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	Válvula Cardiaca Auto - Expansible Sin Sutura PERCEVAL S - SORIN
NO. IDENTIFICACIÓN RISARH	I1703-109
REFERENCIAS DEL DISPOSITIVO MEDICO	PVS21, PVS23, PVS25, PVS27
REGISTRO SANITARIO	2014DM-0012018
INDICACIONES Y USO ESTABLECIDOS	PERCEVAL S es una válvula bioprotésica diseñada para reemplazar una válvula aórtica nativa enferma o una protésica en mal funcionamiento a través de cirugía a corazón abierto, con la característica única de permitir el posicionamiento y anclaje en el sitio de implante sin sutura.
NOMBRE DEL FABRICANTE	Sorin Group Italia S.R.L
DESCRIPCION DEL PROBLEMA	El fabricante informa que a raíz de algunos casos de fuga central intra o perioperatoria, está proporcionando aclaraciones relativas a las instrucciones de implantación que serán integradas a las instrucciones de uso (IFU) y suministrara una guía que proporciona una descripción detallada e ilustrada de los pasos de preparación de la válvula y de implantación como material de apoyo, lo anterior como acción preventiva para disminuir la probabilidad de presentación de eventos serios sobre los pacientes.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	23 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

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ANEXO 1

[High Priority] - A27102 01 : Sorin/LivaNova—Perceval Sutureless Heart Valves: Manufacturer Provides Training Material to Prevent Central Leakage
Medical Device Ongoing Action

Published: Tuesday, March 7, 2017
Last Updated: Thursday, March 9, 2017

UMDNS Terms:

- Prostheses, Cardiac Valve, Artificial [15869]

Product Identifier:

Perceval Sutureless Aortic Heart Valves:	Item Nos.:	Reference Nos.:
Size S	ICV1208	PVS21
Size M	ICV1209	PVS23
Size L	ICV1210	PVS25
Size XL	ICV1211	PVS27

[Consumable]

Geographic Regions: (Impact in additional regions has not been identified or ruled out at the time of this posting), Asia, Australia, Brazil, Canada, Chile, Colombia, Egypt, Europe, Mexico, New Zealand, Panama, South Africa, U.K., U.S., Uruguay

Manufacturer(s): Sorin Group USA Inc A LivaNova Co14401 W 65th Way, Arvada, CO 80004-3503, United States

Suggested Distribution: Cardiology/Cardiac Catheterization Laboratory, OR/Surgery, Risk Management/Continuous Quality Improvement, Materials Management

Summary: This Alert provides additional information based on FDA Center for Devices and Radiological Health (CDRH) source material regarding A27102 . FDA's CDRH states that the manufacturer initiated a product correction by Customer Letter dated October 31, 2016. Additional information is bolded in the Geographic Regions field.

Problem:
[October 11, 2016]
In an August 26, 2016, Field Safety Notice letter posted by the German Federal Institute for Drugs and Medical Devices (BfArM) and the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA), LivaNova states that, following some cases of intra- or perioperative central leak, the firm is providing clarifications on implantation instructions to integrate information in the Instructions for Use (IFU) and an "Inservice Guide," which provides a detailed and illustrated description of the valve preparation and implantation steps as training material. LivaNova has gathered feedback from users regarding critical procedural steps requiring careful execution to reduce the possibility of intraoperative complications, such as valve malpositioning, significant perivalvular or central regurgitation, and permanent pacemaker implantation. The manufacturer has not confirmed the information provided in the source material.

Action Needed:
Identify any affected product in your inventory. If you have affected product, verify that you have received the October 31, 2016, Customer Letter and/or the August 26, 2016, Field Safety Notice letter, IM-00760 "Perceval implant key points" document and Customer Response Form from LivaNova. The following actions are those listed in Alert Accession No. A27102 . The firm recommends that you review the information provided in the IM-00760 "Perceval implant key points" document, considering the following elements:

- Patient pre-operative assessment
- Perceval out of the jar
- Surgical technique
  - Aortotomy
  - Perceval implant-related precautions
  - Decalcification
  - Sizing
  - Guiding sutures
  - Traction sutures
  - Valve deployment
  - Ballooning
  - Inspection before closing the aorta
  - Removal of the guiding sutures
  - Prosthesis removal procedure

For additional questions or clarifications, contact LivaNova using the information below. Complete the Customer Response Form, and return it to LivaNova using the instructions on the form. Notify all relevant personnel at your facility of the information in the letter, and forward a copy of the letter to any facility to which you have further distributed affected product.
For Further Information:
LivaNova quality assurance director
Tel.: 39 (161) 487812

E-mail: FSCA-HV@livanova.com or hv.feedback@livanova.com
Website: Click here

References:

- Germany. Federal Institute for Drugs and Medical Devices. Urgent field safety notice for Perceval sutureless heart valve, Sorin Group Italia S.r.l./LivaNova Canada Corp. [online]. 2016 Aug 22 [cited 2016 Oct 5]. Available from Internet: Click here .
- Great Britain. Medicines and Healthcare Products Regulatory Agency. Sorin: Perceval sutureless aortic heart valve [online]. London: Department of Health; 2016 Sep 5 [cited 2016 Oct 5]. (Field safety notice; reference no. 2016/008/030/291/005). Available from Internet: here .
- United States. Food and Drug Administration. Center for Devices and Radiological Health. Class 2 device recall Perceval sutureless heart valve [online]. 2016 Dec 7 [cited 2017 Mar 3]. 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 Mar 3. MHRA FSN. 2016/008/030/291/005 Download
- 2017 Mar 3. MHRA FSN. FSCA-HV-2016-001 (includes reply form) Download
- 2017 Mar 3. BfArM (Germany). 6895/16 Download
- 2017 Mar 3. BfArM (Germany). FSCA-HV-2016-001 Download
- 2017 Mar 3. FDA CDRH Database. Class II. Z-0716-2017 Download