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URGENT: Field Safety Notice

Date: <<insert date>>

Commercial Name of Product: Alcon 23G Non-Valved Trocar Cannula and Infusion Cannula

Identifier: JP.T12.8REC.001

Type of Action: Advisory Notice on Interaction Between Alcon 23G Non-Valved Trocar Cannula and Infusion Cannula

Dear <<insert appropriate contact information>>:

This letter is to advise you of a voluntary Field Safety Corrective Action initiated by Alcon for specific lots of Alcon's 23G TotalPLUS[®] Paks and 23G Combined Procedure Packs. These products contain an infusion cannula that may not securely fit into the 23G non-valved trocar cannula.

National Competent Authorities have been notified of this action.

Details on Affected Devices:

The Alcon 23G non-valved trocar cannula and infusion cannula are both single use consumable items used to provide internal access to the ocular cavity and the infusion of fluid or air during surgery. The 23G non-valved trocar cannula and infusion cannula are available as components within Accurus[®] and Constellation[®] TotalPLUS[®] Paks and Combined Procedure Packs. The impacted Alcon part numbers are summarized in the following table.

Product	Accurus [®]	Constellation [®]
23G TotalPLUS [®] Pak	8065750828	8065751058
23G Combined Procedure Pack, 0.9mm	8065750814	8065751077

After a thorough review of all impacted lots, below is a list of the impacted 23G product lots shipped to your facility, which may still be in your inventory:

Product	Lot Numbers
Accurus® 23G TotalPLUS® Pak 8065750828	<<to be inserted>>
Accurus® 23G Combined Pack, 0.9mm 8065750814	
Constellation® 23G TotalPLUS® Pak 8065751058	
Constellation® 23G Combined Pack, 0.9mm 8065751077	

Description of the Problem:

Alcon confirmed complaints for the 23G non-valved trocar cannula and infusion cannula related to a loose fit between the non-valved trocar cannula and infusion cannula. This loose fit may cause the infusion cannula to dislodge from the trocar cannula during the surgical procedure, which may eliminate the necessary infusion to the eye required to maintain adequate pressure while operating.

Action to be Taken by the Customer for TotalPLUS® Paks and Combined Packs:

Since the safety of the patients is at the center of what we do at Alcon, we will strongly advise our customers **NOT to use the non-valved trocar cannula for infusion**. To minimize disruption and ensure continuous patient care, replacement valved trocar cannulas will be provided to your facility at no charge.

Please follow these important steps for utilizing your replacement valved trocar cannula:

- 1) Review your inventory of Alcon products to determine if you have any of the impacted products in stock.
- 2) Please complete and return the attached Response form to Alcon at:
 - a. Email: GB.ADR@alconlabs.com; or
 - b. Fax: 01276 673971
- 3) Upon opening an impacted product, Health Care Professionals should **use a single valved trocar cannula (grey handle) for the INFUSION CANNULA ONLY, in PLACE OF the non-valved trocar cannula (black handle)**.
- 4) Discard the unused non-valved trocar cannula (black handle).



If your facility chooses not to use the replacement valved trocar cannula, please indicate this on the Response Form and contact your Alcon Sales Representative to discuss other options.

Future Orders

Unless your facility requests otherwise, to minimize disruption and to ensure continuous patient care, Alcon will continue to supply you with replacement valved trocar cannulas. A communication will be included with your orders to remind you to utilize the replacement valved cannula in place of the non-valved cannula contained in the packs.

Product	Accurus®	Constellation®
23G TotalPLUS® Pak	8065750828	8065751058
23G Combined Procedure Pack, 0.9mm	8065750814	8065751077

Alcon is committed to resolving this issue as quickly as possible.

Transmission of this Notice:

Please IMMEDIATELY forward this information to all departments within your organisation who may be using or ordering 23G Alcon Packs. Additionally, please ensure that a copy of this notification is provided to any other organisations to which the affected devices have been transferred.

Contact reference person:

We appreciate your immediate attention and cooperation and sincerely regret any inconvenience that this may cause you. We hope this action reassures you of our commitment to provide you with the highest quality vision care products and continued quality excellence for you and your patients.

Should you have any questions or concerns about this medical device correction, please contact Alcon on 0871 3760084 or your local Alcon Representative.

Yours sincerely



Tim Cripps
Head of Regulatory Affairs UK and Ireland

FIELD SAFETY NOTICE RESPONSE FORM

Re: Alcon's 23G TotalPLUS[®] Paks and 23G Combined Procedure Packs

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Please read the attached Field Safety Notice. After reading, please acknowledge that you have received, read and understand the actions to be taken by completing the information below. The completed response form should be immediately returned via fax or email to Alcon at:

GB.ADR@alconlabs.com or fax 01276 673971

| Facility Information                                                                                       | 1. Quantity of Single Units Remaining in Facility Inventory             |        |
|------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------|--------|
| <Prefilled Account #><br><Facility Name><br><Facility Address><br><Facility Address><br><Facility Address> | Product                                                                 | Number |
|                                                                                                            | Accurus <sup>®</sup> 23G TotalPLUS <sup>®</sup> Pak<br>8065750828       |        |
|                                                                                                            | Accurus <sup>®</sup> 23G Combined Pack, 0.9mm<br>8065750814             |        |
|                                                                                                            | Constellation <sup>®</sup> 23G TotalPLUS <sup>®</sup> Pak<br>8065751058 |        |
|                                                                                                            | Constellation <sup>®</sup> 23G Combined Pack, 0.9mm<br>8065751077       |        |

| 2. Customer Option for Current Pack Inventory (Check Box)                                                                                                              |                                                                                                                                                                                           | 3. Customer Option for Future Pack Shipments                                                                                                                                                                                                   | Check Box                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
| <input type="checkbox"/><br>This facility agrees to use the supplied 23G replacement valved trocar cannula with the infusion cannula in the 23G pack for my inventory. | <input type="checkbox"/><br>This facility would like to return the inventory and select either Option 3 or 4 for future orders. Please contact me with information to return the product. | 1. For Accurus, this facility agrees to temporarily use the 23G valved trocar cannula with the infusion cannula in the 23G Pack for future orders.                                                                                             | <input type="checkbox"/> |
|                                                                                                                                                                        |                                                                                                                                                                                           | 2. For Constellation, this facility agrees to temporarily use the 23G valved trocar cannula with the infusion cannula in the 23G Pack for future orders.                                                                                       | <input type="checkbox"/> |
|                                                                                                                                                                        |                                                                                                                                                                                           | 3. For Constellation, this facility would like to switch to 23G Valved Trocar Cannula TotalPLUS <sup>®</sup> Paks ( <b>which are not affected by this action</b> ) for future orders. Please have my sales rep provide an in-service.          | <input type="checkbox"/> |
| Replacement product can be sent to the attention of:                                                                                                                   |                                                                                                                                                                                           | 4. For either Accurus <sup>®</sup> or Constellation <sup>®</sup> , this facility would like to switch to either 25+ <sup>™</sup> or 20G ( <b>which are not affected by this action</b> ). Please have my sales rep call me to discuss options. | <input type="checkbox"/> |

4. Signature of Facility Representative:

Printed Name and Title: \_\_\_\_\_

Date: \_\_\_\_\_