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

Date: 2022-08-03
Version: 02

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 identified, 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.)*
GELITA MEDICAL GmbH Susan Klymowsky Stefanie Dettlinger Uferstrasse 7 69412 Eberbach Germany **Susan.Klymowsky@gelitamedical.com** **Stefanie.Dettlinger@gelitamedical.com** **Viktoria.Frank@gelitamedical.com**

GELITA MEDICAL GmbH • Uferstraße 7 • 69412 Eberbach, Germany
Phone: +49 6271 84 - 01 • Fax: +49 6271 84 - 2700 • www.gelitamedical.com • service@gelitamedical.com
• Volksbank Neckartal eG • IBAN: DE 40 6729 1700 0020 2142 01 • BIC: GENODE61NGD
• Deutsche Bank AG • IBAN: DE 13 6727 0003 0031 4609 00 • BIC: DEUTDESM672
• VAT/USt.-IdNr. DE 812 919 302 • District Court: Mannheim HRB 337927
• Managing Director: Dr. Ralf Pietsch, Samy Jandali

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

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
GELITA-SPON® POWDER
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

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	Susan Klymowsky PRRC Viktoria Frank Regulatory & Quality Affairs Manager

	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 appropriate) 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.

2001-22WW-048

Field Safety Notice Distributor/Importer Reply Form

Distributor/Importer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	FSN # CR-22-006
FSN Date*	20th July 2022
Product/ Device name*	The following products are affected (all dimensions): • 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
Product Code(s)	As provided in Annex I to this Form.
Batch/Serial Number (s)	1 XXXX 2 XXXX 3 XXXX

2. Distributor/Importer Details	
Company Name*	
Account Number	
Address*	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Return acknowledgement to Sender	
Email	Quality@gelitamedical.com
Distributor/Importer Helpline	+49 6271 842524 or +49 6271 842523 Outside of office hours, your call will be recorded and the responsible person(s) notified.
Postal Address	GELITA MEDICAL GmbH Address: Uferstrasse 7 69412 Eberbach/Germany quality@gelitamedical.com
Web Portal	Not available
Deadline for returning the Distributor/Importer reply form*	Four weeks from the date of the containment action, 20th July 2022.

4. Distributors/Importers (Tick all that apply)		
☐	*I confirm the receipt, the reading and understanding of the Field Safety Notice.	Distributor/Importer to complete or enter N/A
☐	I have checked my stock and quarantined inventory	Distributor/Importer to enter quantity and date
☐	I have identified customers that received or may have received this device	
☐	I have attached customer list	
☐	I have informed the identified customers of this FSN	Date of communication:
☐	I have received confirmation of reply from all identified customers	
☐	I have returned affected devices - enter number of devices returned and date complete.	Add quantity, Lot/Serial Number/Date Returned (same information as requested by the Customer Reply form
☐	I have destroyed affected devices – enter number destroyed and date complete.	Add quantity, Lot/Serial Number/Date Returned (same information as requested by the Customer Reply form
☐	Neither I nor any of my customers has any affected devices in inventory	
Print Name*		Distributor/Importer print name here
Signature*		Distributor/Importer sign Here
Date *		

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

Annex 1

Product Categorie	Article number	Unit of Use (Primary/ Secondary sterile packaging) UDI-DI (GTIN)	Sales Unit (Suture box) UDI-DI (GTIN)	Transport Unit (Standard transport box) UDI-DI (GTIN)
GELITA® ENT X-BLOD	GE-8382	4260293133748	4260293130747	4260293137746
GELITA® ENT X-BLOD	GE-8385	4260293133755	4260293130754	4260293137753
GELITA® ENT X-DENSE	GE-6385	4260293133724	4260293130723	4260293137722
GELITA® ENT X-DENSE	GE-6311	4260293133731	4260293130730	4260293137739
GELITA® ENT X-PAND	GE-6382	4260293133762	4260293130761	4260293137760
GELITA® ENT X-PASTE	GE-2165	4260293133779	4260293130778	4260293137777
GELITA-SPON® POWDER	GS-265	4260293133113	4260293130112	4260293137111
GELITA-SPON® RAPID³	GR-010	4260293133014	4260293130013	4260293137012
GELITA-SPON® RAPID³	GR-310	4260293133021	4260293130020	4260293137029
GELITA-SPON® RAPID³	GR-610	4260293133038	4260293130037	4260293137036
GELITA-SPON® RAPID³	GR-005	4260293133205	4260293130204	4260293137203
GELITA-SPON® RAPID³	GR-007	4260293133533	4260293130532	4260293137531
GELITA-SPON® STANDARD	GS-010 DP	4260293133045	4260293130044	4260293137043
GELITA-SPON® STANDARD	GS-015	4260293133069	4260293130068	4260293137067
GELITA-SPON® STANDARD	GS-030	4260293133076	4260293130075	4260293137074
GELITA-SPON® STANDARD	GS-060	4260293133083	4260293130082	4260293137081
GELITA-SPON® STANDARD	GS-110	4260293133090	4260293130099	4260293137098
GELITA-SPON® STANDARD	GS-003	4260293133137	4260293130136	4260293137135
GELITA-SPON® STANDARD	GS-325	4260293133144	4260293130143	4260293137142
GELITA-SPON® STANDARD	GS-004	4260293133168	4260293130167	4260293137166
GELITA-SPON® STANDARD	GS-610	4260293133175	4260293130174	4260293137173
GELITA-SPON® STANDARD	GS-950	4260293133199	4260293130198	4260293137197
GELITA-SPON® STANDARD	GS-010 SP	4260293133052	4260293130051	4260293137050
GELITA-SPON® STANDARD	GS-210	4260293133106	4260293130105	4260293137104
GELITA-SPON® STANDARD	GS-310	4260293133120	4260293130129	4260293137128
GELITA-SPON® STANDARD	GS-002	4260293133663	4260293133670	4260293133687