Alcon Nordic A/S
Edvard Thomsens Vej 14
DK-2300 København S

URGENT: VOLUNTARY SAFETY CORRECTIVE ACTION IN THE FIELD	
Description	Voluntary safety corrective action in the field of specific lots of DAILIES TOTAL1® and TOTAL30® contact lenses
Product Reference	DAILIES TOTAL1®, TOTAL30®

August XX, 2024

«Customer_Name»
«Address»
«City», «State» «Zip»
Account «Account_»

Dear Valued Customer,

Alcon has initiated a voluntary safety corrective action in the field for specific lots of DAILIES TOTAL1® and TOTAL30® contact lenses. We identified an isolated quality issue with a material supplied by a third-party vendor that was used in the production of these specific contact lens lots at a single manufacturing site. As a result, the identified contact lens lots may not meet Alcon quality and/or performance standards for the entirety of their labeled shelf life.

The contact lenses from the identified lots are not expected to cause an increased risk to the wearer. As with any contact lens, there is a remote likelihood that wearing a lens from the identified lots may lead to temporary issues such as irritation, redness, or blurred vision. These symptoms typically resolve after lens removal and/or replacement (as directed in the patient leaflet).

We ask that you stop any further distribution of contact lenses from the identified lots and request that you contact any eye care practitioners, patients, or others to whom you have distributed the identified lots.

Alcon is committed to delivering outstanding product quality and customer service, and we regret the inconvenience caused by this safety corrective action in the field.

Sincerely,

Alcon representative

Alcon Nordic A/S
Edvard Thomsens Vej 14
DK-2300 København S

According to our records, the following contact lens lots have been shipped to your firm and are affected by this recall:

Table 1: Affected contact lens lots shipped to your firm		
Product description	**Affected lot(s)**	**Units shipped**
« Material_description »	« Batch_number »	

Actions to take

Alcon asks that you stop distribution of the identified lots of DAILIES TOTAL1® or TOTAL30® and dispose of any remaining product from the identified lots which may remain in your inventory.

To execute this voluntary safety corrective action in the field, please take the following steps:

1. Stop any further distribution of product from the identified lots.
2. Review your inventory to determine if you have any product from the identified lots within your facility. See **Table 1** for affected DAILIES TOTAL1® or TOTAL30® lots that have been shipped to your firm.
3. Dispose of any product from the identified lots which remains at your facility. If immediate disposal is not feasible, ensure the identified lots are segregated from other products until disposal can be completed.
4. Fill out the attached 'Response Form', **even if you have zero (0) units remaining in inventory** and return the form to Alcon using the contact information provided on the form.
5. Forward this notification to others within your organization who may be in possession of product from the identified lots.
6. Contact other organizations, eye care providers and/or individuals, whenever this is feasible, to whom you have transferred or distributed the identified lots to advise them of this voluntary safety corrective action in the field and request they dispose of contact lenses from the identified lots. For your convenience, a voluntary safety corrective action in the field notification template is attached for your use in communicating this issue to your customers.

For further assistance

Topic	Contact
Questions regarding this Voluntary Medical Device Recall, including inquiries regarding stock replacement or account credits	Your Alcon account manager or Customer Service
Report an adverse event or product quality issue to Alcon	Online: local webpage

Alcon Nordic A/S
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RESPONSE FORM	
Alcon DAILIES TOTAL1® and TOTAL30® contact lenses MA# 2024.016	«Customer_Name» «Address» «City», «State» «Zip» Account «Account_»

To execute this medical device recall, please take the following steps:

1. Stop any further distribution of product from the identified lots.
2. Review your inventory to determine if you have any product from the identified lots within your facility. See **the table below** for a list of affected DAILIES TOTAL1® or TOTAL30® lots that have been shipped to your firm.
3. Dispose of any product from the identified lots which remains at your facility. If immediate disposal is not feasible, ensure the identified lots are segregated from other products until disposal can be completed.
4. Fill out this 'Response Form', including the number of packs discarded for each batch, **even if you have zero (0) units remaining in inventory** and return the form to Alcon using the contact information provided below.
5. Forward this notification to others within your organization who may be in possession of product from the identified lots.
6. Contact other organizations, eye care providers and/or individuals to whom you have transferred or distributed the identified lots to advise them of this voluntary safety corrective action in the field request they dispose of contact lenses from the identified lots.

Product description	**Affected lot(s)**	**Number packs discarded** (please complete)
« Material_description »	« Batch_number »	

Return this response form via **email to** qa.nordic@alcon.com

Your signature below attests that you have read and understood this notice, and that you agree to complete the actions specified herein.

Signature:	**Date:**
Printed Name:	
Title:	