

Novartis' Alcon recalling more intraocular lenses in Japan

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Singapore: Novartis' Alcon expanded the recall of its intraocular lenses in Japan, pushing the number of affected units to 89,042, due to a continued increase in reports of postoperative inflammation among patients who received the AcrySof IQ Toric lens.

The recall does not affect IOLs sold outside of Japan, nor any Alcon monofocal and low-cylinder toric IOLs sold in Japan.

The recall was deemed Class 1 by the FDA in its recall database. Class 1 recalls are reserved for situations in which the agency believes "there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death."

The FDA says that Alcon sent a "FDA Notification-Update to Recall" letter on Oct. 1 to consignees in Japan who have received the affected lenses in order to initiate recovery of the device. Under the expanded recall, 43,651 units are affected. The recall notices list the affected model numbers.