# Safe Orthopaedics announces the regulatory approval of SteriSpine<sup>™</sup> PS 2<sup>nd</sup> Generation in Japan

- ▶ Regulatory approval of SteriSpine<sup>™</sup> PS Gen 2 in Japan
- Shipping in march 2020 of hundreds of kits

Éragny-sur-Oise, France, March  $31^{st}$  2020, 18h30 CEST – Safe Orthopaedics (FR0013467123 - ALSAF), a company specialized in the design and marketing of ready-to-use technologies for spinal surgery, delivering the safest treatment of spinal fractures urgently treated, announces the regulatory approval of SteriSpine<sup>TM</sup> PS  $2^{nd}$  Generation in Japan.

In July 2019, Safe Orthopaedics had announced the commercial launch of SteriSpine<sup>™</sup> PS 2<sup>nd</sup> Generation in Europe, and more specifically in the framework of direct distribution, in order to collect several feedbacks from clinical practice and document the effectiveness of this new generation of kit.

In October 2010, Safe Orthopaedics had announced the effectiveness of this new generation, confirmed by dozens of surgeries. More rigid, slimmer, still radio-transparent, it allows an even more mini-invasive approach and to be used on a larger range of spinal diseases.

Today, Safe Orthopaedics announces the regulatory approval of this new generation of kit by the Pharmaceuticals and Medical Devices Agency (PMDA). Locally distributed by our partner (partnership entered into on May 2018), Safe Orthopaedics predicts a quick adoption of this new generation and a rise in the number of surgeries, already well established, for the second half-year of 2020.

A shipment of hundreds of kits has been made in March and new deliveries are planned during the second quarter in order to make available this second generation of products to more hospitals and surgeons, as soon as the COVID-19 health crisis is over.

### **About Safe Orthopaedics**

Founded in 2010, Safe Orthopaedics is a French medical technology company, a pioneer of the design and marketing of innovative ready-to-use technologies (single-use implants and instruments) for spinal diseases, delivering the safest treatment of spinal fractures. The technologies include sterile implants and ready-to-use instruments available to the surgeon at anytime and anywhere, enabling minimally invasive approaches, reducing the risks of cross contamination and infection in the interest of the patient. Protected by 17 patent families, the SteriSpineTM Kits are CE marked, FDA and CFDA approved. Safe Orthopaedics, has its headquarter close to Paris (95610 Eragny-Sur-Oise - France) and has created a subsidiary in the UK, Germany and in the US, employing around 50 employees for a total sales of 4.7M€ in 2019.

For more information: www.SafeOrthopaedics.com

## **PRESS RELEASE**

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