FSN Ref: NC-00176 FSCA Ref: NC-00176

Date: 17th February 2025

Urgent Field Safety Notice
STIMULAN Kit & STIMULAN Rapid Cure

For Attention of: Users, Importers and Distributors of the affected products

Contact details of local representative (name, e-mail, telephone, address etc.)*
Dr Ciara Airey, Biocomposites Ltd, Keele Science Park, Staffordshire, ST5 5NL, UK. Tel: +44 (0) 1782 338 580, email: regulatory@biocomposites.com

Dear Valued Customer,

Biocomposites Ltd., as legal manufacturer has taken the decision to notify you of an issue related to instructions for use (IFU) translation affecting the products detailed below in section 1.7.

All applicable Competent (Regulatory) Authorities have been informed of this action.

1. Information on Affected Devices

1.1 Device Type(s)

STIMULAN Resorbable Calcium Matrix

1.2 Commercial name(s)

STIMULAN Kit & STIMULAN Rapid Cure

1.3 Unique Device Identifier(s) (UDI-DI)

See 1.5 below

1.4 Primary clinical purpose of device(s)

STIMULAN is a resorbable calcium matrix for bone and surrounding soft tissue implantation.

1.5 Device Model/Catalogue/part number(s)

Description	Product Code	Size	UDI-DI
Stimulan Kit	600-005	5cc	15060155710119
Stimulan Kit	600-010	10cc	15060155710126
Stimulan Rapid Cure	620-003	3cc	15060155711451
Stimulan Rapid Cure	620-005	5cc	15060155711024
Stimulan Rapid Cure	620-010	10cc	15060155711031
Stimulan Rapid Cure	620-020	20cc	15060155711048

1.6 Software version

N/A

1.7 Affected serial or lot number range

Registered Office

Biocomposites Ltd.
Keele Science Park, Keele,
Staffordshire,
England. ST5 5NL

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email: info@biocomposites.com
web: www.biocomposites.com

Registered in England and Wales: 03291943

	All Lots
1.8	**Associated devices**
	N/A

	2 Reason for Field Safety Corrective Action (FSCA)
2.1	**Description of the product problem***
	Following an internal review of our instructions for use (IFU), we have identified that certain language pages in the IFUs supplied with the STIMULAN Kit and STIMULAN Rapid Cure devices currently distributed within the EU are missing the following warning: **"WARNING": Do not implant into patients with a known sensitivity or allergic reaction to the device materials".** The warning is present within the English language section of the IFU, however, it is missing from the following language sections: Czech, Danish, Dutch, French, German, Greek, Italian, Lithuanian, Norwegian, Polish, Romanian, Slovenian, Spanish, Swedish & Turkish
2.2	**Hazard giving rise to the FSCA**
	Implanting the device into a patient with a known sensitivity or allergy to the device materials could lead to the patient experiencing an allergic reaction.
2.3	**Probability of problem arising**
	There is a very low (<0.05%) probability of this problem arising in patient. No complaints or incidents related to this issue have been documented in the 15+ years that the devices have been on the EU market.
2.4	**Predicted risk to patient/users**
	This issue is unlikely to present a risk to patients or users. Biocomposites Ltd. are not aware of any complaints or adverse incidents related to this issue.
2.5	**Further information to help characterise the problem**
	N/A
2.6	**Background on Issue**
	N/A
2.7	**Other information relevant to FSCA**
	N/A

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3. Type of Action to mitigate the risk			
3.1	**Action To Be Taken by the User** ☒ Take note of amendment/reinforcement of Instructions For Use (IFU)		
3.2	**By when should the action be completed?**	Biocomposites Ltd. plans to complete this FSCA within the next 3 months.	
3.3	**Is customer Reply Required?** **(If yes, form attached specifying deadline for return)**		Yes - by 14th March
3.4	**Action Being Taken by the Manufacturer** ☒ IFU or labelling change Impacted IFU languages will be updated to in the warning detailed above in all languages and this will be provided with future batches, when available.		
3.5	**Is the FSN required to be communicated to the patient /lay user?**		No
3.6	**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		

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4. General Information		
4.1	**FSN Type**	New
4.2	**Manufacturer information** (For contact details of local representative refer to page 1 of this FSN)	
	Company Name	Biocomposites Ltd.
	Address	Keele Science Park, Keele, Staffordshire, England, ST5 5NL
	Website address	www.biocomposites.com
4.3	**List of attachments/appendices:**	Distributor Response Form Customer Response Form
4.4	**Name/Signature**	Dr. Ciara Airey Regulatory Affairs 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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