FSN / FSCA Ref: CAPA-00048

Date: 14th July 2025

Urgent Field Safety Notice
Biosteon Screw

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 the expiry date listed on the patient notes label provided with the products detailed below in section 1.7.

All applicable Competent (Regulatory) Authorities will be informed of this action.

1. Information on Affected Devices

1.1 Device Type(s)

Biosteon Screw

1.2 Commercial name(s)

Biosteon Screw

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

See 1.5 below

1.4 Primary clinical purpose of device(s)

The Stryker Biosteon® ACL Screw Is a cannulated, single-use bone screw made of a resorbable Poly(L-lactic) Acid and Calcium Phosphate which will be gradually resorbed into the body.

1.5 Device Model/Catalogue/part number(s)

Description	Product Code	Size	UDI-DI
Biosteon Screw	234-010-178	10 x 35mm	15060155710324

1.6 Software version

N/A

1.7 Affected serial or lot number range

BS240520

1.8 Associated devices

N/A

Registered Office

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

Tel: +44 (0) 1782 338580
Fax: +44 (0) 1782 338599
email: info@biocomposites.com
web: www.biocomposites.com

Registered in England and Wales: 03291943

2 Reason for Field Safety Corrective Action (FSCA)	
2.1	**Description of the product problem***
	Biocomposites Ltd received a complaint that the expiry date on the patient notes label (2025-05-31) was incorrect. The expiry date stated on the label is 2025-05-31. The correct expiry date is 2027-05-31. The correct expiry date, which is 2027-05-31, is printed on the product box and other packaging labels.
2.2	**Hazard giving rise to the FSCA**
	There is a risk that users and patients may perceive that an expired device has been implanted into patients.
2.3	**Probability of problem arising**
	The probability of this problem arising with the Biosteon Screw is determined to be (<0.05%), i.e. "very low". There has been only one other labelling complaint received by Biocomposites for the Biosteon Screw device in the 10+ years since the device was placed on the market.
2.4	**Predicted risk to patient/users**
	This error in labelling poses no additional risk to patients or users since the impacted device lot BS240520 has been confirmed to be within its shelf-life until 2027-05-31.
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

3. Type of Action to mitigate the risk		
3.1	**Action To Be Taken by the User**	
	☒ Please acknowledge receipt of this FSN by completing the attached Customer Reply Form and returning the completed form to your local distributor. Please also attach a copy of this FSN to patient notes for all implanted devices relating to Lot BS240520 for reference	
3.2	**By when should the action be completed?**	Please complete the actions above by 31 August 2025
3.3	**Is customer Reply Required? (If yes, form attached specifying deadline for return)**	Yes, by 31 August 2025

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3.4	**Action Being Taken by the Manufacturer** ☒ Issue of FSN to affected Users, Importers and Distributors	
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:**	Customer Reply 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.