



TRENDS-in-MEDICINE

BULLETIN:

ALLERGAN'S XEN ON HOLD

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On Friday, October 18, 2019, Allergan quietly issued a **worldwide hold** on shipments of the Xen 45 and a voluntary recall is expected to follow. Xen is a minimally-invasive glaucoma surgery (MIGS) implant, used by ophthalmologist to lower intraocular pressure in open-angle glaucoma patients for whom previous surgical treatment failed and/or medications alone were insufficient. It was cleared by the FDA for use in November 2016.

The problem, according to Allergan, is a contaminant. During a company inspection process, a “small number of units” in an unreleased Xen 45 lot were found to have “trace amounts of polishing compounds that are used in the needle sleeve manufacturing process.” Allergan did not identify what those polishing compounds are or what chemicals are in them.

Allergan said the hold is “a precautionary measure” while it investigates the problem, and the company is currently discussing the issue with the FDA and other regulatory agencies around the world. A voluntary recall is expected to begin “in the coming days.” But it may be weeks before there is any news on when Allergan can resupply the market with newly manufactured lots of Xen 45.

There has been no press release about this, but Allergan reportedly informed the American Glaucoma Society about the issue. Neither the American Glaucoma Society nor the FDA have yet responded to requests for comment.

Here is the complete statement from Allergan in response to a query from *Trends-in-Medicine*:

“On Friday, October 18th Allergan issued a hold on XEN 45 XEN® Glaucoma Treatment System (XEN® 45 Gel Stent preloaded into a XEN® Injector) in the U.S. and globally. Allergan is currently in conversation with US Food & Drug Administration (FDA) and other International regulatory agencies and the Company is working to initiate a voluntary recall of affected lots.

During our inspection process a small number of units in an unreleased XEN 45 lot were observed to have trace amounts of polishing compounds that are used in the needle sleeve manufacturing process. As a precautionary measure Allergan issued a product hold of XEN 45 while investigating these findings.

Allergan is committed to patient safety, and we anticipate that this voluntary recall will begin in the coming days and additional detailed information will be provided. Allergan will provide further details in the coming weeks on resupplying the market with newly manufactured lots of XEN 45.”

Stay tuned as this is a developing story.

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