GELITA MEDICAL GmbH • Uferstraße 7 • 69412 Eberbach

To Whom It May Concern

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

Date November 13, 2020

FSN reference: CR-20-026

Urgent Field Safety Notice
Device Commercial Name

For Attention of*:

Swissmedic • Hallerstrasse 7 • 3012 Berne • www.swissmedic.ch • Tel. +41 58 462 02 11 • Fax +41 58 462 02 12

No immediate risk is expected but all of the remaining product or the product still left in warehouse must be quarantined and destroyed.

Contact details of local representative (name, e-mail, telephone, address etc.)*
NOVIMED AG Heimstrasse 46 8953 Dietikon SWITZERLAND www.novimed.ch **s.dimichino@novimed.ch** info@novimed.ch

Urgent Field Safety Notice (FSN)
Device Commercial Name
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-SPON® STANDARD
1.	3. Unique Device Identifier(s) (UDI-DI)
	N/A
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)*
	GS-010
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	T02215/1
1.	8. Associated devices
	N/A

	2 Reason for Field Safety Corrective Action (FSCA)*
2.	1. Description of the product problem*
	One of our distributor reported a strand of hair seen in the blister package of batch T02215/1, with product code GS-010.
2.	2. Hazard giving rise to the FSCA*
	It not suspected that the entire batch is affected but to be on the safe side the batch is recalled from the market. In case there would be a second or more blisters with such hair, the hazard to the patient can be classified as serious to critical. If a hair by mistake enters the patient depending on where it is implanted, it can only be serious to very life threatening depending on where it is applied. Also assuming it was actually left at the site of application, which is a highly improbable situation as it would be washed away during the flushing or because of the size of the hair stand, it can also actually easily be seen by the hospital personal even before application, while opening the package. The product is sterilized by gamma irradiation, so if a hair strand is in blister it will also be sterile.
2.	3. Probability of problem arising
	In this batch 1068 suture boxes containing 10 blister each were produced. In total 10680

	blisters. Out these 24 boxes, that is, 240 blisters were sold to distributor in Switzerland. The actual probability of the presence second or more blisters with a hair strand is Occasional ((10−5 < P ≤ 10−4 (1/100.000 < P ≤ 1/10.000)). Also these boxes were already sold in November 2019 and were probably nothing left in warehouses, so also the probability of immediate risk is improbable.
2.	4. Predicted risk to patient/users
	Given the above explanation in 2.2 (Hazard) and 2.3 (probability of occurrence), the severity can be down classified to negligible and probability of the immediate hazard arising can be rated as improbable.
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	Manufacture was made aware of the situation by distributor in Brazil, where, they found the hair strand in the blister in their routine inspection. The incident can be only limited to this batch because the production is packaging sponges into blisters manually, the first number T02215 indicates the sponge manufacturing and the /1, indicates the packaged batch, there were no problems indicated starting with next batch T02215/2. The production is in ISO room class 7 and the hygiene principles are strictly followed by every employee. In fact such incident never occurred in the past 10 years and upon inspection also the retention samples of T02215/1 did not reveal any deviations. The manufacturing of this batch was performed in July 2019, since then number of batches were produced and this instance never occurred. Taking the strict hygiene principles that are commonly followed and the rare or no occurrence of such deviation, we assume it is a onetime mistake of the production employee (for example despite wearing all the protective gear, one time scratching the hair and not changing the gloves after that, before touching the blister and due to the electrostaticity between gloves and blister, the hair might have gotten stuck to blister). Also because no other cases are reported we assume it was actually only that one blister and a onetime occurrence by mistake.
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)	No
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? Choose an item. Choose an item.	

	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. * No devices are sold in Germany from this batch, the relevant notified body will be informed, but the competent authorities of individual member states, where, the device is sold in 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..*