



Safe Orthopaedics receives 510k approval from the FDA for the sale of its 2nd Generation of SteriSpine™ PS in the United States

- ▶ Success of the 2nd generation SteriSpine™ PS range among surgeons in marketed areas
- ▶ New patent in Japan for the Oak screw implant belonging to SteriSpine™ PS range

Eragny-sur-Oise, France, August 10th à 6.00 PM CEST – Safe Orthopaedics (FR0013467123 - ALSAF), a company specializing in the design and marketing of ready-to-use technologies for spinal surgeries, delivering the safest treatment of spinal fractures urgently treated, is announcing today the 510k approval from the American Regulatory Agency Food and Drug Administration (FDA), for the sale its 2nd Generation of SteriSpine™ PS in the United States.

Developed in 2010, SteriSpine™ PS is the first technology of pedicle screws combined to a ready-to-use instrumentation (single use and sterile) worldwide. As more than ten thousand surgeries have been performed, Safe orthopaedics has been announcing in 2019 the launch of its 2nd generation. Significantly thinner, more rigid and still radiolucent, SteriSpine™ PS 2nd generation enables the surgeon to perform the surgery in an even more mini-invasive approach, and can be used on a wider number of spine pathologies.

Safe Orthopaedics has been enhancing business development of SteriSpine™ PS 2nd generation since the beginning of 2020. In the first quarter, technology was delivered to Japan, and in the second quarter, it was available to several European countries and in Asia Pacific area. At the end of the year, all direct French, English and German direct customers will have been converted.

Following this 510k approval from the FDA, Safe Orthopaedics is getting ready for its commercial launch.

« Obtaining the FDA approval for the 2nd Generation SteriSpine™ PS in the United States is an important milestone in entering our second decade, as we observe a real adoption of ready-to-use technologies on a global scale and growing competition. Thanks to the feedback from our European users, we have designed this thinner, more rigid and totally radio-lucent evolution for an easier minimally invasive surgery, now meeting the expectations of American surgeons. », comments Pierre Dumouchel, Safe Orthopaedics Chief Executive Officer. « Following our first experience in the United States, we are very attentive to developments happening in the world's leading market, and are organizing ourselves to make the SteriSpine™ PS second generation available to American surgeons. The acceleration of outpatient surgeries, in dedicated centers called Ambulatory Surgery Centers (ASC), represents a new business opportunity for Safe Orthopaedics. Combined with a very short production cycle made possible by the acquisition of LCI Medical, in 2021 we will launch a new distribution method, totally digital and perfectly fitted to the ASC. »



Finally, Safe Orthopaedics, which already holds around a hundred patents, is also announcing today the acquisition of the Japanese patent for its Oak screw, an implant from the SteriSpine™PS range offering an unprecedented minimally invasive surgical technique for treating high-energy fractures.

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 any time 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 SteriSpine™ Kits are CE marked, FDA and CFDA approved. Safe Orthopaedics, has its headquarters close to Paris (95610 Eragny-Sur-Oise - France) and has created sales subsidiaries in the UK, Germany and in the US, and since July 2020 has industrial subsidiaries in France and Tunisia.

Safe Orthopaedics is employing around 150 employees and delivers its products worldwide.

For more information : www.SafeOrthopaedics.com

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