FSN Ref: CR-22-008

FSCA Ref: CR-22-008

Date: 2022-09-08
Version: 01

Field Safety Notice

GELITA TUFT-IT®

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 TUFT-IT® product appears to have been exceeded in (re)testing using a new method.**
- **As this new test data, cannot yet be reconciled with previous test results obtained, all of which were within specification, GELITA MEDICAL has decided to issue this FSN and preventively recall the GELITA TUFT-IT® product.**

Contact details of local representative (name, e-mail, telephone, address etc.)*
GELITA MEDICAL GmbH Susan Klymowsky Uferstrasse 7 69412 Eberbach Germany Susan.Klymowsky@gelitamedical.com Stefanie.Dettlinger@gelitamedical.com Viktoria.Frank@gelitamedical.com

FSN Ref: CR-22-008 FSCA Ref: CR-22-008

Field Safety Notice (FSN)
GELITA TUFT-IT ®
Risk due to endotoxin concentration

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	The following device is the subject of this FSN: • GELITA TUFT-IT® Product in scope is absorbable gelatin-based hemostat and is 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, undertaken as part of an effort to optimize the production process in regard to the elimination/reduction of Endotoxins in GELITA MEDICAL's gelatin-based devices, higher than the "acceptance" levels of Endotoxins were found in product already admitted to the market.
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). 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.

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

2.	3. Probability of problem arising
	The probability of the problem arising is considered to be "improbable". PMS data obtained for the tens of thousands of units sold since 2016, and the clinical data gathered for this device, report no safety issues related to this product.
2.	4. Predicted risk to patient/users
	If a patient received 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.
2.	6. Background on Issue
	In the effort to optimize the production process with regard to the elimination/reduction of endotoxins in GELITA MEDICAL's gelatin-based hemostats, additional testing of the GELITA TUFT-IT® product using a different test method to that which has always been used for final release. This testing provided results at variance with the final release testing previously done. These data could not immediately be reconciled. It was therefore decided to recall product.
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 MEDICAL GmbH 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!

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

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 notification of this FSN, September 8th 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?	
	Since this product is for use by Physicians, it is not expected that additional information will be solicited by lay-persons. Nevertheless, any information provided as such would be presented in a suitable language.	

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.	

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-22-008 FSCA Ref: CR-22-008

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_Sep2022
4.	10. Name/Signature	DocuSigned by: Susan Klymowksy 48EB16FFB062417... Susan Klymowsky PRRC DocuSigned by: Viktoria Frank 3D62FE3BAEC949D... 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 organization or to any organization where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organizations 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

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 TUFT-IT®	GF-7365	4260293133717	4260293130716	4260293137715
GELITA TUFT-IT®	GF-7336	4260293133793	4260293130792	4260293137791

GELITA MEDICAL GmbH • Uferstraße 7 • 69412 Eberbach

GELITA MEDICAL GmbH
Address:
Uferstrasse 7
69412 Eberbach/Germany
quality@gelitamedical.com

To Whom It May Concern

Doc. No. 2001-22W-055

Date September 05, 2022

Urgent Containment Action GELITA® TUFT-IT

PLEASE ACKNOWLEDGE RECEIPT OF THIS LETTER.

GELITA MEDICAL GmbH, located at Uferstrasse 7, 69412 Eberbach, Germany, as the legal manufacturer of GELITA® TUFT-IT Products, hereby issues important official safety information.

At GELITA MEDICAL, we take the quality of our products very seriously, as our mission is to provide Quality Products that assure "Maximum Safety" for patients. Our robust Quality System has detected a potential safety-related issue in the production process of GELITA® TUFT-IT products. As a consequence of this, GELITA MEDICAL has decided during the ongoing root cause analysis, and although no adverse events related to the safety of the product have been reported to GELITA MEDICAL, to immediately put on hold and quarantine all GELITA® TUFT-IT products.

The following product is affected (all dimensions):

- GELITA® TUFT-IT

GELITA MEDICAL, therefore, requests, that all stock is quarantined, no further distribution takes place, and product already on the shelf at any customers be traced and also quarantined, without delay.

This message will shortly be followed by an official Field Safety Notice (FSN) and Field Safety Corrective Action (FSCA) as it is GELITA MEDICAL's intention to recall this product.

As a valued client, we would like you to know that we are doing our best to resolve the situation quickly.

We sincerely apologize for the inconvenience caused and hope for your understanding, as at GELITA MEDICAL quality and safety is our primary focus and as a result such preventive actions although painful are necessary. We will, of course, inform you of our progress.

Sincerely yours,

Dr. Ralf Pietsch
Managing Director

Susan Klymowsky
PRRC

Viktoria Frank
Regulatory & Quality Affairs Manager

-End of Statement-