



## Safe Orthopaedics announces CE mark for new Hickory screw

- ▶ New screw in the SteriSpine™PS next-generation range
- ▶ New screw to improve bone anchorage in osteoporotic patients
- ▶ Launch of a study in Germany with Dr. Jens A.Richolt
- ▶ Worldwide commercialisation expected in 2022

Éragny-sur-Oise, France, May 27<sup>th</sup>, 2021 at 8:55 a.m. CET – Safe Orthopaedics (FR0013467123 – ALSAF), a company specialising in the design, manufacture and marketing of ready-to-use technologies for back surgery, with a particular focus on the safety of emergency vertebral fractures, announced today that it has obtained CE Mark approval for Hickory, a new treatment for the management of osteoporotic patients.

Osteoporosis is a global clinical issue. This disease, which affects a growing number of people, mainly affects those over 50 years of age and has consequences for the treatment of spinal pathologies. Safe Orthopaedics, which recently announced the launch of Sycamore for the treatment of vertebral fractures, is now offering Hickory for the treatment of other pathologies requiring pedicle screw fixation.

Developed with the help of Dr Jens A.Richolt, a renowned German spine surgeon and author of numerous studies on the subject, Hickory is a new pedicle screw in the SteriSpine™ PS range that improves bone anchorage in osteoporotic patients. Thanks to its new thread design, Hickory is more securely fixed into the vertebral pedicle and reduces the risk of instability due to the reduced bone quality of the osteoporotic subject.

*“The growing challenge of operating on osteoporotic patients has been defined by the inability to achieve an appropriate pedicle screw construct. That problem is not only seen in osteoporotic situations, but also cases with metastatic instabilities where the screw and rod system will not be supported by bony fusion over time. Having tried many screw designs for these indications, I have found that a variable-thread design provides improved haptic feedback as well as superior anchorage in the pedicle and in the vertebral body where fenestrations in the screw also allow for additional fixation by augmentation. In my experience, such a construct reduces the risk of screw loosening dramatically”* comments Dr.med Jens A.Richolt, spine surgeon in Frankfurt, Germany: *“ Concurrently, this fenestrated variable-thread screw design also has the potential to allow us to reduce the number of instrumented levels and thereby supports our pursuit of less invasive solutions. I’m delighted to be collaborating with Safe Orthopaedics on the design and evaluation of their variable-thread screw design and look forward to examining the results”*

Safe Orthopaedics, which has also just obtained the CE mark for Hickory, is launching a study of the technology in Germany, and expects it to be marketed worldwide by 2022. Designed by Safe Orthopaedics and manufactured by Safe Medical, Hickory is a 100% French technology. This new implant increases the number of indications for use of SteriSpine™ PS.



"We thank Dr.med Jens A.Richolt for his support in this project and are proud to announce the CE marking of this new Hickory screw, to complete our SteriSpine™ PS product range in order to offer the maximum number of solutions to our customers" explains Pierre Dumouchel, President and CEO of Safe Group. "In accordance with the new European Medical Devices Regulation (MDR), we are launching a study in Germany and preparing the global launch of Hickory in 2022. Hickory is the second project after Sycamore from our Safe Group consolidation, designed by Safe Orthopaedics and produced by Safe Medical, and is part of our plan for accelerated innovation and double-digit commercial growth."

### About Safe Group

The Safe Group is a French medical technology group that brings together Safe Orthopaedics, a pioneer in ready-to-use technologies for spinal pathologies, and Safe Medical (formerly LCI Medical), a subcontractor of medical devices for orthopaedic surgery. The group employs approximately 150 people.

Safe Orthopaedics develops and manufactures kits combining sterile implants and single-use instruments, available at all times to the surgeon. These technologies are part of a minimally invasive approach aimed at reducing the risk of contamination and infection, to the benefit of the patient and with a positive impact on hospitalisation times and costs. Protected by 18 patent families, SteriSpine™ kits are CE marked and FDA approved. Safe Orthopaedics is headquartered in the Paris region (95610 Eragny sur Oise - France) and has subsidiaries in the UK, Germany, the USA and the Lyon region where the manufacturing company is located.

For more information: [www.SafeOrthopaedics.com](http://www.SafeOrthopaedics.com)

Safe Medical (formerly LCI Medical) produces implantable medical devices and ready-to-use instruments. It has an innovation centre and two production sites in France and Tunisia, offering numerous industrial services: design, industrialisation, machining, finishing and sterile packaging. Supported by the French recovery plan in 2020, the company is investing in additive printing and will be operational in 2022 with this new technology.

For more information: [www.safemedical.fr](http://www.safemedical.fr)

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