FSN / FSCA Ref Number: CC00916 Date: 23/08/2023

GeneX® DS 2.5cc and 5cc
Urgent Field Safety Notice (FSN)

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 a full list.

Contact details of local representative (name, e-mail, telephone, address etc.)*
* This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages.

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Risk addressed by FSN

1.	Information on Affected Devices*	
1	Device Type(s)*	Synthetic resorbable bone graft
2	Commercial name(s)	GeneX® DS 2.5cc and 5cc
3	Unique Device Identifier(s) (UDI-DI)	Genex DS 2.5cc: 15060155710959 Genex DS 5cc: 15060155710966
4	Primary clinical purpose of device(s)*	GeneX® DS provides a mouldable cohesive paste which forms a hard but resorbable matrix that is used to fill bony voids or defects.
5	Device Model/Catalogue/part number(s)*	Genex DS 2.5cc : 980-002 ; Genex DS 5cc : 980-005
6	Software version	Not applicable
7	Affected serial or lot number range	GS220314, GS220315*, GS220609, GS221012 *lot is affected but it was indicated by distributor as consumed in use.
8	Associated devices	N/A

2.	Reason for Field Safety Corrective Action (FSCA)*	
1	Description of the product problem*	First line of Indications in the English part of IFU reads – 'Genex® is indicated only for bony voids or defects/gaps that are intrinsic to the stability of the bony structure'. It should read – 'Genex® is indicated only for bony voids or defects/gaps that are NOT intrinsic to the stability of the bony structure'.
2	Hazard giving rise to the FSCA*	It is possible that the product would be used on an area that it is contraindicated for due to the misleading statement in the Indications For Use section.
3	Probability of problem arising	Low. The product is marketed as a "bone void filler" under non weight-bearing conditions. The Contraindications section of the IFU states that "filling of defects which are intrinsic to the stability of the bony structure" is contraindicated. This is a contradiction to the error in Indications For Use section. The issue is only present in English, the error is not present in other languages. The rest of the IFU reads in agreement with the product being used only in bony voids or defects/gaps that are not intrinsic to the stability of the bony structure. This product has been in clinical use for several year during which time Biocomposites has received no complaints relating to the product use in defects that are intrinsic to stability of the bony structure.

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4	Predicted risk to patient/users	Genex DS is a highly injectable paste which is intended for use as a bone void filler. Due to an error introduced in the most recent update of the English "Indications" section of the IFU, it is possible that genex DS may also be used by customers to fill bony voids or defects that are intrinsic to the stability of the bony structure, resulting in a risk that inadequate or insufficient bone formation at the site would result in collapse of the defect since genex DS is not load bearing. Typically, genex DS is used in conjunction with supporting metalwork. The most common use is in the treatment of tibial plateau fractures where the product is used to fill bone voids caused by trauma, with supporting instrumentation in place. While Biocomposites does not promote genex DS for use in vertebral bodies as it is not weight bearing, spinal defects have also been treated using genex DS to restore bone with supporting instrumentation to stabilize the bony structure. When used with metalwork, the risk of collapse of the defect is low since the metalwork in place will support the stability of the bony structure. It is also possible that genex DS could be used without metalwork in an unsupported load bearing site. For example, it can be used to fill voids in bone cysts but if the cyst is large enough, there is the possibility that this could become a load bearing site with a risk of collapse of the defect due to inadequate or insufficient bone formation. Biocomposites has no history of reported adverse events on record where genex DS was used in an unsupported load bearing site. Additionally, because of the the decision in 2019 to not supply genex DS to new markets, the product has only been provided to existing customers in existing markets who were already experienced with using the product. Therefore the overall risk of this incorrect use of the product resulting in an adverse event is low, and will be further mitigated by the proposed corrective actions.
5	Further information to help characterise the problem	N/A
6	Background on Issue	The Issue was reported to Biocomposites by one of our distributors and logged as a customer complaint CC00916. The issue was found to be reportable through the decision trees within Biocomposites' internal complaint matrix.
7	Other information relevant to FSCA	It was confirmed that the error was a change made to the Genex IFU I.020 at Rev 092011 which is effective from 23.09.2020. Error was not present in prior versions. Only products containing IFU I.020 Rev 092011 are affected.

3. Type of Action to mitigate the risk*

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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.	1. Please provide the following to customers along with the affected lots: - a copy of the customer letter - a clean copy of the updated English IFU section - a redlined copy of the updated English IFU section 2. Complete the attached FSN Distributor/Importer Reply Form and return the completed form to Biocomposites as instructed on the form
2	By when should the action be completed?	04.09.2023 – action is pending response from competent authorities.
3	Particular considerations for: Implantable device	
	Is follow-up of patients or review of patients' previous results recommended?	Implantable device
		Patient-level follow-up not required as filling of defects which are intrinsic to the stability of the bony structure has always been, and continues to be, a contraindication which is listed in the IFU. This event (omission of the word "not" in the indications in the English section of the IFU) is therefore not expected to lead to the death, or a serious deterioration in the state of health, of a patient, a user of the device, or another person.
4	Is customer Reply Required? * (If yes, form attached specifying deadline for return)	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.	The IFU will be updated to correct the error. Affected lots currently in stock have been quarantined until we have agreement from regulators on the IFU corrective action. Quarantined product in stock at Biocomposites will be reworked to contain the corrected IFU. Any released affected stock held by the Sales team will be returned to Biocomposites and reworked to contain the corrected IFU. FSNs will be sent to all affected distributors and customers, as appropriate.

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6	By when should the action be completed?	04.09.2023
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
3	For updated FSN, key new information as follows:	N/A
4	Further advice or information already expected in follow-up FSN? *	No
5	If **follow-up** FSN expected, what is the further advice expected to relate to:	N/A
6	Anticipated timescale for follow-up FSN	N/A
7	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
8	The Competent (Regulatory) Authority of your country has been informed about this communication to customers *	Yes
9	List of attachments/appendices:	- Customer letter - A redlined version of the updated English IFU section to show exactly what is changing - A clean copy of the updated English IFU section - FSN Distributor Reply Form - FSN Customer Reply Form
10	Name & Job Title	Jenia Payne – Quality Assurance Specialist
	Signature	*Jenia Payne*

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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 *

Mandatory fields are marked with * Other fields are optional