

URGENT MEDICAL DEVICE RECALL/URGENT FIELD SAFETY NOTICE
REVISED May 1, 2025

VOLUNTARY RECALL SCOPE CHANGE:

ONLY CERTAIN LOTS of these Intraocular Lens (IOL) models are impacted: enVista Aspire™, enVista Aspire Toric, enVista Envy™, enVista Envy Toric, enVista® monofocal (models starting with EE), and enVista monofocal Toric (models starting with ETE)

May 1, 2025

Dear Valued Customer,

I am writing to inform you that Bausch & Lomb Incorporated is **reducing the scope of its voluntary global recall from ALL lots to only CERTAIN lots of enVista Aspire, enVista Aspire Toric, enVista Envy, enVista Envy Toric, enVista monofocal (models starting with EE), and enVista monofocal Toric (models starting with ETE).**

This reduction in recall scope is based on our investigation outcome which concludes only certain IOL lots manufactured from September 2024 to March 2025 are impacted. The list of impacted lots can be referenced [here](#).

Please immediately confirm any impacted lots within your facility are in quarantine. Do not use and proceed to return the IOLs from the impacted lots to Bausch + Lomb per the instructions provided below.

These products are intraocular lenses (IOLs) which are clear, artificial lens implants used to replace a cloudy natural lens in cataract surgery.

As communicated earlier, this recall is in response to an increased number of acute reports of toxic anterior segment syndrome (TASS) in conjunction with implantation of enVista Aspire, enVista Envy and enVista monofocal IOL models EE and ETE.

TASS, a potential complication in any cataract surgery, is an inflammatory reaction inside the eye that can have a variety of causes. When it occurs, this complication typically appears 12 – 48 hours after eye surgery. -

No other Bausch + Lomb products or lots distributed in the US are impacted by this recall.

According to our records, your facility received certain lots of Bausch + Lomb IOLs that are impacted by this reduced scope recall (for list of impacted product lots click [here](#); product visual examples see pages 3 – 7).

If you previously acknowledged this recall and returned inventory (if applicable), no further action is necessary. You do not need to complete a new acknowledgement form.

If you have not acknowledged the previous communication or returned inventory (if applicable), we ask that you please urgently take the following steps:

1. Check your inventory for the impacted lots of these product models and confirm they are in quarantine. Do not use IOLs from the impacted lots. Reference the list of impacted lots [here](#).
2. Based on your findings please complete the acknowledgment form and take the appropriate steps as outlined below:

If you DO have any of the impacted lots of these product models in your inventory, please complete the enclosed acknowledgement form (page 7), print and include a copy of the acknowledgment form in each shipping box. Follow the attached instructions to create a prepaid shipping label and return the product.

If you DO NOT have any of the impacted lots of these product models or SKUs in your inventory, please complete the enclosed acknowledgement form (page 7) and return it to BLSurgCustSvc@Bausch.com within five business days to confirm you have received this notification.

3. Once the form has been received, Bausch + Lomb will process the return shipment and provide your account with a credit, where applicable.
4. Provide this **revised notice** to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred (as appropriate). Also, please transfer this **revised notice** to other organizations on which this action has an impact (as appropriate). Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.
5. For questions regarding this notice, please call Bausch + Lomb at 1-800-338-2020, Option 9.

Please see the “List of Impacted Lots” [here](#) to carefully ensure impacted lots are quarantined and segregated from non-impacted lots. If lots outside the revised scope of this recall are within your facility, they may be used.

Additionally, NON-impacted lots of these product models are now available for order. Please contact your sales representative for guidance, if desired.

Please report adverse events to Bausch + Lomb at 1-800-338-2020, Option 1 from 8:00 AM – 4:30 EST, Monday - Friday, and the US FDA, if appropriate, at FDA's MedWatch Adverse Event Reporting program: www.fda.gov/medwatch 1-800-332-1088 to request a form, as this provides important feedback.

We appreciate your attention to this matter and apologize in advance for any inconvenience this may cause.

