Class 1 Recall AcrySof IQ Toric IOL

See Related Information[23]

Date Posted	November 25, 2015
Recall Status[1]	Open
Recall Number	Z-0271-2016
Recall Event ID	72377[24]
Product Classification	Intraocular Lens[25] - **Product Code** HQL[26]
Product	Expansion of previous recall of AcrySof IQ ReSTOR and AcrySof IQ ReSTOR Toric IOL; now to include AcrySof IQ Toric models SN6AT6, SN6AT7, SN6AT8, and SN6AT9. Intended for primary implantation in the capsular bag of the eye for visual correction.
Code Information	12156526 12156527 12156528 12156529 12156530 12156531 12158162 12158163 12158164 12158165 12158166 12161289 12161290 12161291 12161292 12161293 12161294 12161295 12161296 12161297 12161298 12161299 12165173 12165174 12165175 12165176 12165179 12165187 12165188 12165192 12165193 12199362 12199363 12199365 12199367 12205570 12205881 12205882 12205883 12205884 12205885 12205886 12205887 12205888 12205889 12205890 12205891 12208850 12208851 12208852 12208853 12208854 12208855 12208856 12208857 12208858 12208859 12208860 12208861 12208862 12216598 12220884 12220956 12220957 12223717 12224422 12224753 12224754 12224755 12224756 12224757 12225701 12230266 12230895 12230896 12230897 12231907 12233505 12233506 12233507 12235083 12238380 12238381 12238382 12238383 12238384 12238385 12238386 12238387 12238388 12238389 12238390 12238391 12238397 12238398 12241033 12241034 12241338 12241339 12241340 12241341 12241342 12241343 12241344 12241345 12241346 12243953 12245144 12245145 12245163 12245164 12245165 12245166 12245167 12245168 12245169 12245170 12245171 12245172 12246221 12247472 12247473 12247474 12247475 12247476 12249098 12249099 12249100 12249101 12250139 12250944 12251348 12251349 12254704 12258373 12261857 12261858 12261859 12261860 12261861 12261862 12261863 12261864 12261865 12267813 12267814 12267815 12267816 12267817 12267818 12267819 12269093 12269094 12269095 12269096 12272159 12272160 12272161 12272162 12272163 12272164 12273173 12273174 12273175 12273176 12273177 12273178 12273179 12273180 12273181 12273182 12273183 12274561 12274562 12275464 12275465 12275466 12275467 12275468 12275469 12275470 12275471 12276613 12276614 12276615 12280534 12280535 12280536 12280537 12280538 12280539 12280540 12280541 12280542 12280543 12280544 12280545 12285570 12285571 12285572 12285573 12285574 12285575 12285576 12288202 12290298 12290362 12290363 12290364 12290365 12290366 12290367 12290368 12290369 12290370 12302748 12302749 12302750 12302751 12302752 12302753 12302754 12302755 12322799 12322800 12330979 12330981 12330982 12330983 12330984 12330985 12330986 12335930 12335931 12335932 12335933 12335934 12335935 12335936 12335937 12335938 12335939 12335940 12335941 12345478 12345479 12345480 12345481 12345482 12345483 12345484 12345485 12345486 12350832 12350833 12350834 12350835 12350836 12350837 12350838 12350839 12350840 12350841 12350842 12350843 12350844 12350845 12350846 12350847 12350848 12353523 12356442 12356443 12356444 12356445 12356446 12356447 12356448 12356449 12363284 12363285 12363286 12363287 12363288 12363289 12372557 12372558 12372559 12372560 12378963 12378964 12378965 12378966 12378967 12378968 12378969 12378971 12378972 12378973 12378974 12378975 12378976 12383974 12383975 12383976 12383977 12383978 12383979 12383980 12383981 12383982 12383983

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Recalling Firm/ Manufacturer	Alcon Research, Ltd. 6201 South Fwy Fort Worth, Texas 76134-2099
For Additional Information Contact	N/A 817-293-0450
Manufacturer Reason for Recall	Continued increase in reports of post-operative inflammation in patients who received AcrySof IQ Toric IOL.
FDA Determined Cause [2]	DESIGN: Process Design
Action	The firm, Alcon, sent an "FDA Notification-Update to Recall Z-2323-2015" letter, dated October 1, 2015, to its Consignee in Japan who have received AcrySof IQ Toric IOL models SN6AT6 to SN6AT9 in order to initiate the recovery of product. The letter described the product, problem and actions to be taken. The consignee was instructed to stop using these

	immediately and put on hold until sales representatives visit their site for withdrawal. Recall does not affect AcrySof IQ Monofocal IOLs or AcrySof IQ Toric IOL models SN6AT3, SN6AT4 and SN6AT5.
Quantity in Commerce	43,651 units
Distribution	International Only Distribution -- Japan.
Total Product Life Cycle	TPLC Device Report[27]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[28]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

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