

Safe Orthopaedics receives CE Mark for a new implant to treat vertebral fractures

- New 4.5 mm version approved of the patented Oak screw for the trauma market
- Range extended to cover thoracic vertebral fractures

Eragny-sur-Oise, France, December 16, 2016 – SAFE ORTHOPAEDICS (FR0012452746 – SAFOR), a company offering innovative ranges of sterile implants combined with their single-use instruments, today announces that it has received CE Mark for a new version of its patented Oak screw used to treat thoracic vertebral fractures.

Previously, 7.5 mm, 6.5 mm and 5.5 mm diameter versions of the screw were available for lumbar (lower back) vertebral fractures. With its smaller diameter, the new 4.5 mm version caters more widely for thoracic (middle-back) vertebral fractures.

Oak is the only pedicle screw in the world to offer simultaneous correction and fixation of trauma-related vertebral fractures. It combines the advantages of a multi-axial screw, which eases insertion of the rod, with the benefits of a mono-axial screw in reducing the fracture without any additional instruments.

This Safe Orthopaedics-patented innovation is ideal for minimally invasive surgeries and is also compatible with conventional open approaches. SteriSpine modular kits can be used with either of these approaches, making it possible to switch from one to the other in mid-surgery should the need arise.

Combined with their sterile single-use instruments, Oak screws are also constantly ready for use, and so surgery can go ahead without any delay—a major advantage in trauma cases. Vertebral fractures, which are usually the result of accidents, require rapid emergency surgery.

Dr. Van Gaalen, orthopedic surgeon at the Utrecht Hospital, Netherland, commented: *“The Oak screw is a major breakthrough for trauma surgery because it facilitates and enhances the treatment of vertebral fractures. The CE Mark of this latest 4.5 mm diameter version of the product, which previously catered largely to lumbar vertebral fractures, opens up new possibilities for the treatment of thoracic vertebral fractures. This means we can now offer the benefits of this technology to a larger number of patients.”*

Dr. Vouaillat, orthopedic surgeon, Cedar Clinic, Echirrolles, France, and co-inventor of the system added: *“This unique system offers new possibilities in the management of trauma surgeries and also opens up new solutions for degenerative surgeries.”*

Pierre Dumouchel, Chief Executive Officer of Safe Orthopaedics, concluded: *“The CE Mark of this new version of the Oak screw further strengthens our position in the key trauma market. Our ground-breaking innovations are ideally suited for trauma treatment because surgical procedures become easier and can go ahead more rapidly. They also open the way for minimally-invasive approaches—still used all too rarely in emergency surgeries.”*

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. The company is based at Eragny-sur-Oise (France), and has 34 employees.

For more information, visit: www.SafeOrtho.com

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