



PRESS RELEASE

Safe Orthopaedics obtains FDA approval to market its unique implant for Spinal Trauma care in the United States

- ▶ Innovative One-step system to correct and stabilize Spinal Trauma in the same surgical stage
- ▶ Patented implant specifically created to address Thoraco-lumbar Trauma through open or MIS surgery
- ▶ Sterile Implant and Single-Use Instruments designed for enhanced patient safety and “on-the-shelf” availability

Eragny-sur-Oise (France), October 13, 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 that the U.S. Food and Drug Administration (FDA) has approved the marketing of Safe Orthopaedics’ new implant for repairing traumatic spinal injuries in the United States.

Unique One-Step system to correct and stabilize Spinal Trauma

The unique One-Step System allows simultaneous fracture correction while stabilizing the spine, reducing the need for additional instruments and simplifying the surgery.

The Innovative self-correcting screw mechanism offers gradual, automatic and reproducible vertebral fracture reduction with a surgical procedure similar to that of a standard thoraco-lumbar fusion, open or MIS.

Often caused by a trauma, vertebral fractures require swift surgical treatment. Designed for one-time use, the new One-Step system combines implants with single-use surgical instruments and is ready for use at all times, thus eliminating unnecessary delays.

Following its success in Europe, Safe Orthopaedics introduces its One-Step system on the U.S. market

The product was successfully launched in Europe in July 2015 shortly after the CE Mark was obtained. To date, more than 20 operations have been successfully performed in 5 Hospitals in France and the Netherlands. Additional Austrian and British Hospitals are about to initiate such operations.

This October, the U.S. Food and Drug Administration (FDA) granted its approval for the new implant, marking a milestone for the company in its U.S. development strategy. With this patented product Safe Orthopaedics gains access to the US spinal trauma market. Every year in the US more than 35,000 Patients will receive Spinal Surgery for repairing traumatic thoraco-lumbar injuries.

The One-Step system to address Spinal Trauma will be launched in the U.S. at the **upcoming 30th North American Spine Society (NASS) annual meeting**, which will be held on October 14 to 17 2015 at McCormick Place West Building, Chicago, IL. Safe Orthopaedics will participate in the exhibition at Booth 1295 at NASS.

About the North American Spine Society (NASS)

The North American Spine Society is a multidisciplinary medical organization dedicated to fostering the highest quality, evidenced-based and ethical spine care by promoting education, research and advocacy. NASS is comprised of more than 8,000 members from several disciplines, including orthopedic surgery, neurosurgery, physiatry, neurology, radiology, anesthesiology, research and physical therapy.

For more information, visit: <https://www.spine.org/AM.aspx>

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 company's CE-marked and FDA-approved SteriSpine™ kits are already being marketed in 12 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 1,143 in the first half of 2015 alone. 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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