Carl Zeiss Meditec AG 10589 Berlin

To Z-HYALON / Z-HYALON plus customers

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Division/Dept.:	Complaint Management & Vigilance
Your contact:	Dr. Lucia Püttmann, Claudia Minke

Your ref.:	N/A
Yours of:	N/A
Our ref.:	FSCA CoCe8 2022-001
Date:	2022-05-20

URGENT/IMMEDATE ACTION REQUIRED:
FIELD SAFETY CORRECTIVE ACTION (FSCA)
RECALL ophthalmic viscoelastic devices Z-HYALON / Z-HYALON plus

Dear Customer,

You are using our ophthalmic viscoelastic devices **Z-HYALON / Z-HYALON plus** and we thank you for your loyalty to our products. High quality and innovation are our main goals, but your safety and satisfaction are our first priority. To ensure that you can continue to use of our system/products reliably with the level of high quality you expect, Carl Zeiss Meditec AG is planning to perform a Field Safety Corrective Action.

With this letter, we inform you that our Original Equipment Manufacturer (OEM) Bohus BioTech AB notified us that they cannot guarantee the sterility of the products listed below and therefore perform a Field Safety Corrective Action. We want to give you a precise description of the situation and provide clear guidance on how to avoid any inconveniences with your patients.

Problem description
OEM Bohus BioTech AB notified us that they have identified deviations in their sterilization process and therefore they cannot guarantee the sterility of the products listed below. The OEM's root cause analysis is in ongoing, and results are not available to us at this time. All products currently on the market that have not expired are part of the FSCA.

Hazard description
Bohus BioTech AB cannot guarantee the sterility of the products on the market. At worst, the patient could develop an inflammatory reaction or other adverse reactions due to a possible unsterility and subsequent contamination.
Bohus BioTech AB assumes that there is no unsterile product on the marked but has reason to believe that the sterilization process has not been handled correctly. No reported incident has led to Bohus BioTech AB's decision to recall the products.

Affected products
Bohus BioTech AB identified that all Z-HYALON / Z-HYALON plus products within expiry date to be affected. Please find hereafter the identification of the involved products:

Product Name	Product Number (REF):
Z-Hyalon 0.55 ml single	000000-1941-242
Z-Hyalon Plus 0.55 ml single	000000-1941-243
Z-Hyalon 0.55 ml Multipack	000000-1941-244
Z-Hyalon 0.85 ml single	000000-1941-245
Z-Hyalon 0.85 ml Multipack	000000-1941-246

The affected OVDs were distributed in the following countries:
- Belgium
- Finland
- Germany
- Great Britain
- Italy
- Luxembourg
- Norway
- Slovenia
- Sweden
- Switzerland

Actions & Recommendation:
Please check the status of all affected products you have:
- If you have still Z-Hyalon / Z-Hyalon Plus in stock, please place it immediately in quarantine and contact your local ZEISS representative. These OVDs have to be shipped back to ZEISS.

- If you have used affected Z-Hyalon / Z-Hyalon Plus, please review the outcome of your patient.

Please inform the relevant persons within your healthcare structure who are involved in use of the above-mentioned Z-Hyalon / Z-Hyalon Plus products.

We kindly ask you to send back to us the acknowledge receipt of the letter which you will find in Appendix 1.

This Field Safety Corrective Action will be reported to your local Health Authorities in accordance with the European regulations.

We thank you for your careful attention, your consequent verifications and your continuous support. We apologize for any inconveniences this situation might cause and remain at your disposal.

Best regards

Carl Zeiss Meditec

Annex

Appendix 1: Confirmation sheet

RECALL Z-Hyalon / Z-Hyalon Plus – FCA CoCe8 2022-001

I have read, understood the FSCA-RECALL related to Z-Hyalon / Z-Hyalon Plus.

I have transmitted the information to the relevant persons within my healthcare structure.

Status of the affected OVD :

Product Name	**Yes / No**	**Product Status :** • **Blocked/sent back to ZEISS** • **Used/Patient outcome**
Z-Hyalon 0.55 ml single		
Z-Hyalon Plus 0.55 ml single		
Z-Hyalon 0.55 ml Multipack		
Z-Hyalon 0.85 ml single		
Z-Hyalon 0.85 ml Multipack		

Confirmation:

Signature:_____ Date:_____

Name:	
Function:	
Address:	
Phone:	
E-mail address:	

Please send back this confirmation form:
By e-mail to

- claudia.minke@zeiss.com or
- lucia.puettmann@zeiss.com

or by FAX to

- +49 30 854001-123