BioSCIENCE GmbH · Walsmühler Straße 18 · 19073 Dümmer

Urgent Field Safety Notice (FSN)

Recipients: Users, physicians, healthcare professionals in aesthetic medicine and dermatology, distributors.

Product Name: Genefill DX

Reference Number: FSN001-2026

Date: July 29, 2026

Dear Madam /Sir,

This is an important notice regarding the use of the product Genefill DX.

Reason for the Field Safety Corrective Action (FSCA)

As part of post-market surveillance, BioScience has recorded an increase in reports of known adverse effects (including edema, swelling, pain, nodule formation) in connection with our product Genefill DX.

The investigation of reported cases showed that a key triggering factor may be the administration of excessively high product volumes within a single treatment session.

Since an increased injection volume significantly increases the risk of tissue reactions and inflammatory side effects, the Instructions for Use (IFU) for Genefill DX are being updated to explicitly limit the maximum recommended injection quantity per session.

Important: There is no quality defect or manufacturing error in the affected batches. The products comply with all specifications. This measure serves to prevent user application errors and to enhance patient safety.

Potential Risks to Patients/Users

Injecting high quantities of product increases the likelihood of known, transient tissue reactions occurring. These notably include pronounced swelling (edema), localized pain, redness, and nodule formation in the injection area.

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Germany

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info@bio-science.org
www.bio-science.org

Geschäftsführer Gabriele Laeschke / Michelle Rahn
HRB 11962
Amtsgericht Schwerin
USt-IdNr. DE 244 346 557

Commerzbank
BLZ 570 400 44, Kto. 202 817 3
SWIFT COBA DEFF 570
IBAN DE53 570 400 44 0202 817 300

Nassauische Sparkasse
BLZ 510 500 15, Kto. 401 003 868
SWIFT NASSDE55 XXX
IBAN DE50 510 500 15 0401 003 868

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Required Actions by Users/Physicians for Risk Mitigation

In the interest of patient safety, please adhere to the following guidelines established in the updated Instructions for Use (IFU):

- An injection volume of a **maximum of 2 ml** is recommended per treatment session.
- Strictly adhere to the indicated injection depth and avoid intramuscular or intravascular administration.
- Inform patients thoroughly prior to treatment regarding the normal side-effect profile, general procedural risks, and appropriate behavior in the event of persistent tissue reactions.

Distribution of Information

Please ensure within your organization that all users of Genefill DX and participating medical personnel are informed of this urgent safety notice.

If you have supplied the product to third parties (e.g., sub-distributors, clinics, or practices), please forward this information to the relevant entities without delay and request an acknowledgment of receipt.

Feedback / Confirmation of Receipt

Please complete the enclosed feedback form and return it to us by email no later than **August 12, 2026**:

Email: info@bio-science.org

By returning the form, you confirm that you have received and understood this safety notice and implemented the necessary measures in your practice/organization.

Contact Person for Inquiries

If you have any questions or wish to report adverse events, please contact:

Michelle Rahn (PRRC)
BioScience GmbH
Walsmühler Str. 18
19073 Dümmer
Email: m.rahn@biopolymer.info

The competent authorities have been informed of this Field Safety Corrective Action (FSCA).

Field Safety Notice (FSN)
Customer / Distributor Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	FSN001-2026
FSN Date	29.07.2026
Product/ Device name	Genefill DX
Product Code(s)	MD004
Batch/Serial Number (s)	All batches

2. Customer / Distributor Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

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3. Customer action undertaken on behalf of Healthcare Organisation				
☐	**I confirm receipt of the Field Safety Notice and that I read and understood its content.***	Customer to complete or enter N/A		
☐	**I performed all actions requested by the FSN.***	Customer to complete or enter N/A		
☐	**The information and required actions have been brought to the attention of all relevant users and executed.***	Customer to complete or enter N/A		
☐	I have returned affected devices - *enter number of devices returned and date complete.*	Qty: add qty	Lot Number: add lot	Date Returned (DD/MM/YY): add date
		Qty: add qty	Lot Number: add lot	Date Returned (DD/MM/YY): add date
		N/A	Comments: add comment if necessary	
☐	I have destroyed affected devices – *enter number destroyed and date complete.*	Qty: add qty	Lot Number: add lot	Date Destroyed (DD/MM/YY): add date
		Qty: add qty	Lot Number: add lot	Date Destroyed (DD/MM/YY): add date
		N/A	Comments: add comment if necessary	
☐	No affected devices are available for return/ destruction	Customer to complete or enter N/A		
☐	I have identified customers that received or may have received this device. I have informed the identified customers of this FSN.	Customer to complete or enter N/A		
☐	Other Action (Define):			
☐	I do not have any affected devices.	Customer to complete or enter N/A		
☐	I have a query please contact me (e.g. need for replacement of the product).	Customer to enter contact details if different from above and brief description of query		
☐	Neither I nor any of my customers has any affected devices in inventory			

Print Name*	
Signature*	
Date*	

4. Return acknowledgement to sender	
Email	m.rahn@biopolymer.info
Postal Address	Walsmühler Str. 18, 19073 Dümmer, Germany
Deadline for returning the reply form	Please return this form **within 14 working days (August 12, 2026)** after receipt.

BioScience GmbH

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Mandatory fields are marked with *

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.

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