FIOR & GENTZ – Dorette-von-Stern-Str. 5 – 21337 Lüneburg (Germany)

Lüneburg, April 2021

Customer Information regarding the Period of Use of FIOR & GENTZ System Joints for Orthoses

Dear Sir or Madam,

From 26 May 2021 onwards, the Regulation (EU) 2017/745 (MDR) will apply to Class I medical devices. These medical devices may then only be placed on the market and operated in accordance with the regulation.

A key objective of this regulation is to ensure the safe handling and proper functionality of medical devices. Within this framework, the manufacturers are required to define a period of use for all active medical devices. For both active and non-active medical devices, the manufacturer must specify all necessary measures to ensure the proper functionality of the medical device as long as it is in use. The necessary measures are to be implemented by the specialised trade or the distributor of the medical device. Furthermore, the patient as well as the cost bearer have to ensure, within the scope of their possibilities, that the specialised trade can carry out these measures.

FIOR & GENTZ develops medical devices for the orthotic treatment of the lower extremity. Our system joints are mounted by our customers (the specialised trade) in custom-made orthoses, also referred to as custom-made products.

In addition to our high quality standards, we also focus on sustainability and cost efficiency. That is why we develop system joints that not only safely support patients in their everyday lives, but are also durable, and therefore sustainable. Our objective is to ensure that our system joints can be used throughout the entire lifespan of the custom-made product, without being limited by a period of use.

That is why we, as the FIOR & GENTZ company, have developed a concept that allows for an unlimited period of use for all our system joints.

To ensure a safe handling and full functionality, the unlimited period of use applies according to the conditions defined in the respective instructions for use.
In particular, the period of use is linked to the complete documentation and compliance with the specified maintenance intervals. Wear parts must be checked and replaced according to specified maintenance schedules.

The period of use of the system joints ends with the period of use of the custom-made product and a multiple use of a system joint in another custom-made product is not permitted.

The new orthosis service passport is used for the documentation of the complete compliance with the maintenance intervals.
All maintenance performed within this framework is documented in the orthosis service passport by the specialised trade (see attachment). Every patient receives the orthosis service passport when their custom-made product is handed over by our customer (the specialist trade). In this way, the patient will always be informed about their next maintenance appointment.

If you have any questions regarding the information mentioned above, please do not hesitate to contact us. Your sales representative Luc Schols will be available to answer your questions at +49 151 40259231.

Kind regards,

Jörg Fior

Ralf Gentz

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