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	Grúas para Transferencia de Pacientes ARJOHUNTLEIGH
NO. IDENTIFICACIÓN RISARH	I1703-87
REFERENCIAS DEL DISPOSITIVO MEDICO	Maxi Move, Maxi Lite y Sara Stedy, instalados antes de marzo de 2016.
REGISTRO SANITARIO	2015DM-0012954
INDICACIONES Y USO ESTABLECIDOS	Estos dispositivos están diseñados para levantar y transferir de forma controlada y segura a los pacientes entre sillas de ruedas, camillas, camas hospitalarias, etc. Pueden usarse a su vez para trasladar y/o mantener suspendido al paciente mientras es aseado o este va al baño. Igualmente el dispositivo ayuda a mantener al paciente en una posición bípeda o suspendida mientras se le realiza cualquier tipo de procedimiento diagnostico o terapéutico.
NOMBRE DEL FABRICANTE	Arjohuntleigh Polska Sp. Z O.O Arjohuntleigh Magog Inc Arjo Hospital Equipment Ab Getinge (Suzhou) Co. Ltd. Arjohuntleight Ab
DESCRIPCION DEL PROBLEMA	El fabricante informa que los dispositivos médicos referenciados podrán tener cinta azul de plástico protectora sobre sus ruedas, la cual debió ser retirada en el momento de su puesta en funcionamiento, si no se elimina, podrá limitar la funcionalidad de las ruedas y afectar la maniobrabilidad de desplazamiento, lo cual podría conllevar a que se presenten retrasos en la atención de los pacientes.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	02 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

[Normal Priority] - S0310 : ArjoHuntleigh—Patient Lifts: Casters May Have Protective Blue Plastic Tape [ECRI Exclusive User Experience Network]
Medical Device Special Report

Published: Thursday, February 23, 2017

UMDNS Terms:

- Lifts, Patient Transfer [12330]

Product Identifier:
Patient Lifts, including the following: (1) Maxi Move, (2) Maxi Lite, (3) Sara Stedy *[Capital Equipment]*
Units installed before March 2016

Geographic Regions: Worldwide

Manufacturer(s): ArjoHuntleigh Inc 2349 W Lake St Suite 250, Addison, IL 60101, United States

Suggested Distribution: Clinical/Biomedical Engineering, Nursing, Risk Management/Continuous Quality Improvement, Facilities/Building Management, Physical Therapy/Rehabilitation, Staff Education

Problem:

1. ArjoHuntleigh patient lifts installed before March 2016 may have protective blue plastic tape on their casters.
2. The blue tape, which was added before shipping, must be removed by an ArjoHuntleigh representative upon installation.
3. If not removed, the blue tape will stick to the casters and limit their functionality.
4. Consequences of this issue may include the following:
    1. Soiled floor due to tape remnants and glue sticking to the floor
    2. Odd steering feel when maneuvering the lift on certain floor types (e.g., carpeted floors

Figure 1: Casters with blue tape (Image courtesy: ECRI Institute Member Hospital)
Manufacturer's Recommendations/Perspectives:

If you observe blue tape on the casters of the affected lifts, report the problem to the ArjoHuntleigh customer care department.

The vendor will work with the facility to remove the tape and glue residue or otherwise correct the issue.

3. ArjoHuntleigh states that only one of its manufacturing sites has shipped patient lifts with blue tape that must be removed during installation. All other manufacturing sites removed the tape before shipment. Since December 2015, all ArjoHuntleigh manufacturing sites have removed the blue tape from casters before shipment of these patient lifts.

4. ArjoHuntleigh's internal simulation of the reported issue found that although some slight sliding was observed, their lifts meet the applicable ISO 10535 standard for stability testing, and no functional issues were detected. ArjoHuntleigh states that the devices have been and remain safe for use.

5. The manufacturer does not expect any risks to arise from the problem. Users may experience a change in feel or tactility when using the lifts.

6. ArjoHuntleigh has received no reports of patient or staff injury from any of these facilities.

ECRI Institute Recommendations:

Clinical/Biomedical Engineering:

1. Identify all lifts in your inventory with blue tape on the casters.
2. Since, to our knowledge, this problem does not present a risk to patient or staff safety, we recommend that you continue normal use of the lifts. However, we recommend contacting ArjoHuntleigh for assessment.

Background

- An ECRI Institute member hospital reported that ArjoHuntleigh's patient lift casters had blue tape. The facility was using these lifts for 18 months. ArjoHuntleigh replaced the casters for the reporting facility.

- In addition, ECRI contacted 7 additional facilities using ArjoHuntleigh patient lifts. All facilities acknowledged that the manufacturer shipped the lifts with the blue tape to protect the casters against superficial damage.
  - 2 of the 7 facilities found blue tape on the lifts in use.
  - The facilities either replaced the casters or left the tape as is.

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 Feb 23. ECRI Institute researched member report. Download