ALERTA

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 una Alerta asociada a:

NOMBRE DEL DISPOSITIVO MÉDICO	Catéteres para Dilatación Coronaria PTCA SIS MEDICAL AG
NO. IDENTIFICACIÓN RISARH	A1708-390
REFERENCIAS DEL DISPOSITIVO MEDICO	PTCA BEO NC tamaños 3x17, 3x20, 3x22, 3.5x15, 3.5x17, 3.5x20, 3.5x22
REGISTRO SANITARIO	2009DM-0003755
INDICACIONES Y USO ESTABLECIDOS	Aumento diámetro luminal de una arteria coronaria
NOMBRE DEL FABRICANTE	Schwager Medica Fabrica Paa Sis Medical Ag
DESCRIPCION DEL PROBLEMA	El fabricante ha detectado informes de dificultades de deflación del balón de los dispositivos referenciados, este problema puede ser el resultado de una reducción en el lumen de inflado / deflación de los catéteres anteriores en su proceso de fabricación, lo que puede conllevar a que se presenten potencialmente eventos adversos serios sobre el paciente.
FUENTE	ANEXO
FECHA DE NOTIFICACION	31 de Agosto de 2017

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] - A29107 : SIS MEDICAL—BEO NC PTCA Catheters: May Exhibit Balloon Deflation Difficulties
Medical Device Ongoing Action

Published: Wednesday, August 23, 2017
Last Updated: Thursday, August 24, 2017

UMDNS Terms:

- Catheters, Vascular, Angioplasty, Balloon, Coronary [34313]

Product Identifier:
BEO NC Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters *[Consumable]*
Sizes: 3 x 17 mm, 3 x 20 mm, 3 x 22 mm, 3.5 x 15 mm, 3.5 x 17 mm, 3.5 x 20 mm, 3.5 x 22 mm

Geographic Regions: Africa, Asia, Europe, Latin America, Middle East

Manufacturer(s): SIS MEDICAL AG Hungerbüelstrasse 12a, CH-8500 Frauenfeld, Switzerland

Suggested Distribution: Cardiology/Cardiac Catheterization Laboratory, Critical Care, Emergency/Outpatient Services, Nursing, OR/Surgery, Perfusion, Materials Management

Problem:
In an August 3, 2017, Urgent Field Safety Notice letter posted by the German Federal Institute for Drugs and Medical Devices (BfArM), SIS MEDICAL states that it has received an increased number of reports of balloon deflation difficulties associated with use of the above catheters (at a rate of 0.06%). SIS MEDICAL also states that this problem may necessitate cardiosurgical intervention and cause myocardial infarction. SIS MEDICAL further states that this problem may be the result of a reduction in the inflation/deflation lumen of the above catheters during production.

Action Needed:
Identify and isolate any affected product in your inventory. If you have affected product, verify that you have received the August 3, 2017, Urgent Field Safety Notice and Product Withdrawal Form from SIS MEDICAL. Complete the Product Withdrawal Form, and return it to SIS MEDICAL by e-mail at ra@sis-medical.com . Notify all relevant personnel at your facility of the information in the Urgent Field Safety Notice letter, and forward a copy of the letter to any facility to which you have further distributed affected product. To arrange for product return and replacement, contact the SIS MEDICAL distribution department by e-mail at info@sis-medical.com .
For Further Information:
Erhard Hüsler, SIS MEDICAL QA/RA head
E-mail: ra@sis-medical.com
Website: Click here

References:

- Germany. Federal Institute for Drugs and Medical Devices. Urgent field safety notice for BEO NC PTCA catheters 3, ø3.0, lengths 17, 20 and 22 mm, and ø3.5, lengths 15, 17, 20 and 22 mm, specific lots by SIS Medical AG [online] 2017 Aug 18 [cited 2017 Aug 23]. 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 Aug 15. BfArM (Germany). 07821/17 Download
- 2017 Aug 15. BfArM (Germany). FSCA20170803 Download
- 2017 Aug 23. Manufacturer. The manufacturer confirmed the information in the source material.