26th May 2023

Dear Customer

Integra Product Recall

FSN Reference Number: FSN 2023-HHE-005

SurgiMend® PRS, SurgiMend® PRS Meshed, SurgiMend®, SurgiMend® MP, PriMatrix®, PriMatrix® Ag

SurgiMend is to be removed from use immediately

We have been advised by our Supplier, Integra Lifesciences, that they have registered an FSCA (Field Safety Corrective Actions) with MHRA (Medicines and Healthcare products Regulatory Agency) and they are issuing a Field Safety Notice (FSN), which includes a full worldwide voluntary product recall of medical devices including SurgiMend.

The FSCA/FSN is following an internal investigation process that was conducted at the Integra Boston Facility whereby deviations during endotoxin testing were found, which may have resulted in the release of products with higher levels of endotoxins than permitted by the product specifications. Higher levels of endotoxins can induce an immune response, leading to a post-operative fever.

Reference FSN 2023-HHE-005

If you have already implanted or used the products affected by this recall, we recommend you monitor the patient for a fever in the immediate postoperative period according to the standard hospital or clinician protocol. If these harms do occur, they would most likely begin to present themselves after the first few days to within a few weeks post-operative care.

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Our Administration team is currently liaising with all customers to ensure all devices are collected and returned to head office**.** Please use the contact details below if you require assistance or further information. Please note that all returned devices will be credited. You will be sent a copy of the Field Safety Notice (FSN) issued by Integra, an MHRA explanatory flyer, and a copy of the customer response, which we require you to complete and return to us.

Integra Lifesciences are working extremely hard to ensure that they can fulfill the requirements of the endotoxin testing and place their device back into the marketplace. Until such time, SurgiMend will not be available for purchase, and we will inform you of any changes to this situation as they arise.

We thank you for your support during this time.

Yours faithfully

Kristi Pillans MSc
Group Director for Quality & Regulatory Affairs
Person Responsible for Regulatory Compliance (PRRC)

Product Recall Contact Information

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QMTL SurgiMend Recall Letter (DOC-547) Ver. 1

Approved By:

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