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	Laringoscopio Óptico AIRTRAQ
NO. IDENTIFICACIÓN RISARH	I1705-166
REFERENCIAS DEL DISPOSITIVO MEDICO	Avant y SP
REGISTRO SANITARIO	2010DM-0006816
INDICACIONES Y USO ESTABLECIDOS	El AIRTRAQ es un laringoscopio óptico para ayudar a la introducción de un tubo endotraqueal a través de las cuerdas vocales de los pacientes.
NOMBRE DEL FABRICANTE	Prodol Meditec Limited
DESCRIPCION DEL PROBLEMA	El fabricante informa que debido a que los dos modelos son muy similares solo el *Avant* es compatible con resonancia magnética (*RM*), por consiguiente instituciones que cuenten con los dos modelos podrían utilizar el modelo *SP* en un entorno de *RM* siendo atraído por el imán del resonador, lo anterior podría conducir a que se presenten posibles eventos adversos sobre el paciente, el usuario y daños en el resonador.
FUENTE	ANEXO
FECHA DE NOTIFICACION	15 de Mayo 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

[Normal Priority] - H0377 : Airtraq—SP and Avant Video Laryngoscopes: Similar Appearance of MR Unsafe and MR Conditional Units Can Lead to MR Safety Problems [ECRI Exclusive Hazard Report]
Medical Device Hazard Report

Published: Friday, May 5, 2017

UMDNS Terms:

- Laryngoscopes, Rigid, Video [23532]

Product Identifier:
Airtraq Video Laryngoscopes: (1) Avant, (2) SP *[Consumable]*

Geographic Regions: Worldwide

Manufacturer(s): Prodol Meditec SA5 Muelle T Olavarri, Guecho (Vizcaya), E-48930, Spain
Teleflex Medical3015 Carrington Mill Blvd, Morrisville, NC 27560, United States

Suggested Distribution: Anesthesia, Clinical/Biomedical Engineering, Critical Care, Emergency/Outpatient Services, OR/Surgery, Pulmonology/Respiratory Therapy, Otolaryngology

Problem:

1. The Airtraq Avant and Airtraq SP video laryngoscopes look very similar; however, only the Avant can be used in a magnetic resonance (MR) environment.
2. Hospitals with both Airtraq devices in their inventory may accidentally allow an Airtraq SP into the MR suite where it can be forcefully drawn into the magnet, potentially leading to patient or staff injury and/or MR system damage and downtime.

Airtraq SP (left) and Avant (right) video laryngoscopes

ECRI Recommendations:

1. Determine if your facility has Airtraq Avant and/or SP video laryngoscopes.
2. If your facility has only Airtraq Avant laryngoscopes:
   - No additional action is required.
3. If your facility has only Airtraq SP laryngoscopes:
   - Promote awareness among relevant personnel that the Airtraq SP is not safe for use in the MR environment.
4. If your facility has both Airtraq Avant and SP laryngoscopes:
   - Apply a label with the standard MR Conditional icon to Airtraq Avant video laryngoscopes intended for use in the MR suite (e.g., those stored on MR-conditional carts).
   - Promote awareness among relevant personnel that these devices are similar in appearance and that the Airtraq SP is not safe for use in the MR environment.
   - Check all Airtraq video laryngoscopes in the MR suite and remove any Airtraq SP device.
5. Refer to Health Devices guidance articles on MR safety for additional information (see links in References below).
6. Include this information in your MR safety training materials.

Background:

1. The Airtraq SP is a single-patient use device. It is not safe to use in an MR environment.
2. The Airtraq Avant has three components. The blade is single-patient use. The optics and eyepiece can be re-used up to 50 times.
3. The Airtraq Avant is classified as MR Conditional, meaning that it can be used in a magnetic field of up to 3 Tesla but must be kept outside the 720 Gauss line.
4. The Airtraq Avant optics packaging clearly indicates that it is MR Conditional; however, that component is reusable and there are no MR Conditional markings on the device itself.
5. MR staff must be able to quickly identify any device that is not safe. In this case the similarity between the MR Conditional device and the MR Unsafe device increases the risk of an unsafe device being introduced to the MR zone IV.
6. Because Airtraq Sp is labeled for single patient use, it would be impractical to label it MR Unsafe.
7. Anything not labeled as either MR Safe or MR Conditional should be assumed to be MR Unsafe (see Safety Labeling for the MR Environment in References below).

References:

1. Safety Labeling for the MR Environment (Health Devices Guidance Article)
2. How to Use Equipment Safely in the MR Environment (Health Devices Guidance Article)
3. The MR Environment: Knowing the Risks (Health Devices Guidance Article)

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 May 4. ECRI Institute researched member report