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	Sistemas de Maquinas Corazón – Pulmón SORIN
NO. IDENTIFICACIÓN RISARH	I1612-569
REFERENCIAS DEL DISPOSITIVO MEDICO	Concerniente a las bombas de centrifugado referencias 60-00-60, 60-00-50, 60-00-00, 164275, 164275X y 824043.
REGISTRO SANITARIO	2009EBC-0004492
INDICACIONES Y USO ESTABLECIDOS	Los sistemas de máquinas corazón-pulmón, también denominadas sistemas de circulación extracorpórea ó sistemas de perfusión, son sistemas modulares de circulación extracorpórea, que pueden configurarse para controlar y monitorizar o supervisar la circulación sanguínea extracorpórea durante una perfusión cardio-pulmonar, incluyendo entre otros: 1. supervisión de la presión 2.indicador de flujo 3.supervisión de la temperatura 4.cronómetro 5.supervisión de nivel/supervisión de burbujas de aire.
NOMBRE DEL FABRICANTE	Sorin Group Deutschland Gmbh Sorin Group S.A. S.R.L
DESCRIPCION DEL PROBLEMA	El fabricante advierte que ha detectado la posibilidad que los dispositivos referenciados presenten una desaceleración brusca o el bloqueo del flujo sanguíneo desde el cabezal de la bomba centrifuga cuando son utilizados con el adaptador de Terumo Sarns, conllevando a que se presenten posibles eventos adversos serios sobre el paciente.
FUENTE	Anexo 1
FECHA DE NOTIFICACION	13 de Diciembre de 2016

INFORME DE SEGURIDAD

DIRECCIÓN DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS

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] - H0342 : Terumo/Sorin— Terumo Sarns Centrifugal Pumps and Adapters with Sorin Pump Drivers: User May Not Recognize Decoupling While Troubleshooting a Low-Flow Condition during Heart-Lung Bypass Surgery [ECRI Exclusive Hazard Report]
Medical Device Hazard Report

Published: Wednesday, November 30, 2016

UMDNS Terms:

- Pumps, Extracorporeal Perfusion [13203]

Product Identifier:

Products:	Product Nos.:
Sorin CP5 Centrifugal Pump Systems	60-00-60
Sorin SCP Integrated Centrifugal Pump Systems	60-00-50, 60-00-00
Terumo Disposable Centrifugal Pumps	164275, 164275X
Terumo Sarns Centrifugal Pump Adapters	824043

[Capital Equipment, Consumable]

Geographic Regions: Worldwide

Manufacturer(s): Sorin Group USA Inc14401 W 65th Way, Arvada, CO 80004-3599, United States
Terumo Cardiovascular Systems Corp6200 Jackson Rd, Ann Arbor, MI 48103, United States

Suggested Distribution: Clinical/Biomedical Engineering, OR/Surgery, Perfusion

Problem:

1. ECRI Institute is aware of the clinical occurrence of abrupt slowing or stoppage of forward blood flow from the Terumo Sarns disposable centrifugal pump head when used with the Terumo Sarns adapter for the Sorin pump drivers during heart-lung bypass procedures.
2. If a perfusionist tries to troubleshoot the flow problem by removing and then replacing the Terumo Sarns pump head from the Terumo Sarns adapter on the Sorin driver, the pump head may not magnetically couple with the Sorin driver, depending on the features and settings of the driver. This may happen even if exchanging the Terumo Sarns pump head with a new one.
3. The failure in such a circumstance to magnetically couple and pump blood can be insidious, is a serious perioperative complication, and may not be detected by the perfusionist during attempts to restore forward flow. It is also likely that the Low RPM Lockout safety feature of the Sorin pump driver can contribute to the perfusionist not recognizing failure of the pump head to couple.
4. When forward flow ceases in the arterial line, blood can free flow by gravity back from the patient into the bypass circuit through the nonfunctioning pump, unless the line is clamped.
5. If the problem is not rapidly detected and the arterial line is not clamped, the patient could experience exsanguination or an air embolism (if air is entrained at the surgical site), resulting in permanent injury or death.

