

SpineGuard® and Zavation® validate “game changing” DSG™ (Dynamic Surgical Guidance) enabled pedicle screw design

‘Smart pedicle screw’ nears commercialization



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PARIS and SAN FRANCISCO, July 15, 2015 – SpineGuard (FR0011464452 – ALSGD), an innovative company that designs, develops and markets disposable medical devices intended to make spine surgery safer, announced today the validation of the design of both SpineGuard’s and Zavation’s components that are combined in the revolutionary DSG “smart screw” instrumentation, a key milestone toward commercialization for both companies who announced a co-development partnership earlier this year.

“This significant milestone for SpineGuard was achieved through an extremely successful lab in Miami with a panel of spine surgeon experts in the field of open and minimally invasive surgery. We are now well-positioned to launch the manufacturing of the first series, destined for regulatory clearances and alpha launch,” said **Stéphane Bette, CTO and co-founder of SpineGuard.**

Pierre Jérôme, CEO and co-founder of SpineGuard, added: *“The feedback from these eminent US spine surgeons about our technology strides is really encouraging in the perspective to perform first surgeries with dynamically guided screws by year end in Europe. This is a very exciting time for SpineGuard”*

“From the first time that we heard a description of this new concept for screw placement, Zavation has been very excited to be a partner in this project. This recent lab was the first opportunity for us to see the DSG technology and Zavation screw in action. I was amazed at the ability to redirect the screw as needed and the speed of screw insertion. We were thrilled with the performance of the system,” said **Lawrence Walker, Head of Engineering, Zavation.**

“The DSG technology will change the way spine surgery is performed. It will allow us to place spinal instrumentation faster, safer and with greater accuracy, minimizing the risks to our patients,” said **Victor M. Hayes, MD, orthopedic surgeon at Trinity Spine Center, Tampa Florida.**

“We are performing increasingly complex procedures on our patients with superior outcomes that we could not have imagined even a decade ago. With this increase in complexity, though, there is more

potential risk. As spinal surgeons, we have a responsibility to embrace any new technology that can help decrease risk to our patients. Dynamic Surgical Guidance does just that," added **Peter G. Gabos, MD, Co-Director, Spine and Scoliosis Center, Alfred duPont Hospital for Children, Wilmington, Delaware**

"I was able to trial the DSG screw in the lab before its release. It worked like a charm. It is an awl (removable), tap, and monitored screw, all in one. No guide pin that can be advanced inadvertently is needed. I knew immediately where the trajectory of the screw was going, even without fluoroscopy. Rather than use 5 steps to put a screw into the spine, only one step was needed. I could redirect it easily if needed. I even used it to perform a new technique that I had never done before, and finished putting the screw in perfectly on two separate tries within 90 seconds from the time of the skin incision using only 3 x-rays per screw. I believe that this novel technology will be a game changer for spine surgeons. I look forward to using it clinically as soon as it gets approved," said **Thomas Freeman, MD, Professor, Department of Neurosurgery and Brain Repair, and Medical Director, Center of Excellence for Aging and Brain Repair, University of South Florida.**

"DSG adds auditory cues combined with visual cues from fluoroscopy during the Cortical Bone Trajectory MIDLF approach. This results in remarkable improvement in accuracy and safety while placing the maximal length screw possible," said **Richard Hynes, MD, Director at TBC (The Back Center), Melbourne, Florida.**

More on the DSG™ technology, its newest applications and surgeon's prospective at [DSG Product-Profile](#)

About SpineGuard®

Co-founded in 2009 in France and the USA by Pierre Jérôme and Stéphane Bette, SpineGuard's mission is to make spine surgery safer. Its primary objective is to establish its proprietary Dynamic Surgical Guidance (DSG™) technology as the global standard of surgical care, initially for safer screw placement in spine surgery and then in other surgeries. PediGuard®, the first device designed using DSG was co-invented by Maurice Bourlion, Ph.D., Ciaran Bolger, M.D., Ph.D., and Alain Vanquaethem, Biomedical Engineer. It is the world's first and only handheld device capable of alerting surgeons to potential pedicular or vertebral breaches. Close to 40,000 surgical procedures have been performed worldwide with PediGuard. Numerous studies published in peer-reviewed medical and scientific journals have demonstrated the multiple benefits that PediGuard delivers to patients, surgical staff and hospitals. In 2015 SpineGuard started to expand the applications of DSG into pedicle screws through partnerships with innovative surgical companies in France and the US. SpineGuard has offices in San Francisco and Paris. For further information, visit www.spineguard.com.

About Zavation®

Zavation is an employee-owned medical device company based in Jackson, Mississippi, which designs, develops, manufactures and distributes spine products that provide comprehensive medical solutions to improve and enhance quality of life for patients around the world.

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