

## Urgent Safety Information

Recall

for

REF SUJ14 25GA Backflush/ Extrusion Handpiece blunt, 6/Box

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Date: 02.12.2020

Sender: Bausch + Lomb GmbH  
Im Schuhmachergewann 4  
D-69123 Heidelberg

**To healthcare professionals who use this product:**

**Dear Sir or Madam,  
we would like to inform you about the following recall:**

**Affected products:** REF SUJ14 25GA Backflush/ Extrusion Handpiece blunt, 6/Box

Lot HD2007193

Lot HD2008208

Lot HD2008216

Product category: Non-active ophthalmologic Products

**Field of application:**

The Backflush Extrusion Handpieces are terminally sterilized single use instruments for fluid handling in vitreoretinal surgery.

**Description of the problem:**

There was feedback that the 25GA handpiece did not fit through the 25GA trocar system.

The recall for these 3 affected lot numbers is made because some packages of the affected lots may contain a 23GA handpiece. This handpiece has a larger cannula diameter. The 23GA handpiece cannot be inserted through the 25GA trocar system.

The 23GA handpiece contains the wrong color coding, the blue O-ring, but the cannula has the larger diameter of 23GA.



## Health Hazard Evaluation

### Summary:

No direct harm to the patient is expected, except that the patient's wound healing may take longer than it would when using a smaller trocar, provided the surgeon decides to continue with the 23GA trocar.

In cases of retinal detachment, where surgery can be time-consuming, discontinuation of surgery could be critical, if the surgeon decides to abort the operation due to the unavailability of appropriate instruments.

In cases where the problem is not detected until after the surgery has begun, delaying the surgery may result in postoperative infection or hypotension.

The overall risk is assessed to be low to moderate.

### One sample for product labeling with lot number:

Labeling on the blister:

**BAUSCH+LOMB**

Bausch & Lomb GmbH  
Im Schuhmachergewann 4  
D-69123 Heidelberg  
Germany

2020-07 Distributed by:  
Bausch & Lomb Incorporated  
Rochester NY 14609 U.S.A.

**1 REF SUJ14**

**LOT HD2007193** 2023-06

EN 25GA Backflush/Extrusion Handpiece blunt	LT 25GA praplovimo/išspaud. įrankis, bukas
DE 25GA Staubsauger/Extrusions Hdck stumpf	NL 25G Zuiger/extrusie handstuk stomp
AR 25GA بخاف/انسراج كنبه 25GA	NO 25G Backflush/ekstrusion, sløv
BG 25GA Напр. за обрат. ириг./екструз., тъл	PL 25GA Głowica do przepl./ekstruzji, tępa
CS 25GA rukojeť pro odsávání/extruzi, tupá	PT 25G Cabo p/ Refluxo/Extrusão rombo
DA 25G Backflush/ekstrusion, stump	RO 25GA P. man. spâl. contrac./extr. teșită
EL 25GA Εργ. χειρ. αντρία έκπρ/εξωθ., αμβλύ	RU 25GA Экструз.након. с обр.продув., туп.
ES 25G extrusión/backflush punta roma	SK 25GA odsávacia/extrúzn. rúčka tupá
ET 25GA vastuvoolu/ekstrusiooni otsik tõmp	SL 25G rokováč vysávaca/vytlačania, tupá
FI 25G Backflush-/ekstrusio typpä	SR 25GA ručka za usis./istiskivanje tupá
FR 25G Backflush/Extrusion, embout mousse	SV 25G Backflush/extrusion, trubbig
HR 25GA Povr. ispir./izl. ruč. Instr. tupi	TR 25GA Ters Yıkama/Çıkarma El aleti kör
HU 25GA tompa visszaöbl./kipréselő kézidb.	UK 25GA наконечник звор.пром./екструз. туп.
IS 25GA baksóts/útsóts áhald stjótt	ZH 25GA 反冲/挤出手柄，钝端
IT 25G backflush/estrusione smusso	

Rx ONLY **STERILE** R **CE 0197** V02.01

Labeling on the cardboard packaging:



**Bausch & Lomb GmbH**  
Im Schuhmachergewann 4  
D-69123 Heidelberg  
Germany

Distributed by:  
**Bausch & Lomb Incorporated**  
Rochester NY 14609 U.S.A.

