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Urgent Field Safety Notice

MEDICAL DEVICE VOLUNTARY PRODUCT RECALL AND FIELD CORRECTION TO LASEREDGE® KNIVES, ACCORDING TO ATTACHED LIST OF LOT NUMBERS OF THE AFFECTED PRODUCTS

Thursday 23rd February 2017

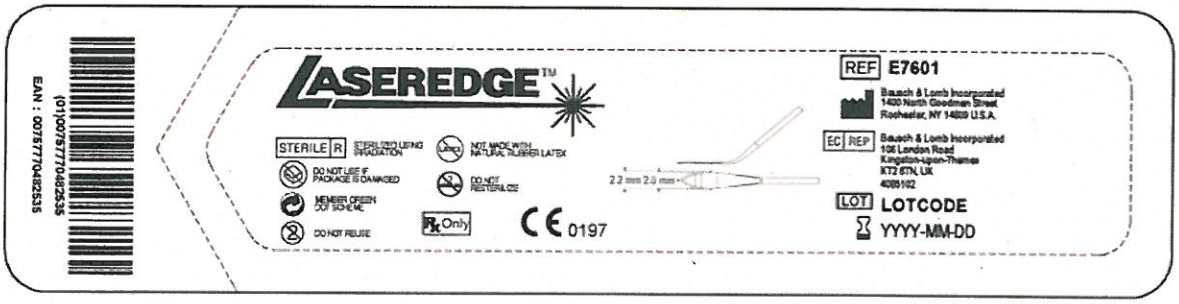
Please forward this information to all users and staff who may use Laseredge® Knives -products manufactured by Angiotech (Surgical Specialties)

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

Dear Valued Customer,

This is to inform you of a medical device voluntary product recall and field correction involving LaserEdge® knives, due to an increase in complaints of a dull knife edge.

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



During the time period of January 2016 – January 2017, it has been determined through the complaint trending program that the 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.

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

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 according to attached a list of Lot numbers of affected products. Please note that only blades in the sealed blister can be returned.

2. **Return the product:** Please complete the enclosed **Recall and Field Correction Acknowledgement Form** and return it to the Customer Services Department at Bausch + Lomb, including all details for the pickup service by UPS (name of your contact person including email address, exact location in your facilities and estimated number of shipper boxes). Once we have received the completed **Recall and Field Correction Form**, we will be in contact to arrange collection of the identified products in your facilities.

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation 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 sincerely apologise for any inconvenience and assure you that we are working diligently to resolve this issue in a timely manner. Should you have any questions or concerns, please feel free to contact customer services on 020 8781 0000 or csd.backoffice@bausch.com.

Yours faithfully,

Duncan Dow
UK/I General Manager

Recall and Field Correction Acknowledgement Form

This is to acknowledge receipt of the above referenced recall and field correction notification dated **February 23rd, 2017**

Product Details:
LaserEdge® Knives (6/Box or individually)
A list of Lot numbers of affected products is attached to this letter

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 Number (RMA) and arrange pick up of the identified products, please complete, sign and return this form to:

Fax: 020 8781 0001 / Email: csd.backoffice@bausch.com

Contact person for communication with UPS: _____
Contact person e-mail address: _____
Pickup location in your facilities: _____
Estimated shipper boxes to be returned: _____

☐ 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.

☐ I hereby certify that I do not have inventory of the Lot numbers of affected products attached to this letter

_____ Date

_____ Name (Print)

_____ Bausch + Lomb Account Number

_____ Signature

_____ Facility Name

_____ Telephone Number