



Bausch & Lomb (Singapore) Private Limited
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Singapore 408600
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[CUSTOMER NAME]
[ADDRESS LINE 1]
[ADDRESS LINE 2]

MEDICAL DEVICE VOLUNTARY PRODUCT RECALL

LaserEdge® Knives

March 06, 2017

Dear Valued Bausch + Lomb Customer,

Bausch + Lomb is conducting a voluntary recall of LaserEdge® knives due to an increase in complaints of a dull knife edge. 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 action.

Through the complaint trending program it has been determined that the following LaserEdge Surgical Knives may have demonstrated higher than normal complaints for dull knives.

If excessive force is required to push a dull knife through the cornea, this may result in:

- 1) Sub-optimal incision shape, such as short tunnel or lack of multi-plane beveling. The consequence may be incisions that are not watertight, requiring sutures, or inducement of corneal astigmatism.
- 2) Uncontrolled penetration through the cornea resulting in injury to anterior segment structures, such as iris, capsule, or lens.

The likelihood of adverse events associated with dull blades is very low (5 ppm). This is due to the fact that surgeons are trained to avoid applying excessive force to the eye, thereby mitigating the potential risk from dull blades.

It has come to our attention that some boxes of LaserEdge® Knives have not been as sharp as previous lots of this product. Please review carefully the notes outlined in this letter regarding your LaserEdge® Knives.

According to our records, your facility may have a supply of LaserEdge® that is impacted by this recall. A complete list of affected lots is attached at the end of this letter. Additionally the recall acknowledgment form will be prefilled with the recall lots that your facility has ordered.

We ask that you please quarantine any unused boxes (full and partial) 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 unused (full and partial) boxes of LaserEdge knives (6/Box or individual packaged knives) from the following lots.

See below an example of a LaserEdge product label for ease in identifying the product.



Tyvek Lid

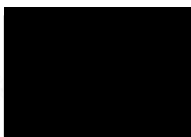
2. Please complete the enclosed Recall Acknowledgement Form and contact Bausch + Lomb representative to arrange for a pickup of the identified product.

Please contact the Bausch + Lomb team with any questions or concerns regarding this process:

1. Khor Cherng Yeh, Regulatory Affairs Manager (+603-76808821, ch.khor@inovapharma.com)
2. Oh Sern Siong, Surgical Sales Manager (+65 97727789, SernSiong.Oh@bausch.com)
3. [Rep contact]

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,



GRACE GUANG
MANAGING DIRECTOR
BAUSCH & LOMB (SINGAPORE) PRIVATE LIMITED

*LaserEdge is a trademark of Bausch & Lomb Incorporated or its affiliates.
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CC: [Chairman Medical Board]
[Hospital]

[CUSTOMER NAME]
[ADDRESS LINE 1]
[ADDRESS LINE 2]

Recall Acknowledgement Form

This is to acknowledge receipt of the above referenced recall notification dated March, 06, 2017.

Product Details:

LaserEdge® Knives (6/Box or individually)

Please confirm inventory levels of the affected product at your facility with the 7-digit lot numbers:

Product Code	Lot #	# Received	# Used	# in inventory/to be returned
[code]	[lot#]	[qty]		
[code]	[lot#]	[qty]		
[code]	[lot#]	[qty]		
[code]	[lot#]	[qty]		
[code]	[lot#]	[qty]		
[code]	[lot#]	[qty]		
[code]	[lot#]	[qty]		
[code]	[lot#]	[qty]		

To arrange for a pickup of the identified product, please **call the Bausch + Lomb Customer Service team at Telephone: 1800 278 1421 or email: Esther.Tan@bausch.com**

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)

Company Stamp

Signature

Please complete, sign and return this form to Bausch & Lomb representative, or

Fax: (65) 6725 8010

Email: Esther.Tan@bausch.com

[customer code]