

**REVISED April 28, 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 Enhanced Monofocal MX60E™, enVista Monofocal Toric MX60ET, SimplifEYE™ Preloaded MX60PL (Combo Kit only (MXPLC)), and SimplifEYE Preloaded MX60PT (Combo Kit only (MXPTC))**

April 28, 2025

Bausch + Lomb Incorporated is revising the scope of its voluntary global recall from ALL lots to only CERTAIN lots of enVista Aspire, enVista Aspire Toric, enVista Envy, and enVista Envy Toric. We are adding certain lots of enVista monofocal models MX60E and MX60ET along with certain lots of SimplifEYE™ Preloaded Combo Kit SKUs: MXPLC and MXPTC.

This recall scope change is based on our investigation, which concluded only certain IOL lots manufactured from September 2024 to March 2025 are impacted. Lists of impacted lots can be found here: [U.S.](#), [Canada](#), [Australia](#), [all other markets](#). Please immediately confirm any impacted lots within your facility are in quarantine. Do not use and please 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.

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 are impacted by this recall.

Lists of impacted lots can be found here:

[U.S.](#)

[Canada](#)

[Australia](#)

[all other markets](#)

**If you may have impacted lenses in your possession, we ask that you please urgently take the following steps:**

1. Check your inventory for the impacted lots of these product models and quarantine them. Do not use IOLs from the impacted lots. Reference lists of impacted lots here: [U.S.](#), [Canada](#), [Australia](#), [all other markets](#).
2. Complete and follow the directions on the recall acknowledgement form you received from Bausch + Lomb. If you do not have an acknowledgement form, please contact your sales representative or Bausch + Lomb Customer Service.

3. For questions regarding this notice, please contact: [margaret.wood@bausch.com](mailto:margaret.wood@bausch.com)
4. If lots outside the revised scope of this recall are within your facility, they may be used.

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

**Impacted Products**

Model Description	Model	Lot Number
enVista Aspire IOL	Certain lots of all models starting with EA	Lists of impacted lots can be found here: <a href="#">U.S.</a> <a href="#">Canada</a> , <a href="#">Australia</a> , <a href="#">all other markets</a>
enVista Aspire Toric IOL	Certain lots of all models starting with ETA	
enVista Enhanced Monofocal	Certain lots of MX60E	
enVista Monofocal Toric	Certain lots of MX60ET	
SimplifEye Preloaded Combo Kit	Certain lots of MX60PL SKU: MXPLC	
SimplifEye Preloaded Combo Kit Toric	Certain lots of MX60PT SKU: MXPLT	

For Patients: Cataract surgery patients experiencing eye discomfort should contact their eyecare professional immediately.

For Eyecare Professionals: Please continue to closely monitor cataract surgery patients for at least 48 hours after surgery. Please instruct patients with new or worsening symptoms to contact your office immediately.

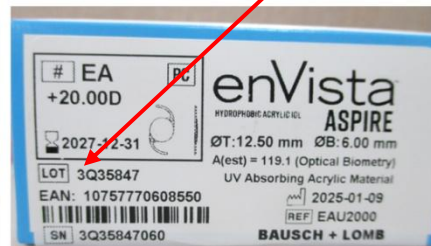
To report an adverse event, please contact Bausch + Lomb Customer Service at 1-800-338-2020, option 1, or submit a report to U.S. FDA’s [MedWatch](#) program (call 1-800-332-1088 to request a form). For more information about this recall, please contact Bausch + Lomb Customer Service at 1-800-338-2020, option 9, 8:00 am to 4:30 pm Eastern, Monday through Friday.

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 Aspire EA, EAU



BAUSCH + LOMB

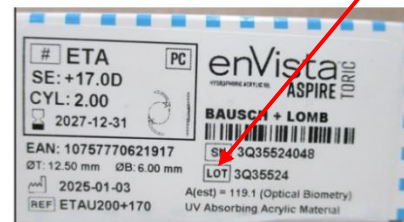


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### EnVista Aspire Toric- ETA, ETAU



BAUSCH + LOMB

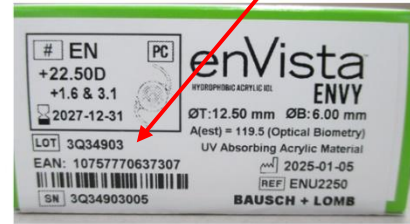


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## EnVista Envy- EN, ENU



BAUSCH + LOMB

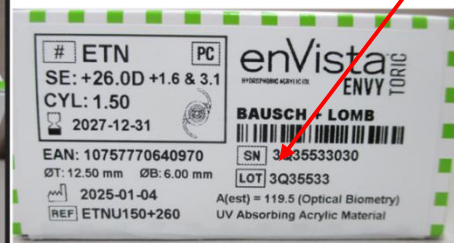
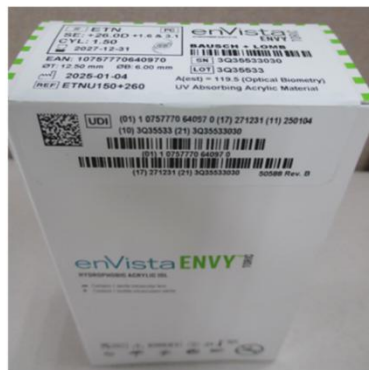


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## EnVista Envy Toric - ETN, ETNU



BAUSCH + LOMB



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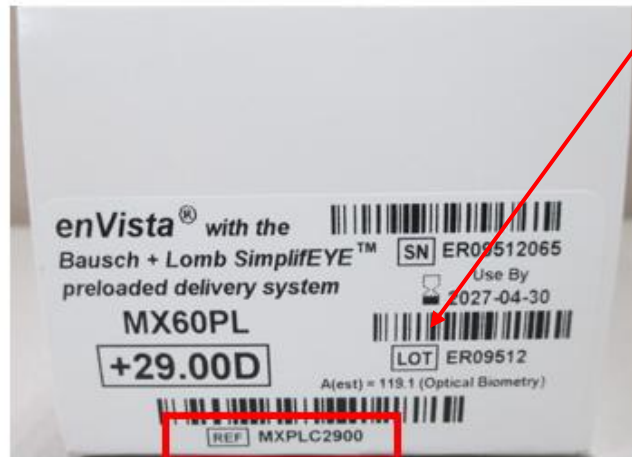
## enVista Monofocal MX60E



## enVista Toric MX60ET



# enVista SimplifEYE Preloaded Monofocal MXPLC = Combo-Kit



# enVista SimplifEYE Preloaded Toric MXPTC = Combo-Kit

