URGENT FIELD SAFETY NOTICE

MEDICAL DEVICE RECALL

Select VERITAS™ Advanced Infusion Packs (VRT-AI) , FUSION® Dual Pump Packs (OPO73),

December XX, 2022

Dear Johnson & Johnson Vision Customer:

RE: Voluntary Recall of VERITAS™ Advanced Infusion Packs (Part Number [P/N]: VRT-AI) and FUSION® Dual Pump Packs (OPO73)

Johnson & Johnson Vision (JJV) is voluntarily initiating a recall of select VERITAS™ Advanced Infusion Packs (P/N: VRT-AI), and FUSION® Dual Pump Packs (P/N: OPO73). **This Action only affects the Phaco Packs with lot numbers listed on page 4 as identified (the "Phaco Packs") in this notice.** The Phaco Packs lot number is displayed on the lid label (see pages 5-6 for label examples).

Reason for Recall:
Johnson & Johnson Vision has initiated this action due to a weld protrusion, which is the physical gap between the housing and cover of the phaco pack, that exceeds the design specification. A weld protrusion that is larger than the design specification could lead to failure during the priming cycle and/or suboptimal vacuum delivered to the phacoemulsification and irrigation/aspiration handpieces during the surgical case. The above may be associated with a delay in surgery and/or longer surgical time, which could result in post-operative ocular sequalae, such as transient corneal edema. As of November 21, 2022, there have been five (5) confirmed complaints related to twenty-eight (28) units, and zero (0) adverse events, associated with this issue.

Required Actions to be Taken:
You are receiving this notice because our records indicate that you received Phaco Packs impacted by this Action**.** Please take the following actions:

1. Identify if any of your inventory contains Phaco Packs with a lot number listed on page 4.
2. **Immediately discontinue** using and remove from your inventory all affected Phaco Packs. ***No other Phaco Packs are affected by this recall.***
3. Complete the attached Customer Reply Form (on page 3). We require this information for reconciliation purposes with regulatory agencies, **even if you have no inventory**.

   If you have product to be returned:

   - Complete the Customer Reply Form, noting the lot numbers of the Phaco Packs.
   - Contact Customer Support at enter phone number to obtain an RGA number and arrange the product return.
   - Email Customer Reply Form to enter e-mail **within 3 business days** of receipt of this letter.
   - Return the affected product as soon as possible. A credit will be issued upon receipt of the customer reply form and product.

If you do not have product to be returned:

- Complete and return the Customer Reply Form and email to enter e-mail within 3 business days of receipt of this letter.

4. Share this notice with anyone within your organization that needs to be informed and 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 Phaco Packs, please inform Johnson & Johnson Vision by calling enter phone number. If you do report a complaint, please provide the Phaco Packs lot number and, if a patient was involved, the date of surgery, a description of the event and patient outcome.

Enter notified body has been informed of this Action.

We apologize for any inconvenience this causes you and your patients. The health and safety of patients is our number one priority at Johnson & Johnson Vision and we thank you for your assistance in expediting the return of this product. If you have questions or concerns with regards to this notification, please contact enter phone number.

Sincerely,

Enter Name
Enter Title

Product RECALL Letter Dated December XX, 2022
2022 VERITAS™ Advanced Infusion Packs (P/N: VRT-AI), FUSION® Dual Pump Packs (OPO73),

RECALL CUSTOMER REPLY FORM

Please complete and return immediately EVEN IF YOU HAVE NO STOCK via email: enter e-mail.

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

☐ All affected products have been used or discarded. No product to return.

☐ Product(s) previously returned to JJSV.

- If product was returned, please provide the RGA#: _____

☐ We are returning affected products.

- If product will be returned, please provide the RGA#: _____
- Indicate the Lot Number(s) and Quantity of the product to be returned below.

