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DALLAS / Privately held <u>Safe Orthopaedics</u> aims to revolutionize the way **orthopedic** and **spi** nal

implant

systems are delivered by introducing the

SteriSpine

[™] PS Pedicle Screw system — the world's first single-use, sterile and traceable system for **fixation**

of the

lumbar

spine

— at the North American Spine Society (NASS) Meeting in Dallas this October 24-27.

"The introduction of SteriSpine PS marks a first," says founder and CEO, Dominique Petit. "The traditional model featuring heavy, reusable instrument systems presents a number of solvable problems. Safe Orthopaedics exists to deliver these solutions to the marketplace."

The SteriSpine PS system meets global calls for value-based innovation by eliminating costly, time-consuming inventorying and management tasks, by allowing comprehensive traceability of implants and instruments and by enhancing surgical efficiency and patient safety in the OR.

Cost containment is on the forefront of all healthcare related issues, and orthopedic implant systems — which are traditionally very large, complex and heavy — present particularly difficult challenges. Hospitals must receive, inspect, wrap and sterilize the systems in preparation for surgery, and then clean and decontaminate the systems to prepare for the next case or return shipment. The SteriSpine PS system from Safe Orthopaedics, however, eliminates this entire expense burden by providing sterile, single-use surgery kits for every procedure.

Challenges have also arisen from new regulatory demands for tracking and traceability of surgical implants and instrumentation. To satisfy the new requirements, all SteriSpine PS components meet expected Unique Device Identifier (UDI) regulatory requirements across Western Europe and the United States. This feature ensures unprecedented tracking capability and comprehensive traceability of the implants and instruments used in each surgical



procedure.

In orthopedics, as with any surgical technology, patient and staff safety remain a critical issue for surgeons and hospitals alike.

"The fact that I'm utilizing never-used-before, sterile instruments and implants gives me, the hospital staff and my patients peace of mind," says Jean-Charles Le Huec, M.D. (Prof Orthopaedic Surgery, Chairman Spine Department, Bordeaux University Hospital (France), President Eurospine 2012 (SpineWeek), Past President, ISASS).

"What strikes me most about the system is the simple efficiency of the technology," says Le Huec. "The instrument sets are comprehensive and recyclable. Everything is new, in perfect condition and calibration, and ready to go at a moment's notice. This is clearly a major step forward in making these systems easier, safer and more cost effective."

The launch of SteriSpine PS at NASS continues the product's introduction to the global spinal community — a process that began in May at the SpineWeek international trade show in Amsterdam.

About Safe Orthopaedics: Safe Orthopaedics was founded (Paris, France) in 2010 by Dominique Petit, a 22-year entrepreneur / engineer veteran of innovative spine technologies, Pierre Dumouchel, industrialization expert, and Thomas Droulout, technology and materials expert.

In line with the significant healthcare issue of today, Safe Orthopaedics is focused on enhancing the cost-effectiveness, safety and efficiency of orthopaedic implant / instrument systems. These enhancements are achieved by a new model of single-use, sterile and traceable orthopaedic procedure kits. By streamlining the expensive, complex and inefficient process by which implant systems are delivered, Safe Orthopaedics endeavors to dramatically improve the value proposition of these procedures for hospitals, surgeons and the collective healthcare systems they serve.

For more information, please visit www.safeortho.com.

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