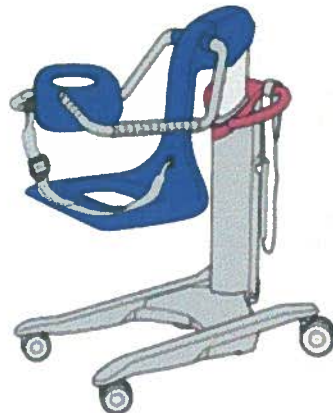


**Notice to Hospitals -  
Health Canada Endorsed Important Safety Information on  
Alenti Lift and Hygiene Chair**

**ARJOHUNTLEIGH**  
GETINGE GROUP



May 3, 2013

Dear Health Professional,

Please distribute this document to all personnel involved in the day to day usage of the Alenti Lift and Hygiene chair and **post this notice** in your facility.

**Subject: Alenti Lift and Hygiene Chair –  
Risk of Chair Tipping and Patient Falls**

ArjoHuntleigh, in collaboration with Health Canada, is providing this notice to re-iterate safety information to prevent the risk of chair tipping and patient falls with the Alenti Lift and Hygiene chair. These incidents can be caused by operator use error and patient factors, and can lead to serious patient injury or death.

Between 2004 and 2007, ArjoHuntleigh conducted Field Safety Correction Actions to provide improved safety instructions and warnings to reduce the risk of Alenti chair tipping and patient falls. The incident rate has since declined; however, ArjoHuntleigh continues to receive several incident reports in Canada each year. To further reduce the number of incidents associated with the Alenti chair, ArjoHuntleigh would like to re-iterate the important safety information.

- **Alenti chair tipping and patient falls can occur if an operator fails to strictly follow all operating and safety instructions in the Instructions for Use.**
- **Alenti chair tipping and patient falls have continued to occur in Canada, some of them leading to serious patient injuries and death.**
- **All personnel who may be involved in operating the Alenti chair should be familiar with the risk factors that are known to cause chair tipping and patient falling incidents.**

## Important Safety Warnings – Risk Factors Associated with Chair Tipping and Patient Falls

The majority of chair tipping and patient fall incidents occur in the hygiene bathing room. Special attention should be taken to precisely follow the Instructions for Use regarding the bathing and patient drying procedures.

**WARNING - The following precautions must be observed at all times when operating the Alenti. Failure to observe these precautions and failure to strictly follow the Instructions for Use can cause serious patient injury.**

1) PATIENT ASSESSMENT	<ul style="list-style-type: none"> <li>- Perform a patient risk assessment prior to each Alenti use.</li> <li>- If a patient is agitated or has a history of aggressive or unpredictable behavior – DO NOT use the Alenti.</li> <li>- The patient must be active or semi-active (i.e. able to sit upright self-supporting on the side of a bed or toilet) and be able to understand and respond to instructions to stay seated in an upright position.</li> </ul>
2) SAFETY BELT	<ul style="list-style-type: none"> <li>- <u>Use the safety belt at all times.</u></li> <li>- Exceptions can be made while the patient is securely positioned in the bath tub.</li> </ul>
3) INTERFERENCES	<ul style="list-style-type: none"> <li>- To prevent tipping, do not raise or lower other equipment close to the Alenti and be aware of stationary objects when lowering the Alenti (e.g. a variable height bath tub).</li> <li>- Be aware of any grab bars that may be within reaching distance of the patient.</li> <li>- Once the patient has been removed from the bath tub, that tub should <u>never be raised</u> until the Alenti and the patient have been removed from the bathing room.</li> </ul>
4) ELEVATION	<ul style="list-style-type: none"> <li>- Always ensure that the chair is in the lowest possible position before attempting to transfer, dress or undress the patient.</li> </ul>
5) SUPERVISION	<ul style="list-style-type: none"> <li>- <u>Never leave a patient unattended</u> (do not turn your back on the patient).</li> <li>- Always maintain eye contact and/or control of the patient and their actions at all times.</li> </ul>
6) REPOSITIONING	<ul style="list-style-type: none"> <li>- Before removing the patient from the bath, make sure that the patient is positioned correctly and that the safety belt is properly positioned and fastened.</li> <li>- To avoid the patient falling out of the chair, make sure that the arm rests are folded down during transfer.</li> </ul>

## Important Information on Alenti Maintenance and Inspection

Incidents have occurred as a result of the Alenti wheels becoming detached during use. The Preventative Maintenance Schedule found in the Instructions for Use must be followed, with special attention to weekly inspection of the wheels to ensure that they are properly fixed and rolling and swiveling freely. Before each use, check that all parts are in place and DO NOT use the Alenti if any part is missing or damaged. Failure to maintain and inspect the device correctly can result in serious patient injury.

## **Important Information on the Aleri Operating Wall Chart**

ArjoHuntleigh has revised the Aleri Operating Wall Chart (attached). The changes in the Wall Chart include:

- The correct instruction to NOT activate the Aleri brake after the patient is removed from the bath tub.
- The correct instruction to dry the patient inside the bath tub.

## **Confirming Receipt of this Aleri Notice to Hospitals**

As confirmation that you have read and understood this Notice to Hospitals and have received the new and improved Aleri Operating Wall Chart, please complete the Customer Response Form online using the information provided on the enclosed postcard.

If you have any further questions or require assistance completing the Customer Response Form online, please contact ArjoHuntleigh at 1-855-312-4265 or via email at AHNA-RA@arjohuntleigh.com.

## **Reporting Adverse Incidents**

Managing marketed health product-related adverse incidents depends on health care professionals and consumers reporting them. Reporting rates determined on the basis of spontaneously reported post-market adverse incidents are generally presumed to underestimate the risk associated with health product treatments. Any cases of Aleri chair tipping or patient falls or other incidents involving Aleri chairs should be reported to ArjoHuntleigh or Health Canada at the following addresses:

ArjoHuntleigh Canada Inc.  
300-90 Matheson Blvd. West  
Mississauga, Ontario L5R 3R3  
Telephone: 1-800-665-4831  
E-mail: info.canada@arjohuntleigh.com

**To correct your mailing address, contact ArjoHuntleigh.**

**Any suspected adverse incident can also be reported to:**

Health Products and Food Branch Inspectorate  
Health Canada  
Address Locator: 2003D  
Ottawa, Ontario K1A 0K9  
Telephone: 1-800-267-9675

The [Medical Devices Problem Report Form and Guidelines](http://www.hc-sc.gc.ca/dhp-mps/compl-conform/info-prod/md-im/index-eng.php) (<http://www.hc-sc.gc.ca/dhp-mps/compl-conform/info-prod/md-im/index-eng.php>) can be found on the Health Canada Web site.

For other medical device inquiries related to this communication, contact Health Canada at:

Marketed Health Products Directorate  
E-mail: mhpd\_dpdc.public@hc-sc.gc.ca  
Telephone: 613-954-6522  
Fax: 613-952-7738

Regards

  
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