INFORME DE SEGURIDAD

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 Informe de Seguridad asociado a:

NOMBRE DEL DISPOSITIVO MÉDICO	Sistema de Stents Esofágicos Biodegradables y No Biodegradables - ELLA-CS
NO. IDENTIFICACIÓN RISARH	I1703-95
REFERENCIAS DEL DISPOSITIVO MEDICO	DANIS/ 019-08S-25-135, 019-08S-25-135-B
REGISTRO SANITARIO	2013DM-0010471
INDICACIONES Y USO ESTABLECIDOS	Para tratamiento de las estenosis esofágicas: -tratamiento de las estenosis esofágicas malignas cuando la cirugía convencional está contraindicada. -tratamiento de las estenosis esofágicas benignas que no responden a la terapia estándar -el tratamiento de las fistulas esofagorespiratorias.
NOMBRE DEL FABRICANTE	Ella-Cs, S.R.O
DESCRIPCION DEL PROBLEMA	El fabricante ha identificado informes de que el tope de profundidad DBS no queda fijado correctamente al electrodo, el análisis de los tres productos devueltos indica que el área roscada del tornillo del tope de profundidad no era lo suficientemente extensa para permitir que el electrodo quedara fijado en el tope de profundidad, por lo que el electrodo se deslizaba a través del tope, conllevando a que se presenten posibles eventos adversos sobre los pacientes.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	13 de Marzo 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

INFORME DE SEGURIDAD

DIRECCIÓN DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS

ANEXO 1

[High Priority] - A28125 : ELLA-CS—Stent Delivery System Fixation-Gastric Balloons Contained in Danis Procedure Packs: Safety Valve May Exhibit Unintended Movement
Medical Device Ongoing Action

Published: Monday, March 6, 2017
Last Updated: Monday, March 20, 2017

UMDNS Terms:

- Procedure Trays, Surgical [17168]
- Stents, Esophageal, Metallic, Self-Expanding [20444]

Product Identifier: Stent Delivery System Fixation-Gastric Balloons contained in Danis Procedure Packs *[Consumable]*
Procedure Pack Reference Nos.: 019-08S-25-135, 019-08S-25-135-B

Geographic Regions: Australia, Austria, Bahrain, Belarus, Belgium, Bolivia, Brazil, Canada, Chile, Colombia, Czech Republic, Denmark, Ecuador, Egypt, Finland, France, Germany, Georgia, Hong Kong, India, Ireland, Italy, Israel, Kuwait, Malaysia, Moldova, Myanmar, The Netherlands, New Zealand, Norway, Panama, Peru, Poland, Russian Federation, Saudi Arabia, Slovakia, Slovenia, South Africa, Spain, Sweden, Switzerland, Turkey, U.K., Vietnam

Distributor(s):

- UK Medical Ltd A CareFusion Company Albreda House, Lydgate Lane, Sheffield S105FH England (U.K. distributor)

Manufacturer(s): ELLA-CS s r oMilady Horakove 504/45, Trebes 400 Hradec Kralove, Czech Republic

Suggested Distribution: Emergency/Outpatient Services, OR/Surgery, Gastroenterology, Materials Management

Problem:
In a February 14, 2017, Urgent Field Safety Notice letter posted by the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA) and the German Federal Institute for Drugs and Medical Devices (BfArM), ELLA-CS states that the safety valve of the fixation/gastric balloons of the above Danis stent delivery systems may exhibit unintended movement, potentially resulting in the following:
(1) Inability of the physician to correctly place the delivery system because it is impossible to insufflate the fixation-gastric balloon.
(2) The physician may need to use another Danis stent or other method to stop acute esophageal variceal bleeding, potentially prolonging the bleeding and/or the procedure.

Action Needed:
Identify any affected product in your inventory. If you have affected product, verify that you have received the February 14, 2017, Urgent Field Safety Notice letter and Acknowledgment of Receipt Form from ELLA-CS. The firm recommends the following actions:
(1) Check the position of the safety valve (refer to the figure in the letter).
(2) If the safety valve does not cover the opening designed for spontaneous deflation of the fixation-gastric balloon, return it to the appropriate position to allow performance of the stent implantation with the fixation of the delivery system in the cardia.
(3) If the safety valve does not cover the opening designed for spontaneous deflation of the fixation-gastric balloon and is not returned to the appropriate position, the Danis stent may be introduced using conventional techniques for implantation of esophageal stents (i.e., under fluoroscopic or combined endoscopic and fluoroscopic guidance).
Inform all relevant personnel at your facility of the information in the Urgent Field Safety Notice letter. Complete the Acknowledgment of Receipt Form, and return it to ELLA-CS using the instructions on the form.
For Further Information:
ELLA-CS
E-mail: vigilance@ellacs.eu
Website: Click here

References:

- Great Britain. Medicines and Healthcare Products Regulatory Agency. Ella-CS: SX-ELLA stent Danis procedure pack (basic) [online]. London: Department of Health; 2017 Feb 20 [cited 2017 Feb 28]. (Field safety notice; reference no. 2017/002/015/291/004). Available from Internet: Click here .
- Germany. Federal Institute for Drugs and Medical Devices. Urgent field safety notice for Danis procedure pack/Basic, Ella-CS s.r.o. [online]. 2017 Mar 2 [cited 2017 Mar 2]. 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 Feb 28. MHRA FSN. 2017/002/015/291/004 Download
- 2017 Feb 28. MHRA FSN. ELLA-CS Reference No. FSN-ELLA-2017-001 Download
- 2017 Mar 2. BfArM (Germany). 01508/17 Download
- 2017 Mar 2. BfArM (Germany). ELLA-CS Reference No. FSN-ELLA-2017-001 Download
- 2017 Mar 6. Manufacturer. The manufacturer confirmed the information in the source material.