



Safe Orthopaedics announces CE mark for Sycamore

- ▶ Novel treatment for osteoporotic fractures
- ▶ Very dynamic market segment
- ▶ Launch of a multi-centric study in France and Germany
- ▶ Worldwide commercialization expected in 2022

Éragny-sur-Oise, France, On May 24, 2021 à 8:35 CET – Safe Orthopaedics (FR0013467123 – ALSAF), a holding of the Safe Group (composed of Safe Orthopaedics, a company specializing in the design, manufacturing and marketing of single-use technologies for spinal surgeries, and Safe Medical (Ex-LCI medical), integrated subcontractor for orthopedic medical devices, today announces the CE mark for Sycamore, a new treatment for the management of patients with one or more osteoporotic fractures.

Osteoporotic fracture is a global clinical issue. Driven by the aging population and the dynamic lifestyle of those 50 years and older, the number of vertebral fractures has increased significantly over the past two decades.

Developed with the help of a dozen European surgeons, Sycamore is a minimally invasive, ready-to-use technology that improves the first treatment of one or more fractures and reduces the risk of recurrence in osteoporotic patients.

In the laboratory, Safe Orthopaedics has demonstrated the potential clinical benefit of this new technology on human vertebrae, increasing the strength of a cementoplasty-reconstructed vertebra by more than 30%, reducing the risk of post-operative vertebral collapse and thus the patient's re-operation.

Prof. Jean-Charles Le Huec, surgeon at the polyclinic Bordeaux Nord Aquitaine and former professor at the Bordeaux University Hospital, France comments: *“Studies have shown that 25% of patients over 50 years of age have a risk of vertebral fracture and 20% of women may suffer an adjacent level fracture within 12 months. With an ageing global population, the treatment of these pathologies is a real challenge over the coming years. In collaboration with Safe Orthopaedics, we have designed and tested in human vertebrae at the biomechanical lab a new solution. The Sycamore implant is based on a new mechanical concept that has shown it can significantly reinforce a fractured vertebra and has the potential to reduce long-term risk of loss of correction commonly seen with some devices. I’m delighted to see the CE mark of the technology and will participate in the evaluation of Sycamore in clinical practice”.*

Dr. Ardeshir Ardeshiri, surgeon at the Itzehoe Clinic, Germany adds: *“Like many surgeons, I continuously look to improve the treatment and outcomes for the increasing number of fracture surgeries that I operate on, seeking options that are minimally invasive, reproducible and efficient. Along with the other evaluation centers, I am proud to participate in the evaluation of the Sycamore implant with Safe Orthopaedics to demonstrate the clinical benefits of the device. Like all Safe Orthopaedics products that I have used, the ready-to-use instrumentation of Sycamore, and the implant design, has the potential to help streamline the surgical process for the entire operating room team whilst also bringing tangible benefits to my patients”.*



Safe Orthopaedics, which recently obtained CE Mark approval for Sycamore, is launching a multi-centric study of the technology in France and Germany and expects Sycamore to be marketed worldwide by 2022. Designed by Safe Orthopaedics and manufactured by Safe Medical, Sycamore is a 100% French technology, which comes in a ready-to-use kit including minimally invasive instrumentation and sterile implants.

“Motivated by the clinical challenges expressed by surgeons, our research team is committed to finding simple and effective solutions. We are proud to announce the launch of this new technology called Sycamore and to complete our range of SteriSpine™VA products for the management of patients with vertebral fractures” explains Pierre Dumouchel, Chairman and CEO of Safe Group. *“In accordance with the new European Medical Devices Regulation (MDR), we are launching a multi-center study in several French and German centers and preparing for the global launch of Sycamore in 2022. Sycamore is the first project resulting from the consolidation of our Safe Group, designed by Safe Orthopaedics and produced by Safe Medical and is part of our plan to accelerate innovation and double-digit commercial growth”*.

About Safe Group

Safe Group is a French medical technology company, composed of Safe Orthopaedics, pioneer of ready-to-use technologies for spinal diseases and Safe Medical (ex-LCI medical), subcontractor of medical devices for orthopaedics surgery. The Group employs around 150 employees.

Safe Orthopaedics develops and manufactures kits combining sterile implants and single-use instruments, available at any time for the surgeon. These technologies enable minimally invasive approach, reducing the risk of cross contamination and infection, in the interest of the patient with a positive impact on hospitalization durations and costs. Protected by 17 patent families, the SteriSpine™ PS are CE marked and FDA approved. Safe Orthopaedics has its headquarters close to Paris (95610 Eragny-sur-Oise - France) and subsidiaries in the UK, Germany, United States and in the Lyon area where the manufacturing company is located.

For more information: www.SafeOrthopaedics.com

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

For more information: www.safemedical.fr

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