

Field Safety Notice - NCR-2023-0068
Urgent Medical Device Removal – Immediate Action Required
oneFIT Knee Guides

SUBJECT: Potential endotoxins level above specifications.

Dear Customers,

As part of our ongoing focus on the performance and safety of our product, we have identified a potential issue with the oneFIT Knee Guides specified in Appendix 1.

This field safety notice aims to provide information concerning:

- The issue in question;
- The measures to be taken by the customer or end user to avoid any risk to patients or users;
- The measures to be taken by EOS imaging.

**This document contains important information relating to the correct and safe use of
oneFIT Knee Guides**

Our records indicate that your customers have received one or more products affected by this notice. Please note that only oneFIT Knee Guides are concerned. No other EOS imaging products have been affected by this field safety notice.

If you identify oneFIT Knee Guides specified in Appendix 1 in your customers' establishment, please read carefully and follow the measures to be taken.

- Please ensure that all potential users of the oneFIT Knee Guides are made aware of this communication and the recommended measures.
- Please save a copy of this field safety notice.

Description of the issue

An above-specification level of endotoxins was found during a routine surveillance test for oneFIT Knee Guides manufactured at one of our subcontractor facilities.

It is therefore possible that oneFIT Knee Guides manufactured between 20 June and 28 September 2023 may present an endotoxin level above specification.

Potential danger

Endotoxins are a major component of the Gram-negative bacterial cell wall, which can be found on sterile products. The endotoxin burden is measured in endotoxin units (EU) or international units (IU). Exposure to a high endotoxin burden in humans could result in symptoms including fever, low blood pressure, increased heart rate, or inflammatory response.

The current test results on the oneFIT Knee Guides, although above the set threshold, remain relatively low. This still poses a risk of triggering symptoms, most likely fever, in patients shortly after surgery. The symptoms could also be compatible with expected postoperative consequences.

To date, no adverse event resulting from this issue has been reported to EOS imaging.

Measures to be taken

- 1) Please transfer all the documentation relating to the field safety notice to whomever it may concern so they can:
- 2) Check for affected oneFIT Knee Guides as per the list of lot number concerned in Appendix 1
- 3) Segregate affected oneFIT Knee Guides
- 4) Complete the reply form and send it to EOS imaging by email at ncr20230068@eos-imaging.com as soon as possible. A comprehensive answer is mandatory to allow reporting to relevant authorities.
- 5) In the event of an affected oneFIT Knee Guides has not been used, prepare a package for product return. An EOS representative will contact you shortly to arrange return.
- 6) In the event of an affected oneFIT Knee Guides has already been used, patient should be monitored for symptoms as described above. No further action is necessary if the patient do not present complications or symptoms.

Measures to be taken by EOS imaging

EOS imaging will arrange free of charge unused product return and will do the best for its replacement.


Please accept our apologies for any inconvenience this may have caused. We thank you for your understanding and willingness to comply with these corrective measures. Rest assured that EOS imaging is monitoring this issue extremely closely to maintain a high level of safety and quality of its devices. If you have any questions, please contact your local EOS imaging representative.

We have duly informed the regulatory authorities worldwide.

Please pay attention to this notice. EOS imaging is committed to providing the highest quality products, and we thank you for your understanding concerning the decision and actions that we have taken to ensure patient safety and customer satisfaction. Please do not hesitate to contact us if you require assistance or further information.

Regards,

Paris, on October 6th, 2023


Director of Quality and Regulatory Affairs

Appendix 1: List of lot numbers affected

Each kit of oneFIT Knee Guides includes 4 individual bags containing:

- A femoral guide
- A tibial guide
- A femoral model
- A tibial model

UDI-DI	REF	LOT	SURGEON

