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	LENSX Sistema Laser
NO. IDENTIFICACIÓN RISARH	I1407-280
REFERENCIAS DEL DISPOSITIVO MEDICO	LENSX SISTEMA LASER, referencias especificas manufacturadas antes de mayo de 2012
REGISTRO SANITARIO	2012EBC-0008624
INDICACIONES Y USO ESTABLECIDOS	El LENSX laser está indicado para usarse en pacientes que se someten a cirugía de cataratas para la eliminación del cristalino.
NOMBRE DEL FABRICANTE	Alcon Lensx Inc.
DESCRIPCION DEL PROBLEMA	El fabricante informa que el *Gantry* puede descender inesperadamente debido a que cuentan con sistemas de freno de motor antiguos, lo que puede conllevar a que se presenten potencialmente eventos adversos sobre el paciente.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	07 de Julio 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

A22137 - High Priority Medical Device Alert

Medical Device Ongoing Action
Updated: July 1, 2014
UMDNS Terms:
- Lasers, Femtosecond Pulse [28161]

Suggested Distribution:
- Clinical/Biomedical Engineering
- Ophthalmology
- OR/Surgery

Geographic Regions:
- Worldwide

Alcon—LenSx Laser Systems: Gantry May Move Downward Unexpectedly

Product Identifier:
LenSx Laser Systems *[Capital Equipment]*
U.S. Serial Nos.: 0112-A099, 0212-A111, 0212-A116, 0212-A117, 0311-A007, 0312-A126, 0312-A130, 0312-A135, 0412-A147, 0412-A152, 0412-A153, 0412-A155, 0511-A013, 0512-A163, 0512-A167, 0512-A169, 0611-A017, 0611-A018, 0711-A021, 0811-A026, 0811-A027, 0811-A033, 0811-A035, 0911-A039, 0911-A045, 1011-A050, 1011-A062, 1111-A067, 1111-A073, 1111-A077, 1111-A080, 1111-A085, 1211-A086, 1211-A087, 1211-A088, 1211-A090
International Serial Nos.: 0112-A106, 0112-A107, 0112-A108, 0112-A109, 0212-A118, 0312-A121, 0312-A122, 0312-A123, 0312-A127, 0312-A132, 0512-A158, 0512-A160, 0512-A162, 0512-A164, 0512-A166, 0611-A020, 0711-A022, 0711-A025, 0811-A030, 0811-A031, 0811-A032, 0811-A037, 0911-A038, 0911-A040, 0911-A041, 0911-A042, 1011-A053, 1011-A054, 1011-A055, 1011-A060, 1111-A069, 1111-A071, 1111-A072, 1111-A074, 1111-A075, 1111-A081, 1111-A082, 1211-A091, 1211-A094
Units manufactured before May 2012

Manufacturer:
- Alcon Laboratories Inc6201 South Frwy, Fort Worth, TX 76134-2099, United States

Problem: In an April 14, 2014, Field Safety Notice letter posted by the German Federal Institute for Drugs and Medical Devices (BfArM), Alcon states that it received reports of unexpected downward motion of the gantry on the above systems. The reports are associated with systems having an older style motor/brake assembly. A new style motor/brake assembly has been used in manufacturing since May 2012. FDA's Center for Devices and Radiological Health (CDRH) states that Alcon initiated a product correction by letter sent the week of March 17, 2014.
Action Needed:
Identify any affected product in your inventory. If you have any affected product, verify that you have received the April 14, 2014, Field Safety Notice letter or March 17, 2014, Medical Device Correction letter and Feedback Form from Alcon. Alcon will replace and install the modified brake design on any affected systems manufactured before May 2012 or that have not been upgraded since then. If you experience any unexpected movement with your system, immediately notify your Alcon local representative and discontinue use of the system. Because the potential error was eliminated as part of an exchange of the affected Z-Engines unit some time ago on your device, no further service activities on your device are necessary. Complete the Feedback Form and return it to Alcon by fax at the number on the form. Forward a copy of the Field Safety Notice letter to any relevant personnel, and to any facility to which you have further distributed affected product.
For Further Information:
Verena Kollek, Alcon
Tel.: (0761) 1304338
Website: Click here

References:

- United States. Food and Drug Administration. Center for Devices and Radiological Health. Class 2 device recall common name: LenSx laser system [online]. 2014 Apr 9 [cited 2014 Jun 23]. Available from Internet: Click here.
- Germany. Federal Institute for Drugs and Medical Devices. Safety notice for the LenSx laser system, Alcon Pharma GmbH [online]. 2014 Apr 22 [2014 Jun 23]. Available from Internet: 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 Jun 27. FDA CDRH Database. Class II. Z-1445-2014
- 2014 Jun 27. BfArM (Germany). 2073/14
- 2014 Jun 27. BfArM (Germany). (includes reply form)
- 2014 Jul 1. Manufacturer. Manufacturer confirmed the information contained in source material