GELITA MEDICAL GmbH • Uferstraße 7 • 69412 Eberbach

GELITA MEDICAL GmbH
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To Whom It May Concern

Date March 08, 2022

FSN reference: CR-22-002

Urgent Field Safety Notice
GELITA® ENT X-PAND (R00112/1)

For Attention of*:

Novimed AG Medizintechnik, Heimstrasse 46, CH-8953 Dietikon, Switzerland

Risk to patients is expected as endotoxin limits of product exceeded, expected patient risk is fever.
But the contamination is not homogenous, it is heterogeneously spread over the batch. Contamination is not in all product boxes that are sold. We only suspect few of the boxes with contamination. Therefore, if it is already used in patients and there were no immediate pyrogenic reactions, most probably you might not have received the contaminated box.

But to minimize the risk the product still left in warehouse must be quarantined and destroyed.

Contact details of local representative (name, e-mail, telephone, address etc.)*
Dr. Sheetal Gangula, Uferstrasse 7, 69412 Eberbach **Sheetal.Gangula@gelitamedical.com**

Urgent Field Safety Notice (FSN)
GELITA® ENT X-PAND
Risk addressed by FSN

	1. Information on Affected Devices*
1.	1. Device Type(s)*
	Absorbable Gelatin Sponge Hemostat, USP
1.	2. Commercial name(s)
	GELITA® ENT X-PAND
1.	3. Unique Device Identifier(s) (UDI-DI)
	4260293130761
1.	4. Primary clinical purpose of device(s)*
	Topical 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)*
	GE-6382
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	R00112/1
1.	8. Associated devices
	N/A

	2 Reason for Field Safety Corrective Action (FSCA)*
2.	1. Description of the product problem*
	In a re-testing ordered by the manufacturer the endotoxin concentration of the product in some samples has been measured above the limit. So far no patient has been harmed to the manufacturer's knowledge.
2.	2. Hazard giving rise to the FSCA*
	Medical devices such as gelatin hemostats are allowed to only have limited amount of Endotoxins. Bacterial endotoxin is the cell wall from gram-negative bacteria. The cell wall is generally composed of lipid polysaccharide material. High endotoxin levels can elicit a fever response in a patient. The generally defined endotoxin level is ≤5 EU/kg. The standard predefined endotoxin limit for GELITA-SPON® product is 20 USP-EU / sample (contact to blood and tissue). The detected endotoxin concentration within the Limulus-Amebocyte-Lysate-Test (LAL) using Kinetic Turbidimetric Method according to the current USP <85> for lot R00112/1 tested in pool was 90.23 USP-EU / sample. The gelatin sponges are used on the surgical part, and don't have contact to the whole body. For an operation an average of 2 gelatin sponges are used. Taking this into consideration, together with the generally divined endotoxin level of ≤5 EU/kg patients > 36.09 kg are within the tolerance of the maximum amount of endotoxins and no fever reaction is expected. For a worst case scenario of 10 gelatin sponges used for a patient patients > 180.46 kg are within the tolerance of the maximum amount of endotoxins and no fever reaction is expected. 2 gelatin sponges used: 90.23 USP-EU/ sample * 2 sponges = 180.46 USP-EU level in the human body / 5 EU/kg = 36.09 kg

	10 gelatin sponges used: 90.23 USP-EU/ sample * 10 sponges = 902.3 USP-EU level in the human body / 5 EU/kg = 180.46 kg That means both in normal use and worst case use the intended patient population are at risk of pyrogenicity, which could affect patients' health by causing pyrogenic reactions after use.
2.	3. Probability of problem arising
	Only 158 boxes from this batch are shipped to 5 distributors (48 boxes, 12 boxes, 84 boxes, 2 boxes, 12 boxes). Distributors are supplying to different hospitals. The probability of the contaminated sponge being used in patient is remote. It can be concluded that the probability of fever occurrence is 10-6 < P ≤ 10-5 (1/1.000.000 < P ≤ 1/100.000).
2.	4. Predicted risk to patient/users
	If the hospital received a contaminated box, pyrogenic reactions can be expected immediately within 2-5 days of use.
2.	5. Further information to help characterize the problem
	Gram-negative bacteria cell wall is generally composed of lipid polysaccharide material. High endotoxin levels can elicit a fever response in a patient. The generally defined endotoxin level is ≤5 EU/kg. The standard predefined endotoxin limit for GELITA-SPON® product is 20 USP-EU / sample (contact to blood and tissue).
2.	6. Background on Issue
	In a routine release testing high endotoxin values have been measured in batches manufactured from 01.10.2021. Subsequently all sales of GELITA-SPON® have been stopped. After the root cause investigation of the OOS and its supposed elimination it was decided to check all the batches that were sold from March 2021, as in March 2021 an OOT result (3 EU/Sample, normally the trend is below 1 EU/sample) was detected. As a result increased testing with higher statistical relevance was performed on all batches produced from March 2021. The results of all the batches were within the limits except for R00111/1 and R00111/2 batches of GELITA-SPON® RAPID and R00112/1 of GELITA® ENT X-PAND, in which so far 7 contaminated boxes were found.
2.	7. Other information relevant to FSCA
	N/A

	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

	Provide further details of the action(s) identified.	
3.	2. By when should the action be completed?	Immediately upon receipt of this notice
3.	3. Particular considerations for: Implantable device Is follow-up of patients or review of patients' previous results recommended? YES	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes, see attached form
3.	**5. Action Being Taken by the Manufacturer** To destroy or quarantine the unused devices.	
3	6. By when should the action be completed?	As soon as possible in the next working days upon receipt of this notice
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?	
	N/A	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	**N/A**
4.	**3.** For Updated FSN, key new information as follows:	
	N/A	
4.	4. Further advice or information already expected in follow-up FSN? *	Not planned yet
	5. If follow-up FSN expected, what is the further advice expected to relate to:	

4	No follow up FSN is expected	
4	6. Anticipated timescale for follow-up FSN	N/A
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	**https://www.gelitamedical.com/**
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * These devices were sold to customers in Germany, Switzerland, France, Spain and Sweden, both the competent authority and notified body will be informed.	
4.	9. List of attachments/appendices:	**N/A**
4.	10. Name/Signature	Dr. Sheetal Gangula, RA/QM Director. 

	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..*

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Response form:

Name and address of the hospital / medical facility		
Department/ to the attention of:		
Date:		
Device Model	Lot number that will be returned back	Amount of product to be returned to ---------- (If no item is returned, please enter 0)

I hereby confirm the receipt of your Urgent Field Safety Notice. Furthermore, I confirm that I have informed the responsible personnel about the Urgent Field Safety Notice. I confirm that I do not have any other affected lot on site, except of the above named quantity, which I will return immediately to _____.

Name (Signature)----------

Name (printed characters)……..

E-Mail address ……

Position…….

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• Managing Director: Dr. Ralf Pietsch, Samy Jandali