El INVIMA informa a los usuarios en general que el Grupo de Tecnovigilancia ha emitido una comunicación relacionada con un Informe de Seguridad asociado a:

NOMBRE DEL DISPOSITIVO MÉDICO	Injerto Endovascular ZENITH COOK
NO. IDENTIFICACIÓN RISARH	I1502-77
REFERENCIAS DEL DISPOSITIVO MEDICO	ZENITH
REGISTRO SANITARIO	2010DM-0006008
INDICACIONES Y USO ESTABLECIDOS	Usados en el tratamiento mínimamente invasivo de patologías de la aorta torácica
NOMBRE DEL FABRICANTE	William Cook Europe Aps
DESCRIPCION DEL PROBLEMA	El fabricante afirma que se debe realizar una actualización de las instrucciones de uso (IFU) para los injertos referenciados para resaltar una cuidadosa planificación y dimensionamiento del dispositivo basado en la longitud de la curva mayor del aneurisma, así como la colocación del dispositivo, cuidado y evaluación de imágenes durante y en la finalización del procedimiento, en respuesta a los recientes hallazgos de endofuga distal tipo I, así como la migración y el crecimiento del aneurisma durante un seguimiento continuo a largo plazo de los pacientes observados, conllevando a que se presenten potencialmente eventos adversos serios 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] - A23783 : Cook—Zenith Alpha Thoracic Endovascular Grafts: Manufacturer Updates Instructions for Use

Medical Device Ongoing Action

UMDNS Terms:

- Stent/Grafts, Vascular, Aortic [20453]

Product Identifier:
Zenith Alpha Thoracic Endovascular Grafts *[Consumable]*

Geographic Regions: Australia, Austria, Belgium, Bulgaria, Canada, Chile, Colombia, Cyprus, Czech Republic, Denmark, Egypt, Finland, France, Germany, Ireland, Israel, Italy, Lithuania, The Netherlands, New Zealand, Norway, Panama, Poland, Portugal, Slovakia, Spain, Sweden, Switzerland, Turkey, United Arab Emirates, U.K.

Manufacturer(s): William Cook EuropeSandet 6, Bjaerverskov, DK-4632, Denmark

Suggested Distribution: Cardiology/Cardiac Catheterization Laboratory, OR/Surgery, Materials Management

Problem:
In January 2015 Field Safety Notice letter posted by the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA), Cook states that it is updating the instructions for use (IFU) for the above grafts to emphasize best practices in response to recent findings of distal Type I endoleak, migration, and aneurysm growth during ongoing longer-term follow-up of patients enrolled in the multi-national clinical investigation of the device. Cook also states that to date, no similar events have been reported from markets in which the device is commercially available. These findings from the clinical investigation were found to be associated with thoracic aneurysms (not ulcers) treated with a single proximal component that resulted in a short distal seal length (i.e., less than 20 mm) and likely inadequate (i.e., less than 10%) distal oversizing for the device. Cook further states that it is essential to ensure that a minimum seal length of 20 mm is achieved and maintained both proximally and distally for all patients. This can be best assured through careful planning and sizing of the device based on the length of greater curve of the aneurysm, as well as careful device placement and evaluation of completion imaging during the procedure. Additionally, a two-component treatment (proximal and distal component repair) is recommended for aneurysms, whereas use of a single proximal component may be appropriate for ulcers. In aneurysm cases in which a 2-component treatment is not achievable, it is essential that a minimum of 20 mm distal seal length is planned and maintained to ensure long term success. Additional warnings and precautions related to these considerations are being implemented in the IFU in order to ensure that long term success is achieved for all patients treated with affected product.

Action Needed:
Identify any affected product in your inventory. If you have affected product, verify that you have received the January 2015 Field Safety Notice letter from Cook. Cook states that patients already treated with a single proximal component who have a short distal sealing length, graft length inadequate to maintain distal seal when settled into the greater curve of the aneurysm, inadequate oversizing, or any other complications (e.g., Type I endoleak, aneurysm/ulcer enlargement, migration) should receive additional surveillance, and treatment if necessary. Adherence to the additional recommendations in the IFU (see instructions in the letter) is necessary for the planning, sizing, placement, and evaluation of the procedural result in future patients receiving affected product. Inform all relevant personnel at your facility of the information in the letter.

For Further Information:
Cook
Website: Click here

References:

- Great Britain. Medicines and Healthcare Products Regulatory Agency. Cook Medical. Zenith Alpha™ thoracic endovascular graft [online]. London: Department of Health; 2015 Feb 17 [cited 2015 Feb 17]. (Field safety notice; reference no. 2015/001/030/701/002). 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 17. MHRA FSN. 2015/001/030/701/002 Download
- 2015 Feb 17. MHRA FSN. Download
- 2015 Feb 19. Manufacturer. Manufacturer confirmed information

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