Clifton Health Department
Food Recall Notification

Food/Drug/Pet Recall: ArjoHuntleigh Polska

ISSUE: ArjoHuntleigh Polska is recalling the Sara Plus floor lift following several complaints of smoke and/or flames coming out of the lift. When the battery is low, the device's printed circuit board may overheat, leading to smoke or fire. If this situation occurs, anyone using the lift or near it could be injured, including smoke inhalation and/or burns.

There have been 44 complaints about this issue. No injuries or deaths have been associated with the use of this device.

For more information and detailed recommendations about this recall, click on the red button **"Read Recall"** below.

BACKGROUND: The ArjoHuntleigh Polska Sara Plus is an active floor lift used for short transfers, such as raising patients from bed to a wheelchair or from a wheelchair to a toilet. It is intended for use in hospitals, nursing homes, and other health care facilities.

RECOMMENDATIONS: On April 8, 2022, ArjoHuntleigh Polska issued an Urgent Medical Device Recall letter to all customers who received affected devices, along with a list of potentially affected devices at each facility. The letter's instructions includes the following guidance for:

For customers:

- Make sure all care givers and/or users of the Sara Plus floor lift are aware of the issue.
- Locate affected devices by their serial number on the lift behind the rechargeable battery pack or by recognizing the affected devices based on the layout of the device's display.
- Make a plan for ArjoHuntleigh Polska service technicians to make a product correction for this issue by completing the Customer Response Form attached to the letter and expect Arjo to contact the facility to schedule the free correction.

For health care providers/device users:

- Stop use of the Sara Plus lift immediately if smoke appears when using.
- Push Emergency Stop Button.
- Remove the battery from battery socket to prevent any further failure.

The company also offered several precautionary steps for health care providers using the lifts. Click on the red button **"Read Recall"** below for additional information.

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Health professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report online.
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on form, or submit by fax to 1-800-FDA-0178.