
Soflens (Pty) Ltd.

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URGENT MEDICAL DEVICE RECALL

Class II Type A

24 May 2021

Dear Valued Customers

We, Soflens (Pty) Ltd. t/a Bausch + Lomb, in consultation with the South African Health Products Regulatory Authority (SAHPRA), herewith want to inform you about a product recall involving specific lots/batches of Bausch + Lomb Contact Lens Solutions and Eye Lubricants.

Reason for the recall

Bausch + Lomb was notified by one of its third-party suppliers in Milan, Italy, which sterilizes some components (bottles, plugs and caps) of our contact lens solutions, prior to manufacturing in our facility in Milan, Italy, of a compliance issue with its sterilization process. Bausch + Lomb is one of many companies impacted by this situation.

Because we cannot confirm the supplier's conformance to process compliance requirements for some of the components of these products, we are conducting a recall of certain lots of Biotrue® Multi-Purpose Solution, Boston® Advance Cleaner, Boston® Advance Conditioning Solution, Boston® Simplus Multi-Action Solution, EasySept® Peroxide Solution, Lens Lubricant®, ReNu® Multi-Purpose Solution, ReNu® MultiPlus Solution and Saline Plus® Solution, that were manufactured in our Milan, Italy facility. A complete list of the Bausch + Lomb products and lots impacted by this recall is enclosed (Annexure 1).

The health and safety of everyone who uses our products is our utmost priority. While there is a low risk of infection with these products, we have chosen to recall these certain lots of products because we cannot confirm the supplier's conformance to process compliance requirements for some of the components of these products. No serious adverse events have been reported to date in association with this issue.

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

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 CONTACT SEDGWICK, THE FIRM CONDUCTING THIS RECALL ON BEHALF OF BAUSCH + LOMB, FOR RETURN INSTRUCTIONS

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 the list of lots (Annexure 1) within this letter or at BLRecall.expertinquiry.com to determine if you have inventory of these products impacted by this recall. For additional product details, including examples of the product label for ease in identifying the product, refer to BLRecall.expertinquiry.com.
2. Remove the affected product from your inventory. Do not sell or distribute these products further.
3. Count the number of products impacted identified in your inventory.
4. Complete the enclosed Customer Reply Form (Attachment 1), including the total number of impacted products identified in your facility and return the form to Sedgwick by email: BLRecall@Sedgwick.com or fax: +44-20-8705-0539 **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.**
5. Contact Sedgwick at 080 099 4885 to arrange for pickup of the identified product and for Return Material Authorization instructions.
6. Print the attached consumer notice (Attachment 2) and place at a visible location for consumers. Please keep the consumer notice visible for 90-days.

For questions regarding this notice, please call Sedgwick at 080 099 4885.

If you receive any product related complaints or adverse event reports; please report these to:
MV-SouthAfrica@bauschhealth.com

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

Sincerely,

Lizé Theunissen
Authorised Representative

Shirona Naidoo
Quality & Vigilance Specialist

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****IMPORTANT NOTE: This notice needs to be passed on to all those who need to be aware within your supply chain 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.***

Annexure 1 – LIST OF PRODUCT BATCHES/LOTS IMPACTED

B+L Code	Product Name	LOT Number
54085305	Biotrue® Multi-purpose Solution Flight Pack [2 x 60 ml]	ME4691
51085303	Biotrue® Multi-purpose Solution 300 ml	ME2771
		ME2783
		ME3304
		ME3697
		ME4244
51085304	Biotrue® Multi-purpose Solution 60 ml	MF1832
31085314	Boston® Advance Cleaner 30 ml	ME4686
		MF0436
31084357	Boston® Advance Conditioning Solution 120 ml	ME2172
		ME2841
		ME3406
31083708	Boston® Simplus Multi-Action Solution 120 ml	ME4140
		ME4420
		ME4538
		MF1870
51085415	EasySept® Peroxide Solution 360 ml	ME4264
6220830	Lens Lubricant® 15 ml	ME3185
623925	Renu® MultiPlus Solution 120 ml	ME2502
		ME3679
		ME4452
		MF0639
		MF2429
		MF3868
2004R Bundle	Renu® MultiPlus Solution 240 ml (1 x 2)	BLBP-00026
2017W Bundle	Renu® MultiPlus Solution 240 ml (1 x 3)	BLBP-00027
623924	Renu® MultiPlus Solution 240 ml	ME2358.B
		ME3254
		ME4547
		MF1446
		MF1854
		ME2449
		MF0370
3012R Bundle	Renu® MultiPlus Solution 360 ml + 240 ml	BLBP-00030
623923	Renu® MultiPlus Solution 360 ml	ME3086
		ME4569
		ME5133
		MF1735
		MF2284
629805	Renu® MultiPlus Solution 60 ml	ME2295
623928	Renu® Multi-Purpose Solution 120 ml	MF1496

