FSN Ref: CR-22-006 FSCA Ref: CR-22-006

Date: 2022-07-21

Field Safety Notice

GELITA-SPON® STANDARD
GELITA-SPON® RAPID3
GELITA® ENT X-BLOD
GELITA® ENT X-DENSE
GELITA® ENT X-PAND
GELITA® ENT X-PASTE
GELITA-SPON® POWDER

For Attention of*: Identify either by name or role who needs to be aware of the hazard and/or take action. If this is multiple recipients then include full list.

- **A risk to patients has been unidentified, as the endotoxin limit/specification for GELITA-SPON products has in a few cases been exceeded.**
- **Not all product has been found to be out of specification for endotoxins.**
- **Nevertheless, as the contamination is not homogenous, and outliers have been detected for some lots, GELITA MEDICAL has decided to issue this FSN and preventively recall all GELITA SPON product.**
- **If the product has already been used in patients and there was no acute inflammatory/pyrogenic response, it is unlikely that you received the contaminated product.**

Contact details of local representative (name, e-mail, telephone, address etc.)*
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Field Safety Notice (FSN)
GELITA-SPON® STANDARD
GELITA-SPON® RAPID3
GELITA® ENT X-BLOD
GELITA® ENT X-DENSE
GELITA® ENT X-PAND
GELITA® ENT X-PASTE
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Risk of endotoxin poisoning

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	The following devices are the subject of this FSN: • GELITA-SPON® STANDARD • GELITA-SPON® RAPID3 • GELITA® ENT X-BLOD • GELITA® ENT X-DENSE • GELITA® ENT X-PAND • GELITA® ENT X-PASTE • GELITA-SPON® POWDER All products are absorbable gelatine-based hemostats and are supplied sterile.
1.	2. Commercial name(s)*
	As given above
1.	3. Unique Device Identifier(s) (UDI-DI)
	Appended in Annex I
1.	4. Primary clinical purpose of device(s)*
	Topical absorbable hemostat for use as an adjunct to hemostasis by tamponade effect, in particular where control of capillary, venous, and arteriolar bleeding, by pressure, ligature, and other conventional procedures, is either ineffective or impractical.
1.	5. Device Model/Catalogue/part number(s)*
	Appended in Annex I
1.	6. Software version
	No software is included with this device
1.	7. Affected serial or lot number range
	This recall is not limited to a particular batch number for the reasons described below. All products described above, still within shelf-life are being recalled. The shelf-life of these products is 5 years.
1.	8. Associated devices
	There are no associated devices.

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	In re-testing ordered by the manufacturer, the endotoxin concentration of the product in some samples has been measured above the limit. Since these "outliers" in testing cannot be reconciled at this time, GELITA MEDICAL GmbH, has decided to take a very conservative approach and recall all product, even that found to be within specification.
2.	2. Hazard giving rise to the FSCA*
	Bacterial endotoxins, found in the outer membrane of gram-negative bacteria are members of a class of phospholipids called lipopolysaccharides (LPS). LPS are not exogenous products of gram negative bacteria. Endotoxin is commonly found everywhere in the environment and it is the most significant pyrogen in parenteral drugs and medical devices. The release of LPS from bacteria takes place after death and lysis of the cell. Endotoxins can elicit a pyrogenic/inflammatory response from the human body. In rare cases, septic or anaphylactic shock might occur.
2.	3. Probability of problem arising
	The probability of the problem arising is considered to be "improbable" (1 in 1,000,000 patients) given the number of units sold (10,337,598 pieces since 2011) and that to date, no events have been reported to GELITA MEDICAL GmbH, possibly related to Endotoxin poisoning.
2.	4. Predicted risk to patient/users
	If the hospital received a contaminated product, an acute pyrogenic reaction might be expected within 2-5 days after use.
2.	5. Further information to help characterize the problem
	Statistics quantifying or qualifying the problem are not available to date. As discussed, there are "outliers" in the Endotoxin levels which cannot be explained or related to production, process, dates, raw materials, etc..
2.	6. Background on Issue
	In routine bioburden testing, higher than acceptable levels of Endotoxins were observed. This product was immediately recalled. 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. Product produced using a thermal hardening or cross-linking process, namely GELITA TUFT-IT gelatine hemostat has never exceeded the requisite Endotoxin levels, consequently, this process step is now being evaluated for the GELITA SPON products itemized above.
2.	7. Other information relevant to FSCA
	No other information is required

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3. Type of Action to mitigate the risk*		
3.	**1. Action To Be Taken by the User***	
	☒ Identify Device ☒ Quarantine Device ☒ Return Device ☒ Destroy Device ☐ On-site device modification / inspection ☐ Follow patient management recommendations ☐ Take note of amendment / reinforcement of Instructions For Use (IFU) ☐ Other ☐ None A containment action has been sent out to all distributors, asking them to identify product still on the shelf, product still available at health care institutions, to retrieve this product, communicate these actions to GELITA MEDICAL GmbH so that GELITA may reconcile the products, and to locally destroy this product and provide confirmation of such, or to send the product back to GELITA MEDICAL GmbH for destruction.	
3.	2. By when should the action be completed?	Without undue delay after receipt of this notice!
3.	3. Particular considerations for: Implantable device Review of patients' previous results is recommended? Yes	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**5. Action Being Taken by the Manufacturer***	
	☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None All product will be recalled from the market, units sold reconciled with products recalled and destroyed.	
3.	6. By when should the action be completed?	This action will be completed without undue delay from the time of the initial containment action, July 20th 2022, and given the minimal risks associated with this incident, the actions must be completed within one month.

3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3.	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	Not Applicable	

4. General Information*		
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	Provide reference and date of previous FSN if relevant.
4.	3. For Updated FSN, key new information as follows:	
	Summarise any key difference in devices affected and/or action to be taken.	
4.	4. Further advice or information already expected in follow-up FSN? *	Choose an item.
4.	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	Eg patient management, device modifications etc.	
4.	6. Anticipated timescale for follow-up FSN	For provision of updated advice.
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Only necessary if not evident on letter-head.
	b. Address	Only necessary if not evident on letter-head.
	c. Website address	Only necessary if not evident on letter-head.
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	Annex 1 to GMED_FSN_July2022
4.	10. Name/Signature	… …

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	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As app ropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.