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February 22nd, 2017

# Urgent Field Safety Notice

## MEDICAL DEVICE VOLUNTARY PRODUCT RECALL
## AND FIELD CORRECTION TO LaserEdge® Knives
## according to attached a list of Lot numbers of affected products.

**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 / 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 Jan 2016 – Jan 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 review carefully 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 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 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 sincerely apologies for any inconvenience and assure you that we are working diligently to resolve this recall in a timely manner. Please feel free to contact customer services with any questions or concerns on:

Phone Number 0800 5893 114
Email: kundenservice@bausch.com

Sincerely

[redacted]
[redacted]

[redacted]
[redacted]

# Recall and Field Correction Acknowledgement Form

This is to acknowledge receipt of the above referenced recall and field correction notification dated **February 22nd, 2017**

**Product Details:**
LaserEdge® Knives (6/Box or individually)
A list of Lot numbers of affected products 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 |
|---|---|---|---|---|---|
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To obtain a Return Material Number (RMA) and arrange pick up of the identified products, please complete, sign and return this form to:

Fax: **01805 90 94 90 94** / Email: **kundenservice@bausch.com**

Contact person for communication with UPS: _____
(please provide email 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 quarantined the above listed

_____ _____
Date Name (Print)

_____ _____
Bausch + Lomb Account Number Signature

_____ _____
Facility Name Telephone Number

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