AMO Ireland
Block B
Liffey Valley Office Campus
Quarryvale
Co.Dublin
Ireland

URGENT FIELD SAFETY NOTICE

Product: Healon EndoCoat Opthalmic Viscosurgical Device
Type of Action: Advice regarding use of the device
FSCA Identifier: FSN 2014-04_01

[November XX, 2014]

Dear AMO Customer:

Abbott Medical Optics Inc. (AMO) is voluntarily issuing this Field Safety Notice for the Healon EndoCoat Opthalmic Viscosurgical Device (OVD) product number:

[VT585 (Healon EndoCoat OVD)]

Please read this Field Safety Notice thoroughly to understand the issue and ensure continued safe use of the product.

This voluntary Field Safety Notice is being sent to re-emphasize proper techniques for the use of the syringe included in the Healon EndoCoat Directions for Use (DFU). It will also provide an additional diagram regarding recommended syringe orientation to avoid finger grip dislodgement.

AMO has received complaints where the finger grip dislodged while depressing the syringe plunger. The finger grip dislodgement could result in the surgeon's hand unintentionally moving the cannula further than intended, resulting in potential trauma to the eye.

Failure to follow the DFU can result in the finger grip becoming detached. You are advised to consult the DFU that is distributed with each device, which contains important precautions for use of the product.

Specifically:

Precautions

CAUTION: The cannula should be fastened securely to the syringe: however over tightening may cause the hub to weaken and possibly detach from the syringe. ***Extrusion of a test drop is recommended prior to entering the eye, and excessive force on the plunger should be avoided.***

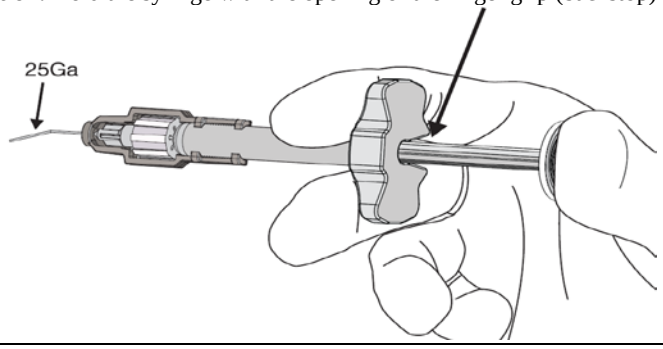
As stated in the precautions section, excessive force on the syringe plunger should be avoided.

In addition, as shown in **Step 5** of the Healon EndoCoat OVD Assembly Instructions, extrusion of a test drop is recommended prior to entering the eye. This will assure flow of the product prior to use.

Also the 25 Ga cannula provided with the product should be used.

This notice is also providing additional instruction on the orientation of the syringe.

Syringe Orientation: Hold the syringe with the opening of the finger grip (backstop) facing the palm.



Abbott Medical Optics will be adding this additional instruction to the "Directions for Use". Your current inventory of product is acceptable for safe use following the current DFU and the Syringe Orientation diagram highlighted above. Therefore, there is no need to return any of the products to Abbott Medical Optics.

The relevant Regulatory Agencies have been made aware of this action.

Thank you for your attention to this matter. Please provide this Field Safety Notice to surgeons and those who need to be aware in you organization. If you have any questions, or in the event of any product complaints or adverse events, please contact your local field sales representative or call [insert local contact information].

Sincerely,

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Michelle Hall
Vigilance Specialist
AMO Ireland
Block B
Liffey Valley Office Campus
Quarryvale
Co.Dublin
DU-Vigilance@amo.abbott.com