



URGENT FIELD SAFETY NOTICE

MEDICAL DEVICE RECALL

Select VERITAS™ Advanced Infusion Packs

September XX, 2022

Dear Johnson & Johnson Vision Customer:

RE: Voluntary Recall of 55 Lots of VERITAS™ Advanced Infusion Packs (Part Number[P/N]: VRT-AI)

Johnson & Johnson Surgical Vision, Inc. (JJSV) is voluntarily initiating a recall of select VERITAS™ Advanced Infusion Packs (P/N: VRT-AI) (this “Action”). **This Action only affects VERITAS™ Advanced Infusion Packs with lot numbers listed on page 5 as identified (the “VERITAS™ Packs”) in this notice.** The VERITAS™ Packs lot number is displayed on the lid label (see page 3 for label example).

Reason for Recall:

Johnson & Johnson Vision has initiated this Action due to the potential for the irrigation luer to crack or break. A crack or break of the irrigation luer could lead to reduced irrigation pressure during surgery, associated with an unstable anterior chamber. This hazard could result in patient harm such as, but not limited to, capsule tear. Additionally, there could be a delay in surgery if a leakage is noticed during or prior to surgery and the pack must be switched out. As of August 29, 2022, there have been forty-one (41) product complaints, including one (1) adverse event, associated with this issue.

Required Actions to be Taken:

You are receiving this notice because our records indicate that you received VERITAS™ Packs impacted by this Action. Please take the following actions:

1. Identify if any of your inventory contains VERITAS™ Packs with a lot number listed on page 5.
2. **Immediately discontinue** using and remove from your inventory all affected VERITAS™ Packs. ***No other VERITAS™ Advanced Infusion Packs are affected by this recall.***
3. Complete the attached Customer Reply Form (on page 4). 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 VERITAS™ Packs.
- Contact Customer Support at **[Insert regional contact number]** to obtain a RGA number and arrange the product return.
- Email Customer Reply Form to **[insert regional email address]** **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 **[insert regional email address]** 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 VERITAS™ Packs, please inform Johnson & Johnson Vision by calling **[Insert regional contact number]**. If you do report a complaint, please provide the VERITAS™ Packs lot number and, if a patient was involved, the date of surgery, a description of the event and patient outcome.

[National Competent Authorities have been notified 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 **[Insert regional contact number]**.

Sincerely,

[insert regional QA contact name and title]

Johnson & Johnson Surgical Vision, Inc.

VERITAS™ Pack Lid Label Example

The diagram shows a rectangular label for the Veritas Advanced Infusion Pack. On the left side, there is a vertical purple bar with the text "VRT-AI" and "Advanced Infusion Pack". The main label area contains the following information:

- veritas** (large font) and **Advanced Infusion** (smaller font)
- Contains (1) each:**
 1. Cassette and Tubing Assembly
 2. Monitor Drape Cover
 3. Mayo Stand Drape Cover
 4. Test Chamber
- Johnson & Johnson VISION** logo and address: Johnson & Johnson Surgical Vision, Inc., 1700 E. St. Andrew Place, Santa Ana, CA 92705 USA. It also states "Product of Mexico".
- Rx only** symbol.
- STERILE EO** symbol.
- REF VRT-AI** and **EC REP AMO Ireland** (Block 8, Liffey Valley Office Campus, Quarryvale, Co. Dublin, Ireland).
- MD** symbol.
- LOT TEST1234** and **YYYY-MM-DD** (twice) with arrows pointing to the lot and expiration date fields.
- www.eifu.com** website.
- CE 0413** symbol.
- PATENTS: www.jnjvisionpro.com/patents**
- © Johnson & Johnson Surgical Vision, Inc. 2021** and **Z353726 Rev. E 02/2021**.

Two callout boxes are present:

- Example: Part Number location**: A red box pointing to the "VRT-AI" text.
- Example: Lot Number location**: A red box pointing to the "LOT TEST1234" text.



Product RECALL Letter Dated **September XX, 2022**

2022 VERITAS™ ADVANCED INFUSION PACKS (P/N: VRT-AI) RECALL CUSTOMER REPLY FORM

Please complete and return immediately **EVEN IF YOU HAVE NO STOCK** via email: **insert regional email address**.

Please place an “X” in one of the boxes below.

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

Product(s) was (were) 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 VERITAS™ Advanced Infusion Packs (P/N: VRT-AI) 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: _____

List of fifty-five (55) impacted lots of VERITAS™ Advanced Infusion Packs (P/N: VRT-AI)

<u>Lot Number</u>	<u>Lot Number</u>
60316112	60353453
60330206	60353772
60330248	60353811
60341105	60353812
60341106	60353813
60341107	60353814
60342401	60353815
60343412	60354982
60343413	60355023
60351691	60355024
60352993	60355025
60352994	60355026
60352995	60355027
60352996	60355330
60352997	60355335
60352998	60355972
60352999	60360065
60353436	60360066
60353443	60362043
60353444	60362044
60353445	60362435
60353446	60362436
60353447	60364566
60353448	60369607
60353449	60369608
60353450	60369609
60353451	60381689
60353452	