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 Implantes Dentales y Componentes Protésicos
NO. IDENTIFICACIÓN RISARH	R1502-76
REFERENCIAS DEL DISPOSITIVO MEDICO	GemLock Long Hex Drivers – RHL2.5, lotes 62712431, 62743168, 62766610, 62702589, 62710484, 62712437, 62743075, 62750487, 62753787, 62756920, 62759862, 62760388, 62768456 y 62773158.
REGISTRO SANITARIO	2011DM-0007748
INDICACIONES Y USO ESTABLECIDOS	Los implantes dentales son indicados en el tratamiento y rehabilitación de pacientes con perdida dentaria, parcial o total.
NOMBRE DEL FABRICANTE	Zimmer Dental Sweden Ab Exopro Industria, Comercio, Importacao e Exportacao S/A
DESCRIPCION DEL PROBLEMA	El fabricante informa que los *Drivers* anteriores pueden no encajar en el montaje de la unidad de transferencia (*FMT*) o hexágono interno del implante, conllevando que se generen posibles eventos adversos sobre el paciente.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	20 de Febrero 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] - A23868 : Zimmer—GemLock Long Hex Drivers: May Not Fit into Fixture Mount Transfer or Internal Hex of Implant

Medical Device Ongoing Action

UMDNS Terms:

- Screwdrivers, Surgical, Bone/Bone Prosthesis [13517]

Product Identifier:
GemLock Long Hex Drivers *[Consumable]*
Catalog No. RHL2.5; Hex Drivers distributed in the Tapered SwissPlus & SwissPlus Implant Systems Kit Catalog No. OPCST, and Tapered Screw-Vent Implant System Surgical Kit Catalog No. TSVKIT
Etched Lot Nos.: 62699693, 62735177; Label Lot Nos.: 62712431, 62743168, 62766610, 62702589, 62710484, 62712437, 62743075, 62750487, 62753787, 62756920, 62759862, 62760388, 62768456, 62773158
599 units distributed

Geographic Regions: (Impact in additional regions has not been identified or ruled out at the time of this posting), Argentina, Australia, Bulgaria, Canada, Chile, Colombia, Costa Rica, Dominican Republic, Ecuador, Egypt, France, Germany, Hong Kong, Hungary, Iran, Israel, Italy, Japan, Lebanon, Lithuania, Malaysia, Mexico, Morocco, The Netherlands, Pakistan, Panama, Poland, Romania, Russia, Saudi Arabia, Serbia, Taiwan, Thailand, Tunisia, Turkey, United Arab Emirates, U.S.

Manufacturer(s): Zimmer Dental Inc 1900 Aston Ave, Carlsbad, CA 92008-7308, United States

Suggested Distribution: Dentistry/Oral Surgery, Materials Management

Problem:
FDA's Center for Devices and Radiological Health (CDRH) states that the above drivers may not fit into the fixture mount transfer (FMT) or the internal hex of the implant. FDA's CDRH also states that the manufacturer initiated a recall by Urgent Device Recall Notice letter on January 22, 2015. The manufacturer has not confirmed the information in the source material.

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 Device Recall Notice letter and Business Reply Form from Zimmer. Contact the Zimmer Dental customer service department by telephone at (800) 854-7019 to obtain a return authorization number and to arrange for product return. Complete the Business Reply Form, and return it to Zimmer by fax at (574) 372-4265 or by e-mail at corporatequality.postmarket@zimmer.com .
For Further Information:
Zimmer Dental
Tel.: (800) 854-7019, Monday through Friday, 7 a.m. to 5 p.m. Pacific time
Website: Click here

References:

- United States. Food and Drug Administration. Center for Devices and Radiological Health. Class 2 device recall Gemlock [online]. 2015 Feb 12 [cited 2015 Feb 16]. 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):

- 2015 Feb 18. FDA CDRH Database. Class II. Z-1115-2015 Download