ECRI Recommendations:
Perfusionists

1. Review and be fully familiar with the function of system safety features. If an adverse event occurs, you might not have time to consider how these features work and how they might impact troubleshooting efforts.
2. Be cognizant of the operational status of the Sorin Low RPM Lockout feature when troubleshooting flow problems with the Terumo Sarns pump head and adapter. If the pump head is displaced or removed while the Low RPM Lockout is engaged, disengage (i.e., override) the Low RPM Lockout and ensure the pump driver speed is at 0 RPM prior to replacing the pump head.
3. If forward blood flow in the arterial line slows or stops, first clamp the arterial line and then deactivate the Low RPM Lockout on the Sorin pump driver before troubleshooting. If the centrifugal pump impeller has become decoupled from the driver once the Low RPM Lockout is disengaged, rotating the driver speed control fully counterclockwise to zero RPMs should allow the impeller to recouple.
4. Ensure that a manual (hand cranked) pump driver is always available for troubleshooting a centrifugal pump flow problem. If an adapter is being used to interface the pump driver with an alternate vendor's centrifugal pump head, recognize that a similar adapter will be needed on the corresponding manual pump driver if the pump head is being hand cranked.
5. Before using any similar centrifugal pump adapter with the pump driver from another manufacturer, confirm with the drive unit manufacturer that the adapter is compatible.

Background:

1. The impeller in disposable centrifugal pumps is magnetically coupled to the pump drive motor. To ensure effective coupling, the base of centrifugal pump head is designed to closely fit and be aligned with the corresponding vendor's pump driver.

2. Terumo markets its Terumo Sarns centrifugal pump adapter to enable use of its disposable centrifugal pump head with the Sorin pump drivers.

3. A review of FDA Manufacturer and User Device Experience (MAUDE) database finds that there have been reports of forward blood flow slowing or stopping during bypass surgeries when the Terumo Sarns centrifugal pump and adapter were being used with the Sorin CP5 and SCP pump drivers.

4. When blood flows in the retrograde direction in the arterial line, because of the pump slowing or stopping, the patient's blood can rapidly drain unless the arterial line is clamped.

5. The Sorin pump drivers are equipped with a safety feature, active by default, known as Low RPM Lockout. It is intended to maintain a minimum pump speed sufficient to support the column of blood in the arterial line and prevent retrograde flow. When this feature is engaged the pump speed control knob can be turned completely down (fully CCW), and the driver speed will automatically drop to the Low RPM Lockout speed (i.e., between 1000 and 2000 RPMs, based on adjustment).

6. When a pump head is displaced or removed from the adapter on the drive unit while it is rotating, the magnets of the pump head get out of rotational synchronization with the adapter magnets. Subsequent reseating of the pump head with the pump driver rotating may not result in proper recoupling of the pump head magnets with the adapter. Even when the pump driver is running at the reduced speed of the Low RPM Lockout, if the pump head is displaced from the pump driver (as might be done during troubleshooting) this can cause the pump head to decouple.

7. Centrifugal pump decoupling is a very rare but recognized problem that has been reported with magnetically coupled impellers. When it occurs, it is usually accompanied by a loud buzzing or rattling sound, alerting perfusionists to the situation; however, ECRI Institute's tests did not produce these sounds when the Terumo Sarns pump head and adapter were decoupled while connected to the rotating Sorin pump driver.

8. If decoupling has occurred, recoupling requires that the perfusionist press the Low RPM Lockout release key and then turn the pump driver speed control knob to zero RPMs. It is essential that the pump be restarted from **ZERO** RPM because continued rotation of the driver motor at the minimum pump speed will impede impeller recoupling. Once the pump is running at a satisfactory speed, the arterial line clamp can be released to confirm forward flow has been restored.

9. Pump heads and adapters from other vendors with the Sorin centrifugal pump drivers, could have a similar problem; however, this has not been reported.

Manufacturer's Perspectives or Comments:

- In a December 2013 customer letter, (before it was aware of the specific problem described in this article) Sorin warned that use of centrifugal pump adapters (including the one from Terumo) with the Sorin SCP and CP5 pumps can lead to dangerous situations. Sorin also states that the alternate vendor pump head could decouple and either stop rotating or rotate at a lower speed leading to insufficient flow for the patient.

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):

- 2016 Sep 14. ECRI Institute
- 2016 Nov 30. Sorin letter Download