**6 REF SUJ14**

2023-06    **LOT HD2007193**    **CE 0197**

EN	25GA Backflush/Extrusion Handpiece blunt
DE	25GA Staubsauger/Extrusions Hdck stumpf
AR	يد شطف/التراجع كلبه 25GA
BG	25GA Накр. за обрат. ириг./екструз., туп
CS	25GA rukojet' pro odsávání/extruzi, tupá
DA	25G Backflush/ekstrusion, stump
EL	25GA Εργ. χειρ. αντίστροφο/εξώθ., αμβλύ
ES	25G extrusión/backflush punta roma
ET	25GA vastuvoolu/ekstrusiooni otsik tõmp
FI	25G Backflush-/ekstrusio tyypä
FR	25G Backflush/Extrusion, embout mousse
HR	25GA Povr. ispir./izl. ruč. instr. tupi
HU	25GA tompa visszaöbl./kípréselő kézídb.
IS	25GA bakskols/útskols áhald sljött
IT	25G backflush/estrusione smusso
LT	25GA praplovimo/išspaud. įrankis, bukas
NL	25G Zuiger/extrusie handstuk stomp
NO	25G Backflush/ekstrusion, sløv
PL	25GA Glowica do przepł./ekstruzji, tępa
PT	25G Cabo p/ Refluxo/Extrusão rombo
RO	25GA P. man. spāl. contrac./extr. teșită
RU	25GA Экструз.након. с обр.продув., туп.
SK	25GA odsávacia/extrúz. rúčka tupá
SL	25G rukovät vysávac/vylácania, tupá
SR	25GA ručka za usis./istiskivanje tupa
SV	25G Backflush/extrusion, trubbig
TR	25GA Ters Yıkama/Çıkarma El aleti kör
UK	25GA наконечник звор.пром./екструз. туп.
ZH	25GA 反冲/挤出手柄，钝端

[01]24058935005669

[17]230600[10]HD2007193

**Sterile Single Use Only**

85 V03.01

**STERILE R**



**Rx ONLY**

The lot numbers concerning the recall are:

Lot HD2007193    Lot HD2008208    Lot HD2008216

## Measures to be initiated:

### 1. Quarantine or separate the product:

- Please separate the packages of the Lots HD2007193, HD2008208 and HD2008216
- Affected products must be quarantined.
- We will then ask you to fill out the quarantine confirmation form for the affected products as well as the number of affected units per lot in your inventory
- Please send the form to Bausch + Lomb Customer Service within one week (date: 10-12-2020):

**Facsimile: 01805 90 94 90 94**

**Email: [kundenservice@bausch.com](mailto:kundenservice@bausch.com)**

**Phone: 0800 58 93 114**

- Please copy the confirmation form and enclose this copy with the separated goods.

### 2. Return the product:

- Send all packages of lots HD2007193, HD2008208, and HD2008216 along with a copy of the confirmation form as soon as possible, but no later than 31.12.2020, to the following address:

**Bausch + Lomb GmbH**

Quality Management

Im Schuhmachergewann 4

69123 Heidelberg

Germany

Please ensure that all persons in your organization who have a need to be informed are aware of this "Urgent Safety Information". Please retain this information at the least until the action has been completed.

The "Bundesinstitut für Arzneimittel und Medizinprodukte" (Federal Institute for Drugs and Medical Devices) has received a copy of this "Urgent Safety Information".

The decision to carry out this recall is part of our commitment to quality and satisfaction of our customers. We apologize for any inconvenience and assure you that we are working hard to complete the present recall as quickly as possible.

If you have any questions, you can reach us at:

**Phone: 0800 58 93 114**    **Email: [kundenservice@bausch.com](mailto:kundenservice@bausch.com)**

Kind regards,

Sabine Kaufmann  
Safety Officer MPG

**Bausch & Lomb GmbH**  
Im Schuhmachergewann 4  
69123 Heidelberg

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[www.storzeye.eu](http://www.storzeye.eu)

Geschäftsführer  
Eberhard Kühne  
William Woodfield

Amtsgericht Charlottenburg  
HRB 26283  
St.-Nr.37/004/49773  
USt-IdNr. DE811322707

## QUARANTINE CONFIRMATION FORM (page 1 of 2)

REF SUJ14 25GA Backflush/ Extrusion Handpiece blunt, 6/Box

Lot HD2007193

Lot HD2008208

Lot HD2008216

Legal Manufacturer: Bausch + Lomb GmbH Heidelberg

We would like to ask you to confirm whether products with the listed lot numbers are in your stock and to first quarantine and then return them to us.

In this case, we ask you to refrain from returning them via the wholesaler.

Of course, upon receipt of your return regarding the recall, a credit note of 100% will be initiated accordingly.

Product	Lot Number	Received units in 6/box	Units used in pieces	Units in stock in pieces	Signature of the responsible person
SUJ14	HD2007193				
SUJ14	HD2008208				
SUJ14	HD2008216				

How many boxes do you expect to return?

Please enter the estimated number of shipping cartons to be returned here: \_\_\_\_\_

For the return shipment please use the service provider UPS. If you have any questions about shipping, please visit the UPS website at:

<https://www.ups.com>

Use the account number below for free shipping with UPS.

**UPS Account number: E95445**

## QUARANTINE CONFIRMATION FORM (page 2 of 2)

- I hereby confirm that the above products have been quarantined as a precautionary measure and that they will be returned.
- I hereby confirm that none of the above mentioned products are in stock.

\_\_\_\_\_  
Name of the institution

\_\_\_\_\_  
Phone number

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name

\_\_\_\_\_  
Bausch + Lomb Customer number

\_\_\_\_\_  
Signature

**Please return the completed and signed confirmation form by fax or email to:**

**Fax: 01805 90 94 90 94**

**Email: [kundenservice@bausch.com](mailto:kundenservice@bausch.com)**

**Please make copy this confirmation form and include it with the return shipment.**