Safe Orthopaedics announces first clinical benefits at 3 months and global launch of Sycamore

- 3-month follow-up result
- 65% pain reduction (ODI & VAS scales)
- Global launch in early January 2022
- 510k expected in 2022

Eragny-sur-Oise, France, December 20th, 2021 17h45 CET – Safe (FR0013467123 – ALSAF), a company specializing in the design, manufacturing and marketing of single-use technologies for spinal surgeries, delivering the safest treatment for spinal fractures urgently treated, announces the end of the first 3-month evaluation of the first surgical cases by the group of surgeon evaluators.

On May 24, 2021, Safe Orthopaedics announced the CE marking of Sycamore, an implant designed to secure the treatment of vertebral fractures and reduce the risk of adjacent fractures.

In a previous biomechanical study on human vertebrae, a 40% increase in compressive strength was demonstrated between a vertebra instrumented with the Sycamore device and a vertebra that had only undergone a simple balloon kyphoplasty.

On December 18, 2021, the French-German surgeon evaluators of Sycamore met to decide on the evaluation of the clinical benefits at 3 months and in particular the evaluation of the reduction of pain on several dozen surgeries. The evaluation group gave very satisfactory conclusions on the new product with a reduction of pain observed in post-surgery of about 65% according to the pain scales Owestry Disability Index (ODI) and Visual Analog Scale (VAS).

Pr Jean-Charles Le Huec, Orthopedic surgeon and traumatologist at the Polyclinic of Bordeaux Nord Aquitaine: "*For many years I have considered the treatments available for VCF fractures, especially in brittle bone, to be sub-optimal. The literature shows re-compression with kyphoplasty is common and sagittal balance can be lost. The Sycamore implant is designed to reduce this chance of re-compression and subsequent adjacent fractures by anchoring the implant, and thus the fracture correction, in the strongest attachment point of the spine, the pedicle. From these early results with Sycamore we can see the Safe Orthopaedics team have developed a safe and effective product and I look forward to analysing the longer term results*".

Pr Kevin Buffenoir, Professor of Neurosurgery at the University Hospital of Nantes, comments: *"The Sycamore system has been adopted quickly by my operating room team with the learning curve being substantially shorter than expected. Over this early series of patients, we have treated a range of ages (27-80+), fracture types and fracture levels and found the Sycamore implant to be extremely capable. With the Sycamore balloon stop one can position the balloon for optimum height restoration and be confident that the cement will be held in place by the implant itself. This combination has the potential to deliver real advantages for the patient over the long term, reducing the chances of future operations. As the data collection continues, I look forward to examining these long-term results for my patients".*

Dr. Ardeshir Ardeshiri, Head of the Spine Surgery Department of the Itzhoe Clinic, Germany: "*Working closely with the design & clinical research teams at Safe Orthopaedics, I have found the Sycamore system has delivered very predictable results. Having now implanted 14 Sycamore implants, my team and I have found the instrumentation to be well designed and, crucially the use of Sycamore does not add significantly more time to the surgical procedure. What's more, I have found the Sycamore procedure to be highly reproducible meaning I can achieve optimal results for every patient*".

Pierre Dumouchel, Safe Group's Chairman and CEO, concluded: *"Sycamore's safety and pain reduction clinical results are in line with our expectations. In agreement with our evaluating surgeons, the commercial launch will take place in early January in all countries where we are present and then in the United States where we expect regulatory approval in mid-2022. In parallel to this launch, we will continue to evaluate the efficacy of Sycamore through an international clinical registry, with the objective of proving the medico-economic benefits of this novel technology and convincing a significant number of surgeons worldwide".*

Sycamore will be launched globally in January 2022, with the exception of the U.S., where Food and Drugs Administration (FDA) approval for Sycamore is expected in the second half of the year.

About Safe Group

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

Safe Orthopaedics develops and manufactures kits combining sterile implants and single-use instruments, available at any time to the surgeon. These technologies are part of a minimally invasive approach aimed at reducing the risks of contamination and infection, in the interest of the patient and with a positive impact on hospitalization times and costs. Protected by 18 patent families, SteriSpineTM kits are CE marked and FDA approved. Safe Orthopaedics is headquartered in the Paris region (95610 Eragny-sur-Oise) and has subsidiaries in the United Kingdom, Germany, the United States and the Lyon region (Fleurieux-sur-l'Arbresle).

For more information: www.safeorthopaedics.com

Safe Medical produces implantable medical devices and ready-to-use instruments. It has an innovation center and two production sites in France (Fleurieux-sur-l'Arbresle, 69210) and in Tunisia, offering numerous industrial services: design, industrialization, machining, finishing and sterile packaging. Supported by the French stimulus plan in 2020, the company invests in additive printing and will be operational in 2022 on this new technology.

For more information: www.safemedical.fr

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