

Major medical publication confirming Safe Orthopaedics' ability to decrease surgical site infection and surgery time

- Risk of surgical site infection could be reduced by two-thirds
- Surgery time potentially shortened by 15 minutes

Eragny-sur-Oise (France), November 2, 2015 – SAFE ORTHOPAEDICS (Euronext: FR0012452746 – SAFOR), a company developing and marketing an innovative range of sterile implants combined with their single-use surgical instruments, today announces the positive conclusion from a prospective bi-centric study published in September 2015 in the *European Journal of Orthopaedic Surgery & Traumatology*, a major peer-review journal with international coverage.

New clinical evidence of the added value of the single-use instrumentation

More than 40,000 patients suffer from surgical site infection after spinal surgery every year. In addition to the clinical impact for the patient, economic consequences of surgical site infections are significant as they prolong a patient's stay by an average of two weeks, double the chance to be re-hospitalized and increase the total cost by 300%.

The results of the study are very encouraging with a potential reduction of surgical site infection from 6% to 2% as only one infection was observed in a 60 years old man with previous spine surgery and two additional risk factors. This can be explained "by the preservation of screws and rods inside their sterile pack" which "reduces their exposure to air-borne bacteria in the operating room". The study shows additional benefits with a significant reduction of surgery time by 12% (15 min) and minimal blood loss which could also participate in the reduction of surgical site infection rate.

Yves Vignancour, Safe Orthopaedics CEO, said: "This publication confirms the results of the recent retrospective clinical study conducted by Dr Gregory Lanford in Nashville. He also reported a potential reduction in infection rate when using our breakthrough single-use surgical instruments for lumbar fusion. It is an important step forward as it confirms the potential gains of using Safe Orthopaedics' products both in the US and Europe."

The study was performed by Pr. J.C. Le Huec, Dr. G. Recanati and Dr. C. Maillot (Department of Spine Surgery, University of Bordeaux), Dr. S. Litrico and Dr. A. Gennari (Department of Neurosurgery, University of Nice) and Dr. M. Saffarini (Centre for Health Management, Imperial College London).

Between January 2013 and September 2013, a total of 49 patients, received an instrumented posterior lumbar fusion for degenerative disc disease at 1 up to 4 levels with Safe Orthopaedics' single-use SteriSpine PS Pedicle Screw System kits in two centers. The patients were followed up and monitored for 1 year and results have been compared to a previous series for the same indication operated by the same surgeons with reusable instrumentation.

The "Single-use instrumentation in posterior lumbar fusion could decrease incidence of surgical site infection: a prospective bi-centric study" paper is available on request.

About Safe Orthopaedics

Founded in 2010, Safe Orthopaedics is a French medical technology company that develops and markets an innovative range of sterile implants and associated single-use surgical instruments, with the aim of facilitating safer, optimized and lower-cost spinal surgery. By avoiding the reuse of surgical instruments, Safe Orthopaedics reduces the risk of infection, avoids the cumbersome and unreliable logistics of instrument sterilization, and limits hospital costs. Protected by 17 patent families, the SteriSpine[™] Kits are CE-marked and FDA cleared; they are already being marketed in 16 countries, in Europe and the United States. They are being rapidly adopted by surgeons throughout the world, with nearly 1,000 procedures performed in 2014 and 1,691 from January 1st until September 30th 2015. The company is based at Eragny-sur-Oise (France), and has 32 employees and a US subsidiary.

For more information, visit: www.SafeOrtho.com

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