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	Circuitos para Anestesia
NO. IDENTIFICACIÓN RISARH	R1410-397
REFERENCIAS DEL DISPOSITIVO MEDICO	313901, 353801, 353811, 353812H, 3653900, 353901 y 353911, lotes específicos
REGISTRO SANITARIO	2008DM-0002942
INDICACIONES Y USO ESTABLECIDOS	Interfase en el procedimiento de ventilación mecánica para pacientes que son sometidos a procedimientos en los cuales deben ser anestesiados.
NOMBRE DEL FABRICANTE	Teleflex Medical
DESCRIPCION DEL PROBLEMA	El fabricante determinó que los extremos de los dispositivos se pueden romper antes y durante su uso y deben ser reemplazados de inmediato, conllevando a que se presenten potencialmente eventos adversos sobre el paciente.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	03 de Octubre 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

A23083 - High Priority Medical Device Alert

Medical Device Ongoing Action
Updated: October 2, 2014

UMDNS Terms:
- Breathing Circuits, Anesthesia [10139]

Suggested Distribution:
- Anesthesia
- Critical Care
- Emergency/Outpatient Services
- Materials Management
- OR/Surgery
- Pediatrics
- Risk Management/Continuous Quality Improvement

Geographic Regions:
- Burkina Faso
- Canada
- Chile
- China
- Colombia
- Czech Republic
- Germany
- Ghana
- Greece
- Japan
- Korea
- Mexico
- Peru
- Puerto Rico
- Russia
- South Africa
- Spain
- U.S.

Teleflex—Hudson RCI Pediatric Anesthesia Breathing Circuits: Ends May Crack

Product Identifier:

Hudson RCI Pediatric Anesthesia Breathing Circuits Material Nos.:	Batch Nos.:
313901	02F1300085, 02G1300088
353801	02A1402409, 02B1400204, 02B1400751, 02B1401805, 02B1400324, 02E1300623, 02E1301891, 02F1300098, 02F1300180, 02H1300172, 02H1300454, 02H1301128, 02H1301838, 02J1300876, 02J1302412
353811	02E1300090, 02E1301383, 02E1301867, 02F1300147
353812H	74G1400057
353900	02D1300854, 02E1301892, 02F1300100, 02F1302029
353901	02E1300618, 02E1301378, 02F1300101, 02F1302047, 02G1300879

353911	02F1300102, 02F1300177, 02F1300729, 02G1300296, 02G1300861

[Consumable]

Manufacturer:
- Teleflex Medical IDA Business & Technology Park, Dublin Road, Athlone, Co. Westmeath, Ireland

Problem:
In a September 10, 2014, Urgent Medical Device Recall letter submitted by an ECRI Institute member hospital and a September 17, 2014, Urgent Field Safety Notice letter posted by the German Federal Institute for Drugs and Medical Devices (BfArM), Teleflex states that it has received reports of the ends of the above breathing circuits cracking before and during use. If the breathing circuits crack during use the device will need to be replaced immediately and the patient may be at risk for respiratory distress. FDA's Center for Devices and Radiological states that the manufacturer initiated a recall by Urgent Medical Device Recall letter dated September 8, 2014.

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 Urgent Medical Device Recall letter and/or the September 17, 2014, Urgent Field Safety Notice letter and Acknowledgement Form from Teleflex. Regardless of whether you have affected product in your inventory, complete the Acknowledgement Form, and return it to Teleflex using the instructions on the form. Contact Teleflex for more information regarding product return and credit.

For Further Information:
Europe:
Shane Kenny, Teleflex customer service department
Tel.: 353 (90) 6460869
E-mail: recalls.intl@teleflex.com
Outside Europe:
Teleflex customer service department
Tel.: (866) 246-6990
Website: Click here

References:

- Germany. Federal Institute for Drugs and Medical Devices. Corrective action for the Hudson RCI® paediatric anaesthesia breathing circuit, Teleflex Medical [online]. 2014 Sep 25 [cited 2014 Sep 29]. Available from Internet: Click here.
- United States. Food and Drug Administration. Center for Devices and Radiological Health. Class 1 device recall Hudson RCI [online]. 2014 Sep 30 [cited 2014 Oct 1]. 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 Sep 27. BfArM (Germany). 6069/14
- 2014 Sep 27. BfArM (Germany). Teleflex Reference: 50000780 (includes reply form)

- 2014 Oct 1. Member Hospital. Teleflex letter submitted by an ECRI Institute member hospital (includes reply form)
- 2014 Oct 1. FDA CDRH Database. Class I. Z-2714-2014
- 2014 Oct 1. Manufacturer. Teleflex confirmed the information provided in the source material.