El INVIMA informa a los usuarios en general que el Grupo de Tecnovigilancia ha emitido una comunicación relacionada con una alerta asociada a:

NOMBRE DEL DISPOSITIVO MÉDICO	Prótesis para Aneurisma Aórtico Torácico con Sistema Portador Transport RELAY
NO. IDENTIFICACIÓN RISARH	A1409-363
REFERENCIAS DEL DISPOSITIVO MEDICO	Relay y Relay NBS referencias 28M3############X y 28N2############X
REGISTRO SANITARIO	2007DM-0000586
INDICACIONES Y USO ESTABLECIDOS	Esta indicado para el tratamiento de patologías de la aorta torácica, como aneurismas, seudoaneurismas, disecciones, ulceras penetrantes y hematomas intramurales, en pacientes adultos. (Con arreglo a las normas locales).
NOMBRE DEL FABRICANTE	Bolton Medical España S.L.U.
DESCRIPCION DEL PROBLEMA	El fabricante informa que la vaina interna secundaria puede no salir completamente del la vaina exterior primaria al llegar a la marca negra del cuerpo principal de la manija, lo que puede conllevar a potenciales eventos adversos sobre el paciente.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	08 de Septiembre 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

A22898 01 - High Priority Medical Device Alert

Medical Device Ongoing Action

Updated: September 5, 2014

UMDNS Terms:
- Stent/Grafts, Vascular, Aortic [20453]

Suggested Distribution:
- Cardiology/Cardiac Catheterization Laboratory
- Materials Management
- OR/Surgery

Geographic Regions:
- Africa
- Asia
- Europe
- South America
- U.K.

Bolton—Relay and Relay NBS Thoracic Stent-Graft Systems: May Exhibit Deployment Difficulty or Failure

Product Identifier:
Thoracic Stent-Graft Systems: (1) Relay, (2) Relay NBS *[Consumable]*
Reference Nos.: 28M3##########X, 28N2##########X
All lots manufactured before August 2014

Manufacturer:
- Bolton Medical Espana, SLUc/ Newton 18-24, 08635 Sant Esteve Sesrovires, Barcelona Spain

Summary:
This Alert provides additional information based on manufacturer correspondence regarding Alert Accession No. A22898. Additional information is provided in the Geographic Regions field (see bolded regions).

Problem:
[August 19, 2014]
In an August 8, 2014, Field Safety Notice letter posted by the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA), Bolton states that, in a small number of cases, the inner secondary sheath of the above systems may not fully exit the outer primary sheath upon reaching the black line on the main handle body and that in this situation, the distal end of the stent-graft may also remain within the outer primary sheath. Bolton also states that failure to recognize this condition before deployment may lead to deployment difficulty or failure. Bolton further states that this problem has no affect on devices already implanted.

Action Needed:
The following actions are those listed in Alert Accession No. A22898. Identify, isolate, and discontinue use of any affected product in your inventory. If you have affected product, verify that you have received the August 8, 2014, Field Safety Notice letter from Bolton. Bolton recommends that the following additional verification steps be taken before proceeding to final stent-graft positioning and deployment:
(1) Upon reaching the intended proximal landing zone, visually confirm that the distal stent marker bands can be seen approximately 2 cm outside of the outer primary sheath.
(2) If the distal stent marker bands do not appear to have exited the outer primary sheath, while in position 1, hold the gray deployment grip stationary while pulling back on the black stationary grip until the distal stent marker bands have exited the outer primary sheath by approximately 2 cm.

For Further Information:
Bolton Medical Espana, SLU local representative
Website: Click here

References:
Great Britain. Medicines and Healthcare Products Regulatory Agency. Bolton Medical. Implants, non active, endoprostheses for aortic aneurysms, endovascular prosthesis. Relay Plus thoracic stent-graft system and Relay NBS thoracic stent-graft with Plus delivery system [online]. London: Department of Health; 2014 Aug 18 [cited 2014 Aug 18]. (Field safety notice; reference no. 2014/008/014/081/015) 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 2. MHRA FSN. 2014/008/014/081/015
- 2014 Sep 2. MHRA FSN. 08-2014-001-C
- 2014 Sep 2. Manufacturer. Bolton confirmed the information provided in the source material.
- 2014 Sep 5. BfArM (Germany). 5051/14
- 2014 Sep 5. BfArM (Germany). 08-2014-001-C