

SPINAL DEVICES

SpineGuard SA

Spinal drilling device for safer pedicle screw placement

Pedicle screws are by far the most common implant used in spinal surgery, yet high rates of screw misplacements, which can lead to major neurologic and vascular damage, including paralysis or even death, continue to plague the industry. Imaging and navigational systems utilized to place screws tend not to be all that accurate and expose surgeons and staff to considerable radiation that over time can lead to diseases such as thyroid cancer or cataracts.

PediGuard from SpineGuard SA, in contrast, is a screwdriver-shaped and sized instrument that uses real-time audio and visual signals to detect changes in tissue type, reducing procedure time and thus exposure to radiation. The tip of the free-hand drilling device measures electrical conductivity to differentiate between bone and soft tissue in preparing the hole for safer positioning of pedicle screws. Additionally, it reduces total operating time by 15%. “PediGuard can detect and anticipate possible vertebral cortex perforation and even small breaches of cortical [dense] bone,” says company CEO Pierre Jérôme.

According to iData Research, almost one million spinal procedures performed in the world each year use pedicle screws during spinal fusion back surgery, ranging from a minimum of four screws to more than 20 screws per operation. This represents a potential market opportunity of \$1 billion for SpineGuard’s technology platform, which is compatible with any pedicle screw system. *PediGuard* received both CE mark and 510(k) clearance in 2005 and is approved in many countries, including India, Brazil, Mexico, Australia, Saudi Arabia, and Taiwan. Registration is pending in China, Japan, and Russia.

SpineGuard, with locations near Paris, France, and in San Francisco, was spun off from another French company, Spine-Vision SA (fusion and motion preservation technologies for spinal treatment), in April 2009. The two founders of SpineGuard, Jérôme and Chief Technology Officer Stéphane Bette, had held executive positions at SpineVision. “We realized the great po-

tential of *PediGuard* and knew it required a dedicated effort,” says Jérôme, who served as VP of sales and marketing for Spine-Vision from 2005 to 2009. Prior, he was with Boston Scientific Corp., in both the US and Europe, from 1997 to 2005, and before then held several marketing positions at Sofamor Danek (now Medtronic’s spine division) for five years. Bette was one of the original founders of SpineVision in 1999 and served first as head of R&D and then ran its US subsidiary until his departure to SpineGuard.

SpineGuard has 10 patents (eight issued, two pending) and does not share any royalties/revenues with an outside entity.

The wireless, battery-operated *PediGuard* is a one-piece device made of stainless steel and plastic, with electronics and a battery in the handle. The tip of the handle has a sensor that five times per second measures the electrical conductivity of tissue. When electrical conductivity changes, the audio and visual signals also change. The audio signal varies in pitch and cadence, depending on electrical conductivity. For example, a normal sound of a medium pitch and a medium cadence emits when the tip makes contact with ideal cancellous (spongy) bone. But if the tip approaches undesirable cortical bone, the sound decreases to a low pitch and cadence. And when there is an imminent cortical breach of soft tissue or blood, the sound increases to a high pitch and cadence.

The most challenging aspect of learning is interpretation of the sound signal, for which it typically takes a surgeon roughly five cases to become proficient. Jérôme likens the detection system to car parking sensors for help in parking. “By relying on audio, the surgeon can concentrate on creating the proper trajectory for the pedicle screw rather than watching a screen,” he notes. *PediGuard* also features a visual flashing LED cadence on the instrument itself that mirrors the sound (less flashing when approaching cortical bone; more flashing with an imminent cortical breach). “As surgeons become increasingly familiar with the interpretation of the

