FSN Ref: CC-00515 FSCA Ref: CC-00515 Date: 27th February 2019

Urgent Field Safety Notice (FSN)
Genex Putty 5cc

For Attention of : - Customer Specific

Contact details of local representative –

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Urgent Field Safety Notice
Genex Putty 5cc
Risk addressed by FSN

1.	Information on Affected Devices*	
1	Device Type(s)*	Bone Void Filler
2	Commercial name(s)	Genex Putty
3	Unique Device Identifier(s) (UDI-DI)	50601557101742
4	Primary clinical purpose of device(s)*	Injectable Bone Graft for surgical use.
5	Device Model/Catalogue/part number(s)*	920-005
6	Software version	N/A
7	Affected serial or lot number range	Genex Putty 5cc LOT# 08/18-GP174
8	Associated devices	None

2.	Reason for Field Safety Corrective Action (FSCA)*	
1	Description of the product problem*	Inner pack may not be adequately sealed
2	Hazard giving rise to the FSCA*	Potential to compromise sterility during aseptic presentation
3	Probability of problem arising	Complaint History for this product shows no previous occurrences with the above issue
4	Predicted risk to patient/users	None – defective units would have been identified prior to use by the operating staff. Intact packaging does not affect device and does not lead to any patient risk.
5	Further information to help characterise the problem	Packaging issue (sealing)
6	Background on Issue	Initial alert of the issue was identified by a customer complaint.
7	Other information relevant to FSCA	N/A

3.	Type of Action to mitigate the risk*	
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.	
2	By when should the action be completed?	Immediately
3	Particular considerations for: Implantable device	
	Is follow-up of patients or review of patients' previous results recommended?	No - Defective units would have been identified prior to use by the operating staff. Intact packaging does not affect device and does not necessitate any patient follow-ups
4	Is customer Reply Required? *	Yes
5	**Action Being Taken by the Manufacturer** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None	
	Provide further details of the action(s) identified.	Unused products to be returned to manufacturer
6	By when should the action be completed?	Immediately
7	Is the FSN required to be communicated to the patient / lay user?	No
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*	
1	FSN Type*	New
2	For **updated** FSN, reference number and date of previous FSN	N/A
	For updated FSN, key new information as follows:	N/A
3	Further advice or information already expected in follow-up FSN? *	No
	If **follow-up** FSN expected, what is the further advice expected to relate to:	N/A
	Anticipated timescale for follow-up FSN	N/A
4	Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a) Company Name	Biocomposites Ltd.
	b) Address	Keele Science Park, Keele, Staffordshire, ST5 5NL, England
	c) Website address	www.biocomposites.com
5	The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	Yes
6	List of attachments/appendices:	None
7	Name	Lynne Ford – Atkinson
	Signature	Lynne Ford- Atkinson

	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.