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	Maquina de Anestesia - DRAEGER
NO. IDENTIFICACIÓN RISARH	I1507-283
REFERENCIAS DEL DISPOSITIVO MEDICO	Fabius GS
REGISTRO SANITARIO	2008EBC-0002304
INDICACIONES Y USO ESTABLECIDOS	Es una máquina de anestesia por inhalación que ha sido concebida para utilizarse en quirófanos y en salas de inducción y recuperación. Sistema de anestesia de flujo de gas continuo
NOMBRE DEL FABRICANTE	Draeger Medical
DESCRIPCION DEL PROBLEMA	El fabricante afirma que si la cubierta metálica protectora no está instalada en la manguera de oxigeno, esta puede deteriorarse y causar fuga significativa a la cantidad de oxigeno; esta fuga seria reconocible por el usuario durante la parte manual de la comprobación previa a su uso y no afectaría el rendimiento del sistema. Los equipos fabricados en el año 2006 o antes de este año, son los más propensos a sufrir de falta de la cubierta metálica.
FUENTE	Anexo 1
FECHA DE NOTIFICACION	07 de Julio 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

[Normal Priority] - S0276 : Draeger—Fabius GS Anesthesia Systems: Oxygen Flush Hose Cover Plate Required to Prevent Leaks [ECRI Exclusive User Experience Network]

Medical Device Special Report

Published: Wednesday, June 24, 2015

UMDNS Terms:

- Anesthesia Units [10134]

Product Identifier:
Fabius GS Anesthesia Systems *[Capital Equipment]*

Geographic Regions: Worldwide

Manufacturer(s): Draeger Medical Inc 3135 Quarry Rd, Telford, PA 18969, United States

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

Problem:

1. If the protective metal cover is not installed on the above systems (see Figure 1), the oxygen flush hose can deteriorate, which can cause the hose to leak. Units manufactured in 2006 or earlier are more likely to be missing the cover.

2. A significant leak in this hose would only affect the amount of oxygen delivered when pressing the oxygen flush button. Draeger states that a significant leak would be recognizable by the user during the manual part of the pre-use check. A non-significant leak in this hose will not affect the performance of the system.

Manufacturer's Corrective Action/Recommendations:

1. Draeger released a protective metal cover in 2006 that protects the hose and prevents deterioration. All units manufactured after 2006 should have the cover (see Figure 1).

2. A retrofit kit exists for units manufactured before 2006. Hospitals that are interested in the retrofit can contact their Draeger local representative to order the kit (part number MX08852; cost of the kit is approximately $14). The kit can be installed by hospital staff; it does not require a Draeger service technician.

Figure 1. The oxygen flush hose on the Fabius GS without and with the cover.

ECRI Institute Recommendations:

Clinical/Biomedical Engineering

1. Determine if any Fabius GS units in your facility are missing the oxygen flush hose cover.
2. If any units do not have the cover, contact your Draeger local representative to order the retrofit kit and install the cover.

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 Jun 24. ECRI Institute researched member report.
- 2015 Jun 24. Figure 1. Download