



**URGENT  
FIELD SAFETY NOTICE**

October 17, 2018

Dear Johnson & Johnson Vision Customer:

**RE: Voluntary Recall of OPO73, Lot 60117908**

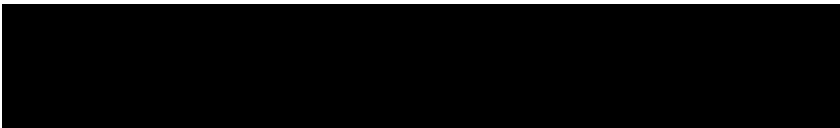
<b>Part Number</b>	<b>Description</b>	<b>Lot Number</b>
OPO73	Fusion Dual Pump Pack	60117908

Johnson & Johnson Surgical Vision, Inc. (JJSV, part of the Johnson & Johnson Vision group of companies) is recalling 372 units of Fusion Dual Pump Packs from one (1) product lot (part number OPO73) (this “Action”). **This Action only affects OPO73 Lot 60117908. No other JJSV OPO73 lots are affected by this Action.** The lot number is displayed on the label attached to each package. **This recall does not impact product distributed in SEA countries.**

JJSV has voluntarily initiated this Action as a result of an inadvertent shipment. This lot involves a new product design and improvements that were made to the OPO73 product. While the changes were made to enhance the product’s performance and there are no concerns regarding product quality, the product was imported into Korea and distributed to customers prior to obtaining approval from the Korean Health Authority (MFDS). The product has since been approved by MFDS. There is no expected patient harm associated with this issue.

This voluntary action reflects JJSV’s commitment to high quality standards and ensuring that our products fully meet your expectations. JJSV remains fully committed to serving you and your patients with safe and effective products. We recognize the inconvenience this causes you and thank you for your kind understanding.

Sincerely,



Christopher Lim, APAC Director – Business Regional Quality  
Johnson & Johnson Surgical Vision, Inc.

CC:  
Chairman Medical Board and relevant Head of Departments

Wendy Tan (Regulatory) – Email: [Redacted] ; / Local Tel No.: +65 6918 6525