BOHUS
SCANDINAVIAN HA

Field Safety Notice

FSN Ref.number: NCR-2636 FSCA Ref.number Vk_20240805_19
ver.1 - July 2024
FSN Type: New

For Attention of*: Distributor

Description of the issue

Due to a vigilance complaint by a distributor in Germany, a drop-like foreign body has been seen during the surgical procedure administrating the medical device Minivisc Plus (hyaluronic acid 14 mg/ml) Lot no MPFX09100. There is unclear information regarding the number of suspected units. The Lot number is distributed in Germany, Finland, Sweden, Latvia, Spain, UK, Switzerland and UAE and there are no similar incidents reported from the other countries regarding this LOT. There have also been demonstrated no noticeable problems, no unusual intraocular pressure, no negative impact to the visual acuity and there been no necessity to remedial action by the health care facility.

Concerned products and batches

This Field Safety Notice affects all batches listed below.

Table 1

Product Name	Article number	LOT (batch) number	UDI
Minivisc Plus	1183	MPFX09100	17350030051894

Risks

Possible operational delay.

Progress report by the manufacturer

Review of the batch documentation has been performed. No irregularity was found.

Review of complaints has been performed. Neither other complaints regarding this batch nor similar complaints with other batches have been reported to the manufacturer. For information, a batch contains approximately 16 000 units.

Reference samples of the same LOT have been inspected under the microscope. No irregularities observed. Number of units being inspected is 120.

Based on the results of these investigations, it was determined that a recall was not necessary; however, in considering the nature of incident, the manufacturer has decided to offer the German distributor who provided the products to this end-user to replace

Action to be taken by the distributor

1. Please confirm of receipt, reading and understanding of this notice to the manufacturer.

2. Please check your inventory and quantity of products of the LOT affected by this FSN.

3. BOHUS offers the replacement of products of the LOT affected by this FSN with products from other LOT. Please let BOHUS know if you accept the offer or not. If the relevant LOT product is not in stock, it is not eligible for this replacement.

4. Please identify your customers that received or may have received products of affected LOT. If any similar complaints with the affected LOT is reported by your customer, please contact BOHUS.

5. Please Complete the Distributor reply form at the end of this document. Please return the completed form to BOHUS – QA Manager cathrine.loga@bohusbiotech.com.

6. Please save all information of your customers when communicating with them in this subject.

Further advice or information already expected in follow-up FSN?

No

Yours sincerely,
Magnus Nylén, CEO Magnus Nylén
Magnus Nylén (Aug 7, 2024 16:01 GMT+2)

BOHUS
SCANDINAVIAN HA

Information on Affected Devices

1. Device Type(s)
Clear solution (sodium hyaluronate gel) supplied in a disposable syringe.
2. Commercial name(s)
Minivisc Plus
3. LOT/batch number
MPFX09100
4. Unique Device Identifier(s) (UDI-DI)
17350030051894
5. Primary clinical purpose of device(s)
The ophthalmic viscoelastic devices (OVDs) are sterile, single-use injectable medical devices used in ophthalmic surgery. OVD is intended to protect, lubricate and support delicate ophthalmic cells or tissues, to assist in maintaining intraocular space and to enhance visualization during surgery. OVD is particularly suitable for the following types of surgical procedures: (1) Cataract surgery and implantation of intraocular lenses (IOL), (2) Glaucoma surgery, (3) Anterior segment surgery, (4) Corneal transplantation
6. Associated devices
N/A

BOHUS
SCANDINAVIAN HA

Distributor Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	NCR-2636 (MIR ref.no. given by BfArM: 23897/24)
Version of the FSN	ver. 1
FSN Date	2024-07-24
Product name	Minivisc Plus

2. Distributor/User Details *(Distributor; please enter your information below)*	
Company/facility Name	Ophthalmo Pro
Address	Im Reihersbruch 1, D-66386 St. Germany
Shipping address if different to above	
Contact Name	Thomas Zimmer
Title or Function	IngbertGeschäftsführer
Telephone number	+49 (0) 6894 - 99 88 770
Email	t.zimmer@ophthalmo-pro.de

3. Return acknowledgement to BOHUS	
Email	cathrine.loga@bohusbiotech.com
Postal Address	Trädgårdsgatan 4, 452 31 Strömstad, Sweden
Deadline for returning the Distributor Reply Form (for the confirmation of receipt of the FSN)	2024-08-02

4. Checklist *Please tick all boxes that apply and enter your information and send this form back to us.*			
4.1	I confirm the receipt, the reading and understanding of the Field Safety Notice (FSN).		☐
4.2	I have checked my stock and quarantined inventory (please **choose one** of the following)		
	☐	I do not have any products that are affected by this FSN in my stock and quarantined inventory.	
	☐	I have products that are affected by this FSN in my stock or quarantined inventory.	
4.3	My answer to the question at 4.2 is “I have products that are affected by this FSN in my stock or quarantined inventory”, and I take the replacement offer.		Yes ☐ No ☐
	If your answer is “Yes”, please enter the quantity here;		
4.4	I confirm that my actions to be taken regarding this FSN are completed.		☐

Print Name	*(Distributor)*
Signature	*(Distributor)*
Date	*(Distributor)*

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.

FSN and Distributor Reply Form (EN)_Replacement ver 1

Final Audit Report 2024-08-07

Created:	2024-08-07
By:	Mehrdad Jalali (mehrdad.jalali@bohusbiotech.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAqkxqS5lCYKV9qBQSLYRDWRHa_SUwbILU

"FSN and Distributor Reply Form (EN)_Replacement ver 1" History

Document created by Mehrdad Jalali (mehrdad.jalali@bohusbiotech.com)
2024-08-07 - 1:55:01 PM GMT

Document emailed to Magnus Nylén (magnus.nylen@bohusbiotech.com) for signature
2024-08-07 - 1:55:04 PM GMT

Email viewed by Magnus Nylén (magnus.nylen@bohusbiotech.com)
2024-08-07 - 2:00:39 PM GMT

Document e-signed by Magnus Nylén (magnus.nylen@bohusbiotech.com)
Signature Date: 2024-08-07 - 2:01:06 PM GMT - Time Source: server

Agreement completed.
2024-08-07 - 2:01:06 PM GMT