

<< Customer Information >>

Name: Verena Kollek
Department: Regulatory Affairs
Telephone: +49 (0) 761 1304 338
Fax: +49 (0) 761 1304 99 338
E-Mail: verena.kollek@alcon.com

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Corrective Action Urgent Notice

Alcon Monarch® IOL Delivery System Cartridges

Monarch® III IOL Delivery System Cartridge C mislabeled as Monarch® II IOL Delivery System Cartridge B

Dear Healthcare Professional,

This letter is to advise you that a Field Safety Corrective Action (FSCA) is being initiated by Alcon for a small number of its Monarch® III IOL Delivery System Cartridges.

Alcon is conducting a voluntary medical device replacement of a small number of its Monarch® III IOL Delivery System Cartridges due to mislabeling.

Based on internal investigation, a small amount of Monarch® III Delivery System Cartridge **C** lots (indicated below) were inadvertently mislabeled with Monarch® II Delivery System Cartridge **B** labels for qualified IOL-combinations at our European distribution center.

To date there have been no reports of injuries associated with the affected lots. As an additional precaution, Alcon has chosen to initiate a voluntary replacement of the potentially impacted lots.

According to our records, you have been provided Monarch® Cartridges from the following lot numbers:

Part Number	LOT Number	Product Description
8065977758/ 8065977762	32342054 32342055 32342058	Monarch® III IOL Delivery System - Cartridge C

National Competent Authorities are advised of this action.

Description of the Affected Device:

Alcon has identified the mislabeling of a small amount of Monarch® III Delivery System Cartridges C.

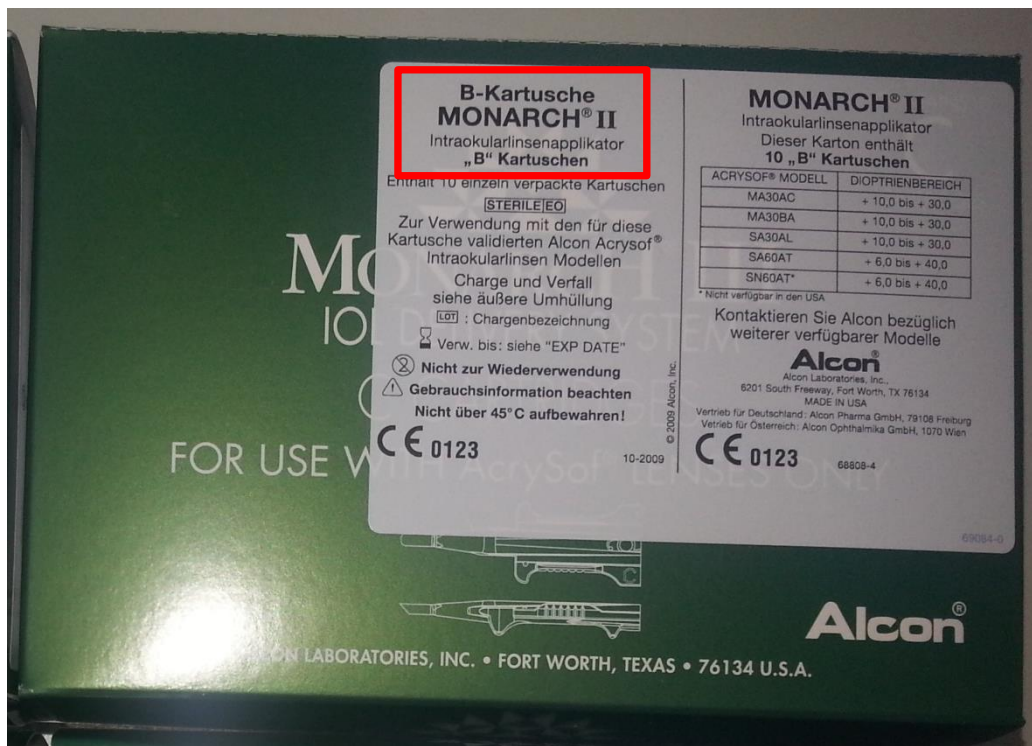
In the affected lots, the packaging has been mislabeled with a Monarch® II Delivery System Cartridge B label for qualified IOL-combinations and part number. This deviation can be easily identified by the green color and artwork of the product packaging (both typical characteristics of cartridge C) and the identification by name as Cartridge B on the label for qualified IOL-combinations.

