BAUSCH + LOMB

URGENT FIELD SAFETY NOTICE

Stellaris Elite™ Single Port Vitrectomy Cutters in Gauge Sizes 20, 23, and 25

August XX, 2018

Dear Valued Bausch + Lomb Customer,

Bausch + Lomb is conducting globally a voluntary recall of 60 lots of Stellaris Elite™ single port vitrectomy cutters in gauge sizes 20, 23, and 25. A complete list of lots impacted by this voluntary recall is included (see page 4).

We are initiating this recall after having received a limited number of customer reports of the back cap separating from the body of the cutter during surgery. No related adverse events have been reported to date in association with this issue. However, separation of the back cap during surgery could potentially cause unintended movement of the handpiece, possibly leading to patient injury.

We are committed to ensuring that all of our products meet the highest standards of quality and take matters such as this very seriously, which is why we are taking this voluntary action.

QUARANTINE PRODUCT AND RETURN TO BAUSCH + LOMB

According to our records, your facility may have a supply of product from the lots included in this voluntary recall. We ask that you please cease use of any product impacted from these lots immediately and take the following steps to return the product to Bausch + Lomb at our company's expense:

1. Please review your inventory and hold all boxes of Stellaris Elite™ single port vitrectomy cutters in gauge sizes 20, 23, and 25 from the lots impacted by this voluntary recall (see page 4). Below is an example of a label, which contains the lot number (highlighted in red) to identify the product.

2. Please complete the enclosed Recall Acknowledgement Form return this Acknowledgement Form even if you do not have any Stellaris Elite™ single port vitrectomy cutters in your inventory to **<to be completed by country representative>.**

IMPORTANT NOTE: No other Bausch + Lomb products are affected by this action.

If you have questions about this voluntary recall or would like to request replacement product, please contact the Bausch + Lomb Surgical Customer Service team by calling **<to be completed by country representative>.**

The decision to conduct this voluntary recall is part of our commitment to quality and customer satisfaction. We greatly appreciate your understanding and prompt assistance and apologize for any inconvenience this may have caused.

Sincerely,

Name
Function
<to be completed by country representative>.

BAUSCH + LOMB

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Acknowledgement Form

This form is to acknowledge receipt of the above referenced medical device voluntary recall notification regarding Stellaris Elite™ single port vitrectomy cutters, dated August XX, 2018.

PRODUCT DETAILS

Stellaris Elite™ single port higher speed vitrectomy cutters in gauge sizes 20, 23, and 25

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

❑ We have reviewed the attached Bausch + Lomb Voluntary Drug Product Recall notification and acknowledge the alert.

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

❑ We do not have Stellaris Elite™ single port vitrectomy cutters in gauge sizes 20, 23, and 25 in our inventory from the lots impacted by this voluntary recall.

❑ We do have Stellaris Elite™ single port vitrectomy cutters in gauge sizes 20, 23, and 25 in our inventory from the lots impacted by this voluntary recall. If checked, please fill out chart below.

Please confirm inventory levels of the affected product identified in your facility:

Lot No.	No. Received	No. Returned

I hereby certify that I have quarantined the above listed product to prevent use and am awaiting pick up by a Bausch + Lomb representative or agent.

_____ _____

Date Name (Print)

_____ _____ _____

Bausch + Lomb Account Number Signature

_____ _____

Facility Name Telephone Number

Please complete, sign and return this form to:

<to be completed by country representative>.

Confidentiality Agreement: The information contained in this facsimile message is privileged and confidential information intended for the use of the addressee 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

URGENT MEDICAL DEVICE VOLUNTARY RECALL

List of Stellaris Elite™ Single Port Vitrectomy Cutters Impacted

V9300	W0870
V9301	W0871
V9400	W0874
V9401	W1002
V9708	W1003
W9807	W1019
W0019	W1108
W0147	W1106
W0148	W1107
W0149	W1108
W0157	W1115
W0188	W1116
W0189	W1129
W0190	W1222
W0191	W1223
W0781	W1224
W0782	W1225
W0783	W1226
W0784	W1258
W0785	W1259
W0786	W1260
W0787	W1365
W0788	W1366
W0861	W1439
W0862	W1467
W0863	W1468
W0869	W1659
W0872	W1660
W0873	W1675
W0888	W1721