Sincerely,



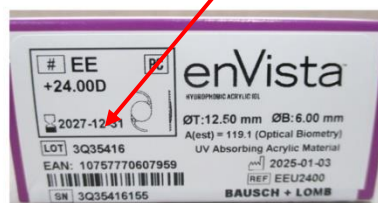
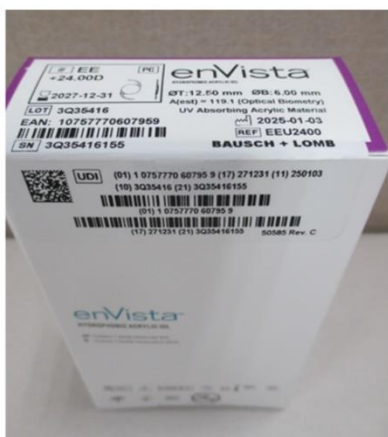
Anthony Wallace
Vice President & General Manager
Region North America
Bausch + Lomb Surgical

Impacted Product

Model Description	Model or SKU Identifier	Lot Number
enVista Monofocal IOL	Certain Lots of all models starting with EE	Click here for List of Impacted Lots
enVista Aspire IOL	Certain Lots of all models starting with EA	
enVista Envy IOL	Certain Lots of all models starting with EN	
enVista Monofocal Toric IOL	Certain Lots of all models starting with ETE	
enVista Aspire Toric IOL	Certain Lots of all models starting with ETA	
enVista Envy Toric IOL	Certain Lots of all models starting with ETN	

These photographs are examples to help identify products and location of product lot number (follow red arrow) and may not be an exact match with your product packaging.

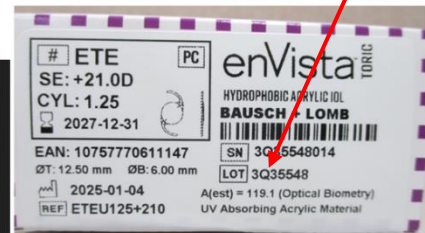
EnVista Monofocal EE, EEU



BAUSCH + LOMB

1

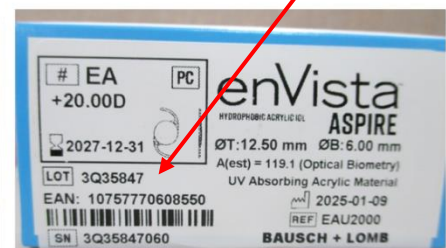
EnVista Monofocal Toric ETE, ETEU



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2

EnVista Aspire EA, EAU



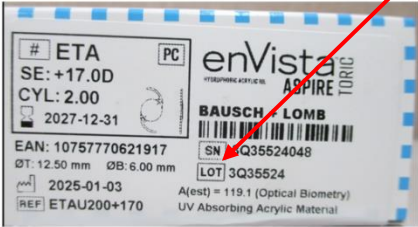
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3

EnVista Aspire Toric- ETA, ETAU



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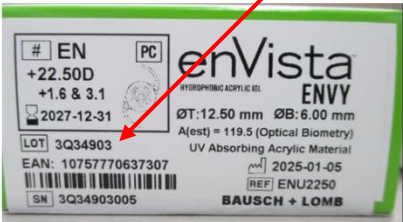
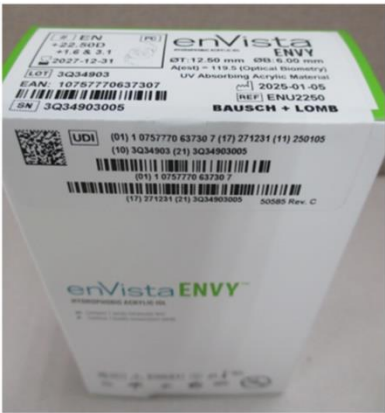


