



FIRM INITIATED VOLUNTARY REMOVAL –clariti® 1 day and Fresh Day® – CONTACT LENSES

ACTION REQUIRED

Dear Eye Care Practitioner:

CooperVision is conducting a voluntary removal of a limited number of lots of **clariti® 1 day/Fresh Day®** lenses packaged in 2016.

-) **clariti 1 day/Fresh Day 90-Pack** (-1.00) – Lot 14376100252004
Exp. Date - 7/20/2031 (carton)
-) **clariti 1 day 90-Pack** (-1.25) – Lot 14377101733005
Exp. Date - 6/20/2030 (carton)
-) **clariti 1 day/Fresh Day - Fit Set/Individual Carton**
 -) Silicone Hydrogel 1 Day 10-Pack-Trial (-4.50) – Lot 14364100237018
Exp. Date - 9/30/2022 (carton)
 -) Silicone Hydrogel 1 Day 10-Pack-Trial (-2.50) – Lot 14364100378010
Exp. Date - 5/31/2020 (carton)

Our routine quality monitoring system identified that a limited number of clariti 1 day/Fresh Day lots were packaged that do not meet their labeling specification (secondary package (carton) contains incorrect expiration date; whereas the primary package (blister) label contains the correct expiration date). The actual contact lens shipped meets specification of the product.

A patient using one of the lenses will not experience any change in visual acuity, and the issue does not pose any medical risks. We have decided to conduct this voluntary removal of the affected lots to ensure a positive experience for you and your patients. This removal is being performed with our first-level customers; it is not a consumer-level removal. You are not required to notify your patients.

Our records indicate that you may have received affected product. Enclosed is a list of the affected product and lot numbers we have a record of shipping to you. Please take the following actions immediately:

-) Examine your inventory (may include carton within fit set) for any affected lot numbers listed below.
-) Stop any further distribution of the specified lot(s) of **clariti 1 day/Fresh Day** contact lenses listed below.
-) Please discard product and contact CooperVision, Inc. Customer Service department at 1-800-341-2020 to receive credit and/or complimentary replacement product.

Product Name Outer Carton	Power	Pack Size	Lot No
Example: clariti 1 day/Fresh Day	-1.00	90- packs	14376100252004



CooperVision®

This action is being taken in full cooperation with the Food and Drug Administration (FDA). The removal only affects clariti 1 day/Fresh Day lenses with the lot numbers specified on the enclosed letter. No other clariti 1 day/Fresh Day products – or any other CooperVision products – are affected.

We appreciate your assistance and apologize for any inconvenience you may have experienced. If you have any further questions, please feel free to contact your Account Representative or Customer Service at 1-800-341-2020, 9:00 AM – 7:00 PM ET, Monday - Friday.

Sincerely,



Christine Moench

Vice President, Global Regulatory Affairs & Quality Assurance