

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	I1711-542
REFERENCIAS DEL DISPOSITIVO MEDICO	Maxi Sky 600
REGISTRO SANITARIO	2015DM-0012954
INDICACIONES Y USO ESTABLECIDOS	Estos dispositivos están diseñados para levantar y transferir de forma controlada y segura a 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 diagnóstico o terapéutico.
NOMBRE DEL FABRICANTE	Arjohuntleigh Polska Sp. Z O.O Arjohuntleigh Magog Inc Arjo Hospital Equipment Ab Getinge (Suzhou) Co. Ltd. Arjohuntleigh Ab
DESCRIPCION DEL PROBLEMA	El fabricante ha detectado que las ruedas que llevan el carro a lo largo de los rieles montados en el techo, pueden tener grietas, ninguna ha causado que la porción de plástico sobremoldeado de la rueda se rompa en pedazos, lo cual podría conllevar a que se presenten dificultades en la atención, eventos adversos sobre pacientes y/o los operadores.
FUENTE	Anexo
FECHA DE NOTIFICACION	24 de noviembre de 2017

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

www.ecri.org . Printed from *Health Devices Alerts* on Tuesday, December 19, 2017 Page 1

[Normal Priority] - S0336 : ArjoHuntleigh— Maxi Sky 600 Patient Lifts: Trolley Wheels May Be Cracked [ECRI Exclusive User Experience Network] Medical Device Special Report

Published: Wednesday, November 22, 2017

UMDNS Terms:

- Lifts, Patient Transfer [12330]
- Lifts, Patient Transfer, Overhead Track [19015]

Product Identifier:

Maxi Sky 600 Patient Lifts [Capital Equipment]

Geographic Regions: Worldwide

Manufacturer(s): ArjoHuntleigh Inc A Getinge Group Co2349 W Lake St Suite 250, Addison, IL 60101, United States

Suggested Distribution: Clinical/Biomedical Engineering, Critical Care, Nursing, Orthopedics, Home Care, Physical Therapy/Rehabilitation, EMS/Transport

Problem:

1. The Maxi Sky 600 trolley wheels, which carry the trolley along the ceiling-mounted rails, may have cracks (see Figure 1).
2. All of the reported cracks are in the same positions on the wheels.
 - None have caused the plastic overmold portion of the wheel to break into pieces.
3. This problem is unlikely to cause catastrophic lift failure as the bearing and wheel shaft will keep the trolley secured in the track.

Figure 1. Cracked trolley wheels

ECRI Recommendations:

Biomedical Engineering Staff:

1. If your facility has Maxi Sky 600 ceiling lifts, perform inspection preventative maintenance (IPM) as per vendor recommendations.
2. If cracked wheels are identified, contact ArjoHuntleigh to discuss trolley replacement.

Capital Equipment Purchasers:

1. Before ceiling lift purchases, consider that the Maxi Sky 600 has an expected service life of seven years.

Background:

- An ECRI Institute member hospital reports that cracks in the trolley wheels were discovered during routine IPM.
 - Of 49 lifts inspected, all but one had cracked wheels. The facility is replacing all of their 96 trolleys at a cost of \$375.75 each (\$36,072).
- Because the wheels alone cannot be replaced, the whole trolley assembly must be replaced.
 - Replacement trolley assemblies are currently backordered. The facility is replacing them when they are available.
- Each wheel has three small dimples where the cracks are forming.
- The new trolley assembly has an updated wheel shaft design.

Manufacturer's Perspectives:

- Affected lifts are all beyond their service life of 7 years.
- The wheels are riveted to the trolley and the vendor does not think that facilities can replace just the wheels, so the firm does not offer them as replacement parts.
- The instructions for use (IFU) for this lift indicates that the user inspection must include the following:
 - Inspect the wheels in the rail for damage, rust or cracks, and replace the trolley if the wheels are damaged. Perform this inspection every year or 2500 cycles.
 - Inspect the lift for evidence of external damages, missing parts, or broken panel before every use.
- This risk has been assessed per ArjoHuntleigh's risk management process and deemed acceptable.

Comments:

©2017 ECRI Institute
5200 Butler Pike, Plymouth Meeting, PA 19462-1298, USA
May be reproduced by subscribing institution for internal distribution only.

INFORME DE SEGURIDAD

DIRECCIÓN DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS

www.ecri.org . Printed from *Health Devices Alerts* on Tuesday, December 19, 2017 Page 2

- 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 Nov 22. ECRI Institute researched member report