Friday, 9 September 2022

To Whom It May Concern,

Re: FSN Reference: CR-22-008 FSCA Reference: CR-22-008

Delta Surgical Ltd, UK distributor for the Gelita range of Haemostats, has been notified of the attached preventative recall on GELITA TUFT-IT® products.

In routine bioburden testing, higher than acceptable levels of Endotoxins were observed. This product was immediately quarantined at the factory. Other batches, within specification, were put on hold until a proper route cause analysis (RCA) had been conducted. This RCA is still in progress and is examining end-to-end the production process for all possible sources of this contamination. Meanwhile, a viable process for eliminating Endotoxins is thought to have been identified.

Please see attached the relevant FSN/FSCA for more information. GELITA MEDICAL has decided to preventively recall all GELITA TUFT-IT® products.

Over the last 11 years Gelita Medical has sold in excess of 10.3 million pieces; with no adverse events been reported to GELITA MEDICAL GmbH, possibly related to Endotoxin contamination.

Despite no reported incidents of endotoxin contamination, the following devices are recalled-

- GELITA TUFT-IT®

Please identify and isolate any product that is still on the shelf, and complete the attached Form (Customer Acknowledgement Form) within 5 working days from receipt of this notice.

GelitaCel® standard, GelitaCel® Fibrillar, GelitaCel® Xsorb are not affected.

Please don't hesitate to contact your local representative for further information.

Yours Sincerely,

Robin Humble
Managing Director
Delta Surgical Ltd

Customer Acknowledgement Form

1. Customer Details		
Hospital Name		
Hospital Address		
Contact Name		
Title		
Telephone Number		
Email		
2. Customer action undertaken on behalf of Hospital		
☐	I can confirm receipt of the Field Safety Notice (FSN) and confirm that I have read and understood its content.	
☐	The information has been brought to the attention of all relevant users and departments.	
3. Return Acknowledgement		
☐	I have isolated affected devices for return to Delta Surgical.	Please include quantity, LOT number, date isolated.
☐	I do not have any affected devices on the shelf.	
Print Name		
Title		
Signature		
Date		

Please return to quality@deltasurgical.co.uk