<<insert local address>>

URGENT: MEDICAL DEVICE FIELD SAFETY CORRECTIVE ACTION	
Description	**Increased Complaints for Knife Sharpness**
Relevant Products	**Various Ophthalmic Knives and Valved Entry Systems**
Action Identifier	**2024.007**

July XX, 2024

«Ship_to_Name»
«Address»
«City_», «State» «Zip_Code»
Account «Account»

Dear Healthcare Professional,

Alcon has detected increased complaint reports related to sharpness for specific ophthalmic knives. Based on our investigation, there is a potential for some knives and trocar entry systems within specific lots to not meet sharpness expectations. Our records indicate that the potentially affected product has been shipped to your site as a sterile standalone, within a Vitrectomy/Combined Procedure Pak, or an Alcon Custom Pak®.

This Medical Device Field Safety Corrective Action only affects specific lots of ophthalmic knives and trocar entry systems, and specific lots of Alcon Custom Pak® which contain affected knives/trocar entry systems. Please see *Appendix 1* for affected products and associated lot numbers distributed to your site.

Description of Issue:

Alcon's investigation has determined that there was a process shift on one electropolish machine, which resulted in the potential for a portion of knives/trocar entry system within these lots to not meet sharpness expectations.

If a knife does not meet expectations for sharpness, a user might apply increased penetration force. The use of increased penetration force should be avoided as using additional force during an anterior segment ophthalmic surgical procedure could potentially cause intraoperative complications such as corneal abrasion, Descemet's detachment, or wound leakage. Extra penetration force during vitreo-retinal surgery could lead to ciliary body detachment, vitreous base traction, or retinal tear in the worst-case scenario.

<<insert local address>>

Alcon

Actions to be taken by the Customer / User:

Our records indicate that you have received affected sterile standalone knives/trocar entry systems, Vitrectomy/Combined Procedure Pak, or an Alcon Custom Pak® with an affected knives/trocar entry system lot number.

- **If you received sterile standalone knives or trocar entry system**, we are asking that you dispose of the affected ophthalmic knife/trocar entry system and use a replacement. Alcon is sending sufficient replacement quantities to cover your estimated remaining impacted inventory.
- **If you received a Vitrectomy/Combined Procedure Pak ® with affected trocar entry system lot numbers,** we are asking that, upon opening your Vitrectomy/Combined Procedure Pak for surgical use, you remove and dispose of the affected trocar entry system and use a replacement trocar entry system. Alcon is sending sufficient replacement quantities to cover your estimated remaining impacted inventory.
- **If you received an Alcon Custom Pak® with affected knife or trocar entry system lot numbers**, we are asking that, upon opening your Custom Pak® for surgical use, you remove and dispose of the affected knife or trocar entry system contained within your specific lot(s) of Alcon Custom Pak® and use a replacement knife or trocar entry system. If you have a Custom Pak® lot listed in *Appendix 1*, then one or two of the knives/trocar entry systems in your Custom Pak® may be affected by the field correction. Please refer to the impacted lot list in *Appendix 1* to ensure that the appropriate knife/trocar entry system is removed. Alcon is sending replacement quantities of knives and/or trocar entry system to cover your estimated remaining impacted inventory, and any future shipments of impacted Custom Pak® lots.
  NOTE: Alcon surgical products are sterile and should not be opened before surgery. The remaining components of the Alcon Custom Pak® are unaffected by this Medical Device Field Correction and can be used as intended.

To assist with this Medical Device Field Safety Corrective Action, please take the following steps:

1. Forward this notification to all departments or organizations who may be using impacted ophthalmic knives and/or trocar entry systems.
2. See *Appendix 1* for a list of affected sterile standalone, Vitrectomy/Combined Procedure Pak or Alcon Custom Pak® lots that were distributed to your facility. You may receive Custom Pak® lots assembled before this Field Correction notification, and as a result, you may be receiving affected inventory in future shipments. If you receive any affected Alcon Custom Pak® lots in the future, they will be identified by a sticker.

Example Sticker

3. Review your inventory of sterile standalone lots, Vitrectomy/Combined Procedure Paks and Alcon Custom Pak® lots against the table in *Appendix 1*.
4. For current on-hand affected sterile standalone lots, please dispose of all impacted knives/trocar entry system lots identified in *Appendix 1*.
5. For your current on-hand affected inventory of Vitrectomy/Combined procedure packs and Alcon Custom Pak®, affix the provided stickers directly to the outside of your identified affected units in a location most easily seen for your facility. Upon opening your identified Vitrectomy/Combined procedure packs and Alcon Custom Pak® for surgical use, remove and dispose of the enclosed affected knife/trocar entry system. *NOTE: Alcon Vitrectomy/Combined procedure packs and Custom Pak® units are sterile and should not be opened before surgery.*
6. For your impacted Vitrectomy/Combined procedure packs and Custom Pak® lots, use a separate sterile standalone knife/trocar entry system, either from your inventory or those supplied by Alcon. For impacted Custom Pak® inventory that will ship in the future, Alcon will ship unaffected sterile standalone replacements to your facility.
7. Keep *Appendix 1* and post near your product inventory should you receive any affected Alcon Custom Pak® lots in the near future, or to know the part numbers for the affected knives/trocar entry system.
8. Please complete the attached *"Response Form"* indicating your understanding of these instructions, including how many units you have in inventory that will be disposed of, and return the form to Alcon.

