

January 24, 2014

Company Name  
Address

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**URGENT: VOLUNTARY DEVICE RECALL**

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To Whom It May Concern:

Otto Bock Healthcare, LP (“Otto Bock”) is committed to customer safety and satisfaction. In keeping with our mission of providing high-quality, innovative and technologically superior products, Otto Bock is conducting a voluntary recall of all Otto Bock Aerial and Aerial Active Wheelchair Cushions (not Aerial Sport) with the following material numbers:

476C00=SK751  
476C00=SK752  
476C00=SK753  
476C00=SK754  
476C00=SK755  
476C00=SK756  
476C00=SK757  
476C00=SK701  
476C00=SK702  
476C00=SK703  
476C00=SK704  
476C00=SK705  
476C00=SK706  
476C00=SK707

During internal and routine testing, Otto Bock has discovered that there is a small risk of flammability to the cushion after it has been washed at high temperatures and on numerous occasions. Otto Bock has not received any customer or end-user product complaints or incident reports about this.

Our records show you purchased (quantity) of these products prior to January 18, 2014. In order to comply with the United States Food and Drug Administration (“FDA”) regulations, we kindly request your prompt assistance.

Therefore, you are asked to either return the product (s) and/or destroy the product (s) in your possession.

You will need to immediately:

1. Inspect each of these products in your stock for the correct material number (s). The material number is found on the tag at the back of the cushion cover. If you have product (s) with the applicable material numbers in your stock, please contact Otto Bock Customer Service at 1-800-328-4058, extension 5189 to request a return authorization and arrange for a call tag pick-up by UPS. Immediately return them to Otto Bock after you have received the UPS call-tag.
2. Contact each patient who has received from you either of the products identified by the above-described material numbers prior to January 18, 2014 and arrange to inspect the products for the correct material numbers. Please use the “Dear Aerial and Aerial Active Wheelchair Cushion Product User” letter on page 4 of this notice.
3. Contact Otto Bock Customer Service at 1-800-328-4058, extension 5189 to request return authorization and arrange for a call tag pick by UPS. We will deliver another Otto Bock cushion of the patient’s choice

and clinical indication. You must return the product (s) subject to this recall notice after replacement cushions have been provided to your patients.

4. If you choose not to return the product (s), please destroy the product (s) and provide photographic evidence of such destruction, along with the reply questionnaire described in number 5 below (and found on page 3 of this notice).
5. Complete the attached reply questionnaire and promptly return it in the pre-paid UPS envelope accompanying this notice.

We appreciate your immediate attention to this matter. If you have technical questions please contact [REDACTED] in our customer service department at 800-328-4058, extension [REDACTED]. For any other questions concerning this Voluntary Recall Notice, please contact [REDACTED], Quality Systems Manager at 801-956-[REDACTED]

Regards,

[REDACTED]  
General Counsel

Attachments

Company Name  
Address

**Otto Bock Healthcare, LP**  
**Aerial and Aerial Active Wheelchair Cushions**  
**Reply Questionnaire**

PLEASE READ EACH QUESTION AND CIRCLE THE PROPER ANSWER YOU HAVE CHOSEN. PLEASE CHECK WITH ANYONE WHO MAY HAVE RECEIVED THIS NOTIFICATION BEFORE ANSWERING.

1. Did your firm receive notification that Otto Bock is recalling its Aerial and Aerial Active Wheelchair Cushions?  
YES NO
2. Did your firm receive shipments of the product (s) being recalled? (If **NO**, please sign and return). YES NO
3. Do you now have any of the recalled product (s) in your stock? (Please check inventories before answering).  
YES NO
4. If the answer to question 3 is YES, do you intend to return the product (s) to Otto Bock requested? YES NO
5. If the answer to question 4 is NO, please destroy the product (s) and provide photographs with this questionnaire.
6. Have you received any reports of illness or injury related to this product? YES NO

(If yes, please provide details as a separate document attached with this questionnaire).

7. Name and contact information of person completing questionnaire:

Name: \_\_\_\_\_

Telephone Number: \_\_\_\_\_

Email Address: \_\_\_\_\_

Business Name & Address: \_\_\_\_\_

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Please provide the Serial Numbers of all product (s) in your stock below:

**Im Rahmen des Medizinproduktegesetzes haben Sie eine Mitwirkungspflicht in der Nachweisführung des Herstellers über durchgeführte korrektive Maßnahmen.**

**Customer response of scrap disposal for the wheelchair cushions "Aerial / Aerius and Aerial active / Aerius active"**

This document is to confirm that the necessary scrap action, as documented in Field Notice, dated 2014-28-01, is now complete.

Please return the form with Mobility order number **and** serial number to the Otto Bock Customer Care Center via fax or e-mail.

**Reply**

Fax: 0049 69 9999 9392

E-mail: [ccc@ottobock.com](mailto:ccc@ottobock.com)

The Mobility Solutions GmbH order numbers and serial numbers of the scrapped products are as follows:


**Action completed**

Company.....

Date/Signed.....  
(Market Manager)

**Notice:**

**You have a responsibility under the Medical Device Directive (MDD) to notify the manufacturer when corrective actions have been completed.**