

SpineGuard obtains EC-MDR certification and launches its Threaded PediGuard for anterior spine surgery in Europe

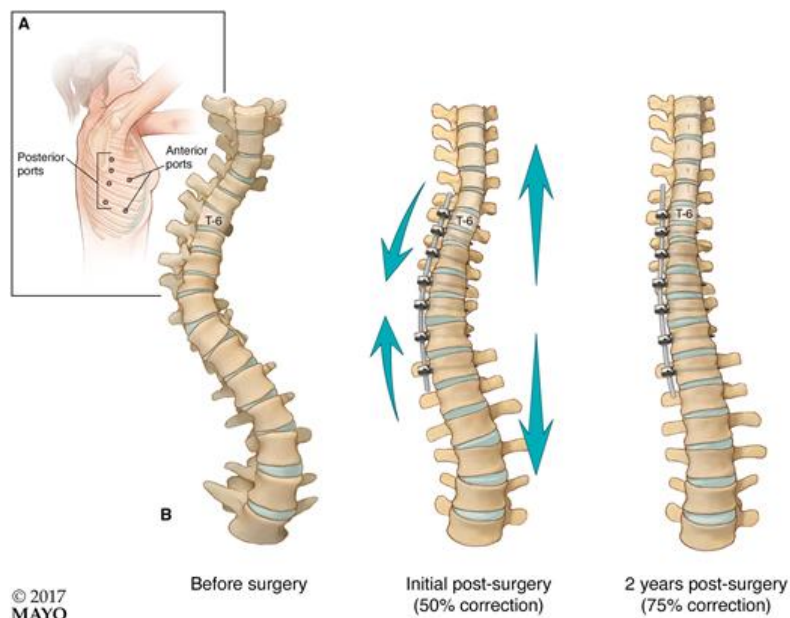
PARIS and BOULDER (CO), September 3, 2024 – 8:00 am CEST - SpineGuard (FR0011464452 – ALSGD), an innovative company that deploys its DSG® (Dynamic Surgical Guidance) local conductivity sensing technology to secure and streamline the placement of bone implants, announced today the obtention of the EC-MDR certification for its class IIa and IIb devices, and that it can now launch its Threaded PediGuard for the indication of anterior approach in spine surgery under the MDR (Medical Device Regulation) in Europe.

The Medical Device Regulation (MDR) is the new regulation applicable within the European Community for medical device manufacturers to be allowed to sell their products. It progressively replaces the European Medical Devices Directive (MDD), significantly elevating the requirements for clinical benefits evidence as well as safety measurements and follow-up.

Stéphane Bette, Deputy CEO and Co-Founder of SpineGuard, stated: *“We are very proud to have obtained this MDR certification which has involved our entire team for more than two years. It is another evidence of the dedication and professionalism of our company which makes every effort to provide safe, effective and innovative products to hospitals, physicians and patients.”*

Already being widely utilized in posterior approach in various spinal indications with success, the Threaded PediGuard range of application is now being extended to include anterior scoliosis correction in Europe. Some adolescents suffering from idiopathic scoliosis require a spinal surgery to stop the progression of their curve and correct their spine. A new trend is to treat these patients using growth modulation. Instead of fixing the back of these patients with posterior pedicle screws and rods, this new technique aims to insert screws in the convex side of the spine and link them with a cord that is partially tighten during the surgery. As these adolescents have remaining growth, blocking the convexity will help them open their concavity and further correct their scoliosis by themselves while they complete their growth. The potential benefits for the patients are immediate; thanks to a minimally invasive surgery, they can have a quick recovery and keep their spine flexibility. That is why, more and more pediatric surgeons adopt this new technique for their patients, representing an increasingly growing market.

Lateral screws placement in vertebral bodies is not without risk. There are some neurological and vascular challenges to avoid and the Threaded PediGuard is particularly well suited to help secure this drilling unlike other modalities like neuromonitoring, navigation or robotics.



Patricia Lempereur, Vice President of International Sales and Global Marketing, added: *“A large number of surgeons performing anterior scoliosis correction are looking forward to use the Threaded PediGuard in their practice. It will help them secure their bi-cortical drilling which is crucial to ensure a good screw anchorage but represents a surgical challenge. Surgeons will significantly reduce the amount of X-rays needed during screw placement and also reduce the surgical time. It will streamline their procedure and make them more confident.”*

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 34 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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