

Valeant Pharmaceuticals International, Inc. 400 Somerset Corporate Boulevard, Bridgewater, NJ 08807 Tel: 908-927-1400, Fax: 908-927-1856 www.valeant.com

URGENT VOLUNTARY PRODUCT RECALL AND FIELD CORRECTION TO LASEREDGE 1.5mm X 1.7mm Trapezoid Angled, E7599 LOT MAXZ170

June 27, 2016

Re: Notice of Dull Blades for LASEREDGE 1.5mm X 1.7mm Trapezoid Angled 6/Box SKU#E7599 Lot MAXZ170

<u>Product Details:</u> 1.5mm X 1.7mm Trapezoid Angled Knife with handle (SKU# E7599 -6 per box) manufactured by Angiotech (Surgical Specialties)

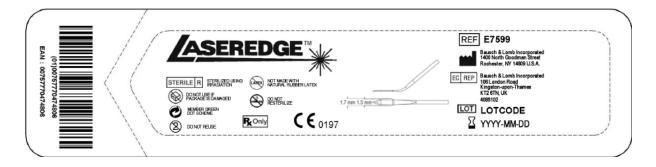
Product Name: LASEREDGE 1.5mm X 1.7mm Trapezoid Angled 6/Box SKU#E7599

Lot numbers of affected product shipped to you: MAXZ170

<u>Please Note</u>: This recall is limited to E7599 Lot# MAXZ170 and does not affect other lots shipped to your facility

Dear Valued Customer,

This is to inform you of a medical device voluntary product recall and field correction involving LASEREDGE 1.5mm X 1.7mm TRAPEZOID ANGLED 6/Box, SKU#E7599 Lot MAXZ170. 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 1.5mm X 1.7mm Trapezoid Angled Knives 6/Box, SKU#E7599 Lot MAXZ170 have not been as sharp as previous lots of this product. Please review carefully the notes outlined in this letter



regarding your LASEREDGE 1.5mm X 1.7mm Trapezoid Angled Knives 6/Box, SKU#E7599 Lot MAXZ170.

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:

- Quarantine the product: According to our records, your facility may have a supply of LASEREDGE 1.5mm X 1.7mm Trapezoid Angled Knives 6/Box, SKU#E7599 Lot MAXZ170. Please quarantine any unused boxes (full and partial) of the above product that you have in your facility. All unused boxes of <u>LASEREDGE 1.5mm X 1.7mm Trapezoid Angled Knives 6/Box, SKU#E7599 Lot MAXZ170</u> shall be returned to Valeant/B+L distribution center at the address below for a disposal.
 - a. Customers will be asked in the letter to return the product before 15th of July 2016 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 XXXXXXXX

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: XXXXXX

PLEASE CUSTOMIZE FOR YOUR COUNTRY HERE AND ON FAX FORM.

Sincerely,

Signatures



Recall and Field Correction Acknowledgement Form

Product Details LASEREDGE 1.5mm X 1.7mm Trapezoid Angled Knives 6/Box, SKU#E7599 Lot MAXZ170

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

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

Product	Lot #	#	# used	# in	Responsible
		Shipped		inventory	person initials
E7599	MAXZ170				

If you have inventory of affected E7599, Lot MAXZ170 at your facility and would like to receive replacement product, please check the box below:

Please complete, sign and return the Fax: XXXXXX	his Form to: Email: XXXXXX			
Facility Name	Telephone Number			
Bausch + Lomb Account Number	Signature			
Date	Name (Print)			
facility and ask that repla	e returned the existing inventory of E7599, Lot MAXZ170 in our accement product equal to the amount of quarantined product PO#, be shipped to our facility.			

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