URGENT FIELD SAFETY NOTICE

MEDICAL DEVICE RECALL

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

June 14th, 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 sequalae, 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 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.. 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,

[redacted]

[redacted]
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.

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:	

Country:	
Telephone Number:	
E-Mail	

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

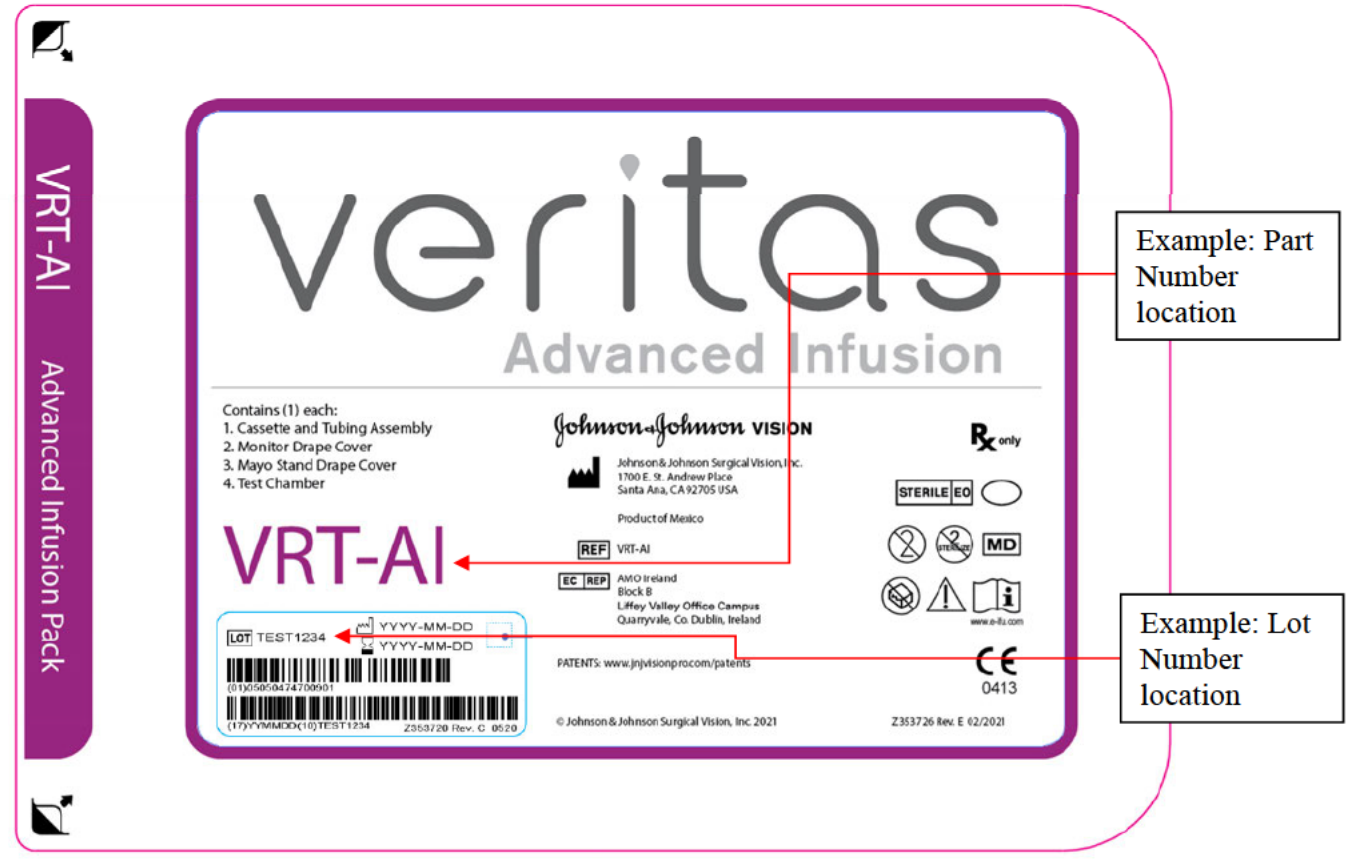
Name: (print) _____

Title/Position: _____

Signature: _____

Date: _____

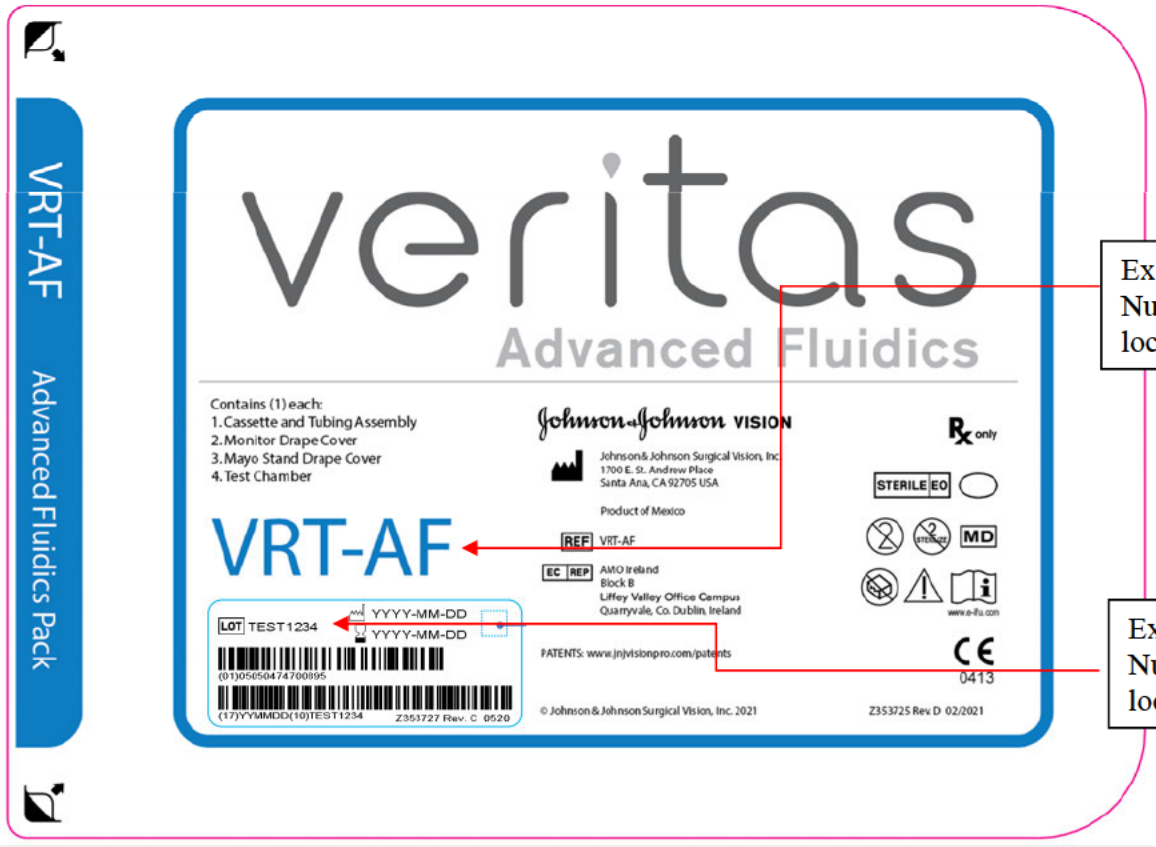
VRT-AI Pack Lid Label Example



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



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