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

VOLUNTARY FIELD SAFETY CORRECTIVE ACTION	
Description	**Specific lots of Alcon Constellation Pak® with Damaged Tyvek®**
Product Reference	**Alcon Constellation Pak®**
Market Action Identifier	**2025.007**

May 8th 2025

MEDIC D.O.O.

Dear partner,

The purpose of this letter is to notify you that Alcon has initiated a Voluntary field safety corrective action for specific lots of its Alcon Constellation Pak®. Alcon is conducting this Voluntary field safety corrective action as there is potential for some trays within impacted lots to have damage in the Tyvek® cover.

The following affected product has been shipped to your facility:

Legacy code	Description	Batch	Quantity
8065752435	TOTAL PLUS,23G,10K VALVE STD	176CCJ	180
8065752438	TOTAL PLUS,25+,10K VALVE WD	1776AD	6
8065752435	TOTAL PLUS,23G,10K VALVE STD	1782HN	120
8065752448	23G CMB PAK 10K CPM,V,STD 0.9	1782J4	126
8065752450	25+ CMB PAK 10K CPM,V,STD 0.9	1782J7	60
8065751155	ANTERIOR PAK,0.9,W/0 PROBE/IL-LUMINATIO	178D51	60
8065752448	23G CMB PAK 10K CPM,V,STD 0.9	178TA4	54
8065752437	TOTAL PLUS,25+,10K VALVE STD	178TD4	36
8065752448	23G CMB PAK 10K CPM,V,STD 0.9	17930J	6
8065752448	23G CMB PAK 10K CPM,V,STD 0.9	179EH3	114
8065752435	TOTAL PLUS,23G,10K VALVE STD	179TY4	120
8065752448	23G CMB PAK 10K CPM,V,STD 0.9	179TYL	6
			888

This event was identified internally, and to date Alcon has not received any reports of customer complaints or adverse events related to this issue.

Description of the Issue

There is the potential that 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. The use of non-sterile surgical products may increase the risk of post-operative infection, which may require additional medical and/or surgical intervention.

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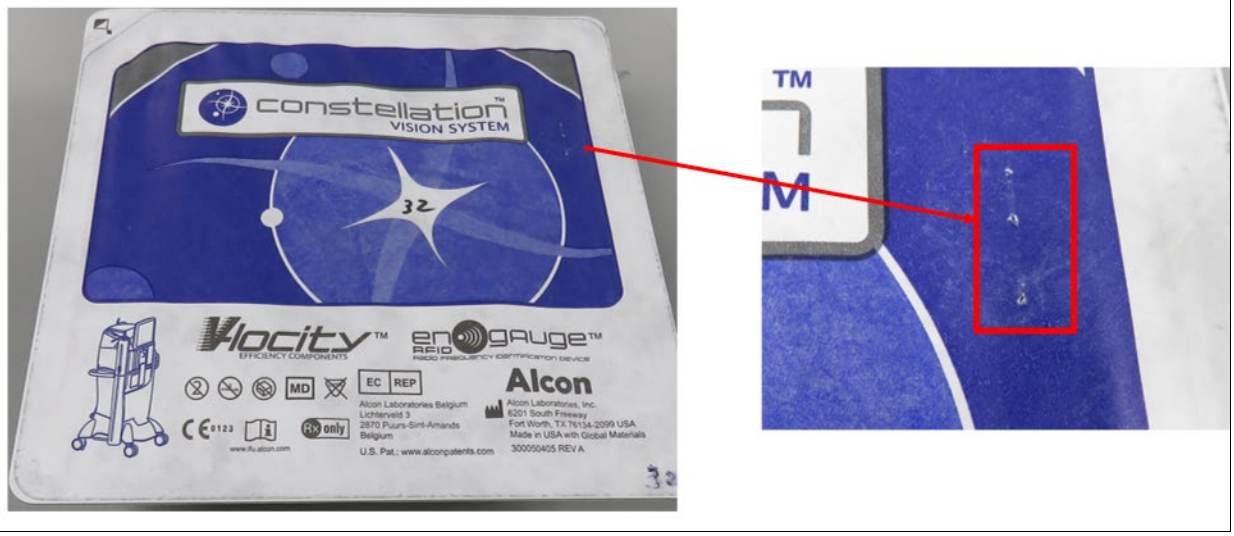
Exhibit 1: Image of Constellation Pak® with Damaged Tyvek®



Actions to be taken by the Customer / User

We are asking that you locate and dispose of any affected lots of Alcon Constellation Pak® remaining in your inventory. To comply with this Voluntary field safety corrective action and request the replacement of any unused product, please take the following steps:

1. Review your inventory to determine if you have any unused affected product within your facility. See table on page 1 for affected Constellation Pak® lots shipped to your location.
2. Segregate and **dispose** of any unused affected product from your inventory.
3. Contact Alcon Customer Service 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. Respond to Alcon indicating your understanding of these instructions **even if you have zero (0) units remaining in inventory** by completing and returning the attached "Response Form" and returning to Alcon via email or fax.
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.

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Alcon Corrective Action

To prevent immediate market shortage of Constellation Pak® and the risk of cancelling emergency surgeries (e.g., retinal procedures), Alcon will reinspect the remaining inventory of affected Constellation Pak® lots. In the future, you may receive shipments of identified lots. The 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 for use. An example of a Constellation Pak® with a green indicator sticker is provided in Exhibit 2 below.

Exhibit 2: Image of example green indicator sticker on Constellation Pak®

Contact for Further Questions about this Voluntary field safety corrective action

In the event you have experienced adverse events or product quality issues related to this communication, please contact Alcon qa.complaints@alcon.com.

Adverse events or quality problems experienced with the use of this product may also be reported to the your Health Authority complaint/AE reporting portal.

Should you have any questions or concerns about this matter, please feel free to contact Alcon Customer Service or contact your Alcon Representative.

Sincerely,

Heather Attra
SVP, Chief Quality & Regulatory Affairs Officer

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RESPONSE FORM

Specific lots of Alcon Constellation Pak®
with Damaged Tyvek®
MA# 2025.007

MEDIC D.O.O.

To comply with this Voluntary field safety corrective action, please take the following steps:

1. Review your inventory to determine if you have any unused affected product within your facility.

Product Number	Product Description	Affected Lot(s)	Units Disposed
<<Pak #>>	<<Description>>	<<Lot #>>	

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 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. Respond to Alcon indicating your understanding of these instructions **even if you have zero (0) units remaining in inventory** by completing and returning this "Response Form" and returning to Alcon via email or fax.
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.

Please return this Response Form via fax or email to Alcon:
Email: jelena.bjelanovic@alcon.com and sanja.banek-babic@alcon.com

Your signature below attests that you have read and understood this notification.

Signature:	**Date:**
Printed Name:	
Title:	