Press Release

Robotic detection of bone breach via SpineGuard's DSG® technology: 100% efficacy proven again in lab experiment

A more challenging and clinically relevant pedicle trajectory model with oblique bone surface contact

PARIS and BOULDER (CO), March 8, 2023, at 06:00 pm CET – **SpineGuard** (FR0011464452 – ALSGD), an innovative company that deploys its DSG® (Dynamic Surgical Guidance) sensing technology to secure and streamline the placement of bone implants, today announced new impressive results reached in the development of its robotic application.

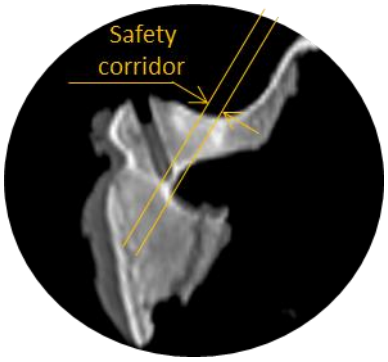
Spineguard's DSG enabling technology is based on the local measurement of electrical conductivity of tissues in real time without X-ray imaging, with a sensor located at the tip of the drilling instrument. Its efficacy was proven by more than 90,000 surgeries across the globe and 24 scientific publications. SpineGuard has entered in 2017 a collaboration with the ISIR *(Institut des Systèmes Intelligents et de Robotique)* lab of Sorbonne University, CNRS and INSERM, for the application of DSG to surgical robots and the enhancement of their safety, accuracy and autonomy as well as the optimization of the surgery workflow.

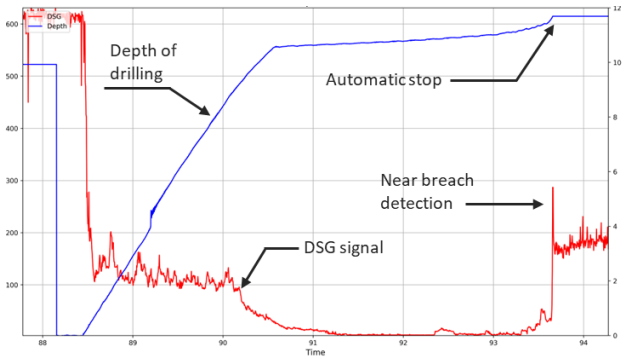
A new experiment in a more challenging and clinically relevant configuration

The experiment, which results are announced today, continuation from those reported late 2021, consists in automatically stopping the drill bit as the tip is aiming at the bone boundary during a vertebral drilling performed autonomously by a robot. However, in order to go further in the challenge and the demonstration of DSG efficacy, the trajectory is now pedicular. It presents tangential configurations perfectly matching delicate surgical situations where the spinal canal protecting the spinal cord must be avoided, and where the tip does not coast the bone surface in a perpendicular way. The algorithm used for the detection was tuned before the 50 drilling series was performed, and no adjustments or calibrations are needed for each specimen. The *ex vivo* pig vertebra validation model (butcher shop) does not involve any animal sacrifice.

Outstanding results: 100% success

100% of the drillings stopped within a corridor considered as clinically safe, which consists of 2 millimeters on each side of the interface between bone and the spinal canal. More precisely, all drillings belonged to a -0.9mm/+1.4mm interval, with a mean distance of 0.7mm. This was obtained although the drilling was performed in a totally "blind" manner, with neither utilization of pre-op nor intra-op imaging.





Stephane Bette, Cofounder and Deputy CEO of SpineGuard, declares: *"These new results confirm the power of the DSG technology applied to bone surgery robotics. They follow a succession of prestigious scientific recognitions and are the object of granted patents in the USA and more recently in France. They answer a real clinical issue with current robots used in spine surgery, which is the potentially undetected deviation of the drill bit in oblique contact with the bone wall. More generally, the need of verifying by a feedback loop the actual position of tools relative to the anatomy via a sensor that measures directly at the tissue contact, in real time and without utilizing X-Rays. The several years of hand-in-hand collaboration with Sorbonne's ISIR continues and allows us to further prepare the integration of our technology in present and future robotic platforms. We intend to implement this integration via commercializing universal DSG drill bits and through strategic licensing agreements."*

Pr. Roger Widmann, Chief of the Pediatric Orthopedic Surgery, Hospital for Special Surgery, New York, US, and Professor at Weill Cornell Medical College, adds: *"Navigated DSG probes combine the safety and accuracy of surgical navigation with the additive value of DSG technology. DSG technology helps detect and avoid pedicle probe skive, pedicle breach and spinal canal violation. DSG technology provides added safety and accuracy in the setting of surgical navigation."*

Pr. Faheem Sandhu, Professor of Neurosurgery and Director of Spine Surgery, Georgetown University Hospital, US, completes: *"The DSG technology has the potential of significantly improving safety during robotic screw placement in the spine."*

Dr. Richard Hynes, Director of The Back Center TBC in Melbourne, Florida, US, adds: *"In the past, I have had great success with placement of screws via CBT and pedicle options using this impedance device. I am a true robotic enthusiast with extensive clinical experience in 3 varying robotic systems for the spine and sacroiliac joint. This technology facilitates our advance to even a higher level of robotic surgery eventually leading to precise and dependable decompression of delicate neural elements. I am truly excited about DSG robotic trajectory potential use for spinal applications."*

Pr. Richard Assaker, Professor of Neurosurgery at the University Hospital in Lille, France, concludes: *"As a long-standing user of PediGuard devices, I have been practicing the robotic assistance in spine surgery for several months. The single technical frustration remains the control of drill bit skiving in pedicle canulation when the entry point is situated on an oblique bony surface. The idea of combining a technology that can detect the skiving and stop the pedicle drilling will increase my trust in robotic assistance particularly when it comes to percutaneous approaches."*

SPINEGUARD'S PRIORITIES

SpineGuard is focusing on the following priorities while investing selectively and with rigor:

1. Boost commercial activities with DSG-Connect and WishBone Medical
2. Develop a DSG drill bit and a universal drill guide embedding the DSG robotic intelligence
3. Implement the agreement recently signed with Omnia Medical
4. Deploy the DSG digital technology in the surgical robotic and dental fields
5. Sign new strategic partnerships

About SpineGuard®

Founded in 2009 in France and the USA by Pierre Jérôme and Stéphane Bette, SpineGuard is an innovative company deploying its proprietary radiation-free real time sensing technology DSG® (Dynamic Surgical Guidance) to secure and streamline the placement of implants in the skeleton. SpineGuard designs, develops and markets medical devices that have been used in over 90,000 surgical procedures worldwide. Twenty-four studies published in peer-reviewed scientific journals have demonstrated the multiple benefits DSG® offers to patients, surgeons, surgical staff and hospitals. Building on these strong fundamentals and several strategic partnerships, SpineGuard has expanded the scope of its DSG® technology in innovative applications such as the « smart » pedicle screw, the DSG Connect visualization and registration interface, dental implantology and surgical robotics. DSG® was co-invented by Maurice Bourlion, Ph.D., Ciaran Bolger, M.D., Ph.D., and Alain Vanquaethem, Biomedical Engineer. SpineGuard has engaged in multiple ESG initiatives.

For further information, visit www.spineguard.com

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