



This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

PSB/PSD Notification

No.0224-2

February 24, 2026

To: Representative of Alcon Japan Ltd.

Director of the Pharmaceutical Safety Division, Pharmaceutical Safety Bureau,
Ministry of Health, Labour and Welfare
(Official seal omitted)

Revision of Precautions for Medical devices

In cases where the retinal reattachment prosthetic material "Perfluoron" (Approval No.: 21600BZY00003000) was used off-label, there have been reports suggesting that the product accidentally migrated into blood vessels, possibly resulting in fatal air embolism. In light of the above, please take the following necessary measures with regard to the product.

Details

1. As shown in the Attachment, revise the "Precautions for Use" section of the package insert.
2. In accordance with item 1 above, post the revised package insert on the website of the Pharmaceuticals and Medical Devices Agency (PMDA) under the medical device package insert information.
3. By March 25, 2026, report to the Division of Medical Device Safety and Vigilance, Office of Vigilance and Standards for Medical Devices, PMDA, on the status of the actions described in items 1 and 2 above, as well as on the status of information dissemination regarding the revised contents of the package insert to healthcare professionals and related

Pharmaceuticals and Medical Devices Agency



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parties.

Attachment

(Underlined text indicates changes.)

Current	Revised
[Warnings] (Newly established)	[Warnings] <u>Exercise caution to prevent this material from entering intraocular blood vessels (e.g., damaged choroidal vessels). [If this material enters the bloodstream via blood vessels, it may cause embolic events that could result in a fatal outcome.]</u>
[Precautions for Use] <Important Precautions> There have been reports suggesting that residual perfluorohydrocarbon (PF5070) used in the manufacturing process of hollow-fiber dialyzers may have entered the bloodstream and caused pulmonary embolism. This material is a related substance of perfluorohydrocarbon (PF5070).	[Precautions for Use] <Important Precautions> (Deleted)