B+L Code	Product Name	LOT Number
		ME1920
623927	Renu® Multi-Purpose Solution 240 ml	ME2443
623927	Renu® Multi-Purpose Solution 240 ml	ME3429
		ME4152
		ME4653
		ME4974
		MF1717
1002R Bundle	Renu® Multi-Purpose Solution 240 ml (1 x 2)	BLBP-00034
2018W Bundle	Renu® Multi-Purpose Solution 240 ml (1 x 3)	BLBP-00033
623926	Renu® Multi-Purpose Solution 360 ml	ME3915
		ME4531
		MF0615
		MF1740
1000R Bundle	Renu® Multi-Purpose Solution 360 ml (1 x 2)	BLBP-00035
3033R Bundle	Renu® Multi-Purpose Solution 360 ml + 240 ml	BLBP-00028
		BLBP-00032
629807	Renu® Multi-Purpose Solution 60 ml	ME2410
		ME3603
629808	Renu® Multi-Purpose Solution Flight Pack [2 x 60 ml]	ME3221
		ME4309
		ME4580
		MF1469
		MF2085
51082573	Saline Plus® Solution 360 ml	ME2461
		MF1538

Product Descriptions

BIOTRUE® MULTI-PURPOSE SOLUTION is a sterile solution containing Hyaluronan, sulfobetaine, poloxamine, boric acid, sodium borate, edetate disodium, sodium chloride; preserved with polyaminopropyl biguanide 0.00013% and polyquaternium 0.0001%.

BOSTON® ADVANCE CLEANER is a sterile, concentrated, homogeneous surfactant solution containing alkyl ether sulfate, ethoxylated alkyl phenol tri-quaternary cocoa-based phospholipid and silica gel as cleaning agents; with titanium dioxide.

BOSTON® ADVANCE CONDITIONING SOLUTION is a sterile, aqueous, buffered, slightly hypertonic solution containing a cationic cellulose derivative polymer, cellulosic viscosifier, polyvinyl alcohol and derivatized polyethylene glycol as wetting and cushioning agents; preserved with chlorhexidine gluconate (0.003 %), polyaminopropyl biguanide (0.0005%) and edetate disodium (0.05%).

BOSTON® SIMPLUS MULTI-ACTION SOLUTION is a sterile, aqueous, buffered solution that contains poloxamine, hydroxyalkylphosphonate, borate acid, sodium borate, sodium chloride,

hydroxypropylmethyl cellulose, glucam and preserved with chlorhexidine gluconate (0.003%), polyaminopropyl biguanide (0.0005%).

EASYSEPT® PEROXIDE SOLUTION is a sterile and buffered 3 % hydrogen peroxide solution with a phosphonic acid stabilizer, sodium chloride and phosphate buffers.

RENU® MULTIPLUS SOLUTION is a sterile, isotonic solution that contains HYDRANATE (hydroxyalkylphosphonate) 0.03%, boric acid, edetate disodium, poloxamine 1%, sodium borate and sodium chloride; preserved with DYMED (polyaminopropyl biguanide) 0.0001%.

RENU® MULTI-PURPOSE SOLUTION is a sterile, isotonic solution that contains boric acid, edetate disodium, poloxamine 1%, sodium borate and sodium chloride; preserved with DYMED (polyaminopropyl biguanide) 0.0005%.

SALINE PLUS® SOLUTION is a sterile, isotonic buffered solution that contains boric acid, sodium borate, potassium chloride, sodium chloride, preserved with DYMED® (polyaminopropyl biguanide) 0.00003%, and disodium edetate.

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****IMPORTANT NOTE: This notice needs to be passed on to all those who need to be aware within your supply chain 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 MEDICAL DEVICE RECALL CUSTOMER REPLY FORM

This is to acknowledge receipt of the above referenced recall notification dated May 24, 2021.

