Valeant Pharmaceuticals International, Inc.
400 Somerset Corporate Boulevard, Bridgewater, NJ 08807

Tel: 908-927-1400, Fax: 908-927-1856
www.valeant.com

February 15th, 2017

Urgent Field Safety Notice

MEDICAL DEVICE VOLUNTARY PRODUCT RECALL
AND FIELD CORRECTION TO LaserEdge® Knives with an Expiration Period from July 2020 to May 2021

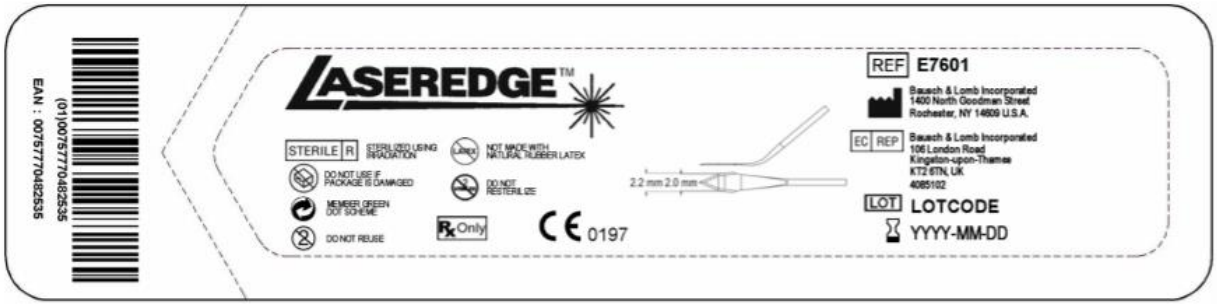
PLEASE FORWARD THIS INFORMATION TO ALL USERS AND STAFF WHO MAY USE TO LASEREDGE KNIVES PRODUCTS manufactured by Angiotech (Surgical Specialties)

FSCA-identifier: CAC-2016-006 - LaserEdge® Knives from date 15.02.2017
Type of Action: VOLUNTARY PRODUCT RECALL

Re: Attached please find the list of lot numbers of affected product shipped
or
for your ease of review all lots expiration date between July 2020 to May 2021 are affected.

Dear Valued Customer,

This is to inform you of a medical device voluntary product recall and field correction involving LaserEdge® knives (expiration period from July 2020 to May 2021) due to an increase in complaints of a dull knife edge.
See below an example of a LaserEdge product label for ease in identifying the product.



During the time period of Jan 2016 – Sept 2016 it has been determined through the complaint trending program that the following LaserEdge Surgical Knives may have demonstrated higher than normal complaints for dull knives. 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.

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.

Surgeons are trained to avoid applying excessive force to the eye, thereby mitigating the potential risk from dull knives. Since May 2016, updated in-process controls and penetration force testing have been implemented. The risk has been evaluated as moderate for patients.

It has come to our attention that some boxes of LASEREDGE Knives 6/Box have not been as sharp as previous lots of this product. Please review carefully the notes outlined in this letter regarding your LASEREDGE Knives 6/Box.
This action represents a voluntary product recall and we have notified the appropriate authority of this voluntary recall.

According to our records, your facility may have a supply of LaserEdge knives that falls within the expiration period from July 2020 to May 2021.

Actions to be taken:

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. **Quarantine the product:** Please review your inventory and hold all unused (full and partial) boxes of LaserEdge knives (6/Box or individual packaged knives) with an expiration period from July 2020 to May 2021.

2. **Return the product:** Please complete the enclosed **Recall Acknowledgement Form** and contact Valeant/Bausch + Lomb to obtain a Return Material Authorization Number (RMA) and arrange for a pickup of the identified product. You can contact the Valeant/Bausch + Lomb Surgical Customer Service team by calling ***XXXXXX (local customer service phone number, email)***, Customer Service (option 2), Product Returns and Adverse Event Reporting (option 2). Customers will be asked in the letter to return the product before 15.03.2017 .

IMPORTANT NOTE: This recall is limited to LaserEdge knives with an expiration period from July 2020 to May 2021 only. It does not affect other lots with expiration dates of June 2021 or later. This also does not affect product with expiration date prior to July 2020.

Please contact the Valeant/Bausch + Lomb Surgical Customer Service team with any questions or concerns regarding this process**: XXXXXX (local customer service phone number, email)**.

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

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,

Signatures

XXXXX

Recall and Field Correction Acknowledgement Form

This is to acknowledge receipt of the above referenced recall and field correction notification dated **February 15th, 2017**

Product Details:
LaserEdge® Knives (6/Box or individually)
Expiration period from **July 2020 to May 2021**

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

Product	Lot #	# Received	# used	# in inventory	Responsible person initials

To obtain a Return Material Authorization Number (RMA) and arrange for a pickup of the identified product, please **call the Surgical Valeant/Bausch + Lomb Customer Service team at XXXXXX (local customer service phone number, email)**, Customer Service (option 2), Product Returns and Adverse Event Reporting (option 2).

☐ I hereby certify that I have quarantined the above listed product to prevent use and am awaiting pick up by a Valeant/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: XXXXXXXX **Email:** XXXXXXXXX

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.