



URGENT Voluntary Medical Device Recall

Bari Lift and Transfer

January 2, 2024

Dear Valued Customer:

Sizewise Manufacturing, an Agiliti company, is issuing a voluntary recall of the Bari Lift and Transfer patient transfer device.

Product Information

This recall applies to all serial numbers of Bari Lift and Transfer devices manufactured since product introduction in 2010.

The Bari Lift and Transfer device will no longer be manufactured or distributed. No instances of patient injury or adverse events that could potentially cause injury or death to a patient have been reported. This notice is being issued out of an abundance of caution and provides instructions for immediate discontinuation of use and disposal of the devices.

Issue

Retrospective engineering analysis against current ISO standards for hoists has determined:

1. The device cannot physically perform at maximum documented weight specifications when a factor of safety of two times the maximum load is applied.
2. The device is not equipped with a safety device to ensure a person with disability would not fall in the event of a single-fault condition of the lifting device.

Actions to be Taken by Customer

1. Immediately share this Notice with all necessary parties within your organization.
2. Examine the stock in your organization to determine if you have any of the devices in your organization.
3. Discontinue use of all Bari Lift and Transfer devices.
4. Dispose of all Bari Lift and Transfer devices.



5. Complete the attached Customer Response Form and log serial number(s).
6. Email completed Customer Response Form to: recalls@agilitihealthcom.

Other Information

If you have any questions regarding this Notice or the Recalled Device, please contact the our customer care team at 800-814-9389.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

This notice has been reported to the appropriate Regulatory Agencies.

Sincerely,

A handwritten signature in black ink that reads "Heidi Drafall". The signature is written in a cursive, flowing style.

Heidi Drafall
Senior Vice President of Quality
Agiliti

CUSTOMER RESPONSE FORM

**Receipt of Voluntary Recall
Bari Lift and Transfer**

Name of Facility	
Serial Number(s) of Affected Device(s) at Facility	
Address of Facility	
Please type or print the following information for the person completing customer response form:	
Name and title:	
Email Address:	
Telephone Number:	

By signature completion of this form, I certify the following:

- ✓ I have read and understand the contents of this Recall and confirm that I understand all instructions noted within the letter and attachments.

Signature of person completing form	
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Please return this form via email to:
recalls@agilitihealth.com