

## Topic: Incomplete Seal for Alcon Standalone Vitrectomy Consumables

**Last updated:** 04 August 2025  
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### Reactive Statement and Q&A

**FOR REACTIVE USE ONLY** – This document is intended to be used to reactively address any external inquiries. The information contained within this document should be used as a resource to respond to questions; the document itself should not be distributed.

**Before responding with the correct Reactive Statement ask the customer whether they have potentially affected standalone Alcon Standalone Vitrectomy Consumables inventory, or potentially affected inventory within the Custom Pak®.**

### Reactive Statement – for customers who have specific lots of Alcon Standalone Vitrectomy Consumables

- Alcon is conducting a Medical Device Recall of specific lots of Alcon Standalone Vitrectomy Consumables, as there is potential for some pouches within impacted lots to have an incomplete seal.
- With the potential incomplete seal, there is a risk that the sterility of the Alcon Standalone Vitrectomy Consumable has been compromised.
- Therefore, Alcon is recalling all potentially affected lots of Alcon Standalone Vitrectomy Consumables. Alcon is notifying customers who were shipped affected lots.
- At the time of Market Action initiation, Alcon had not received any reports of customer complaints or adverse events related to this specific issue. However, the use of non-sterile surgical products may increase the risk of post-operative infection, which may require additional medical and/or surgical intervention.

### Reactive Statement – for some EU customers who have potentially affected lots of inventory within the sealed Custom Pak® (in core pak).

- All components inside the Custom Pak®, including the Alcon Standalone Vitrectomy Consumables, are sterile as part of the terminal sterilization process.
- There may be an incomplete seal of Alcon Standalone Vitrectomy Consumables of specific lots; therefore, Alcon is advising that after an affected Custom Pak® is opened in the sterile surgical field, the affected Alcon Standalone Vitrectomy Consumables be used for that specific surgical case and discarded at the end of the case. Do not save the Alcon Standalone Vitrectomy Consumables for future use.

- At the time of Market Action initiation, Alcon had not received any reports of customer complaints or adverse events related to this specific issue. However, the use of non-sterile surgical products may increase the risk of post-operative infection, which may require additional medical and/or surgical intervention.

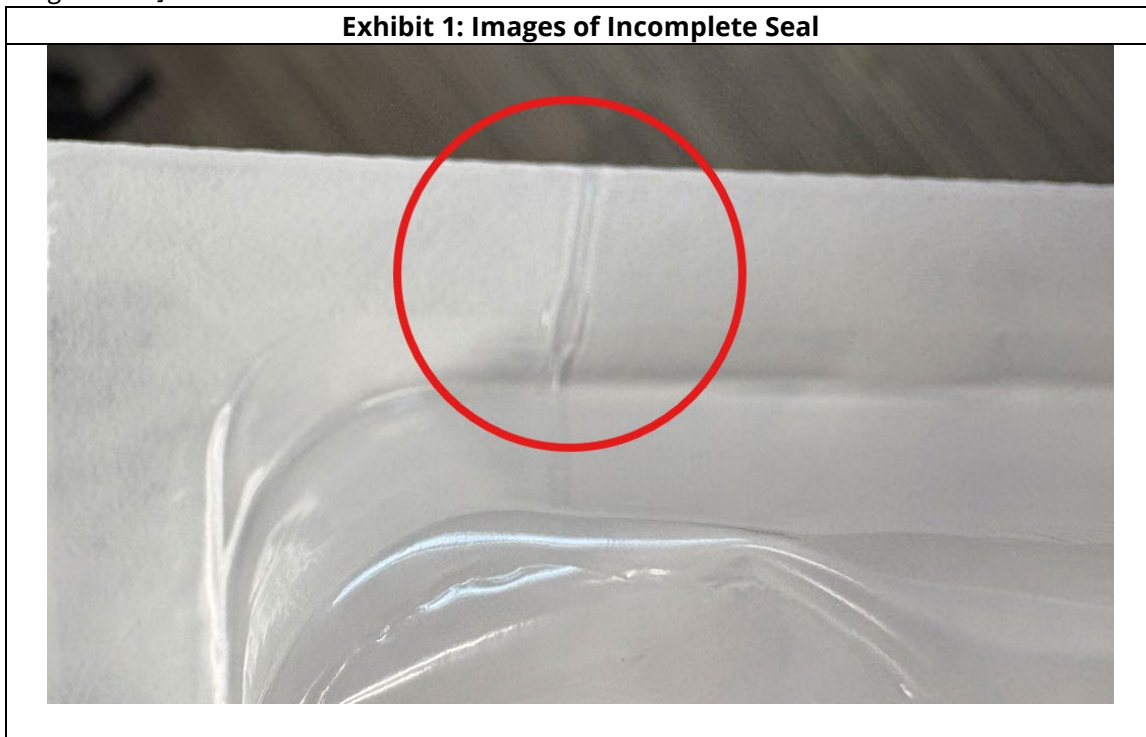
## **External Q&A for Customers**

### **Q What is the nature of the issue?**

**A** There is the potential that the pouch seal of some units within specific lots of Alcon Standalone Vitrectomy Consumables to have an incomplete seal. Please see photo below for an example. Due to the risk of sterility being compromised, Alcon is recalling potentially affected lots.

