Press Release

SpineGuard reaches the milestone of 100,000 surgeries and over 30 publications with DSG® technology

PARIS and BOULDER (CO), February 6, 2024 at 06:00 pm CET – **SpineGuard** (FR0011464452 – ALSGD), an innovative company that deploys its DSG® (Dynamic Surgical Guidance) unique sensing technology using electrical conductivity local measurement in real time to secure and streamline the placement of bone implants, today announces having reached 100,000 surgeries secured with the DSG technology and having passed 30 scientific publications.

Pierre Jérôme, Chairman, CEO and co-founder of SpineGuard, said: *"Reaching these symbolic thresholds is a great pride for the whole SpineGuard team. It reminds us that so many patients suffering from back pain have already benefited from the accuracy of our real time surgical guidance platform and that we enable numerous surgical teams across the globe to significantly reduce their radiation exposure and associated risks in using it routinely. The clinico-economic value of DSG now leans on 32 scientific studies in a large spectrum of applications. I wish to warmly thank all those who accompany us in this wonderful adventure: all the surgeons who trust our DSG technology, our shareholders, the inventors of DSG, our advisors, as well as our industry and commercial partners. Nonetheless, it is only a step in the development of the Company. We are implementing our roadmap, as presented during our recent capital increase, to get back to double-digit growth this year, fueled by our new US sales organization and the successive launches of three new products."*

Randal R. Betz M.D., Pediatric Spine Specialist, Institute for Spine and Scoliosis, Lawrenceville, NJ and Head of the Scientific Advisory Board (SAB) of SpineGuard since its inception, added: *"This is a great milestone not only for the Company but for the hundred thousand patients who have benefited from safer surgery avoiding neurologic injury and from less radiation. Kudos to Pierre Jérôme and Stéphane Bette for their top-level leadership and staying the course using DSG in newer ways to keep advancing spine surgery. With robotic assistance becoming adopted by many spine surgeons, the combination with real time feedback provided by DSG will drive further acceptance and trust in robotically assisted surgery."*

In 2023, eight new studies about DSG have been published in peer-reviewed scientific journals including three on surgical robotic work and five on non-sponsored clinical studies highlighting DSG strong benefits in various spine surgery indications via anterior and posterior approach. This brings to thirty-two the total number of scientific publications demonstrating DSG's technology value, which represents a significant acceleration compared to previous years. Below are the eight recently published articles:

- **Robotic studies**

Saghbiny et al - Protocol for Electrical Conductivity Signal Collection and Processing in Scoliosis Surgery.
This French study establishes a protocol to collect electrical conductivity signals in spine surgery with synchronization to the depth of the instrument. Real-time conductivity signal feedback alerts the surgeon of a probable breach in the spinal canal, allowing for a change of direction/trajectory within the pedicle.

Leblanc et al - Automatic Spinal Canal Breach Detection During Pedicle Screw Placement.
The results in this other French study demonstrated that the specialized algorithm could predict perforations and prevent the robotic setup from causing an unwanted breakthrough in 100% of 24 drilled vertebrae. In addition, this proved that using electrical conductivity combined with a robotic setup allowed for the detection of imminent perforations of the spinal canal during pedicle drilling.

Timmermans et al - State-of-the-Art of Non-Radiative, Non-Visual Spine Sensing with a Focus on Sensing Forces, Vibrations and Bioelectrical Properties: A Systematic Review.
This systematic review from a Belgium team explores the current state of non-visual, non-radiative spine sensing for robotic spine surgery, with a focus on enhancing surgical techniques and automation. This review emphasizes the shift towards achieving surgeon-like autonomous behavior and surgical accuracy in robotics, and the need to go beyond traditional engineering precision. The review also identifies the 6DOF f/t sensor, microphone and electrical conductivity measurement as commonly used sensors, highlighting their respective characteristics.

- **Anterior/Vertebral Body Tethering (VBT) scoliosis treatment**

Da Paz, Trobisch & Baroncini - The Use of Electronic Conductivity Devices Can Effectively Reduce Radiation Exposure in Vertebral Body Tethering.
This German team noted that they reduced intro-operative radiation by 41% thanks to the use of Electrical Conductivity Local Measurement.

Courvoisier et al - Vertebral Body Tethering in Adolescent Idiopathic Scoliosis Management – A Preliminary Report.
This French team indicated that in their study, Electrical Conductivity Local Measurement proved to be helpful to secure screw precise trajectory without adding intra-operative radiation.

- **Posterior scoliosis multi-modality comparison treatment**

Kudo et al - Accuracy of Pedicle Screw Placement by Fluoroscopy, a Three-Dimensional Printed Model, Local Electrical Conductivity Measurement Device, and Intraoperative Computed Tomography Navigation in Scoliosis Patients.
This Japanese study incorporating several modalities for screw placement assistance concluded that electrical conductivity local measurement is useful to prevent perforations.

- **Novice & experienced surgeon comparison**

Bhogal et al - Bone Conductivity and Spine Fluoroscopy, Hand-Eye-Ear Dialogue, during Pedicle Screw Positioning: a New Human Cognitive System for Precision and Radiation-Decrease; Better than Artificial Intelligence and Machine Learning System?
This single center Belgium study involved two surgeons - one novice and one experienced. The novice surgeon in this study showed a 50% reduction of fluoroscopy radiation usage (in time measurements) when using electrical conductivity local measurement.

- **Cervicothoracic treatment**

Santos et al - Accuracy and safety of 3D Printed Surgical Guides Combined with Monitored Guidewires for Placement of Cervicothoracic Pedicle Screws: Technical Note.
This Portuguese study demonstrated that electrical conductivity local measurement provided the investigator with additional assurance of an intra-osseus trajectory. The authors mentioned that the safety and real-time feedback of electrical conductivity local measurement may also assist with preventing neuro-vascular injuries if one of the 3D printed guides was flawed or incorrectly adapted to the vertebra.

Stéphane Bette, Deputy CEO and co-founder of SpineGuard, concluded: "*Our DSG technology shines particularly in two new fast-growing applications where it has no equivalent. In anterior approach surgery, it is not easy to use Navigation or Robotics because of a deep wound in quite mobile regions, which limits the precision of these technologies. As for Neuromonitoring, it is of limited use in the thoracic segments. Besides, we have the only real-time feedback technology direct from the tissues at the tip of the effector, that has demonstrated its efficacy and can be seamlessly embedded into surgical assistance platforms.*"

Perspectives

Backed by these factors and in order to get back to double digit growth from 2024 onwards, SpineGuard is intensifying its commercial efforts, in particular in the United States, and will be introducing three new products derived from its DSG technology:

1. PediGuard Threaded adapted to scoliosis correction via anterior approach;
2. Cannulated PediGuard for sacroiliac fusion in collaboration with Omnia Medical; and
3. DSG Drill Bit compatible with power drills and navigation.

In parallel, the Company is actively working on obtaining the clearance of the whole PediGuard product range in China and seeking partners for dental implantology and surgical robotics.

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 embedding its technology. Over 100,000 surgical procedures have been secured worldwide thanks to DSG® and 32 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 is expanding the scope of its DSG® technology to the treatment of scoliosis via anterior approach, sacroiliac joint fusion, dental implantology and innovations such as the « smart » pedicle screw and power drill or 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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