



*News Release*

**FOR IMMEDIATE RELEASE**

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## **Safer spine surgery: SpineVision® reports preliminary data from postmarketing study of its *PediGuard*™ device**

**“Given our own preliminary results in combination with published European data, there is a very strong clinical trend that using *PediGuard* makes spine surgery safer—not only for patients but for surgeons too.”**

Randal R. Betz, MD  
Chief of Staff  
Shriners Hospitals for Children  
Philadelphia

Podcast available at [MedtechMatters.com](http://MedtechMatters.com)

SAN FRANCISCO and PARIS, Jan. 7, 2008—SpineVision® announced today that [preliminary data from an ongoing postmarketing study](#) show that its FDA-cleared *PediGuard*™ device allows a two-fold reduction of the risk of inadvertent pedicle screw “misplacement” during lumbar degenerative spine surgery. In addition, the preliminary results show that the use of *PediGuard* leads to a six-fold reduction of medial breaches, and suggest an approximately 10 percent decrease in average screw-placement time, as well as a reduction of surgeons’ exposure to radiation by approximately 30 percent. The study’s final results are expected to be even more outstanding when the more challenging thoracic and deformity cases will be included.

*PediGuard* is the first and only FDA-cleared Class II device for *real-time detection* of possible penetration outside the vertebral pedicle. Accuracy of pedicle screw placement is still an issue in spine surgery: published rates of intraoperatively “misplaced” pedicle screws range from 10 to 40 percent, some of which result in pathological consequences such as spinal cord damage, including paraplegia or tetraplegia. Consequently, liability risks for spine surgeons are high.

“Using *PediGuard*, I have a 90 percent chance of placing all my pedicle screws properly, compared to an 80 percent or less chance using standard manual technique,” said Randal R. Betz, MD, an orthopaedic spine surgeon and Chief of Staff at Shriners Hospitals for Children, Philadelphia, who is Principal Investigator for an ongoing, multi-site, randomized postmarketing study of *PediGuard*. “Given the solid published clinical data from Europe in combination with our preliminary data, this is a very significant clinical trend toward making spine surgery even safer for patients. If the trend continues, I see no reason why *PediGuard* can’t become standard of care for spine surgery. Anything we can do to help us get a safer screw insertion is certainly worthwhile, given that published rates of pedicle screw misplacements can range as high as 40 percent.”

“*PediGuard* has changed my practice tremendously,” adds Luis F. Vasquez, MD, a Texas-based neurosurgeon. “Not only has it greatly simplified the accuracy of pedicle screw placement, making spine surgery safer for my patients, but also the use of *PediGuard* has drastically reduced radiation exposure for me.”

(more)

Without the use of PediGuard, *fluoroscopy* is used to continuously monitor the correct placement of pedicle screws into the pedicles of the spine. *Fluoroscopy* is an imaging technique commonly used by physicians to obtain real-time images of the internal structures of a patient through the use of a fluoroscope (C-Arm). *Fluoroscopy* involves the use of x rays, a form of ionizing radiation; while the exposure to a patient during one surgery is minimal, spine surgeons may perform 140 or more cases per year. On the other hand, surgeons who use PediGuard do not have to use continuous fluoroscopic guidance. Indeed, use of PediGuard may reduce surgeons' radiation exposure by approximately 30 percent.

"Less use of fluoroscopy per case means significantly less accumulated radiation exposure over the course of a typical year's worth of cases," explains Dr. Betz. "PediGuard is now our standard of care on all spine surgeries that require placement of pedicle screws."

PediGuard is the first patented, wireless, handheld instrument capable of accurately detecting changes in tissue type, thus alerting surgeons to potential pedicular or vertebral breaches during pedicle screw site preparation. Real-time feedback is provided to surgeons via audio and visual signals, giving them new additional information. The use of *PediGuard* requires no change in surgical technique.

### **About SpineVision**

SpineVision ([www.spinevision.com](http://www.spinevision.com)) is exclusively focused on bringing innovative *motion preservation* and *fusion* devices to spine specialists around the world.

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