

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

URGENT FIELD SAFETY NOTICE

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

[November XX, 2014]

Dear AMO Customer:

Abbott Medical Optics Inc. (AMO) is voluntarily issuing this Field Safety Notice for the Healon EndoCoat Ophthalmic 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 in the following specific areas can result in the finger grip becoming detached:

- Use of a cannula not provided with the device
- Use of excessive force

You are advised to consult the DFU that is distributed with each device, which contains important warnings and precautions for use of the product.

Specifically:

Warnings

The Healon EndoCoat OVD Delivery system is not designed or intended to be attached to instruments other than the one provided with the product. Failure to follow the "Directions for Use" may result in cannula detachment.

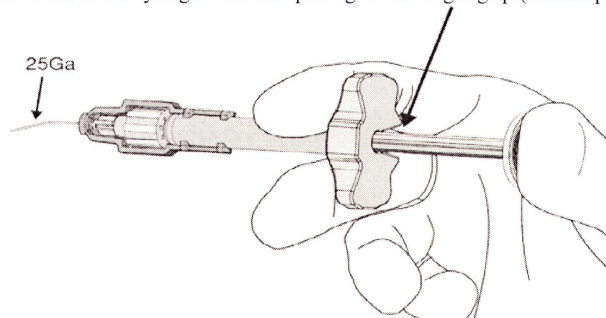
Precautions

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 and warning section, excessive force on the syringe plunger should be avoided and the provided 25 Ga cannula should be used. In addition, as stated in **Step 5** of the Healon EndoCoat OVD Assembly Instructions, **“Check proper function by holding the syringe barrel and gently depressing the plunger rod until the OVD appears at the cannula tip.”** This will assure flow of the product prior to use.

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,

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