

URGENT FIELD SAFETY NOTICE***Recall of Certain Lots of Biotrue®, ReNu® and Sensitive Eyes™ contact lens solutions***

May 04, 2021

For the attention of Bausch + Lomb Wholesaler Customers,*

Bausch + Lomb (1400 North Goodman Street, Rochester, NY 14609) was notified by one of its suppliers, which sterilizes some components of our contact lens solutions, of an issue with its sterilization process.

As a result, Bausch + Lomb is conducting a recall of certain lots of Biotrue®, ReNu® and Sensitive Eyes™ contact lens solution, since we cannot confirm the compliance of the supplier's sterilization process used for some components of these products. A complete list of the Bausch + Lomb contact lens solutions products and lots impacted by this recall is attached (see page 6).

If these products are used by a consumer, the possibility of a risk of infection as a result of this issue is rare. Bausch + Lomb sterility and preservative efficacy testing demonstrate that the products are safe and are unlikely to result in any immediate or long-range health consequences. Additionally, no adverse events have been reported to date in association with this issue.

The health and safety of everyone who uses our products is of our utmost priority. While the risk of infection to the consumer is rare, we are taking this action out of an abundance of caution.

No other Bausch + Lomb products or lots are affected by this action.

All appropriate regulatory bodies have been informed of this action. Additionally, details regarding this recall are included in this document, therefore, no further information will be distributed.

REMOVE THE IMPACTED PRODUCT FROM YOUR FACILITY AND RETURN IT TO BAUSCH + LOMB

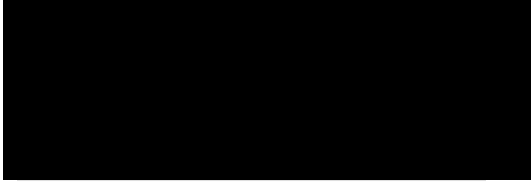
According to our records, your facility has received products that are impacted by this recall. We urgently ask you to take the following steps in response:

1. Review your inventory for all products impacted by this recall in your facility (see page 5 for additional product details, including examples of the product label for ease in identifying the product).
2. Count the number of products impacted identified in your inventory.
3. Complete the enclosed Customer Reply Form (see pages 3-4), including the total number of impacted products identified in your facility, and return it to Bausch + Lomb by email: cs.vc.uk@bausch.com within 5 days. **It is important to return the Customer Reply Form even if you do not have any products from these impacted lots in your facility.**
4. Contact Bausch + Lomb at 0845 602 2350 to obtain a Return Material Authorization Number and arrange for pickup of the identified product.

For questions regarding this notice, please call Bausch + Lomb at 0845 602 2350

We greatly appreciate your understanding and prompt assistance and apologize for any inconvenience this may cause.

Sincerely,



Timo Jackle
Vice President, Quality, Global Medical Devices
Bausch + Lomb

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****IMPORTANT NOTE: This notice needs to be passed on to all those who need to be aware within your organisation where the potentially affected devices have been transferred. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.***

URGENT FIELD SAFETY NOTICE CUSTOMER REPLY FORM

This is to acknowledge receipt of the above referenced recall notification dated May 04, 2021. Once this form and impacted product is returned to Bausch + Lomb, appropriate credit for product returns, plus handling and shipping expenses, will be issued. All recalled product returned without a customer reply form may delay the issuance of your credit.

Product Details:

Bausch + Lomb is recalling only the lots outlined in this letter (see page 6) for Biotrue®, ReNu® and Sensitive Eyes™ contact lens solution.

Please review and acknowledge (X) the following statement below:

☐ We have reviewed the attached urgent field safety notice and acknowledge the alert.

Please review and acknowledge (X) one of the statements below that applies to your facility:

☐ We do not have any of these product lots in our inventory.

☐ We do have these product lots in our inventory. If checked, please fill out chart below.

Please insert the following information for all impacted product lots identified at your facility:

Products	Lot Number	Quantity Returned
Sensitive Eyes™ Plus Saline 500ml		
ReNu® MPS multi-purpose solution 120 ml		
ReNu® MPS multi-purpose solution 240 ml		
Biotrue® multi-purpose solution 300 ml		

I hereby certify that I have removed all products impacted by this recall from my facility to prevent use and will contact Bausch + Lomb to arrange pickup of the products.

Date

Name (Print)

Bausch + Lomb Account Number

Signature

Facility Name

Telephone Number




Please complete, sign and return this form (page 3-4) to:

Email: cs.vc.uk@bausch.com

For questions regarding this notice, please call Bausch + Lomb at 0845 602 2350.

Confidentiality Agreement: The information contained in this message is confidential information intended for the use of the address listed above. If you are neither the intended recipient nor the employee or agent responsible for delivering this message to the intended recipient, you are hereby notified that any disclosure, copying, distribution or the taking of any action in reliance on the contents of the information is strictly prohibited. If you have received this in error, please immediately notify us by telephone to arrange for the return of the original document to us.

URGENT FIELD SAFETY NOTICE

Product Details	
Dates of Manufacture	May 2018 – February 2021
Expiration Dates	May 2021 – February 2024
 Biotrue® multi-purpose solution	 ReNu® MPS multi-purpose solution
 Sensitive Eyes™ Plus Saline	

See below an example of the bottle and carton labels, which contain the lot number and expiration to easily identify the product. The lot number consists of two letters and four number (AA####) and the expiration is the four digit year, hyphen, two digit month (YYYY-MM).

Label Examples

Lot and Expiration on Bottle Label	Lot and Expiration on Carton Label
	

URGENT FIELD SAFETY NOTICE***List of Product Lots Impacted***

LOT	Labelled Product Name
ME2386	Sensitive Eyes™ Plus Saline 500ml
ME2728	ReNu® MPS multi-purpose solution 120 ml
ME3685	
ME4641	
ME1843	ReNu® MPS multi-purpose solution 240 ml
ME2446	
ME2930	
ME4652	
MF0630	
MF1112	
MF1285	
ME2101	Biotrue® multi-purpose solution 300 ml
ME4344	
ME4576	
MF0944	