



News Release

FOR IMMEDIATE RELEASE

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

Study shows use of PediGuard® reduced the incidence of clinically relevant misplaced pedicle screws in spine surgery

Results published in the peer-reviewed medical journal *Spine*



PediGuard® Curv (top), PediGuard® Classic (bottom)

SAN FRANCISCO and PARIS, Sept. 15, 2011 — [SpineGuard®](#) announced today that the third published clinical study of its FDA-cleared and CE-marked [PediGuard®](#) platform for enhanced pedicle screw placement has concluded that “the use of PediGuard significantly reduced the incidence of clinically relevant misplaced screws, thereby increasing the safety of pedicle screw implantation*.” Principal investigator for the study was **Dr. Dror Ovadia**, Department of Pediatric Orthopaedics, Dana Children’s Hospital, Tel Aviv, Israel. The study has been published in the September 15 issue of the peer-reviewed medical journal [Spine](#).

The high incidence of misplaced pedicle screws is well-documented in the scientific literature. Indeed, misplaced pedicle screws occur in about 20% of cases, according to numerous studies published in peer-reviewed medical journals during the 1987-2009 time period. Clearly, this error rate is undeniable and unacceptable given the potentially dire consequences of misplaced pedicle screws—such as spinal cord damage resulting in various degrees of neurological impairment.

“The scientific literature is rife with clinical evidence that the conventional modalities for implanting pedicle screws are potentially dangerous not only to spine surgery patients but

also OR staff,” said **Stéphane Bette**, Chief Technology Officer and General Manager of U.S. Operations for SpineGuard. “The PediGuard technology platform is designed to be a safe and effective alternative to conventional modalities for implanting pedicle screws. There are now more than 200 spine surgeons who have performed nearly 17,000 procedures using PediGuard.”

“The published clinical evidence that spine surgery can be made safer for patients is becoming incontestable,” added **Pierre Jérôme**, CEO of SpineGuard. “This latest clinical evidence supporting the use of PediGuard as standard of care for placing pedicle screws should spawn widespread adoption of PediGuard by the spine surgery community. It is a ‘must-have’ solution to the well-documented clinical need for safer pedicle screw placement—the number one challenge in spine surgery.”

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®** platform as the global standard of care for pedicle screw placement in spine surgery.

About the *PediGuard®* 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. Nearly 17,000 procedures have been performed with PediGuard on all continents. Multi-center clinical studies of PediGuard have been published demonstrating that PediGuard doubles the pedicle breach detection rate, limits radiation exposure by 30 percent, and decreases by up to 10 percent the average time for pedicle screw placement.

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.

* Statements made by surgeons are based upon their own experiences with the PediGuard products and may not comply with the specifics of the U.S. FDA-approved indications for use. These statements are opinions and are provided for information only.

#####