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	Motor para Cirugía Ortopédica
NO. IDENTIFICACIÓN RISARH	R1502-70
REFERENCIAS DEL DISPOSITIVO MEDICO	SYSTEM 6, modelo 6126-120-000, lotes 13205, 13209, 13210 y 13212.
REGISTRO SANITARIO	2008DM-0002802
INDICACIONES Y USO ESTABLECIDOS	Estos equipos están destinados a generar el movimiento controlado de sus accesorios e instrumental asociado con el fin de facilitar procedimientos ortopédicos mediante la potencia, velocidad en movimientos circulares, rotativos y oscilantes controlados entre otros para cortes y perforaciones eficientes en hueso así como para la colocación y extracción del material atornillable del material de osteosíntesis.
NOMBRE DEL FABRICANTE	Stryker Instruments Stryker Ireland-Instruments
DESCRIPCION DEL PROBLEMA	El fabricante informa que el soldador láser pudo haber fallado en la unión de línea continua para los housings referenciados, esta falla en la soldadura podría conducir a la separación de las dos secciones del housings ocasionando la pérdida de la conexión mecánica entre la pieza de mano y la batería, conllevando que se generen posibles eventos adversos sobre el paciente y la prolongación del tiempo quirúrgico.
FUENTE	https://www.ecri.org/Components/Alerts/Pages/TrackingUser/AlertDisplay.aspx?GL=Y&AId=1621431&entryID=2&Page=AlertDisplay
FECHA DE NOTIFICACION	17 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] - A23858 : Stryker—System 6 Aseptic Housings: Sections May Separate

Medical Device Ongoing Action

UMDNS Terms:

- Handpieces, Surgical [17949]

Product Identifier:
System 6 Aseptic Housings used with Nonsterile Batteries for the following Handpieces: (1) Cordless Driver 3, (2) System 6 Handpieces, (3) System 7 Handpieces *[Capital Equipment]*
Housing Part No. 6126-120-000; Lot Nos.: 13205, 13209, 13210, 13212
Also sold as part of System 6 Aseptic Battery Kits Part No. 6126-000-000
399 units distributed between July 26 and September 12, 2013

Geographic Regions: Australia, Canada, Chile, Colombia, France, Hong Kong, India, Korea, The Netherlands, Poland, Puerto Rico, South Africa, Switzerland, U.S.

Manufacturer(s): Stryker Instruments Div Stryker Corp4100 E Milham Ave, Kalamazoo, MI 49001, United States

Suggested Distribution: Clinical/Biomedical Engineering, OR/Surgery, Orthopedics

Problem:
In a January 16, 2015, Urgent Medical Device Recall Notification letter, Stryker states that the laser welder may have failed to produce a continuous line bond for the above housings. Stryker also states that lack of a continuous bond line could lead to separation of 2 sections of housing, loss of mechanical connection between the handpiece and the battery, intraoperative complications, unavailability of the handpiece and surgical delay while a backup is prepared, and/or breach of the sterile field. FDA's Center for Devices and Radiological Health (CDRH) states that the manufacturer initiated a recall by letter on January 16, 2015.

Action Needed: Identify and discontinue use of any affected product in your inventory. If you have affected product, verify that you have received the January 16, 2015, Urgent Medical Device Recall Notification letter and Business Reply Form from Stryker. Complete the Business Reply Form, and return affected product to Stryker, Attn: Regulatory Department, by fax at (866) 521-2762 or by e-mail at kara.spath@stryker.com . Upon receipx of the form, Stryker will provide your facility with replacement housings and a shipping label to be used for product return. Using the shipping label, return affected product to Stryker. Forward a copy of the letter to any facility to which you have further distributed affected product, and notify Stryker of the transfer. 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 MedWatch website .

For Further Information:
Kara Spath, Stryker Instruments
Tel.: (269) 389-4518
E-mail: kara.spath@stryker.com
Website: Click here

References:

- United States. Center for Devices and Radiological Health. Class 2 device recall System 6 aseptic housing [online]. 2015 Feb 9 [cited 2015 Feb 10]. 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 10. FDA CDRH Database. Class II. Z-1066-2015 Download
- 2015 Feb 11. Manufacturer Letter. Stryker letter Download
- 2015 Feb 11. Manufacturer Letter. (includes reply form) Download
- 2015 Feb 11. Manufacturer. The manufacturer confirmed the information provided in the source material.