Alcon

| URGENT: FIELD SAFETY NOTICE | |
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| **Description** | Field Safety Corrective Action of specific lots of DAILIES TOTAL1® and TOTAL30® contact lenses |
| **Product Reference** | DAILIES TOTAL1®, TOTAL30® |

August XX, 2024

Dear Valued Customer,

Alcon has initiated a Field Safety Corrective Action (FSCA) 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 FSCA.

Sincerely,

According to our records, the affected contact lenses have been shipped to you and are concerned by this Field Safety Corrective Action – **please check annex 1.**

Alcon

## 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 FSCA, 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 within Annex 1 document** 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 and sign (with your name) the attached 'Response Form' from Annex 1, **even if you have zero (0) units remaining in inventory** and return the form to Alcon using the contact information provided on the form per email. Upon receipt of the signed response form, the credit will be processed to you.
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 Field Safety Corrective Action and request they dispose of contact lenses from the identified lots if feasible. For your convenience, a Field Safety Corrective Action notification template is attached for your use in communicating this issue to your customers.

## For further assistance

| Topic | Contact |
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| Questions regarding this Field Safety Corrective Action, including inquiries regarding account credits | Your Alcon account manager or Customer Service |
| Report an adverse event or product quality issue received from a consumer to Alcon | https://notifeye.alcon.com/ |