Lot Number	Quantity of Phaco Packs to be Returned (P/N: VRT-AI and/or OPO73)

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: _____

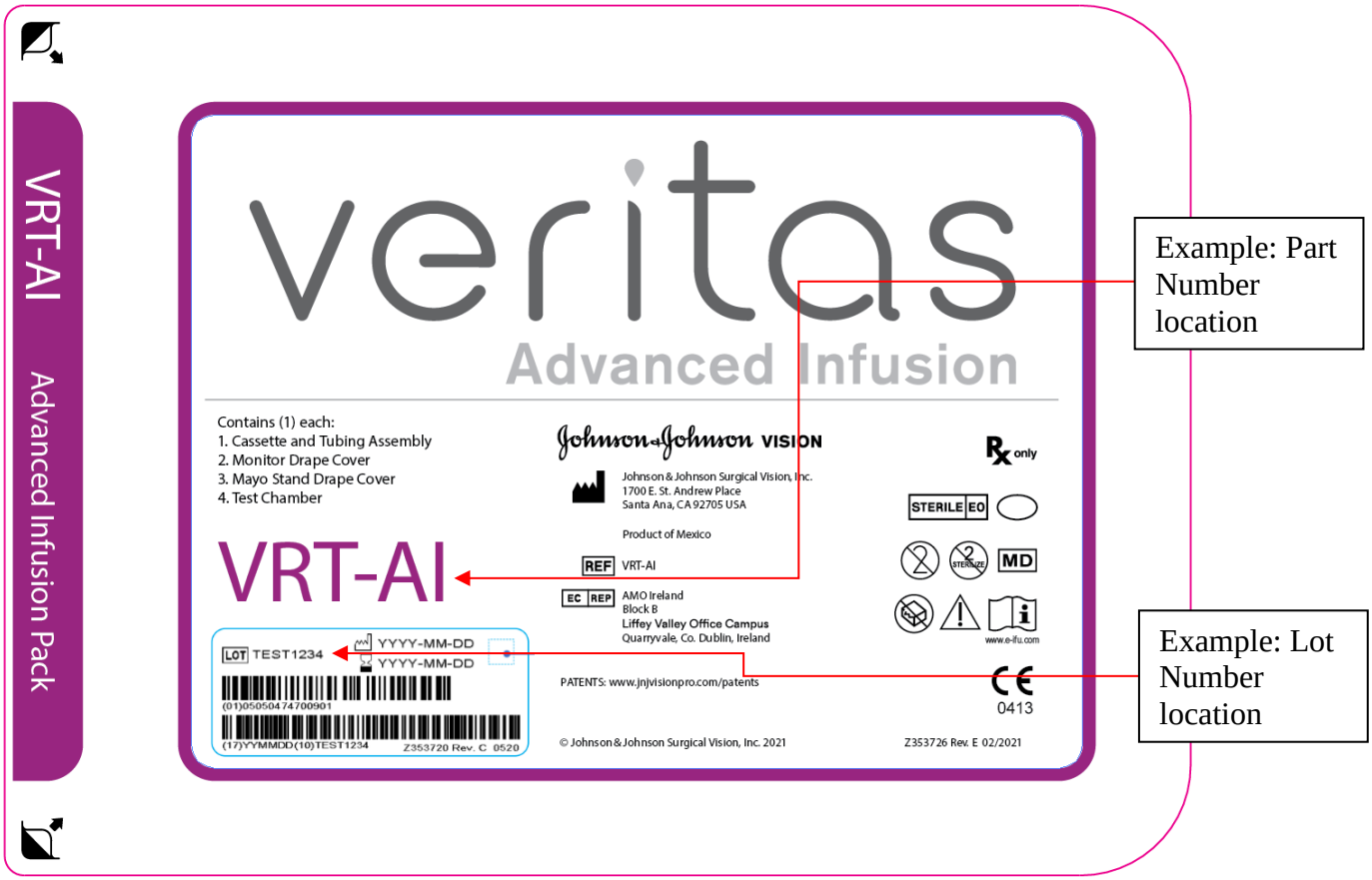
Date: _____

List of impacted lots of:

- VERITAS™ Advanced Infusion Packs (P/N: VRT-AI)
- Fusion® Dual Pump Packs (OPO73)

Product Name	P/N:	Lot Number
FUSION® Dual Pump Packs	OPO73	
		60394037
		60308197
VERITAS™ Advanced Infusion Packs	VRT-AI	
		60401982

VRT-AI Pack Lid Label Example



OPO73 Pack Lid Label Example

Example: Part Number location

Example: Lot Number location