

## URGENT FIELD SAFETY NOTICE

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

August 07, 2018

Dear Valued Bausch + Lomb Customer,

Bausch + Lomb is conducting a global 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).

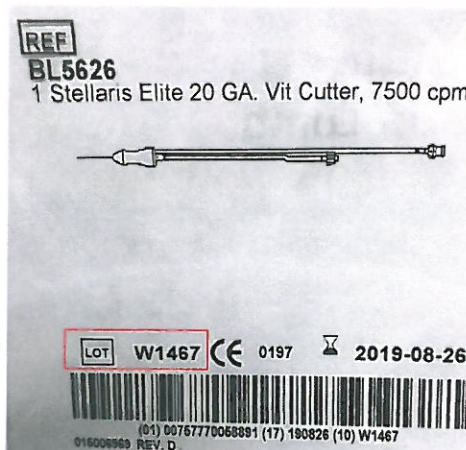
We are initiating this recall after having received a limited number of customer reports of the back cap separating from the body of the cutter during surgery. No related adverse events have been reported to date in association with this issue. However, separation of the back cap during surgery could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



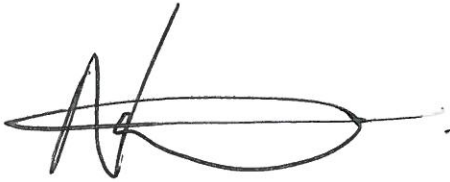
2. Please complete and return the enclosed Recall Acknowledgement Form even if you do not have any Stellaris Elite™ single port vitrectomy cutters in your inventory to [UKPricing.UKPricing@bausch.com](mailto:UKPricing.UKPricing@bausch.com).
3. Keep product quarantined until details are provided on how to return product.

**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 020 8781 0000.

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,

A handwritten signature in black ink, appearing to read 'Nick Meakin', with a stylized flourish extending to the right.

Nick Meakin  
Head of Customer Services UK and Ireland

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## URGENT FIELD SAFETY NOTICE Acknowledgement Form

This form is to acknowledge receipt of the above referenced voluntary medical device recall notification regarding Stellaris Elite™ single port vitrectomy cutters, dated August 07, 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 Medical Device 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:

Product Code	Lot No.	No. Received	No. Returned

I hereby certify that I have quarantined the above listed product to prevent use and I am awaiting details of how to return the product.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name (Print)

\_\_\_\_\_  
Bausch + Lomb Account Number

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Facility Name

\_\_\_\_\_  
Telephone Number

Please complete, sign and return this form to:

[UKPricing.UKPricing@bausch.com](mailto:UKPricing.UKPricing@bausch.com)

**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 MEDICAL DEVICE VOLUNTARY RECALL**  
**List of Stellaris Elite™ Single Port Vitrectomy Cutters Impacted**

Product Code	Lot Number
BL5627	V9300
BL5628	V9301
BL5626	V9400
BL5628	V9401
BL5628	V9708
BL5627	V9807
BL5627	W0019
SE5423MV	W0147
SE5423WV	W0148
SE5425MV	W0149
SE5425WV	W0157
SE5423MV	W0188
SE5423WV	W0189
SE5425MV	W0190
SE5425WV	W0191
SE5423MV	W0781
SE5423WV	W0782
SE5523MV	W0783
SE5523WV	W0784
SE5425MV	W0785
SE5425WV	W0786
SE5525MV	W0787
SE5525WV	W0788
SE5420M	W0861
SE5420W	W0862
SE5520M	W0863
SE5520W	W0869
SE5523MV	W0872
SE5523WV	W0873
SE5525MV	W0888

Product Code	Lot Number
SE5423MV	W0870
SE5423WV	W0871
SE5425MV	W0874
SE5423WV	W1002
SE5525MV	W1003
BL5628	W1019
SE5425MV	W1108
SE5423WV	W1106
SE5523MV	W1107
SE5425MV	W1108
SE5420M	W1115
SE5425MV	W1116
SE5525MV	W1129
SE5525MV	W1222
SE5423WV	W1223
SE5523MV	W1224
SE5425WV	W1225
SE5525MV	W1226
SE5423MV	W1258
SE5423WV	W1259
SE5523MV	W1260
SE5523MV	W1365
SE5525MV	W1366
BL5626	W1439
BL5626	W1467
BL5627	W1468
SE5420W	W1659
SE5520M	W1660
BL5628	W1675
SE5423MV	W1721