

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

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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
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 root 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? * <i>(If yes, form attached specifying deadline for return)</i>	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	

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 • Managing Director: Dr. Ralf Pietsch, Samy Jandali

	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.

Annex 1

		Unit of Use (Primary/ Secondary sterile packaging)	Sales Unit (Suture box)	Transport Unit (Standard transport box)
Product Categorie	Article number	UDI-DI (GTIN)	UDI-DI (GTIN)	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® RAPID ³	GR-010	4260293133014	4260293130013	4260293137012
GELITA-SPON® RAPID ³	GR-310	4260293133021	4260293130020	4260293137029
GELITA-SPON® RAPID ³	GR-610	4260293133038	4260293130037	4260293137036
GELITA-SPON® RAPID ³	GR-005	4260293133205	4260293130204	4260293137203
GELITA-SPON® RAPID ³	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