FSCA-Ref: CAC-2024-001

Bausch + Lomb GmbH · Lilienthalstrasse 16,18 · 69214 Eppelheim

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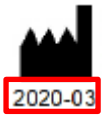
Urgent safety information
Handling instructions
concerning
Corneal Irrigator, 82020S

July 2024

Bausch & Lomb GmbH
Lilienthalstr. 16, 18
69214 Eppelheim

For the attention of ophthalmological professionals

Identification of the medical device concerned:
Corneal Irrigator, article number: 82020S
All lot numbers with a production date from July 2023 to November 2023 are affected.



The production date can be found next to this symbol on the label.

Dear Customer,

Description of the problem including the identified cause:

A corneal irrigator from one of the affected lots had burrs on the head of the irrigator. These burrs are very small and cannot be seen with the naked eye:

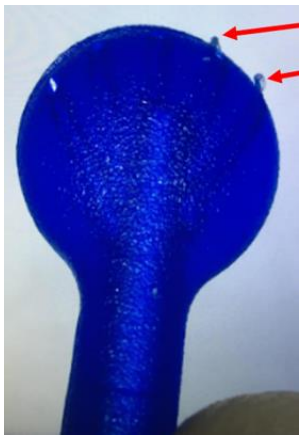


Fig 1: Burr on corneal irrigator

There was one case of corneal erosion following contact of the eye by the instrument tip, which might have been related to the contact with the burr. If the corneal irrigator is used in such a way

that there is physical contact with the eye, e.g. by accidentally touching the cornea, there is a risk of the cornea being injured by the burrs or the irrigator.

For patients who have already been treated with a potentially affected irrigator, there is no further risk if there was no injury after the operation.

What measures should be taken by the user?

Within the scope of its intended use, the Corneal Irrigator is intended for irrigation of the eye, whereby no physical eye contact is involved. Contact with the cornea occurs either accidentally or through use outside of the intended purpose of the instrument. The product should always be used at a sufficient distance from the eye to avoid contact. It is only intended for superficial irrigation of the eye with Balanced Saline Solution. As long as the product is used within its intended purpose, it can be used safely despite any burrs.

Passing on the information described here:
Please ensure in your organisation that all users of the above-mentioned products and other persons to be informed are made aware of this Urgent Safety Information. If you have supplied the products to third parties, please forward a copy of this information or inform the contact person listed below.
Please keep this information at least until the action has been completed. The Federal Institute for Drugs and Medical Devices (BfArM) has received a copy of this "Urgent Safety Information".

The competent authority in your country has been informed of this safety notice.

We regret the inconvenience caused by this measure and thank you for your understanding to ensure the safety of our patients and the satisfaction of our customers.

Please fill the form on page 3 and return to the indicated address on the form within 5 business days. If you have any questions or require assistance with the implementation of this safety notice, please contact Sebastian Froehlich-Itte, phone: +49(0) 6221 823 204.

Yours sincerely

Sebastian Froehlich-Itte
Bausch & Lomb GmbH
Deputy Quality Site Lead

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Urgent Safety Information
Confirmation form

We hereby confirm that we have received the above field safety notice.

We confirm that the content was understandable and that we have no further questions regarding the safe use of the Corneal Irrigator:

☐ We have no further questions about safe use

Details of the person completing the form:

Name of the clinic/doctor's surgery	
Name of the person completing the form	
Street and house number	
Postcode and town	
Date, signature	

Send the filled form to:

Storz-Instruments@bausch.com

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