

## URGENT MEDICAL DEVICE VOLUNTARY RECALL

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

August 6, 2018

Dear Valued Bausch + Lomb Customer,

Bausch + Lomb is conducting a voluntary recall in the Singapore of 6 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** and contact Customer Service at 6725 8010 and arrange for a pickup of the identified product. **We ask that you please return this Acknowledgement Form even if you do not have any Stellaris Elite™ single port**

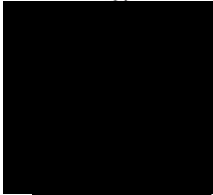
**vitrectomy cutters in your inventory.**

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

If you have questions about this voluntary recall, please contact the Bausch + Lomb Regulatory Affairs  
603 8610 7020.

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,



Khor Cherng Yeh  
Regulatory Affairs Manager  
Bausch & Lomb (Singapore) Pte Ltd

*Stellaris Elite is a trademark of Bausch & Lomb Incorporated or its affiliates.  
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SEP.0031.USA.18 (Singapore)*

cc: Chairman Medical Board and relevant Head of Departments

## URGENT MEDICAL DEVICE VOLUNTARY RECALL

### 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 06, 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 (units)	No. Returned (units)	Remark

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:

Fax: 603 8601 7001

Phone: 603 8601 7020

Email: [REDACTED]

**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



**URGENT MEDICAL DEVICE VOLUNTARY RECALL**

**List of Stellaris Elite™ Single Port Vitrectomy Cutters Impacted Globally**

Lot Numbers	V9300	W0872
	V9301	W0873
	V9400	W0874
	V9401	W0888
	V9708	W1002
	V9807	W1003
	W0019	W1019
	W0147	W1105
	W0148	W1106
	W0149	W1107
	W0157	W1108
	W0188	W1115
	W0189	W1116
	W0190	W1129
	W0191	W1222
	W0781	W1223
	W0782	W1224
	W0783	W1225
	W0784	W1226
	W0785	W1258
	W0786	W1259
	W0787	W1260
	W0788	W1365
	W0861	W1366
	W0862	W1439
	W0863	W1467
	W0869	W1468
	W0870	W1675
	W0871	W1721

**List of Stellaris Elite™ Single Port Vitrectomy Cutters Impacted in Singapore**

Lot Numbers	V9400
	V9401
	V9708
	W0019
	W0781
	W1107