



Safe Orthopaedics announces first SORA-assisted surgeries and production of two new units

- ▶ First surgeries performed with the SORA surgical assistant in the first French evaluation center and the support of Doctor Pierre Vallèse
- ▶ Two new SORA units produced for installation in France and Germany
- ▶ Interview with Dr. Pierre Vallèse, orthopaedic and trauma surgeon at the Convert Clinic in Bourg-en-Bresse

Éragny-sur-Oise, Fleurieux-sur-l'Arbresle, October 13, 2021 at 5:45 pm CET - Safe Orthopaedics (FR0013467123 - ALSAF), a company specializing in the design, manufacture and marketing of ready-to-use technologies for back surgery, particularly safe for emergency-treated vertebral fractures, announces the first surgeries performed under SORA and the deployment of two other SORA units.

SORA offers three main functions:

- 1) Assisted selection of implants and instruments in the operating room: SORA eliminates the risk of error in product selection, tracks lot numbers and informs all relevant hospital departments of what has been implanted.
- 2) Virtual assistant for surgeons and medical staff: the surgical documentation of implants and instruments contained in SORA is accessible via the software and online surgical assistance. SORA offers virtual assistance via the interactive touch screen. Safe Orthopaedics experts can also be invited virtually to answer questions before, during and after the procedures.
- 3) Automated replenishment and inventory management support: through automated ordering processes, SORA helps reduce delivery times after each surgery, improve operations planning, and reduce time, resources, and logistics costs for hospitals.

As announced on January 4, 2021, during the launch of the Virtual Operating Room Assistant, the first targeted evaluation was launched with Dr. Vallèse, Head of Department at the Convert Clinic in Bourg-en-Bresse. Two other SORA units are currently being deployed in Paris and Frankfurt.

Pierre Dumouchel, Chairman and CEO of Safe Orthopaedics, said: *"In addition to the medico-economic benefits of our Safe Orthopaedics ready-to-use*



technologies, we are now deploying new digital services to improve patient care, increase logistical efficiency in hospitals and reduce associated costs. SORA is a strategic platform for innovation and growth for the Safe Group. We thank Dr Vallèse and his team at the Convert Clinic for their full involvement in the evaluation of SORA and we look forward to manufacturing new SORA units for deployment in new French and German centers by the end of 2021. We hope to deploy this model internationally in 2022 and develop new clinical and digital education features”.

Dr. Pierre Vallèse, Orthopedic Surgeon, first evaluator of the SORA Operating Assistant, gives a first progress report:

How important is it for you to optimize the operating time, for the medical team to have a simple and fast solution to ensure the traceability of the implantation and a restocking of the material within 24 hours?

“Operating time is an essential parameter of our surgical practice. Without falling into the trap of excessive profitability, optimizing operating time can have a beneficial effect on the incidence of septic complications, on team efficiency and on improving the flow of operations.

The management of implantable devices in health care institutions has become increasingly complex over the last few years, with frequent problems of restocking or inventory. All this generates stress within the team with a transfer of responsibilities and can lead to undesirable events.

The SORA solution is the perfect answer to this problem by providing real-time access to the availability of materials on the screen. As soon as an implant is delivered by the machine, the order form is immediately transmitted via an Internet connection to Safeortho, which ensures rapid restocking in less than 24 hours. By limiting the number of intermediaries between the implanter and the manufacturer, traceability is made more reliable and responsibilities are better assumed.

Indeed, when the problem of availability or expiration of an implant arises, it is useless to look for a person in charge in the pharmacy or in the operating room because only the surgeon is in the front line with his CPR. It is therefore a good thing that the surgeon has control over the implants while freeing himself from the administrative part.”

Do you think that virtual assistance in the operating room by Safe can help you (or your OR team)?

“In addition to the logistical support provided by the SORA solution, virtual assistance is an innovative step forward. All operating techniques can be consulted directly on the machine screen by the staff and, in the event of a problem, a video connection can be established with a technical advisor. This limits the number of people in your operating room while guaranteeing the technical assistance often desired. I have noticed a real interest from the young IBODEs in this digital aid that they master perfectly, with intuitive information on the tablet of very good quality.

Do you think that the industry should develop digital solutions to facilitate patient management, from the first consultation to the scheduling of surgery and post-operative follow-up?

“Yes, of course, because we need to provide our patients with the best techniques and the best implants. The partnership between the industry and the surgeon is essential for the realization of quality studies. The digital tool brings an undeniable performance in this field because it allows the cross-referencing of clinical and conceptual data on implants. It also allows to secure this data by referring to the RGPD rules. The accesses are controlled and can be restricted for each operator to avoid any drift of the system. Indeed, it is important that each party (surgeon and industrialist) keeps its independence and that the main actor, i.e. the patient, keeps the full ownership of his



data and prohibits any exploitation that could be harmful to him. The SORA system will therefore have to meet these requirements in the collection and processing of data. This is a daring challenge, as many solutions exist today but are still struggling to emerge due to the complexity of the regulation in force and the coveted search for DATA."

Would you be willing to connect SORA during your surgeries to remotely train young surgeons in new surgical techniques and/or the use of Safe products?

"Companionship is an important part of our surgical training. For the past two years, the pandemic has had a negative impact on this training and we may have to review the way it is carried out. Giving access to live surgeries is a very interesting option of the SORA solution. I would be happy to share my experience but also to be able to call upon the experience of other surgeons in my practice."

About Safe Group

Safe Group is a French medical technology group that brings together Safe Orthopaedics, a pioneer in ready-to-use technologies for spine pathologies, and Safe Medical (formerly LCI Medical), a subcontractor of medical devices for orthopedic surgery. The group employs approximately 150 people.

Safe Orthopaedics develops and manufactures kits combining sterile implants and single-use instruments, available at any time to the surgeon. These technologies are part of a minimally invasive approach aimed at reducing the risk of contamination and infection, for the benefit of the patient and with a positive impact on hospitalization times and costs. Protected by 18 patent families, SteriSpine™ kits are CE marked and FDA approved. Safe Orthopaedics is headquartered in the Paris region (Eragny-sur-Oise (95610)) and has subsidiaries in the United Kingdom, Germany, the United States and the Lyon region (Fleurieux-sur-l'Arbresle).

For more information: www.safeorthopaedics.com

Safe Medical produces implantable medical devices and ready-to-use instruments. It has an innovation centre and two production sites in France (Fleurieux-sur-l'Arbresle, 69210) and Tunisia, offering a wide range of industrial services: design, industrialisation, machining, finishing and sterile packaging. Supported by the French recovery plan in 2020, the company invests in additive printing and will be operational in 2022 on this new technology.

For more information: www.safemedical.fr

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