Description of the Problem:

Based on internal investigation, a small amount of affected Monarch® III Delivery System Cartridge C lots were inadvertently mislabeled with Monarch® II Delivery System Cartridge B labels for qualified IOL-combinations.

The described deviation is shown on the following figure.

Monarch® II label for qualified IOL-combinations on Monarch® III product



Actions to be taken by the Customer/User:

To assist in this FSCA, please take the following steps:

1. Immediately stop further use of the affected lots.
2. Review your inventory to confirm whether you have any units of the affected lots.
3. Isolate affected lots from not affected lots to ensure that they are not used.
4. Please fill out, sign and return the attached Response Form via fax to Alcon.
5. **Please fill out and return the attached Response Form even if you do not have any inventory from these lots (0).**
6. An Alcon Customer Service Representative will work with you to place a new order to replace the affected units or contact Alcon Customer Service at +49 (0) 761 1304 400 to arrange for the return of your inventory.

Contact reference person

Alcon is committed to the safety of our patients and our products. We appreciate your immediate attention and cooperation, and sincerely apologize for any inconvenience caused by this voluntary recall.

Should you have any questions or concerns about this matter, please contact:

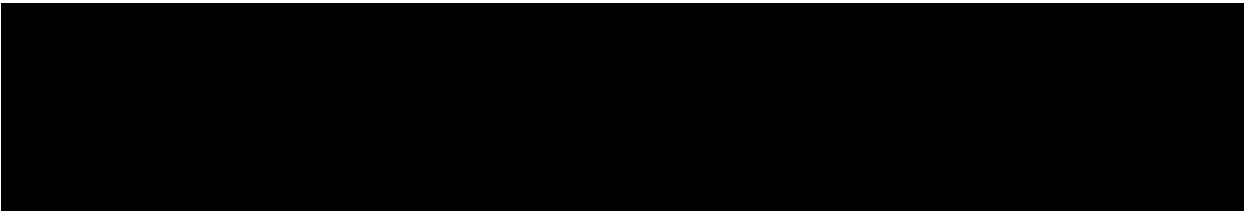
Mrs. Dr. Ulrike Isele available by phone: +49 (0) 761 / 1304-318
Mrs. Dr. Verena Kollek available by phone: +49 (0) 761 / 1304 - 338

Sincerely,

Alcon Pharma GmbH

b.o.

b.o.



Dr. Ulrike Isele
Head Quality Assurance/QMB

Dr. Verena Kollek
Quality Assurance Supervisor

Attachment: Response Form

RESPONSE FORM

CORRECTIVE ACTION
Alcon Monarch® IOL Delivery System Cartridges

Please follow these important steps:

1. Immediately stop further use of the affected lots.
2. Review your inventory to confirm whether you have any units of the affected lots.
3. Isolate affected lots from not affected lots to ensure that they are not used.
4. Please fill out, sign and return the attached Response Form via fax to Alcon.

Fax-No.: 0761 / 1304 - 99417

*Please return the Response Form even if you do not have any inventory from these lots (0).
 Your signature bellow attests that you have read and understood Alcon's request and instructions.*

An Alcon Customer Service Representative will work with you to place a new order to replace the affected units or contact Alcon Customer Service at +49 (0) 761 1304 400 to arrange for the return of your inventory.

Catalog Order	Lot number	Units in Inventory

Signature of Facility Representative:

Printed Name and Title:

Date:

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