*[Note: if a customer requests an image, please direct them to their customer letter, which has the image below.]*

**Exhibit 1: Images of Incomplete Seal**





**Q Has Alcon received any customer complaints or adverse events related to this specific issue?**

A At the time of Market Action initiation, Alcon had not received any reports of customer complaints or adverse events related to this issue. In the event you have experienced an adverse event or a product quality issue related to this communication, please report to Alcon using one of the following methods:

Web: <https://notifeye.alcon.com>

Phone: 1-800-757-9780, Option 5

Adverse reactions or quality complaints experienced with the use of this product may also be reported directly to the FDA MedWatch Adverse Event Reporting program, please visit <http://www.fda.gov/Safety/MedWatch/HowToReport>

**Q Does this issue pose a patient safety concern?**

A Due to the potential risk of compromised sterility of specific lots of the Alcon Standalone Vitrectomy Consumables, Alcon is recalling units within the affected lots. The use of non-sterile surgical products may increase the risk of post-operative infection, which may require additional medical and/or surgical intervention.

To identify the affected lot sent to your facility, please see your Medical Device Recall notification letter. *[Your affected lots are listed in the notification letter]*

**Q How do I know if I have potentially affected Alcon Standalone Vitrectomy Consumables?**

A Alcon has notified customers who received units from affected lots via a Medical Device Recall letter and/or email. Affected lots shipped to the customer facility are identified in the Medical Device Recall notification.

**Q What should customers who have been notified do with affected Alcon Standalone Vitrectomy Consumables?**

A Customers should follow the instructions provided in the recall notification letter sent to their facility.

*[Note for field: If the customer did not receive a letter, please contact Customer Service to confirm the customer is within scope and to send a copy of their site-specific recall notification. Instructions provided in the recall notification are detailed below.]*

- **If customers receive their Alcon Standalone Vitrectomy Consumables as sterile standalone, PikPak (US only), or as a Custom Pak<sup>®</sup> add-after (US, Australia, Canada, Puerto Rico):**

1. Review your inventory to determine if you have any unused affected product within your facility. See table on page 1 of customer notification letter for affected Alcon Standalone Vitrectomy Consumable lots shipped to your location.
2. Segregate and dispose of any unused affected product from your inventory.
3. Call Alcon Customer Service to arrange for replacement of your affected inventory.
4. Fill out the attached 'Response Form', even if you have zero (0) units remaining in inventory and return the form to Alcon using the contact information provided on the form.
5. Please forward this notification to all departments within your organization who may be in possession of this affected product; and any other organization to which this product may have been transferred.

**Q What do I do if I have used the affected lots and have none in stock?**

A Respond to Alcon as directed in the Medical Device Recall notification letter sent to your facility **even if you have zero (0) units remaining in inventory** and return the form to Alcon using the contact information provided.

*[Note for the field – the letter/response form is personalized for each customer. If your customer does not have a copy of the response form, please contact Customer Service so they can send a letter and associated response form to customer.]*

**Q How would I know if my Alcon Standalone Vitrectomy Consumables had an incomplete seal?**

A Please see the lot numbers in your Medical Device Recall notification letter for lots that may have potential incomplete seals. The incomplete seal may not be present in all impacted lots, nor be present on all units within an impacted lot. This Medical Device Recall is being sent to you as there is a *potential* for incomplete seals in the impacted lots.

**Q What if I used an Alcon Standalone Vitrectomy Consumables from an affected lot during surgery?**

A The incomplete seal may not be present in all impacted lots, nor be present on all units within an impacted lot. This Medical Device Recall is being sent to you as there is a *potential* for incomplete seals in the impacted lots.

If you have already used units within an impacted lot, no further actions are required beyond routine post-operative procedures and follow up care. At the time of Market Action initiation, we had not received any reports of adverse events related to this Medical Device Recall. As always, please report product complaints to Alcon using one of the following methods:

Web: [notifeye.alcon.com](http://notifeye.alcon.com)

Phone: 1-800-757-9780, Option 5

Adverse reactions or quality complaints experienced with the use of this product may also be reported directly to the FDA MedWatch Adverse Event Reporting program, please visit [fda.gov/Safety/MedWatch/HowToReport](http://fda.gov/Safety/MedWatch/HowToReport).

**Q How prevalent / widespread is this issue?**

A This event was limited to specific impacted lots. The incomplete seal may not be present in all impacted lots, nor be present on all units within an impacted lot.

**Q Have all customers with affected lots been notified of this issue?**

A Yes, all affected customers have been notified of this issue. If you have not received a Medical Device Recall notification letter directly from Alcon, your Alcon Standalone Vitrectomy Consumables units are not affected.

**Q What countries are affected?**

A Affected lots have been shipped globally, and customers who have potentially affected lots are being notified.

**Q Has the FDA (or other Health Authority) been notified of this issue?**

A Alcon has notified the FDA and global Health Authorities according to applicable local regulations.

**Q Will this affect my supply of Alcon Standalone Vitrectomy Consumables?**

A We are working diligently to minimize any potential customer impact. At this time, no supply impact is expected for Alcon Standalone Vitrectomy Consumables products. Please contact customer service at 1-800-862-5266 (*for USA, other markets please use local contact information*) for specific details regarding your account.

**\*\* Only for markets with customers who include the impacted lots of Alcon Standalone Vitrectomy Consumables within an Alcon Custom Pak® (within the core pak): Belgium, Czech Republic, Italy, and Poland.**

**Q Why is it safe to use Alcon Standalone Vitrectomy Consumables provided inside Alcon Custom Pak®?**

A Custom Pak® surgical kits are terminally sterilized after assembly, therefore, all components inside your Custom Pak®, including the Alcon Standalone Vitrectomy Consumables, are sterilized as part of the terminal sterilization process. Customers who received an affected Alcon Standalone Vitrectomy Consumable inside their Custom Pak® were notified via letter. Alcon advises customers to follow the labeling guidance and use affected Alcon Standalone Vitrectomy Consumables only on the specific surgical case for which the Custom Pak® is opened. Do not save the Alcon Standalone Vitrectomy Consumables for future use.

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