El INVIMA informa a los usuarios en general que el Grupo de Tecnovigilancia ha emitido una comunicación relacionada con un Retiro de Producto del Mercado asociado a:

NOMBRE DEL DISPOSITIVO MÉDICO	Sistema de Facofragmentación INFINITI
NO. IDENTIFICACIÓN RISARH	R1411-455
REFERENCIAS DEL DISPOSITIVO MEDICO	INFINITI, referencias y lotes específicos
REGISTRO SANITARIO	2008EBC-0002390
INDICACIONES Y USO ESTABLECIDOS	Equipo de cirugía oftálmica que ha sido diseñado para procedimientos quirúrgicos del segmento anterior del ojo que exijan simultáneamente la extracción (facofragmentación), irrigación y aspiración del cristalino, así como procedimientos asociados tales como vitrectomia (aspiración vítrea) y la coagulación (corte y coagulación).
NOMBRE DEL FABRICANTE	Alcon Laboratories Inc
DESCRIPCION DEL PROBLEMA	El fabricante informa que un trozo de tubo puede estar presente en la línea de aspiración de los sistemas anteriores, resultando en la reducción del flujo y/o las oclusiones de la línea de aspiración, conllevando a que se generen posibles eventos adversos sobre el paciente.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	07 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

A23290 - High Priority Medical Device Alert

Medical Device Ongoing Action
Updated: November 6, 2014
UMDNS Terms:
- Tubing, Synthetic Polymer [24498]
- Aspirator/Irrigators, Eye Surface [26681]

Suggested Distribution:
- OR/Surgery
- Materials Management
- Ophthalmology

Geographic Regions:
- Worldwide

Alcon—INFINITI Fluidic Management Systems: Aspiration Line May Contain a Piece of Tubing

Product Identifier:
INFINITI Fluidic Management Systems (FMSs) *[Consumable]*

INFINITI FMS Products:	Catalog Nos.:	Lot Nos.:
1.1 mm Flared Round 30°	8065750274	1642683H
1.1 mm Round 30°	8065741089	1634767H, 1637202H, 1640123H, 1642724H, 1642725H, 1642678H
1.1 mm Flared 30°	8065741097	1642728H, 1645753H, 1634768H, 1647570H, 1647569H
1.1 mm Basic MICROSMOOTH Tipless	8065741082	1647572H, 1647573H, 1647789H, 1647790H, 1647791H
Basic Tipless	8065741080	1623755H, 1623756H, 1637071H, 1637072H, 1637073H, 1642718H, 1642719H, 1642720H, 1642721H, 1644878H, 1647623H, 1647624H, 1647625H, 1647626H, 1647627H, 1647628H, 1647973H, 1647974H, 1647975H, 1647976H, 1647977H, 1665496H, 1665497H, 1665498H, 1665499H
Flared 30°	8065741093	1645640H
High-Infusion Sleeve Tipless	8065741083	1623130H, 1639845H, 1639846H, 1639847H, 1639848H, 1642518H, 1647969H, 1647970H
Kelman 30°	8065750268	1642682H
Kelman 45°	8065741088	1642677H, 1647896H
Micro Mini-Flared OZiL 30°	8065751723	1628719H, 1631848H, 1636407H, 1637207H
Micro KELMAN 30°	8065741087	1631566H, 1631567H, 1631568H, 1645638H, 1645752H, 1631281H
Micro Mini-Flared OZiL 45°	8065751724	1634766H, 1631849H, 1642516H, 1642687H, 1645650H
MICROSMOOTH Flared Kelman 45°	8065741096	1634748H, 1634749H, 1637201H, 1647571H
MICROSMOOTH Tapered 30°	8065750278	1623132H, 1623761H

MICROSMOOTH Tapered Kelman 30°	8065750280	1623134H, 1628712H, 1628713H, 1628714H, 1631846H, 1637065H, 1637064H, 1637203H, 1637204H, 1642684H, 1642688H, 1642723H, 1643014H, 1645642H, 1645643H
MICROSMOOTH Tipless	8065741081	1634595H, 1634596H, 1634597H, 1628801H, 1634593H, 1634594H, 1634598H, 1636464H, 1636465H, 1636466H, 1636467H, 1636468H, 1636469H, 1637069H, 1637070H, 1642428H, 1642429H, 1642430H, 1642431H, 1642432H, 1642433H, 1642478H, 1642481H, 1642482H, 1642479H, 1642480H, 1642919H, 1642920H, 1645689H, 1645690H, 1645688H, 1647792H, 1647793H, 1647794H, 1659148H, 1665493H
Mini-Flared Kelman 30°	8065751721	1634769H, 1637206H, 1639849H, 1639850H, 1645648H, 1647854H
Round 30°	8065750266	1634750H
Round 30°	8065741085	1647971H, 1647972H
Tapered Kelman 45°	8065751722	1631534H, 1631529H, 1631535H, 1639483H, 1645207H, 1645684H, 1645685H
Tapered Kelman 45°	8065750281	1610411H, 1636451H, 1636450H, 1642534H, 1642535H
Ultra Mini-Flared Kelman 45°	8065751718	1636429H, 1634765H, 1636430H, 1639661H, 1639662H, 1642537H, 1645647H, 1647967H, 1647968H
Ultra Mini-Flared OZiL 30°	8065751719	1631559H, 1639851H, 1639852H
Ultra Mini-Flared OZiL 45°	8065751720	1636405H, 1636406H, 1645686H, 1645687H
Ultra Tipless	8065751716	1628072H, 1628073H, 1636431H, 1637205H, 1645646H
Ultra Tipless MF30K	8065751717	1631847H, 1637067H, 1637066H
PAK, 0.9 mm High-Infusion Sleeve (HIS) Infusion Japan	8065751010	1634763H, 1634764H, 1647786H
PAK, 1.1 mm HIS Infusion Japan	8065751011	1647785H
PAK, 1.1 mm Infusion Japan	8065751009	1628716H, 1640124H, 1640125H, 1640126H, 1640127H

Manufacturer:
- Alcon Laboratories Inc 6201 South Frwy, Fort Worth, TX 76134-2099, United States

Problem: In an October 30, 2014, Urgent Medical Device Voluntary Recall letter submitted by ECRI Institute member hospitals, Alcon states that a piece of tubing may be present in the aspiration line of the above systems. Alcon also states that use of affected product may result in reduced aspiration flow and/or occlusions of the aspiration line.

Action Needed:
Identify, isolate, and discontinue use of any affected product in your inventory. If you have affected product, verify that you have received the October 30, 2014, Urgent Medical Device Voluntary Recall letter and Response Form from Alcon. Regardless of whether you have affected product, complete the Response Form and return it to Alcon using the information on the form. To arrange for product return and replacement, contact the Alcon customer service department by telephone at (800) 862-5266. Inform all relevant personnel at your facility of the information in the letter, and forward a copy of the letter to any facility to which you have further distributed affected product. U.S. customers should report serious adverse events or product quality problems relating to the use of affected product to FDA's MedWatch Adverse Event Reporting program by telephone fax at (800) 332-0178; by mail (using postage-paid FDA Form 3500, available here) at Food and Drug Administration, HF-2, 5600 Fishers Lane, Rockville, MD 20852-9787; or online at the MedWatch website.

For Further Information:
Alcon customer service department
Tel.: (800) 862-5266
E-mail: Market.Actions@alcon.com
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 3. Member Hospital. Alcon letter submitted by ECRI Institute member hospitals (includes reply form)
- 2014 Nov 5. Manufacturer. Manufacturer confirmed information