California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Bausch & Lomb Surgical, Inc. enVista Monofocal, Aspire, and Envy Intraocular Lens

Recall Date	Product Description	Recalling Firm	Recall Reason
05/02/2025	enVista Monofocal IOL, All models starting with EE enVista Aspire IOL, All models starting with EA enVista Monofocal Toric IOL, All models starting with ETE enVista Aspire Toric IOL, All models starting with ETA enVista Envy IOL, All models starting with EN enVista Envy Toric IOL, All models starting with ETN Intraocular lens.	Bausch & Lomb Surgical, Inc.	In response to an increased number of reports of toxic anterior segment syndrome (TASS) in conjunction with implantation of enVista Aspire and enVista Envy IOLs, and certain enVista monofocal lenses in the U.S.

Recall Class	Product Identification	Distribution	Affected Dates
I	enVista Monofocal IOL (EEU) Lot Number: 3Q25120 - 3R02827 UDI: 10757770635921 - 10757770608154 enVista Aspire IOL (EAU) Lot Number: 3Q24836 - 3Q34818	285,077 units nationwide	March and prior

	UDI: 10757770608277 - 10757770608833 enVista Monofocal Toric IOL (ETEU) Lot Number: 3Q24827 - 3R05231 UDI: 10757770610843 - 10757770616425 enVista Aspire Toric IOL (ETAU) Lot Number: 3Q25130 - 3R03125 UDI: 10757770618276 - 10757770622501 enVista Envy IOL (ENU) Lot Number: 3Q24764 - 3R05627 UDI: 10757770636478 - 10757770636492 enVista Envy Toric IOL (ETNU) Lot Number: 3Q25926 - 3R05141 UDI-DI: 10757770640000 - 10757770636607		

For additional information, please visit: FDA Website (Monofocal and Aspire) and FDA Website (Envy).