RECALL

DIRECCIÓN DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS

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	Pesarios Siliconado / Pesario Ginecológico COOPERSURGICAL
NO. IDENTIFICACIÓN RISARH	R1705-157
REFERENCIAS DEL DISPOSITIVO MEDICO	MXKPINFS, MXKPINFM, MXKPINFL, MXKPINFXL, MXPINFS, MXPINFM, MXPINFL, MXPINFXL, lotes específicos.
REGISTRO SANITARIO	2015DM-0014123
INDICACIONES Y USO ESTABLECIDOS	Excepto que se especifique lo contrario en las instrucciones se recomienda que la colocación la realice personal médico. Usos: los pesarios se emplean como soporte de ciertos órganos pélvicos que hayan sufrido prolapso con el fin de reposicionarlos en su ubicación original. Algunos pesarios están diseñados específicamente para estabilizar la uretra en casos de incontinencia urinaria por stress (perdida de orina al toser, reír o realizar ejercicio intenso, ciertos tipos de pesario requieren que la paciente se lo quite por las noches o cuando la paciente tenga relaciones sexuales.
NOMBRE DEL FABRICANTE	Coopersurgical Inc
DESCRIPCION DEL PROBLEMA	El fabricante informa que la caja de embalaje secundario de los dispositivos referenciados, se encuentra marcada como producto libre de látex, generando un alto riesgo a una reacción alérgica grave para las usuarias alérgicas al látex, conllevando a que potencialmente se presenten eventos adversos sobre las pacientes.
FUENTE	ANEXO
FECHA DE NOTIFICACION	02 de Mayo de 2017

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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

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DIRECCIÓN DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS

ANEXO

[High Priority] - A28445 01 : CooperSurgical—Inflatoball Pessaries and Pessary Kits: May Be Mislabeled as Latex Free
Medical Device Ongoing Action

Published: Thursday, April 27, 2017

UMDNS Terms:

- Pessaries [13004]

Product Identifier:

Inflatoball Products:	Part Nos.:	Lot Nos.:
Small Pessary Kits	MXKPINFS	137426, 139579, 141316, 142945, 144531, 150148, 153075, 157412, 157413, 166920, 166921, 166922, 178337, 178338, 178340, 178341, 185974, 185976, 185977, 185979, 201918, 211778, 212982, 218672
Medium Pessary Kits	MXKPINFM	135401, 137425, 141314, 141315, 142942, 142943, 144529, 146346, 150145, 150146, 150147, 153071, 153072, 153073, 157408, 157409, 157410, 160840, 160841, 166918, 166919, 178324, 178326, 178328, 178329, 182452, 183623, 201920, 211777, 212981, 215759, 218653, 218654, 218655
Large Pessary Kits	MXKPINFL	139576, 141311, 141312, 142939, 142940, 144527, 146345, 150142, 150143, 150144, 153066, 153067 , 153068, 157403, 157404, 157405, 160837, 160838, 166912, 166913, 166914, 182446, 182447, 182448, 182450, 183622, 200098, 200099, 212979, 215757, 218630
Extra Large Pessary Kits	MXKPINFXL	142947, 142948, 142949, 146348, 153078, 153079, 157415, 160844, 166923, 166924, 166925, 178346, 178347, 178348, 182458, 185831, 185832, 185834, 185835, 185836, 211779, 219502
Small Pessaries	MXPINFS	121937, 142944, 144530, 153074, 157411, 160842, 178332, 178333, 178334, 178335, 182453, 185826, 185827, 218669
Medium Pessaries	MXPINFM	135402, 141313, 142941, 144528, 153069, 153070, 157406, 157407, 160839, 166915, 166916, 166917, 178320, 178321, 178322, 178323, 185818, 185822, 185823, 185824, 201919, 212980, 215758
Large Pessaries	MXPINFL	139577, 141310, 142937, 146344, 150141, 153064, 153065, 157402, 160467, 162612, 166911, 178317, 183618, 183619, 185809, 185810, 185812, 185814, 211776, 212978, 218621, 218622
Extra Large Pessaries	MXPINFXL	139581, 139582, 139583, 142946, 144532, 146347, 153076, 153077, 157414, 178343, 178344, 182455, 182456, 182457, 200176, 212983, 215760

[Consumable]

Geographic Regions: Australia, Bahamas, Brazil, Canada, Colombia, Costa Rica, Denmark, Greece, Guam, Israel, Lithuania, Malaysia, The Netherlands, New Zealand, Panama, Poland, Portugal, Puerto Rico, Romania, Sweden, U.K., U.S.

Manufacturer(s): CooperSurgical Inc95 Corporate Dr, Trumbull, CT 06611, United States

Suggested Distribution: Obstetrics/Gynecology/Labor and Delivery, OR/Surgery, Urology, Materials Management

Summary: This Alert provides additional information based on manufacturer correspondence and an April 10, 2017, Inflatoball Pessary and Inflatoball Pessary Kit Recall letter posted by the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA) regarding Alert Accession No. A28445 . New information is bolded in the Geographic Regions field.

Problem:
[April 21, 2017]In an April 10, 2017, Inflatoball Pessary and Inflatoball Pessary Kit Recall letter submitted by an ECRI Institute member hospital, CooperSurgical states that the current secondary packaging box containing the above pessaries and kits incorrectly states that the products are latex free,

posing a risk of serious allergic reaction for users allergic to latex. The product is made with 100% latex. The label on the package that contains the product and the instructions for use (IFU) correctly states that the pessary is manufactured from latex rubber. CooperSurgical also states that it has received no reports of adverse events or patient injury related to this problem.

Action Needed: The following actions are those listed in Alert Accession No. A28445 . Identify, isolate, and discontinue use of any affected product in your inventory. The lot number is printed on the opening tab of the secondary packaging and on the clear plastic pouch containing the pessary. If you have any affected product, verify that you have received the April 10, 2017, Inflatoball Pessary and Inflatoball Pessary Kit Recall letter and Acknowledgment and Receipt Form from CooperSurgical. Complete the Acknowledgement and Receipt Form, and return it to CooperSurgical using the instructions on the form. Upon receipt of the form, a CooperSurgical representative will contact your facility to arrange for product return and refund or exchange.

For Further Information:
CooperSurgical
Tel.: (203) 601-5200
Website: Click here

References:

- Great Britain. Medicines and Healthcare Products Regulatory Agency. CooperSurgical: Inflatoball pessary [online]. London: Department of Health; 2017 Apr 24 [cited 2017 Apr 26]. (Field safety notice; reference no. 2017/004/012/701/007). 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):

- 2017 Apr 26. MHRA FSN. 2017/004/012/701/007 Download
- 2017 Apr 26. MHRA FSN. (includes reply form) Download