

**VOLUNTARY PRODUCT RECALL
AND FIELD CORRECTION TO LASEREDGE 2.0MM X 2.0MM Trapezoid Angled,
E7601 LOT MAYL350**

January 31, 2017

**Re: Notice of Dull Blades for LASEREDGE 2.0MM X 2.0MM Trapezoid Angled 6/Box
SKU#E7601 Lot MAYL350**

Product Details: 2.0MM X 2.0MM Trapezoid Angled Knife with handle (SKU# E7601 -6 per box)
manufactured by Angiotech (Surgical Specialties)

Product Name: LASEREDGE 2.0MM X 2.0MM Trapezoid Angled 6/Box SKU#E7601

Lot numbers of affected product shipped to you: MAYL350

Dear Valued Customer,

This is to inform you of a medical device voluntary product recall and field correction involving LASEREDGE 2.0MM X 2.0MM TRAPEZOID ANGLED 6/Box, SKU#E7601 Lot MAYL350. See below the enclosed product label for ease in identifying the product at retail level.



Valeant Pharmaceuticals International wants to ensure that our products provide customer satisfaction and ease of use. It has come to our attention that some boxes of LASEREDGE 2.0MM X 2.0MM Trapezoid Angled Knives 6/Box, SKU#E7601 Lot MAYL350 have not been as sharp as previous lots of this product. Please review carefully the notes outlined in this letter regarding your LASEREDGE 2.0MM X 2.0MM Trapezoid Angled Knives 6/Box, SKU#E7601 Lot MAYL350.

This action represents a voluntary product recall and we have notified the appropriate authority of this voluntary recall.

Please take the following steps to ensure the recalled product is handled appropriately:

1. **Quarantine the product:** According to our records, your facility may have a supply of LASEREDGE 2.0MM X 2.0MM Trapezoid Angled Knives 6/Box, SKU#E7601 Lot MAYL350. Please quarantine any unused boxes (full and partial) of the above product that you have in your facility. All unused boxes of LASEREDGE 2.0MM X 2.0MM Trapezoid Angled Knives 6/Box, SKU#E7601 Lot MAYL350 shall be returned to Valeant/B+L distribution center at the address below for a disposal. Customers will be asked in the letter to return the product before 28.02.2017 to VALC for the attention of the QA department

Bausch+Lomb OPS B.V.
Quality Department
Koolhovenlaan 110
1119 NH Schiphol-Rijk
The Netherlands

2. **To obtain replacement product**

To obtain replacement product free of charge please acknowledge receipt of this notification by completing and returning the attached Recall and Field Correction Acknowledgement Form, with the date of this letter's receipt noted.

When completing this form be certain to do the following:

- Count the number of product packages in quarantine and note on the Form.
- Indicate your choice for receiving replacement product
- Fax the Form to 01805 90 94 90 94

We sincerely apologize for any inconvenience and assure you that we are working diligently to resolve this issue in a timely manner. Please feel free to contact customer services with any questions or concerns: 0800 5893 114

Sincerely,

Signatures

Bausch + Lomb Team

Recall and Field Correction Acknowledgement Form

Product Details LASEREDGE 2.0MM X 2.0MM Trapezoid Angled Knives 6/Box, SKU#E7601 Lot MAYL350

This is to acknowledge receipt of the above referenced recall and field correction notification dated

Please confirm inventory levels of the affected cannulas with 4-digit lot numbers at your facility:

Product	Lot #	# Shipped	# used	# in inventory	Responsible person initials
E7601	MAYL350				

If you have inventory of affected E7601, Lot MAYL350 at your facility and would like to receive replacement product, please check the box below :

- I hereby certify that I have returned the existing inventory of E7601, Lot MAYL350 in our facility and ask that replacement product equal to the amount of quarantined product shown above, referencing PO# _____, be shipped to our facility.

_____ Date

_____ Name (Print)

_____ Bausch + Lomb Account Number

_____ Signature

_____ Facility Name

_____ Telephone Number

Please complete, sign and return this Form to:

Fax: 01805 90 94 90 94

Email: kundenservice@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.