

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 Health Care Professional:

Alcon has previously advised you of a voluntary Field Safety Corrective Action for specific lots of Alcon's 23G TotalPLUS[®] Paks and 23G Combined Procedure Packs. The 23G TotalPLUS[®] Paks and 23G Combined Procedure Packs in this shipment are impacted and 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
23G Combined Procedure Pack 1.1mm	8065750816	8065751065

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, in a separate shipment Alcon is providing replacement valved trocar cannulas to your facility at no charge.

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

- 1) The 23G TotalPLUS® Paks and 23G Combined Procedure Packs you are receiving are impacted.
- 2) 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)**.
- 3) Discard the unused non-valved trocar cannula (black handle).



Transmission of this Notice:

Please IMMEDIATELY forward this information to all departments within your organization who may be using or ordering 23G Alcon Packs. Additionally, please ensure that a copy of this notification is provided to any other organizations 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 at xxxxxxxxxxxx or your local Alcon Representative.

Sincerely,

<<Insert Affiliate Information>>