At Spine Innovations (supplier of the ESP disc replacements), quality and patient's safety have always been our main concerns.

Since the beginning of last year and the degradation of the sanitary situations in Europe and worldwide, we have strengthened safety procedures to protect employees, maintain continuation in our supply and ensure patient's safety through the whole process:

1. At the office

- As a medical device supplier, the access to our offices is secured with a digit code at the main door and a key for each office.
- Our offices were already cleaned and aired every day. Now they are cleaned using of specific disinfectant.
- Bins are emptied every day.
- Working from home was already part of the organization of our company. We have increased this practice since the beginning of the crisis. We prefer now videoconference for our meetings.
- Each employee has received a full "Anti Covid-19" package with a booklet with recommendations, reusable masks for each day of the week, hydroalcoholic gel and no touch door opener.
- It is mandatory to wear masks inside the buildings and hydroalcoholic gel is provided in each room.

2. On our logistic platform

- As a medical device supplier, the access to our logistic platform is restricted to people who work there. The access to the logistic platform must be granted by the manager.
- All instruments are quality controlled by people specifically trained. First when they are delivered from our manufacturing site and then when they return from loans to customers. Customers must fill a shuttle form for loans indicating type of cleaning and sterilization applied to the material. If cleaning or sterilization are judged insufficient our instruments are sent again through a cleaning and sterilization process. In the context of Covid-19, our loan sets are put in quarantine a few days before handling when they return from customers.
- Our implants are delivered sterile, all boxes are quality controlled when they are delivered from our manufacturing site and when they come back from loans to customers.
- Our logistic platform is certified ISO 9001 and ISO 13485.

3. At our manufacturing site

- As a medical device manufacturer, our industrial site has received specific certifications (ISO 13485) from notified body meaning that the manufacturing process respects all the standards in terms of quality and safety.
- We have a strong Regulatory Affairs / Quality Affairs department, responsible for the writing and the follow-up of the procedures. RA/QA department regularly organizes self-audit to check conformity with the current regulations.
- Our manufacturing site (such as our logistic platform) is regularly audited by the notified body who delivers our certifications.
- Numerous steps of the manufacturing of our prostheses are realized under clean area in rooms with restricted access. In those clean rooms, working people must wear masks, gloves, and blouses.
- Raw materials, spare parts of implants and final implants are quality controlled at each step of the manufacturing process.
- Our prostheses are provided sterile to ensure patient safety.

Throughout its history, our dedicated team has always valued strong partnerships with distributors, agents and health professionals sharing the same commitment to quality and patient's safety.

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