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 Cadera VERSYS
NO. IDENTIFICACIÓN RISARH	R1407-274
REFERENCIAS DEL DISPOSITIVO MEDICO	784301108, 784301126, 784301156, 784301208, 784301226, 784301256, 784301326, 784301356, 784301382, 784301511, 784301581, lotes específicos
REGISTRO SANITARIO	2011DM-0000950-R1
INDICACIONES Y USO ESTABLECIDOS	Reemplazo total y parcial de cadera
NOMBRE DEL FABRICANTE	Zimmer Inc
DESCRIPCION DEL PROBLEMA	El fabricante informa que ha detectado en dichas referencias que pueden no cumplir con los requisitos de aleación de materiales (CoCrMo) para los vástagos de cadera, conllevando a que se presente ruptura del material y en consecuencia posibles 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

A22571 - Normal Priority Medical Device Alert

Medical Device Ongoing Action
Updated: June 26, 2014
UMDNS Terms:
- Prostheses, Joint, Hip, Femoral Component [16095]

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

Geographic Regions:
- (Impact in additional regions has not been identified or ruled out at the time of this posting)
- AL (U.S.)
- AZ (U.S.)
- CA (U.S.)
- CO (U.S.)
- CT (U.S.)
- FL (U.S.)
- GA (U.S.)
- IL (U.S.)
- IN (U.S.)
- MA (U.S.)
- MI (U.S.)
- MN (U.S.)
- NC (U.S.)
- ND (U.S.)
- NJ (U.S.)
- NY (U.S.)
- OH (U.S.)
- OK (U.S.)
- PA (U.S.)
- TN (U.S.)
- TX (U.S.)
- VA (U.S.)
- WI (U.S.)
- Canada
- Colombia
- Dominican Republic
- Japan
- Korea
- Peru
- Taiwan
- Thailand

Zimmer—VerSys Hip System Beaded Fullcoat Stems: May Not Meet Material Requirements

Product Identifier:
VerSys Hip System Beaded Fullcoat Stems *[Consumable]*

Item Nos.:	Lot Nos.:
784301108	62478967, 62479742, 62503408, 62528282, 62530786, 62544915, 62554360
784301126	62544885
784301156	62587079
784301208	62503411, 62509385, 62530790, 62547217, 62554362
784301226	62515502, 62547216
784301256	62489572, 62522386
784301326	62496464, 62594428, 62622893
784301356	62622894
784301382	62544907
784301511	62472423
784301581	62496469

147 units distributed

Manufacturer:
- Zimmer Inc1800 W Center St, PO Box 708, Warsaw, IN 46581-0708, United States

Problem: FDA's Center for Devices and Radiological Health (CDRH) states that the above implants may not meet ZES 2A-102 processing of beaded CoCrMo alloy hip stem material requirements per ATS #14-04818 and ATS #14-05549. FDA's CDRH also states that the manufacturer imitated a recall by Urgent Medical Device Recall letter on June 2, 2014. The manufacturer has not confirmed the information provided in the source material.
Action Needed:
Identify any affected product in your inventory. If you have affected product, verify that you have received the Urgent Medical Device Recall letter from Zimmer.
For Further Information:
Zimmer
Website: Click here

References:

- United States. Food and Drug Administration. Center for Devices and Radiological Health. Class 2 device recall VerSys hip system, beaded fullcoat stems [online]. 2014 Jun 20 [cited 2014 Jun 25]. 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 25. FDA CDRH Database. Class II. Z-1842-2014