



Carl Zeiss Pte. Ltd., Singapore

Date: 1 February 2019

<< Name of Hospital >>

<< Address of Hospital >>

Attn: << Name of Doctor / OT Sister >>

**Carl Zeiss Pte. Ltd.**

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### ACTION REQUIRED: FIELD CORRECTION NOTICE

#### List of concerned products:

003500-0009-066	COMBIVISC
003500-0009-065	COMBIVISC MULTIPACK 5-PACK
000000-1861-152	Z-HYALCOAT MULTIPACK 10-PACK
000000-1861-153	Z-HYALIN MULTIPACK 10-PACK
000000-1861-154	Z-HYALIN PLUS MULTIPACK 10-PACK

Dear Doctor / OT Sister,

You are using the ZEISS Ophthalmic Viscosurgical Devices (OVDs). As you know, high quality and innovation is our main goal, but the safety of your patients is our first priority. To ensure that you are able to continue reliably using our products, our manufacturer, Carl Zeiss Meditec AG, is issuing a proactive Field Correction Notice regarding the products listed above.

With this letter, we would like to inform you that manufacturer has received one report from the field that an OVD has been found, whose pouch has not been sealed. If the pouch is not sealed, the surface of the syringe will not be sterile and contamination of the surgeon's gloves is possible. The syringe contents will still be sterile and are not comprised.

#### Actions to be taken:

We have checked our stock and not found any additional unsealed pouches. Despite the low remaining risk that there are more unsealed pouches in the market, we kindly ask you to check the seal of each OVD before it is used.

potentially  
missing  
bottom seal



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**Affected Products:**

This notice applies to ZEISS OVDs delivered in pouches (see list above).

**Additional information:**

The risk of an accidental use of a unsealed pouch is very low, as the impaired seal is easily detectable. Therefore, according to European and U.S. regulations this Field Correction Advisory is not reportable to the authorities.

If you identify an OVD with an open pouch seal, please inform us to get a free replacement.

The pouching station at the manufacturing site ensures a strict separation between unsealed and sealed pouches followed by visual inspection. Manufacturer is still investigating how an unsealed pouch can have reached the market and will implement further action to prevent a reoccurrence.

We thank you very much for your attention, your consequent verifications and your continuous support. We apologize for any inconveniences this situation might cause.

If you have any further questions, please do not hesitate to contact us.

Thank you.

Yours sincerely



Sujay Debnath  
Carl Zeiss S.E.Asia  
Medical Business Group  
Regional Director

cc: Chairman of Medical Board and all relevant Head(s) of Department