6201 South Freeway
Fort Worth, Texas 76134-2099
www.alcon.com

Topic: Alcon Constellation Pak® with Damaged Tyvek® Cover

Last updated: **2 May 2025**
Created by: **Quality, Communications, Marketing**

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 Constellation Pak inventory.**

Reactive Statement – for customers who have potentially affected lots of standalone Constellation Pak® inventory

- Alcon is conducting a **Medical Device Recall** of specific lots of Constellation Pak®, as there is potential for some trays within impacted lots to have damage in the Tyvek® cover.
- With the potential damage to the cover, there is a risk that the sterility of the Constellation Pak® has been compromised.
- Therefore, Alcon is recalling all potentially affected lots of Constellation Pak®. Alcon is notifying customers who were shipped affected Constellation Pak®.
- To date, Alcon has not received any reports of customer complaints or adverse events related to this 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 the Tyvek® cover of some units within specific lots of Alcon Constellation Pak® were damaged during the manufacturing process. Please see photo below for an example. Due to the risk of Constellation Pak® 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.]

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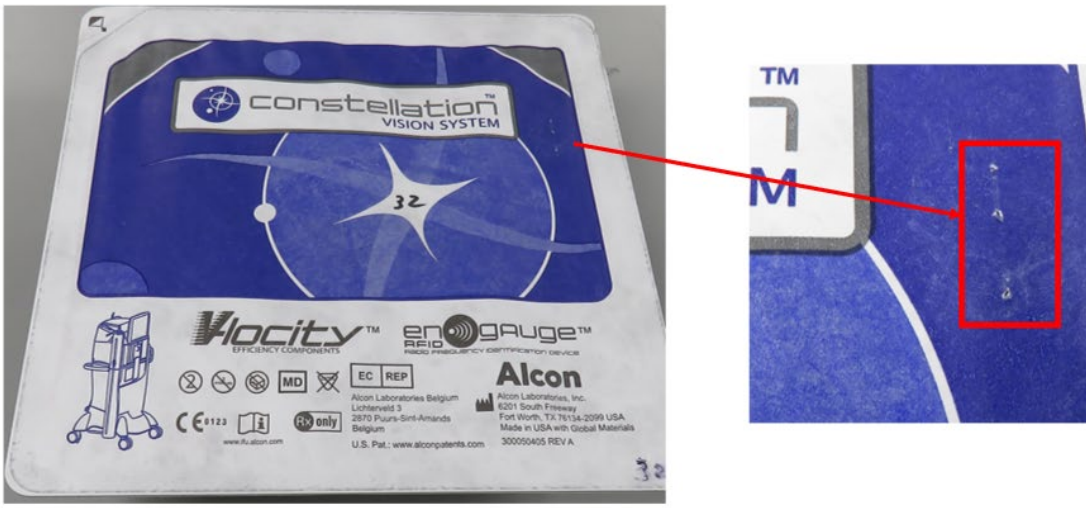
Image of Constellation Pak® with Damaged Tyvek®



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

A No. To date, Alcon has 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 NotifEye or email to apac.complaint@alcon.com.
Adverse reactions or quality complaints experienced with the use of this product may also be reported directly to MDA and/or PFDA

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

A Due to the potential risk of compromised sterility of the Constellation Pak®, 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. *[Affected lots are listed in the notification letter]*

Q **How do I know if I have potentially affected Constellation Pak® units?**

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 Constellation Pak® builds?**

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

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[. Instructions provided in the recall notification are detailed below.]

- **If customers receive their Constellation Pak® as sterile standalone:**
  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 Constellation Pak® lots shipped to your location.
  2. Segregate and dispose of any unused affected product from your inventory.
  3. Call Alcon Customer Service or Alcon Sales Representative to arrange for replacement of your affected inventory of Alcon Constellation Pak®.
  4. Post this notification letter near where affected products are stored to ensure awareness of the recall and continued shipment of corrected Constellation Pak®.
  5. 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.
  6. 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.

Q **How would I know if my Constellation Pak® had a damaged Tyvek® cover?**

A Please see the lot numbers in your Medical Device Recall notification letter for lots that may have potentially damaged units.

Q **What if I used a Constellation Pak® from an affected lot during surgery?**

A The Tyvek® damage 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 damage 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. To date, we have not received any reports of adverse events related to this Medical Device Recall. As always, please report product complaints to Alcon at apac.complaint@alcon.com.

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

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

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Q **I received a new shipment of Constellation Pak® from a lot listed in the Medical Device Recall notification letter. Is this acceptable to use?**

A To prevent immediate market shortage and the risk of cancelling emergency posterior segment surgeries, Alcon will reinspect the remaining inventory of affected Constellation Pak® lots. *Future shipments may contain packs from the affected lots identified in the recall.* For your convenience, these reinspected packs will be *marked with a green indicator sticker* to visually distinguish them from packs distributed prior to the recall initiation. **The green sticker indicates the Constellation Pak has been inspected and confirmed to be undamaged, and is safe to use.**

Image of example green indicator sticker on Constellation Pak®
   

Q **I received a Constellation Pak® with a green dot/sticker on the exterior. Is this safe to use?**

A Yes. The green sticker indicates the Constellation Pak® is from a lot potentially affected by the recall, but the unit has been inspected and confirmed to be undamaged and safe to use. To ensure continued supply of Alcon Constellation Pak®, Alcon is currently inspecting our existing inventory of affected lots. For your convenience, these reinspected packs will be marked with a green indicator sticker to visually distinguish them from packs distributed prior to the recall initiation.

Q **Are Constellation Paks with no green dot safe to use?**

A Yes. To ensure continued supply of Alcon Constellation Pak®, Alcon is currently inspecting our existing inventory of affected product. The green dot is applied to reinspected packs for customer convenience, allowing personnel to visually distinguish the acceptable reinspected packs from packs from the same lot that were distributed prior to the recall initiation.

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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 Constellation Pak® 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 Constellation Pak® units?**

A We are working diligently to minimize any potential customer impact. At this time, no supply impact is expected for Constellation® products or for Alcon Custom Pak®. Please contact the local customer service for specific details regarding your account.

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