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	Implantes Quirúrgicos MEDPOR
NO. IDENTIFICACIÓN RISARH	R1501-17
REFERENCIAS DEL DISPOSITIVO MEDICO	86001, 9305, 9312 y 81036, lotes específicos.
REGISTRO SANITARIO	2008DM-0002162-R1
INDICACIONES Y USO ESTABLECIDOS	Implantes diseñados para aumentar o restaurar el contorno de los huesos craneofaciales.
NOMBRE DEL FABRICANTE	Howmedica Osteonics Corp. Stryker Corporation
DESCRIPCION DEL PROBLEMA	El fabricante informa que los dispositivos mencionados pueden presentar problemas por ruptura de los componentes y ubicación incorrecta de sus componentes, 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] - A23634 : Stryker—Various MEDPOR Implants: May Be Susceptible to Damage during Intraoperative Handling
Medical Device Ongoing Action

UMDNS Terms:

- Augmentation/Reconstruction Implants, Facial, Chin/Mandible [23866]
- Orbital Floor Implants [20671]

Product Identifier:

MEDPOR Products:	Part Nos.:	Lot Nos.:
MEDPOR Contoured 2-Piece Chin Implants	86001	A1404026, A1405048
MEDPOR Barrier Sheets—Orbital Floor	9305	69698, 77004, 81799, A1310051, A1311008, A1311044, A1312011, A1402023, A1404010
MEDPOR Barrier Sheets—Rectangle	9312	A1403008
TITAN MAX Orbital Floor and Wall (OFW) MEDPOR-Titanium-Barrier (MTB), Right	81036	A1402020, A1405060

[Consumable]

Geographic Regions: Argentina, Australia, Canada, Chile, China, Colombia, France, Israel, Italy, Lithuania, Malaysia, The Netherlands, Russia, Singapore, South Africa, South Korea, Spain, Sweden, Switzerland, Turkey, U.K., U.S.

Manufacturer(s): Stryker Leibinger GmbH & Co KGBoetzinger Strasse 39-41, D-79111 Freiburg, Germany

Suggested Distribution: OR/Surgery, Orthopedics, Materials Management

Problem: In a December 23, 2014, Urgent Medical Device Recall letter submitted by an ECRI Institute member hospital, Stryker states that the referenced lots of the above products may be affected by the following problems:

(1) MEDPOR Contoured 2-piece chin implants: The prostheses may exhibit a higher incidence of damage/breakage during intraoperative handling.

(2) MEDPOR BARRIER sheets: The above BARRIER sheets may separate from the porous sheet during intraoperative handling and modification.

(3) TITAN MAX OFW/MTB: The barrier is on the inferior (bottom) surface of the above TITAN MAX OFW MTBs (right) instead of the superior (top) surface when correctly oriented in the patient's right orbit.

Stryker also states that it has received no reports of injuries associated with these problems and that the breakage and incorrect location should be detectable by the surgeon.

Action Needed:
Identify any affected product in your inventory. If you have affected product, verify that you have received the December 23, 2014, Urgent Medical Device Recall letter and Customer Response on Receipx Form from Stryker. Notify all relevant personnel at your facility. Return affected product to Stryker Craniomaxillofacial (CMF), Attn: Recall Coordinator, at the above address, or contact the Stryker customer service department. Refer to PFA reference number 2014-126. Complete the Customer Response on Receipx Form, and return it to Stryker by fax at (877) 648-7114 or by e-mail at CMF-custserv@stryker.com . Retain a copy of the form for your records. Report adverse events or quality problems to Stryker CMF customer service department by telephone at (800) 962-6558. U.S. customers should report serious adverse events or product quality problems relating to the use of affected product to FDA's MedWatch Adverse Event Reporting program by telephone at (800) 332-1088; by fax at (800) 332-0178; by mail (using postage-paid FDA Form 3500, available here) at Food and Drug Administration, HF-2, 5600 Fishers Lane, Rockville, MD 20852-9787; or online at the website .

For Further Information:
Stryker CMF customer service department
Tel.: (800) 962-6558
Website: 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 31. Member Hospital. Stryker letter submitted by an ECRI Institute member hospital. Reference No. PFA 2014-126 (includes reply form) Download
- 2015 Jan 5. Manufacturer. The manufacturer confirmed the information in the source material.