



## URGENT FIELD SAFETY NOTICE

### MEDICAL DEVICE RECALL

VERITAS™ Advanced Infusion Packs (VRT-AI) and VERITAS™ Advanced Fluidics Packs (P/N: VRT-AF)

June 14<sup>th</sup>, 2023

Dear Johnson & Johnson Vision Customer:

**RE: Voluntary Recall of All VERITAS™ Advanced Infusion Packs (P/N: VRT-AI) and VERITAS™ Advanced Fluidics Packs (P/N: VRT-AF) within their expiration date**

Johnson & Johnson Vision (JJV) is voluntarily initiating a recall of **All VERITAS™ Advanced Infusion Packs (P/N: VRT-AI) and VERITAS™ Advanced Fluidics Packs (P/N: VRT-AF) within their expiration date**. **This Action only affects VERITAS™ Advanced Infusion Packs (P/N: VRT-AI) and VERITAS™ Advanced Fluidics Packs (P/N: VRT-AF) within their expiration date (the “VERITAS Packs”).**

#### Reason for Recall:

Johnson & Johnson Vision is initiating this new action due to a manufacturing issue with VERITAS Packs which could result in a weld protrusion, which is the physical gap between the housing and cover of the VERITAS Packs, 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 sequelae, such as transient corneal edema. As of May 25, 2023, there have been a total of 25 complaints that have been confirmed to be related between May 25, 2021, and May 24, 2023. One (1) complaint resulted in an adverse event, however its relationship to this manufacturing issue could not be confirmed.

#### 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 (VRT-AI/VRT-AF) within their expiration date.
2. **Immediately discontinue** using and remove from your inventory all VERITAS 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 VERITAS Packs.
- Contact Customer Support at JJV-ORDERS.UK@ITS.JNJ.COM to obtain an RGA number and arrange the product return.
- Email Customer Reply Form to JJV-ORDERS.UK@ITS.JNJ.COM **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 [JJV-ORDERS.UK@ITS.JNJ.COM](mailto:JJV-ORDERS.UK@ITS.JNJ.COM) 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 emailing [UK-QA-Complaints@its.jnj.com](mailto:UK-QA-Complaints@its.jnj.com). 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.

The MHRA 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 0800 376 7949.

Sincerely,

A large black rectangular redaction box covering the signature of the sender.

  
**EMEA Commercial Quality Senior Manager**  
Johnson & Johnson Surgical Vision.



Product RECALL Letter Dated June 15th, 2023  
2023 VERITAS™ Advanced Infusion Packs (P/N: VRT-AI) and VERITAS™ Advanced Fluidics Packs (P/N: VRT-AF)

**RECALL CUSTOMER REPLY FORM**

Please complete and return immediately **EVEN IF YOU HAVE NO STOCK** via email: [JJV-ORDERS.UK@ITS.JNJ.COM](mailto:JJV-ORDERS.UK@ITS.JNJ.COM).

**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 VERITAS Packs to be Returned (P/N: VRT-AI or VRT-AF)

JJV Account Number:	
Account Name:	
Address:	
City, County, Post Code:	



<b>Country:</b>	
<b>Telephone Number:</b>	
<b>E-Mail</b>	

**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:** \_\_\_\_\_

**VRT-AI Pack Lid Label Example**

The diagram shows a rectangular label for a VRT-AI pack lid. 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:

- Product Name:** "veritas" in a large, lowercase, sans-serif font, with "Advanced Infusion" below it in a smaller font.
- Contents:** "Contains (1) each: 1. Cassette and Tubing Assembly, 2. Monitor Drape Cover, 3. Mayo Stand Drape Cover, 4. Test Chamber".
- Manufacturer:** "Johnson & Johnson VISION" logo, followed by "Johnson & Johnson Surgical Vision, Inc., 1700 E. St. Andrew Place, Santa Ana, CA 92705 USA". Below this, it says "Product of Mexico".
- Regulatory Markings:** "Rx only", "STERILE EO", "MD", "REF VRT-AI", "EC REP AWO Ireland, Block B, Liffey Valley Office Campus, Quarryvale, Co. Dublin, Ireland".
- Barcode and Lot Information:** A barcode with "LOT TEST1234" and "YYYY-MM-DD" fields. Below the barcode is the number "01305050474700901" and "(17)YYMMDD(1)TEST1234".
- Other Markings:** "PATENTS: www.jnjvisionpro.com/patents", "© Johnson & Johnson Surgical Vision, Inc. 2021", "Z353726 Rev. E. 02/2021", and the CE mark "0413".

Two callout boxes on the right side of the label point to specific areas:

- Example: Part Number location:** Points to the "REF VRT-AI" marking.
- Example: Lot Number location:** Points to the "LOT TEST1234" marking.

Lot numbers distributed in EMEA:

**VRT-AI**

60304175  
60305661  
60305662  
60306935  
60306936  
60308193  
60309845  
60309850  
60314642  
60314676  
60314677  
60316112  
60372490  
60374945  
60376930  
60378840  
60378842  
60378844  
60400795  
60401984  
60413115  
60413117  
60414191  
60415077  
60415078  
60416304  
60420003  
60425389  
60426315  
60428217  
60429442  
60433653  
60433655  
60435921  
60435923  
60437988  
60437989  
60440239  
60440240  
60442450  
60442452  
60442453  
60442454  
60446059  
60448857

VRT-AF Pack Lid Label Example

The diagram shows a rectangular label for the VRT-AF Advanced Fluidics Pack. The label features the 'veritas' logo in a large, lowercase font, with 'Advanced Fluidics' underneath. To the left, a vertical blue bar contains the text 'VRT-AF' and 'Advanced Fluidics Pack'. The main body of the label contains the following information:

- Contents (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. Product of Mexico.
- VRT-AF** in large blue font.
- REF VRT-AF** and **EC REP** information for AMO Ireland, Block B, Liffey Valley Office Campus, Quarryvale, Co. Dublin, Ireland.
- STERILE EO** and **MD** (Medical Device) symbols.
- CE** mark with '0413' below it.
- LOT TEST 1234** and **YYYY-MM-DD** expiration date fields.
- Barcode with numbers: (01)05050474700895 and (17)YYMMDD(10)TEST1234.
- Patents: [www.jnjvisionpro.com/patents](http://www.jnjvisionpro.com/patents)
- © Johnson & Johnson Surgical Vision, Inc. 2021 and Z353725 Rev D. 02/2021.

Two callout boxes with red arrows point to specific areas on the label:

- Example: Part Number location:** Points to the 'VRT-AF' text in the center of the label.
- Example: Lot Number location:** Points to the 'LOT TEST 1234' text in the bottom left corner of the label.

VRT-AF Lot numbers distributed in  
EMEA:

**VRT-AF**

60304172  
60304173  
60304174  
60305658  
60305659  
60306930  
60306932  
60306933  
60308189  
60308190  
60309847  
60309848  
60314641  
60314674  
60314675  
60378839  
60420004  
60446054  
60446055