

Study: PediGuard Makes Spine Surgery Safer

“The use of PediGuard significantly reduced the incidence of clinically relevant misplaced [pedicle] screws.”

That’s the conclusion of a clinical study published in the September 15 issue of the peer-reviewed medical journal, *Spine*¹. It’s the third clinical study published about SpineGuard S.A.’s PediGuard FDA-cleared and CE-marked platform.

According to a company announcement on September 15, the high incidence of misplaced pedicle screws is well-documented in the scientific literature and occurs in about 20% of cases. Misplaced pedicle screws can result in spinal cord damage and the resulting various degrees of neurological impairment.

Stéphane Bette, chief technology officer and general manager of U.S. Operations for SpineGuard, said, “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.”

The principal investigator of the study, Dr. Dror Ovadia of the Department of Pediatric Orthopaedics, Dana Children’s Hospital, Tel Aviv, Israel, concluded that using the device increased the safety of pedicle screw implantation.

“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.”

PediGuard, according to the company, 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. The device alerts the surgeon prior to a breach by accurately analyzing the electrical conductivity of the surrounding tissues.

Nearly 17,000 procedures have been performed by more than 200 spine surgeons with PediGuard. Multi-center clinical studies have been published demonstrating that the device doubles the pedicle breach detection rate, limits radiation exposure by 30%, and decreases by up to 10% the average time for pedicle screw placement.

The company notes that 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.

—*WE (September 16, 2011)*

¹ **The Contribution of an Electronic Conductivity Device to the Safety of Pedicle Screw Insertion in Scoliosis Surgery**
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