Notice: New Service Lifetime Regulations, effective January 1, 2023

Dear valued customer,

As a global medical device manufacturer, Leftside Industries Incorporated ("Leftside") is legally obligated to comply with **The European Union Medical Device Regulation of 2017 (EU MDR 2017/745).** To ensure its products are compliant with EU MDR 2017/745, effective January 1, 2023, Leftside will adhere to **service lifetime** standards that are determined by the design and development of its products. Additionally, Leftside is required to and will maintain strict Post Market Surveillance for any of its products placed into the market.

A product's **Service Lifetime** is the amount of time that the manufacturer determines the product to be "serviceable" and for which it can function safely and effectively. Service and maintenance cannot be provided beyond the product's designated service lifetime. Product lifetime is the time period a product is expected to maintain safe and effective use, and is listed either as a number of years, or as a number of load cycles and years. Service Lifetime is equal to or longer than Product Lifetime to ensure our ability to repair and maintain our devices for as long as possible.

What does this mean?

In practice, this new legal regulation means that Leftside will provide no further maintenance or repair services once the product has reached its specified End of Service (EOS) lifetime. Leftside can no longer accept maintenance and repair orders for products that have reached EOS. Leftside takes these obligations very seriously as they concern the safety and performance of our products.

G3IK

Product Lifetime: 3-5 Years
End of Service Lifetime: 5 Years

FAQs

- New regulation is effective January 1, 2023
- **Applies retroactively to all sold products on the market**
- Excludes repairs that are covered by warranty claims on previous repair work
- Product Service Lifetime clock starts on the day of delivery by Leftside to the customer as documented in the delivery note

Leftside understands that the new statutory requirements detailed in this MDR will have an impact on our customers and end-users; particularly those who will need to pursue a new fitting or device when their product can no longer be repaired or serviced by Leftside. If you require a product specific statement on Service Lifetimes, please reach out to our authorized distributor at contact@g3ik.com.

We kindly ask for your understanding and patience as this change goes into effect. We are confident that the EU MDR 2017/745 was passed to help ensure the long-term safety and benefit of those who use prosthetic products. Our mission is to help people maintain or regain their freedom of movement, and we continually strive to meet that mission with your support.

With kind regards,

Leftside Industries Incorporated