# URGENT Voluntary Medical Device Recall

# Bari Lift and Transfer - UPDATE

April 19, 2024

Dear Valued Customer:

On January 2, 2024, Sizewise Manufacturing, an Agiliti company, issued a voluntary recall of the Bari Lift and Transfer patient transfer device, **Model Number: 38060000**. This notice reflects updates and classification from FDA on this recall.

Instructions were added for those who distributed or resold the devices. Additionally, customer specific serial numbers and purchase dates for delivered devices were previously provided in letter format with the customer response forms.

**Product and Distribution Information**

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

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 device.

**Recall Classification and Potential Risk to patients associated with the use of the device:**

Use of the device may contribute to an increased risk of injury to patients due to a fall. This recall has been classified as: Class II by the FDA.

**Reason for the Voluntary Recall:**

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.

3. No instances of patient injury or adverse events have been reported.

**Actions to be Taken by Customer**

1. If you are a distributor or resold the device, immediately forward this notice to device recipient.

2. Immediately share this Notice with all necessary parties within your organization.

3. Examine the stock in your organization to determine if you have any of the devices.

4. Discontinue use of all Bari Lift and Transfer devices.

5. Dispose of all Bari Lift and Transfer devices.

6. Complete the attached Customer Response Form and log serial number(s).

7. Email completed Customer Response Form confirming disposal of the device(s) to: recalls@agilitihealthcom.

**Other Information**

If you have any questions regarding this Notice or the Recalled Device, please contact 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,

Heidi Drafall
Senior Vice President of Quality
Agiliti

Sizewise®
Manufacturing

*CUSTOMER RESPONSE FORM*

# Receipt of Voluntary Recall
# Bari Lift and Transfer

| | | |
|---|---|---|
| **Name of Facility** | | |
| **Serial Number(s) of Affected Device(s) at Facility** | | |
| **Serial Number** | **Status of Device** | **Initials** |
| | ☐ **Disposed** ☐ **No longer Own** | |
| | ☐ **Disposed** ☐ **No longer Own** | |
| | ☐ **Disposed** ☐ **No longer Own** | |
| **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** | |

Please return this form via email to:
recalls@agilitihealth.com

# 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,

Heidi Drafall
Senior Vice President of Quality
Agiliti

Sizewise®
Manufacturing

*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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recalls@agilitihealth.com