Product Details:

Bausch + Lomb is recalling only the lots outlined in this letter (see Annexure 1) for Biotrue® Multi-Purpose Solution, Boston® Advance Cleaner, Boston® Advance Conditioning Solution, Boston® Simplus Multi-Action Solution, EasySept® Peroxide Solution, Lens Lubricant®, ReNu® Multi-Purpose Solution, ReNu® MultiPlus Solution and Saline Plus® Solution.

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

☐ We have reviewed the attached Medical Device Recall 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.

Product Name	LOT Number	Quantity Returned	Invoice number
Biotrue® Multi-purpose Solution Flight Pack [2 x 60 ml]	ME4691		
Biotrue® Multi-purpose Solution 300 ml	ME2771		
	ME2783		
	ME3304		
	ME3697		
	ME4244		
Biotrue® Multi-purpose Solution 60 ml	MF1832		
Boston® Advance Cleaner 30 ml	ME4686		
	MF0436		
Boston® Advance Conditioning Solution 120 ml	ME2172		
	ME2841		
	ME3406		
Boston® Simplus Multi-Action Solution 120 ml	ME4140		
	ME4420		
	ME4538		
	MF1870		
EasySept® Peroxide Solution 360 ml	ME4264		
Lens Lubricant® 15 ml	ME3185		
Renu® MultiPlus Solution 120 ml	ME2502		
	ME3679		
	ME4452		
	MF0639		
	MF2429		
	MF3868		
Renu® MultiPlus Solution 240 ml (1 x 2)	BLBP-00026		
Renu® MultiPlus Solution 240 ml (1 x 3)	BLBP-00027		
Renu® MultiPlus Solution 240 ml	ME2358.B		
	ME3254		

Product Name	LOT Number	Quantity Returned	Invoice number
	ME4547		
	MF1446		
	MF1854		
	ME2449		
Renu® MultiPlus Solution 240 ml	MF0370		
Renu® MultiPlus Solution 360 ml + 240 ml	BLBP-00030		
Renu® MultiPlus Solution 360 ml	ME3086		
	ME4569		
	ME5133		
	MF1735		
	MF2284		
Renu® MultiPlus Solution 60 ml	ME2295		
Renu® Multi-Purpose Solution 120 ml	MF1496		
	ME1920		
Renu® Multi-Purpose Solution 240 ml	ME2443		
	ME3429		
	ME4152		
	ME4653		
	ME4974		
	MF1717		
Renu® Multi-Purpose Solution 240 ml (1 x 2)	BLBP-00034		
Renu® Multi-Purpose Solution 240 ml (1 x 3)	BLBP-00033		
Renu® Multi-Purpose Solution 360 ml	ME3915		
	ME4531		
	MF0615		
	MF1740		
Renu® Multi-Purpose Solution 360 ml (1 x 2)	BLBP-00035		
Renu® Multi-Purpose Solution 360 ml + 240 ml	BLBP-00028		
	BLBP-00032		
Renu® Multi-Purpose Solution 60 ml	ME2410		
	ME3603		
Renu® Multi-Purpose Solution Flight Pack [2 x 60 ml]	ME3221		
	ME4309		
	ME4580		
	MF1469		
	MF2085		
Saline Plus® Solution 360 ml	ME2461		
	MF1538		

I hereby certify that I have removed all products impacted by this recall from my inventory to prevent further sale and use and will contact Sedgwick to arrange pickup of the identified products and for Return Material Authorization instructions.

Date

Name (Print)

Bausch + Lomb Account Number

Signature

Facility Name

Telephone Number

Please complete, sign and return this form to:

Email: BLRecall@Sedgwick.com **or Fax:** +44-20-8705-0539

For questions regarding this notice, please call Sedgwick at 080 099 4885.

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.

- ATTENTION CONSUMERS -

Bausch + Lomb is voluntarily recalling certain lots of its contact lens solutions and eye lubricants.

Only Bausch + Lomb products manufactured in Italy are affected.

This product recall follows a notification received by Bausch + Lomb from one of its third-party suppliers in Milan, Italy, which sterilizes some components (bottles, plugs, and caps) of these products prior to manufacturing, of a compliance issue with its sterilization process. Bausch + Lomb is one of many companies impacted by this situation.

While there is a low risk of infection with these products, Bausch + Lomb has chosen to voluntarily recall these certain lots of products because it cannot confirm the supplier's conformance to process compliance requirements for some of the components of these products.

To learn more, please use the QR code below or visit
BLRecall.expertinquiry.com

