

## **Field Safety Notice**

FSN Ref.no: 20240829ENv1  
NCR-2735  
Ver: 1.0 - EN  
Type: New  
Date: August 29<sup>th</sup>, 2024

**For the attention of:** Distributors and End-users

**Subject:** Recall of Minivisc® Plus, LOT MPFX16100 and MPFX17100

**Reason for recall:** BOHUS, legal entity Bohus BioTech AB, has voluntarily initiated a recall of two product LOTs of Minivisc® Plus. This action follows an internal post-market surveillance that identified a potential isolated issue with a higher percentage of a crosslink body between HA (hyaluronic acid) and PDMS (polydimethylsiloxan) on the surface of the plunger stopper, which may lead to a delay in procedures.

You are receiving this notice because our or our distributors records indicate that you received Minivisc® Plus from the batch impacted by this Action.

### **Affected Products and batches**

This Field safety Notice affects batches listed below:

<b>Product Name</b>	<b>Article Number</b>	<b>LOT (Batch) number</b>	<b>UDI-DI</b>
Minivisc® Plus	1183 / 1184	MPFX16100	17350030051894
		MPFX17100	

### **Risks:**

Possible delay in procedures.

**Action Required by the Distributors and End-Users:**

1. **Inventory Check:** Review your inventory to identify and quantify any affected products from the LOTs listed above.
2. **Acknowledgement:** Confirm receipt, review, and understanding of this notice by completing the attached Customer Reply form. Return the completed form to BOHUS QA Manager, Cathrine Loga, at [cathrine.loga@bohusbiotech.com](mailto:cathrine.loga@bohusbiotech.com) or Head of QARA, Michelle Johansson, at [quality.manager@bohusbiotech.com](mailto:quality.manager@bohusbiotech.com)
3. **Customer Notification:** Identify and inform any customers who received products from the affected LOTs. Report any complaints related to these LOTs to BOHUS QA Manager, Cathrine Loga, at [cathrine.loga@bohusbiotech.com](mailto:cathrine.loga@bohusbiotech.com) or Head of QARA, Michelle Johansson, at [quality.manager@bohusbiotech.com](mailto:quality.manager@bohusbiotech.com)
4. **Internal Communication:** Ensure that this information is communicated to all relevant individuals within your organization and to any entities where the product has been distributed.
5. **Record Keeping:** Maintain records of all communications related to this issue.
6. **Shipping within EU:** Once you have finalised the collection of batches, please inform BOHUS ([order@bohusbiotech.com](mailto:order@bohusbiotech.com)), and we will arrange the pickup from your designated location.

**Shipping outside EU:** Once you have finalised the collection of batches, please arrange shipping and inform BOHUS at ([order@bohusbiotech.com](mailto:order@bohusbiotech.com)), please forward the shipping invoice to [faktura@bohusbiotech.com](mailto:faktura@bohusbiotech.com)

**Further Information**

No additional follow-up FSNs are expected at this time.

Yours sincerely,  
Magnus Nylén, CEO   
Magnus Nylén (Aug 29, 2024 15:48 GMT+2)

## BOHUS RECALL CUSTOMER REPLY FORM

Please complete and return this form **even if you have no stock** of the affected products. Email the completed form to BOHUS Quality Assurance at [cathrine.loega@bohusbiotech.com](mailto:cathrine.loega@bohusbiotech.com) or [quality.manger@bohusbiotech.com](mailto:quality.manger@bohusbiotech.com) within 3 business days of receipt of this notice.

Please indicate your response:

- All affected products have already been used or discarded
- We are returning affected products

LOT number	Quantity of Minivisc® Plus to be returned

*Please add information about the shipping:*

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<b>Company name</b>	
<b>Address</b>	
<b>City, Zip Code</b>	
<b>Country</b>	
<b>Telephone number</b>	
<b>Email address</b>	

Person completing this form acknowledge the receipt and understanding of the actions, as stated in the Product Recall letter:

**Name: (print)** \_\_\_\_\_

**Title/Position** \_\_\_\_\_

**Signature:** \_\_\_\_\_

**Date:** \_\_\_\_\_

# FSN and Distributor Reply Form (EN-EU)\_v.1.0

Final Audit Report

2024-08-29

Created:	2024-08-29
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## "FSN and Distributor Reply Form (EN-EU)\_v.1.0" History

-  Document created by Mehrdad Jalali (mehrdad.jalali@bohusbiotech.com)  
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-  Document emailed to Magnus Nylén (magnus.nylen@bohusbiotech.com) for signature  
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-  Email viewed by Magnus Nylén (magnus.nylen@bohusbiotech.com)  
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