4

EnVista Envy- EN, ENU

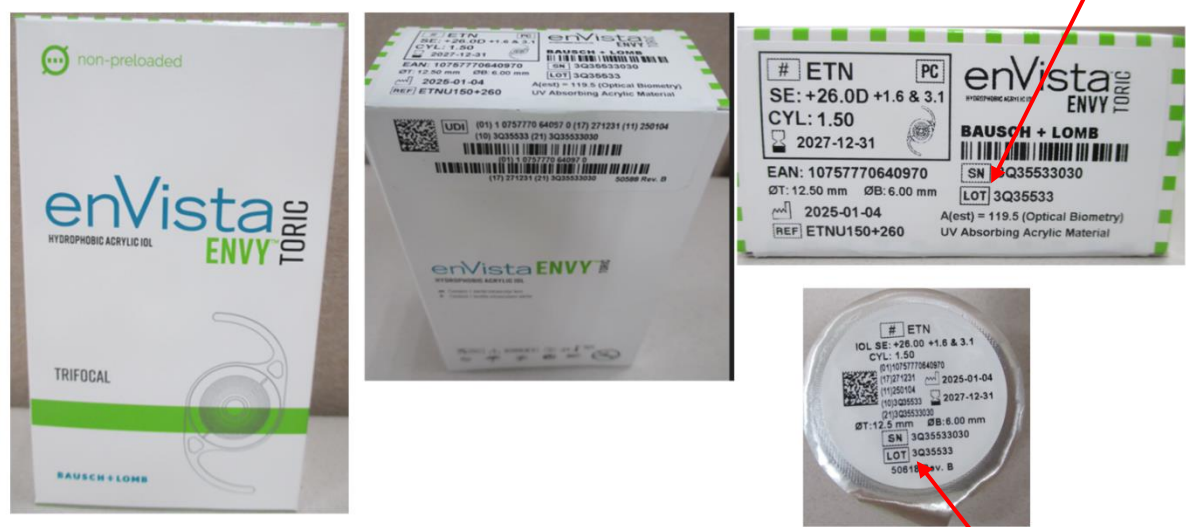


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5

EnVista Envy Toric - ETN, ETNU



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**URGENT MEDICAL DEVICE VOLUNTARY RECALL/URGENT FIELD SAFETY NOTICE
REVISED ACKNOWLEDGEMENT FORM
RECALL SCOPE CHANGE – April 28, 2025**

This form is to acknowledge receipt of the above referenced revised notification dated April 28, 2025.

Product Details: Voluntary recall for: Certain Lots of Intraocular Lens (IOL) models: enVista Aspire™, enVista Aspire Toric, enVista Envy™, enVista Envy Toric, enVista® monofocal (models starting with EE), enVista monofocal Toric (models starting with ETE)

Please mark (X) the following statement below:

- ☐ We have reviewed the attached notification and acknowledge the alert.

Please review and mark (X) one of the statements below that applies to your facility:

- ☐ We DO NOT have any impacted Voluntary recall lots of enVista Aspire, enVista Aspire Toric, enVista Envy, enVista Envy Toric, enVista monofocal (models starting with EE), enVista monofocal Toric (models starting with ETE) **If no impacted lots of these products are in your inventory to return, send a completed copy of this form to BLSurgCustSvc@bausch.com.**
- ☐ We DO have impacted Voluntary recall lots in our inventory (purchased or consignment) for one or more lots of enVista Aspire, enVista Aspire Toric, enVista Envy, enVista Envy Toric, enVista monofocal (models starting with EE), and enVista monofocal Toric (models starting with ETE). If you have impacted product in inventory, include a completed copy of this form in each box of product to be returned.

Please confirm inventory levels of the impacted product lots identified in your facility:

Model Description	Model Identifier:	Lot Number	Number of affected units from impacted lots identified and quarantined in Facility
enVista Monofocal IOL	Certain Lots of all models starting with EE	Click here for list of impacted lots	
enVista Aspire IOL	Certain Lots of all models starting with EA		
enVista Envy IOL	Certain Lots of all models starting with EN		
enVista Monofocal Toric IOL	Certain Lots of all models starting with ETE		
enVista Aspire Toric IOL	Certain Lots of all models starting with ETA		
enVista Envy Toric IOL	Certain Lots of all models starting with ETN		

I hereby certify that I have identified and quarantined the impacted lots of IOL models **enVista Aspire, enVista Aspire Toric, enVista Envy, enVista Envy Toric, enVista monofocal (models starting with EE), and enVista monofocal Toric (models starting with ETE)** to prevent use and confirm that they will be processed for return.

Date

Name/Title (Print)

Bausch + Lomb Account Number

Signature

Facility Name

Telephone Number

Confidentiality Agreement: The information contained in this message is confidential information intended for the use of the address 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.

Please complete, sign and return this form within 5 business days to BLSurgCustSvc@bausch.com