5-7 RUE DE L’AMIRAL COURBET
94160 ST. MANDÉ, FRANCE
Phone: +33 1 45 18 45 19
Web Site: WWW.SPINEGUARD.COM

Contact: Pierre Jérôme, CEO
Business: Pedicle screw placement
Founded: January 2009
Founders: Pierre Jérôme; Stéphane Bette, CTO
Employees: 25
Financing To Date: \$20 million
Investors: Omnes Capital; IPSA (formerly Innoven Partenaires SA); A Plus Finance; Delta Partners
Board Of Directors: Alan Olsen (founder of Danek Medical Inc.); Pierre Jérôme; Stéphane Bette; Maurice Bourlion, PhD (*PediGuard* co-inventor); Alexia Perouse (Omnes Capital); Thomas Balland (IPSA); Jean Michel Pimont (A Plus Finance); Joey Mason (Delta Partners)
Scientific Advisory Board: Randal Betz, MD (Shriners Hospitals for Children, Philadelphia); Ciaran Bolger, MD (Beaumont Hospital, Dublin, Ireland); Maurice Bourlion, PhD; André Kaelin, MD (Children’s Hospital of Geneva, Switzerland); Larry Khoo, MD (The Spine Clinic of Los Angeles); John Williams, MD (Parkview Ortho Hospital, Fort Wayne, IN); Hee-Kit Wong, MD (National University Hospital, Singapore)

audio and visual signals, they rely less and less on fluoroscopy,” Jérôme says.

The latest meta-analysis reveals that about 20% of pedicle screws are misplaced using conventional techniques (free-hand and fluoroscopy), causing a 2 to 5% overall complication rate from misplaced screws. “If a screw is placed too lateral, it can damage soft tissue or nerves,” Jérôme explains. “Likewise, a screw placed too medial can damage the spinal cord.” Five published clinical studies of *PediGuard* in peer-reviewed journals demonstrate superior screw placement accuracy. “On average, *PediGuard* has a 97% accuracy placement rate,” Jérôme says. Furthermore, one of the five studies showed a three-fold reduction in neuromonitoring alarms, whereas two others found a 25 to 30% decrease in radiation exposure.

The most commonly used modality for monitoring the placement of pedicle screws is fluoroscopy. Computer-based navigational systems offered by

Medtronic Inc. (*Stealth Station, O-arm*), **Stryker Corp.**, and **Brainlab AG** (*NaviVision 3D*) are expensive, time-consuming (entailing CT scans), and rather complicated to use. “The accuracy of these navigational devices varies, depending on the complexity of the surgery,” Jérôme says. Medtronic and especially **NuVasive Inc.** have also successfully marketed intraoperative nerve monitoring systems for the safer placement of pedicle screws; however, they require a neurophysiologist in the room and are basically limited to assessing the lumbar region of the spine. “PediGuard works in the thoracic area as well, which is probably the most problematic, plus the cervical and lumbar where it can detect any kind of pedicle breach,” Jérôme says.

PediGuard began selling in 2005. To date, over 20,000 spinal procedures, in 40

countries, have included the device, and currently there are more than 250 regular users (100 of whom are in the US). Since the company’s spin-out in early 2009, sales have nearly tripled “in a spine market that is basically flat,” Jérôme points out. The product, which is priced at \$1,500, is sold directly to hospitals in the US and France through commissioned agents, whereas in other countries sales are made through contracted resale distributors. Reimbursement in the US is covered by an existing DRG code and most international markets provide coverage.

In April, the company launched *Cannulated PediGuard* to primarily access the rapidly growing minimally invasive spine surgery (MISS) market. “This new version effectively addresses the two main reasons why many orthopedists and neurosurgeons remain reluctant to embrace MISS: the lack of direct visual

anatomical landmarks and the excessive use of fluoroscopy,” Jérôme explains.

SpineGuard has raised \$20 million so far: a \$15 million Series A upon inception and a \$5 million Series B in the summer of 2011. Funding came mainly from four VC firms. The company is also on the radar of several large spine players. “With about 170 pedicle screw systems available, it becomes very difficult for these firms to differentiate their products. They need innovation,” Jérôme says. On the R&D front, SpineGuard is miniaturizing PediGuard’s sensor and adding to its array of tips. The fertile platform is also applicable to trauma, hip revision, craniomaxillofacial, and dental procedures, where there are the same safety concerns about the placement of screws in bony structures.

[\[A#2012900188\]](#)

— BOB KRONEMYER