is expanding its Dynamic Surgical Guidance platform for enhanced pedicle screw placement by introducing the *Bevel-Tip Cannulated* **PediGuard** at the occasion of the WCMISST (World Congress of Minimally Invasive Spine Surgery and Techniques) on June 11-14 in Paris.

"The bevel-tip is a much needed addition to the Cannulated PediGuard product offering. In my experience, using needles with such a tip minimizes "skiving" of the needle at the pedicle entry point and helps me steer the needle as I am advancing down a pedicle. This tip and the PediGuard technology are a perfect complement to each other: the technology tells me accurately in real-time what's ahead and the tip helps me effortlessly steer accordingly," said **John Williams, M.D.,** a spine surgeon from Ft. Wayne, Indiana, USA.

"The unique and substantial benefits to patients, surgeons & OR staff directly related to the use of the PediGuard Dynamic Surgical Guidance technology have been validated by growing clinical evidence published in peer-reviewed medical journals," says **Pierre Jérôme**, **CEO & Co-founder of SpineGuard**. "We believe that the Cannulated PediGuard will play a significant role in accelerating the shift of more spine surgeries toward minimally invasive procedures."

About Minimally Invasive Pedicle Screw Placement*

Minimally Invasive Spine Surgery (MIS) has been developed to treat disorders of the spine with less disruption to the muscles. This can result in decreased operative blood loss and reduced soft tissue destruction, allowing quicker recovery and faster patient return to normal function. However the pedicle screw placement challenge is even greater in these less invasive procedures because surgeons must compensate for the lack of visual landmarks and tactile feel with massive use of fluoroscopy, exposing themselves and the rest of the OR team to considerable amounts of radiations. So in addition to unacceptably high rates of *misplacements* that can lead to a number of serious complications for patients—such as spinal cord damage resulting in various degrees of neurological impairment, pedicle screws placed with conventional techniques show high exposure of surgeons, staff and patients to radiation. Indeed, spine surgeons more than double their life time radiation exposure limits in less than 10 years when using fluoroscopy and/or x-ray to guide pedicle screw placement.

Cannulated PediGuard expands the applicability of pedicle screw placement with real-time feedback by allowing spine surgeons to benefit from the PediGuard Dynamic Surgical Guidance technology in the small, confined spaces of MIS. Nearly one million spine procedures using pedicle screws are performed annually worldwide**. We estimate that 15% of these procedures are now done via a minimally invasive approach; this percentage is rapidly growing driven by innovation and surgeon training.

* Source: www.spineuniverse.com
**: I-Data research

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. 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 is also exploring other applications for its Dynamic Surgical Guidance technology platform. SpineGuard has offices in San Francisco and Paris. For further information, visit www.spineguard.com.

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Contacts

Ronald Trahan, APR, Ronald Trahan Associates Inc.
+1-508-359-4005, x108

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