



Explanation on the Recommended Service Life of Prosthetic Components

Dear Business Partners,

the topic "Service Life of Prosthetic Components" has recently been the subject of controversial interpretations and discussions in our industry.

We strive to offer you security and reliability regarding our products, and are therefore happy to share our views on and interpretation of this topic with you.

Both the EU Directive 93/42/EEC and the EU Medical Devices Regulation 2017/745 (MDR) state as a central requirement that the safety of medical devices must be ensured by the manufacturer of these products in accordance with the required standard specifications.

In order to meet these requirements, all prosthetic components manufactured and/or sold by us are developed and manufactured in accordance with DIN EN ISO 13485:2016.

On that basis, the prosthetic components manufactured and/or sold by us are tested statically and dynamically in accordance with DIN EN ISO 10328, with the 3 million load cycles demanded by the standard. Based on these load tests, a recommended service life of 3 to 5 years can be deduced for the tested products in accordance with the standard.

Of course, this is only an average assessment which cannot take into account the individual user and their activity with their prosthesis. This important assessment can only be made through an expert evaluation by the care provider.

Our information on the recommended service life therefore should serve as an estimate of a typical period of use, which can be assumed to be the average period of use for the prosthesis wearer with the product.

In our opinion, the recommended service life for the products manufactured and/or sold by us does not represent an across-the-board maximum permissible period of use for these products.

Best regards,

ppa. Christoph Thiel
QM

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