10 000th Case for PediGuard

Elizabeth Hofheinz, M.P.H., M.Ed. • Mon, Jan 11th, 2010

Listen up…it's your pedicle talking...SpineGuard has announced that the 10,000th case has been performed using PediGuard, a device for safer pedicle screw placement in spine surgery—one that offers auditory feedback to enhance screw placement.

"PediGuard will probably become a standard tool in any spine surgery requiring instrumentation," said Randal Betz, M.D., Chief of Staff, Shriners Hospitals for Children, Philadelphia, in the news release. "Anything we can do to help us get a safer screw insertion is certainly worthwhile, given that published rates of pedicle screw misplacements are as high as 20%. PediGuard makes spine surgery safer for surgeons also. Fluoroscopy (a type of X-ray) is an imaging technique commonly used by physicians to obtain real-time images of the spine during surgery. While the exposure to a patient during one surgery is minimal, spine surgeons may perform 140 or more cases per year. Studies are showing that the use of PediGuard reduces fluoroscopy time by one-third in some surgeons' cases. Less use of fluoroscopy per case means significantly less accumulated radiation exposure over the course of a typical year's worth of cases."

"As a PediGuard user for over eight years, I have enjoyed using this device for pedicle screw insertion," added André Kaelin, M.D., Chief, Department of Paediatric Orthopaedics, Children's Hospital, Geneva, Switzerland. "After training and a brief learning curve, you add a third sense—the auditory—as an additional help for pedicle preparation. With time, the sound frequency and tone becomes a preeminent part of your technique. For a University Hospital, PediGuard is an invaluable teaching tool: you can assist your residents *and* ensure safe control of their actions."

Pierre Jérôme, CEO of SpineGuard, told *OTW*,

> Each change in electrical conductivity leads to an immediate change of sound pitch and cadence, thus guiding the surgeon through the pedicle while drilling. When going into the cancellous bone the surgeon will hear a medium pitch, medium cadence. Into the cortical bone the surgeon will hear a low pitch, low cadence. If a breach occurs, the surgeon will be alerted by a high pitch high cadence. By guiding the surgeon through the pedicle, the PediGuard makes safer pedicle screw placement by alerting the surgeon prior to full breach, allowing for redirection of instrument in real time and reducing X-ray exposure.

According to the company, PediGuard is the first and only handheld, wireless device that can detect possible vertebral cortex perforation during pedicle preparation for screw placement. The PediGuard technology is based on electrical conductivity, which enables discrimination of cortical bone, cancellous bone and soft tissues.

Regarding the company's future plans, Jérôme commented to *OTW*,

> 2009 was for SpineGuard primarily about putting the business fundamentals in place and transferring the PediGuard technology from SpineVision—remember that the company got off the ground on April 7th after eight months of fund raising, negotiation and foundation. In 2010, our three main operational objectives are to increase market adoption, initiate new clinical studies and drive innovation. All those are geared towards the accomplishment of our vision: establish the PediGuard technology as a standard of care in spinal screw placement.

"To increase market adoption, we are expanding our commercial network, we are investing in the training of our sales forces and we are fostering surgeon to surgeon exchange thru case review forums. The fact that we are totally dedicated to PediGuard and our mission of making spine surgery safer allows us to partner with high performing distributors regardless of the spinal screw brand they commercialize," added Jérôme.

He continued, “PediGuard clinical efficacy has already been clearly demonstrated in several peer reviewed journal publications, multiple abstracts and posters as well as through the 10,000 cases already performed. However, we wish to continue to invest in clinical studies to further establish its superiority over other modalities i.e. manual techniques, fluoroscopy, navigation, EMG and to highlight its cost effectiveness. Not to mention that clinical studies on Pediguard cost much less time and money than traditional clinical studies in spinal surgery because you can measure its accuracy at the time of the case (no need to follow-up patients) and there are least four screws placed on every patient.”

Jérôme also told *OTW*,

> With SpineGuard and our full focus on PediGuard, we have identified more than 40 potential technology developments. We are now in the process of precisely defining, qualifying and calibrating those R&D projects, all derived from the PediGuard technology platform. Our product is unique, our IP is strong but we want to develop it further and remain ahead of the game in making spine surgery safer. At the end of January, we will be holding our first SAB (Scientific Advisory Board) meeting with the objective to prioritize our clinical and R&D pipeline. This will be a very important step forward for us.