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 Acetábular TRILOGY
NO. IDENTIFICACIÓN RISARH	R1501-18
REFERENCIAS DEL DISPOSITIVO MEDICO	Tornillos referencia 00-6250-065-25 y 00-6250-065-35, lotes específicos.
REGISTRO SANITARIO	2011DM-0007492
INDICACIONES Y USO ESTABLECIDOS	Indicados como componentes de una prótesis total de cadera en pacientes primarios o de revisión en alto riesgo de dislocación de cadera debido a un historial de dislocación anterior, perdida de hueso, laxitud de tejidos blandos, enfermedad neuromuscular, o inestabilidad intraoperativa. Para rehabilitar caderas dañadas como resultado de una enfermedad no inflamatoria degenerativa de las articulaciones (NIDJD) o de sus diagnósticos compuestos de osteoartritis, necrosis avascular, protusio acetábular, artritis traumática, deslizamiento de la epífisis, cadera fundida, fractura de pelvis, y variante distrófica.
NOMBRE DEL FABRICANTE	Zimmer Inc
DESCRIPCION DEL PROBLEMA	El fabricante informa que los dispositivos médicos mencionados pueden presentar problemas por ruptura durante la inserción, conllevando a que se generen posibles eventos adversos sobre el paciente o retraso de los tiempos quirúrgicos.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	13 de Enero de 2015

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

[High Priority] - A23471 01 : Zimmer—Trilogy Bone Screws: May Fracture during Insertion
Medical Device Ongoing Action

UMDNS Terms:

- Screws, Bone [16101]

Product Identifier:

Trilogy Bone Screws:	Product Nos.:	Lot Nos.:
6.5 x 25 mm	00-6250-065-25	62784617, 62784618, 62784619, 62784621, 62784622, 62818701, 62818702, 62818703, 62818707, 62818709, 62818710, 62825611, 62836984
6.5 x 35 mm	00-6250-065-35	62748089, 62754329, 62793494, 62793495, 62793501, 62793502, 62793503, 62813612, 62813613

[Consumable]
Units distributed between August 19 and November 18, 2014

Geographic Regions: (Impact in additional regions has not been identified or ruled out at the time of this posting), Albania, Australia, Austria, Belgium, Brazil, Bulgaria, Canada, Canary Islands, Chile, China, Colombia, Czech Republic, Denmark, Egypt, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Japan, Korea, Malaysia, The Netherlands, Norway, Poland, Portugal, Russia, Saudi Arabia, Serbia, Singapore, Slovakia, South Africa, Spain, Sweden, Switzerland, Taiwan, Turkey, U.K., U.S.

Manufacturer(s): Zimmer Inc 1800 W Center St, PO Box 708, Warsaw, IN 46581-0708, United States

Suggested Distribution: OR/Surgery, Orthopedics, Materials Management

Summary:
This alert provides additional information based on FDA Center for Devices and Radiological Health (CDRH) and U.K. Medicines and Healthcare Products Regulatory Agency (MHRA) source material regarding Alert Accession No. A23471 . FDA's CDRH states that the manufacturer initiated a recall by Urgent Medical Device Recall letter dated November 2014. Additional information is provided in the Geographic Regions field (see bolded region).

Problem:
[December 4, 2014]
In a November 21, 2014, Urgent Medical Device Recall Lot Specific letter submitted by an ECRI Institute member hospital, Zimmer states that the above screws may fracture during insertion. This problem may result in the following:

- If a screw fractures and does not protrude into the space occupied by an acetabular liner, a minor surgical delay may occur. If the fractured screw does protrude into the space occupied by an acetabular liner, a more lengthy delay may occur as the screw would have to be removed.
- If a screw fractures while being used to affix a knee femoral cut guide, a minor surgical delay may occur.
- If the fractured screw protrudes into the liner space, efforts to remove the screw and/or shell may result in pelvic bone damage, compromised fixation, and subsequent implant migration and revision.

The manufacturer has not confirmed the information provided in the source material.

Action Needed:
The following actions are those listed in Alert Accession No. A23471 . Identify, isolate, and discontinue use of any affected product in your inventory. If you have affected product, verify that you have received the November 21, 2014, Urgent Medical Device Recall Lot Specific letter from Zimmer. Your Zimmer representative will contact your facility to arrange for product removal. Notify 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. Zimmer recommends that you continue your normal post-operative follow-up routine for patients who have previously had affected product implanted. Inform Zimmer of any adverse events associated with use of affected product by e-mail at zimmer.per@zimmer.com . U.S. customers should also report any adverse events to FDA's MedWatch Adverse Event Reporting program by fax at (800) 332-0178 ; by mail (using postage-paid FDA Form 3500, available here) at Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852-9787; or online at the MedWatch website .

For Further Information:
Zimmer customer call center
Tel.: (800) 348-2759, 8 a.m. to 8 p.m. Eastern time Monday through Friday, or (877) 946-2761
Website: Click here

References:

- United States. Food and Drug Administration. Center for Devices and Radiological Health. Class 2 device recall Trilogy bone screws [online]. 2014 Dec 17 [cited 2015 Jan 2]. Available from Internet: Click here .

- Great Britain. Medicines and Healthcare Products Regulatory Agency. Zimmer. Osteosynthesis. Trilogy bone screws—6.5mm X 35mm & 6.5mm X 25mm [online]. London: Department of Health; 2014 Dec 22 [cited 2015 Jan 5]. (Field safety notice; reference no. 2014/012/015/081/002). Available from Internet: Click here .

Comments:

- 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 Dec 4. Member Hospital. Zimmer letter submitted by an ECRI Institute member hospital. Download
- 2015 Jan 2. FDA CDRH Database. Class II. Z-0824-2015 Download
- 2015 Jan 5. MHRA FSN. 2014/012/015/081/002 Download
- 2015 Jan 5. MHRA FSN. (includes reply form) Download