El INVIMA informa a los usuarios en general que el Grupo de Tecnovigilancia ha emitido una comunicación relacionada con un Informe de Seguridad asociado a:

NOMBRE DEL DISPOSITIVO MÉDICO	Dispositivo Viscoquirúrgico Oftálmico
NO. IDENTIFICACIÓN RISARH	I1411-479
REFERENCIAS DEL DISPOSITIVO MEDICO	Healon EndoCoat y Healon Duet Dual
REGISTRO SANITARIO	2013DM-0010182
INDICACIONES Y USO ESTABLECIDOS	El dispositivo Viscoquirúrgico oftálmico HEALON ENDOCOAT se emplea en procedimientos quirúrgicos oftálmicos del segmento anterior, entre ellos: cirugía de cataratas con una lente intraocular, cirugía de catarata sin una lente intraocular, implantación de lente intraocular secundaria.
NOMBRE DEL FABRICANTE	Amo Ireland. Abbott Medical Optics Inc.
DESCRIPCION DEL PROBLEMA	El fabricante afirma que ha recibido informes de incidentes en los que la agarre con los dedos de los dispositivos se desalojaron mientras el usuario oprime el émbolo de la jeringa, si la ranura de agarre se desaloja, la mano del cirujano podría mover accidentalmente la cánula, resultando en un traumatismo en el ojo del paciente, dicha situación puede desprenderse si el usuario no sigue las instrucciones de uso (DFU), conllevando a que se presenten potencialmente eventos adversos sobre el paciente.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	21 de Noviembre de 2014

RECOMENDACIÓN:

En caso de identificar la existencia del producto mencionado anteriormente comuníquese con su proveedor quien determinara las acciones que se llevaran a cabo.

Es importante mantener un estado de alerta, realizando un seguimiento permanente a los productos que se fabrican y/o comercializan en el país, divulgando la información de seguridad respectiva entre los profesionales de la salud que realizan uso de estos recursos tecnológicos.

Para mayor información comuníquese al teléfono 2948700 extensión 3880 en Bogotá, ó al correo electrónico tecnovigilancia@invima.gov.co

ANEXO 1

A23348 - Normal Priority Medical Device Alert

Medical Device Ongoing Action
Updated: November 20, 2014
UMDNS Terms:
- Viscoelastic Solutions, Intraocular [29717]
- Viscoelastic Solutions [33785]

Suggested Distribution:
- Materials Management
- Ophthalmology

Geographic Regions:
- Worldwide

Abbott Medical Optics (AMO)—Healon EndoCoat Opthalmic Viscosurgical Devices and Healon Duet Dual Packs: Manufacturer Reminds Users of Proper Syringe Technique to Avoid Finger Grip Dislodgement

Product Identifier:
Healon EndoCoat Opthalmic Viscosurgical Devices (OVDs) *[Consumable]*
U.S. Product Nos.: VT585U, 57502000 (packaged in Healon Duet Dual Pack Product No. 10290080)
International Product Nos.: VT585, 57550500 (packaged in Healon Duet Dual Pack Product Nos. 10220010, 10220011, 10220012)

Manufacturer:
- Abbott Medical Optics1700 E. St. Andrew Place, Santa Ana, CA 92705, United States

Problem: In a November 4, 2014, Urgent Physician Advisory Notice letter submitted by ECRI Institute member hospitals, Abbott Medical Optics (AMO) states that it has received reports of incidents in which the finger grip on the above opthalmic viscosurgical devices (OVDs) dislodged while the user depressed the syringe plunger. If the finger grip dislodges, the surgeon's hand could accidentally move the cannula further than intended, potentially resulting in trauma to the patient's eye. AMO states that the finger grip may become detached if the user fails to follow the directions for use (DFU) by using a cannula not provided with the device or by using excessive force.

Action Needed:
Identify affected product in your inventory. If you have affected product, verify that you have received the November 4, 2014, Urgent Physician Advisory Notice letter and additional diagram from AMO. AMO will add the new diagram to the affected product's DFU. AMO also recommends the following:
- Only use the 25 gauge cannula provided with affected product.
- Avoid excessive force when using the syringe plunger.
- Check proper function by holding the syringe barrel and gently depressing the plunger rod until the OVD appears at the cannula tip.

Inform all relevant personnel of the information in the Urgent Physician Advisory Notice letter, and provide a copy of the letter to any facility to which you have distributed affected product.

For Further Information:
AMO
(877) 266-4543
Website: Click here

Comment:
- This alert is a living document and may be updated when ECRI Institute receives additional information. In circumstances in which we determine that it is appropriate for customers to repeat their review of an issue (e.g., when additional affected product has been identified), we will post a separate update alert. In other cases, we may add information, such as additional commentary, recommendations, and/or source documents, to the original alert. For additional information regarding the format of this alert, refer to our HDA Format Guide.

Source(s):
- 2014 Nov 13. Member Hospital. Abbott letter submitted by ECRI Institute member hospital
- 2014 Nov 20. Manufacturer. Manufacturer confirmed information.