FSN Ref: FSN001-2021 / FSCA Ref: FSCA001-2021

Date: 01.11.2021

Urgent Field Safety Notice (FSN)
Crespine Gel +
Recall

Dear Customer

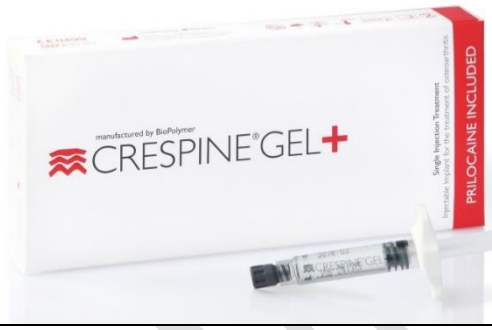
BioPolymer as manufacturer of Crespine Gel +, hereby notifies about the issue of a Field Safety Corrective Action relating to the aforementioned product.

BioPolymer GmbH & Co. KG

Walsmühler Straße 18
19073 Dümmer
Tel. +49(0)2602/83868-0
Fax +49(0)2602/83868-20

FSN Ref: FSN001-2021 / FSCA Ref: FSCA001-2021

Urgent Field Safety Notice (FSN)
Crespine Gel +
Recall

	1. **Information on Affected Devices**
1.	1. Device Type(s)
	Crespine Gel + is a syringe of a visco-supplement containing prilocaine HCl. 
1.	2. Commercial name(s)
	Crespine Gel +
1.	3. Unique Device Identifier(s) (UDI-DI)
	0426011548004
1.	4. Primary clinical purpose of device(s)
	Crespine Gel + is injected into joints as a visco-supplement for the reduction of pain symptoms and improved functioning of the joints. For pain relief during injection the medical device contains prilocaine HCl as a medicinal substance with ancillary action →Minimized pain perception caused
1.	5. Device Model/Catalogue/part number(s)
	MD057
1.	6. Software version
	Not applicable
1.	7. Affected serial or lot number range
	All lots
1.	8. Associated devices
	Not applicable

	2 **Reason for Field Safety Corrective Action (FSCA)**
2.	1. Description of the product problem
	Manufacturer of prilocaine HCl not qualified and released by BioPolymer as supplier of raw materials for Crespine Gel +.
2.	2. Hazard giving rise to the FSCA
	Deviation from supplier qualification standards
2.	3. Probability of problem arising
	All products on the market are affected.
2.	4. Predicted risk to patient/users
	No risk for patients is predicted, as the used material conforms to Ph. Eur. specifications and is manufactured by GMP standards. No safety related complaints have been received.

BioPolymer GmbH & Co. KG

Walsmühler Straße 18
19073 Dümmer
Tel. +49(0)2602/83868-0
Fax +49(0)2602/83868-20

2.	Further information to help characterise the problem
	Problem can be characterized as a registration issue with no risk for patient safety.
2.	Background on Issue
	BioPolymer's supplier for prilocaine HCl did not notify about a change of the manufacturer.
2.	Other information relevant to FSCA
	None.

	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	
3.	2. By when should the action be completed?	Specify where critical to patient/end user safety Not specified because not critical to patient safety.
3.	3. Particular considerations for: Implantable device Is follow-up of patients or review of patients' previous results recommended? No As mentioned before, the used raw material met all required safety specifications and manufacturing standards.	
3.	4. Is customer Reply Required? (If yes, form attached specifying deadline for return)	Yes
3.	5. Action Being Taken by the Manufacturer ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None	
3	6. By when should the action be completed?	Specify where critical to patient/end user safety
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?	
	N/A	

BioPolymer GmbH & Co. KG

Walsmühler Straße 18
19073 Dümmer
Tel. +49(0)2602/83868-0
Fax +49(0)2602/83868-20

	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?	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	N/A	
4	6. Anticipated timescale for follow-up FSN	N/A
4.	7. Manufacturer information	
	a. Company Name	BioPolymer GmbH & Co KG
	b. Address	Walsmühler Str. 18, 19073 Dümmer, Germany
	c. Website address	www.biopolymer.info
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	[redacted]
4.	9. List of attachments/appendices:	
4.	10. Name/Signature	

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.

BioPolymer GmbH & Co. KG

Walsmühler Straße 18
19073 Dümmer
Tel. +49(0)2602/83868-0
Fax +49(0)2602/83868-20

FSN Ref: FSN001-2021

Field Safety Notice (FSN)
Distributor Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	FSN001-2021
FSN Date	01.11.2021
Product/ Device name	Crespine Gel +
Product Code(s)	MD057
Batch/Serial Number (s)	All lots

2. Distributor Details	
Company Name	
Address	
Contact Name	
Title or Function	
Telephone number	
Email	

3. Return acknowledgement to Sender	
Email	info@biopolymer.info
Postal Address	Walsmühler Str. 18, 19073 Dümmer, Germany
Deadline for returning the Distributor reply form	Please return this form **within 5 working days** after receipt, even if your facility does not have any of the affected products in stock.

BioPolymer GmbH & Co. KG

Walsmühler Straße 18
19073 Dümmer
Tel. +49(0)2602/83868-0
Fax +49(0)2602/83868-20

4. Distributors Please check the boxes below to indicate which measures have been completed. If a measure does not apply, please enter N/A in the right column.		
☐	**I confirm the receipt, the reading and understanding of the Field Safety Notice.**	
☐	I have checked my stock	
☐	I have identified customers that received or may have received this device	
☐	I have informed the identified customers of this FSN	
☐	I have received confirmation of reply from all identified customers	
☐	I have returned affected devices - enter number of devices returned and date complete in list below.	
☐	Neither I nor any of my customers has any affected devices in inventory	

Print Name	
Signature	
Date	

5. List of returned products When returning affected products, please include the lot number and quantity	
Lot Nr	Quantity

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

BioPolymer GmbH & Co. KG

Walsmühler Straße 18
19073 Dümmer
Tel. +49(0)2602/83868-0
Fax +49(0)2602/83868-20