Press Release

SpineGuard's PediGuard® bone-monitoring device is adopted by 20th U.S. spine-surgery teaching institution

PARIS and SAN FRANCISCO, May 13, 2014 – **SpineGuard** (FR0011464452 – ALSGD) announced today that its **PediGuard** platform has been adopted by the 20th major spine-surgery teaching institution in the United States: **Children's Hospital of New Orleans**.

"We are very pleased that twenty of the U.S.'s finest teaching hospitals have now adopted our PediGuard bone-monitoring devices to ensure optimal training of their residents and fellows for safe pedicle screw placement", said **Stephane Bette**, Co-founder and US General Manager of SpineGuard.

"An obvious advantage of the PediGuard technology is that there is no radiation required during pedicle screw placement. There is increasing concern about the long term consequences of medical treatment based radiation exposure. The dosage is cumulative, and has been shown to significantly affect the lifetime risk for cancer", said **Andrew G. King, M.D.,** Orthopedic Surgeon, Children's Hospital New Orleans; and, Professor and Chair, Department of Orthopedic Surgery, LSU Health Sciences Center. "For this reason alone, pedicle screw placement navigated by sensors in the pedicle probe is gaining popularity, and with technological advances, should become standard."

"PediGuard has helped me guide residents in placing safe and accurate pedicle screws. This was corroborated by a recent cadaver study we conducted comparing the accuracy of screw placement among residents with varied experience implanting pedicle screws," said **Faheem Sandhu, M.D., PhD**, Professor of Neurosurgery, Director of Spine Surgery, Georgetown University Hospital.

Dean Chou, M.D., Associate Professor of Neurosurgery, The UCSF Spine Center, University of California San Francisco says that "To consistently ensure safe and accurate pedicle screw placement while training the future generation of surgeons, we provide our residents and fellows with the best technologies available. The PediGuard device certainly ranks as a critical instrument to ensure safe spine surgery."

"I have found the PediGuard probe to be an invaluable tool to assist me in the safe placement of pedicle screws in my pediatric patients with often challenging spinal deformities", says **Brian G. Smith, M.D.**, Professor, Program Director, Director of Pediatric Orthopaedics, Yale University School of Medicine. "The PediGuard probe enables me to identify very accurately the path for pedicle screw insertion in a manner that both enhances patient safety and minimizes radiation exposure to the patient and surgical staff. In addition this device has been a wonderful teaching aid for fellows and residents. I use the PediGuard probe on all my spinal deformity cases."

"The PediGuard provides me with auditory and tactile feedback to help accurately position pedicle screws, particularly in severe deformities." said **Jacques D'Astous, M.D.,** Clinical Professor, Orthopaedic Surgery, University of Utah, Shriners Hospital in Salt Lake City. "Most importantly, the auditory feedback is helpful in warning me of potential breaches when the resident or fellow across the table is probing the pedicles on the contralateral side. It is a valuable teaching tool which improves the safety of pedicle screw insertion particularly in a teaching hospital."

"PediGuard is a great training tool for spine fellows like myself," said Ali M. Maziad, M.D., the Pediatric Orthopaedics and Spine Deformity Fellow at Connecticut Children's Medical Center in Hartford, Conn.

"There's a very narrow margin for error. Misplaced pedicle screws can result in catastrophic complications. Also, multiple attempts at screw placement can result in less-than-optimal fixation. You only have one shot to get the best possible screw for any given level. I strive to have safe and accurate screw placement the first time, every time, and I make sure to use every possible technological advantage available to ensure the safety of my patients, which is where PediGuard is advantageous," concluded Dr. Maziad, who was trained to use PediGuard during his previous spine deformity fellowship at the Hospital for Special Surgery (HSS) in New York.

"Through our collaboration with a number of international scientific societies and the presence of our technology in many teaching institutions across the globe, we are committed to enabling young spine surgeons such as Dr. Ali Maziad to be trained on our PediGuard® bone-monitoring devices. It is definitely part of SpineGuard's mission i.e. *making spine surgery safer*." concluded **Pierre Jérôme**, Co-founder and CEO of SpineGuard.

See other testimonials from eminent spine surgeons regarding the challenges of pedicle screw placement and the dangers of radiation exposure on this page.

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.

About the PediGuard® Bone-Monitoring 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 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 pedicle screw-based stabilization

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 2-9% 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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