



**URGENT
MEDICAL DEVICE RECALL**

April 12, 2022

Dear Johnson & Johnson Vision Customer:

RE: Voluntary Recall of Tray Ring Covers (P/N: OM271000)

Johnson & Johnson Surgical Vision, Inc. (JJSV) is voluntarily initiating a recall of the Johnson & Johnson Surgical Vision Tray Ring Cover (P/N: OM271000) (this “Action”). **This Action only affects Tray Ring Covers with a part number of OM271000 as identified (the “Tray Ring Covers”) in this notice. No other JJSV Tray Ring Covers are affected by this Action.** The Tray Ring Cover part number is displayed on the pouch label (see page 3 for label example).

JJSV has voluntarily initiated this Action due to the potential of a breach in the sterility barrier for the noted Tray Ring Covers. During the execution of packaging studies, units were found to have a breach in the sterility barrier. A breach in the sterility barrier could lead to potential contamination, which may result in an intraocular infection or endophthalmitis. No complaints or adverse events associated with this issue or failure mode have been reported. **You are receiving this notice because our records indicate that you received Tray Ring Covers impacted by this Action.**

REQUIRED CUSTOMER ACTION

Since you may have an impacted unit, please take the following actions:

1. Identify if any of your inventory contains Johnson & Johnson Surgical Vision Tray Ring Covers with Part Number OM271000.
2. **Immediately discontinue** using and remove from your inventory all affected Tray Ring Covers (P/N: OM271000). **Note that no other JJSV Tray Ring Covers are affected by this recall.**
3. **EVEN IF YOU HAVE NO INVENTORY**, please complete the attached Customer Reply Form (on page 6). JJSV requires this information for reconciliation purposes with regulatory agencies.

If you have inventory of the Tray Ring Cover with part number OM271000, please complete the Customer Reply Form, noting the Lot numbers of the Tray Ring Covers, and contact Customer Support at **Toll Free 800-120-4986 email at surgicalvisionSG@its.jnj.com** to obtain a RGA number and arrange the product return.

Credit will be issued upon receipt of the customer reply form and return of product.

The completed Customer Reply Form should be emailed to **JJV_SEA_BQ@ITS.JNJ.COM** within **3 business days of receipt of this letter.**

This notice should be shared with anyone who needs to be aware within your organization or to any organization where the potentially affected products have been transferred.



If you have product complaints or adverse events to report regarding the use of these Tray Ring Covers, please inform JJSV by emailing RA-VISAP-JJSV-APAC-C@its.jnj.com. If you do report a complaint, please provide the Tray Ring Cover Lot Number and, if a patient was involved, the date of surgery, a description of the event and patient outcome.

MDA have been notified of this action.

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 appreciate your assistance in expediting the return of this product.

Sincerely,

Chua Seng Wee / Manager, Commercial Quality (SEA)

Johnson & Johnson Surgical Vision, Inc.

Tray Ring Cover Pouch Label Example

Johnson & Johnson VISION

TRAY RING COVER
REF OM271000

CONTAINS (1) TRAY RING COVER

  **STERILE R** **Rx Only**

 Johnson & Johnson
Surgical Vision, Inc.
1700 E. St. Andrew Place
Santa Ana, CA 92705 USA

Product of USA

LOT SAMPLE12

 2018-03-15  2020-03-15



(01)05050474520707



(17)200315(10)SAMPLE12 Z353358 Rev. A 318

Example: Part Number location

Example: Lot Number location



JJSV Product RECALL Letter Dated April 12, 2022

2022 JJSV Tray Ring Cover RECALL CUSTOMER REPLY FORM

Please complete and return immediately **EVEN IF YOU HAVE NO STOCK** via email:
JJV_SEA_BQ@ITS.JNJ.COM

Please place an "X" in one of the boxes below.

- All affected products have been used or discarded.
- Product(s) was(were) previously returned to JJSV.
- We are returning affected products.

RGA # _____

Lot Number	Quantity of Tray Ring Covers to be Returned	Lot Number	Quantity of Tray Ring Covers to be Returned

JJV Account Number:	
Account Name:	
Address:	
City, State, Zip Code	
Country	
Telephone Number:	

Person completing this form acknowledges the receipt and understanding of the actions, as stated in the Product Recall letter:

Name: (print) _____

Title/Position: _____

Signature: _____

Date: _____