In the event you have experienced adverse events or product quality issues related to this communication, please contact Alcon via <<insert local Alcon Adverse Event reporting contact info>>.

Adverse events or quality problems experienced with the use of this product may also be reported to the <<insert local Health Authority MoH and reporting contact if applicable>>.

Should you have any questions or concerns about this matter or need help finding a replacement or substitute sterile standalone ophthalmic knives or trocar entry systems, please call Alcon Customer Service at <<insert local contact info>> or contact your Alcon Sales Representative.

Sincerely,

<<insert local QA/RA contact>>

<<insert local address>>

Alcon

Appendix 1

Please post this near the product inventory

This Medical Device Field Safety Corrective Action only affects specific lots of sterile standalone knives/trocar entry system, and specific lots of Vitrectomy/Combined procedure pack or Alcon Custom Pak® which contain affected knives and trocar entry system. Please refer to the impacted lot list below.

The following sterile standalone product lots have been shipped to your site:

Knife/Trocar #	Knife/Trocar Description	Lot Number(s)
«part_number»	«kniveTrocar_description»	«lot_numbers»

The following Vitrectomy/Combined procedure packs or Alcon Custom Pak® lots have been shipped to your site:

Product #	Product Description	Impacted Knife or Trocar within Pak	Product Lot Number(s)
«custom_pak»	«Custom_pak_descriptions»	«impacted_knives_within_pak»	This is CPK or Vit pak lot # «Concat_batch_numbers»

If you have any questions about the lots you have in inventory, please feel free to call our Customer Service at <<insert local contact info>> or contact your Alcon Sales Representative.

<<insert local address>>

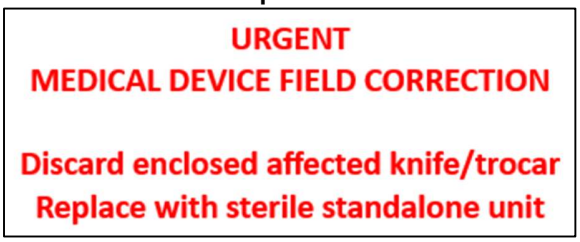
Alcon

RESPONSE FORM	
MA 2024.007 **Increased Complaints for Knife Sharpness**	LAPIDOT

To assist with this Medical Device Field Safety Corrective Action, please take the following steps:

1. Forward this notification to all departments or organizations who may be using impacted ophthalmic knives and/or trocar entry systems.
2. See *Appendix 1* for a list of affected sterile standalone, Vitrectomy/Combined Procedure Pak or Alcon Custom Pak® lots that were distributed to your facility. You may receive Custom Pak® lots assembled before this Field Correction notification, and as a result, you may be receiving affected inventory in future shipments. If you receive any affected Alcon Custom Pak® lots in the future, they will be identified by a sticker.

Example Sticker



3. Review your inventory of sterile standalone lots, Vitrectomy/Combined Procedure Paks and Alcon Custom Pak® lots against the table in *Appendix 1*.
4. For current on-hand affected sterile standalone lots, please dispose of all impacted knives/trocar entry system lots identified in *Appendix 1*.
5. For your current on-hand affected inventory of Vitrectomy/Combined procedure packs and Alcon Custom Pak®, affix the provided stickers directly to the outside of your identified affected units in a location most easily seen for your facility. Upon opening your identified Vitrectomy/Combined procedure packs and Alcon Custom Pak® for surgical use, remove and dispose of the enclosed affected knife/trocar entry system. *NOTE: Alcon Vitrectomy/Combined procedure packs and Custom Pak® units are sterile and should not be opened before surgery.*
6. For your impacted Vitrectomy/Combined procedure packs and Custom Pak® lots, use a separate sterile standalone knife/trocar entry system, either from your inventory or those supplied by Alcon. For impacted Custom Pak® inventory that will ship in the future, Alcon will ship unaffected sterile standalone replacements to your facility.
7. Keep *Appendix 1* and post near your product inventory should you receive any affected Alcon Custom Pak® lots in the near future, or to know the part numbers for the affected knives/trocar entry system.
8. Please complete this *"Response Form"* indicating your understanding of these instructions, including how many units you have in inventory that will be disposed, and return this form to Alcon.

Fax: <<insert local fax if applicable>> **Email**: <<insert local email if applicable>>

Your signature below attests that you have read and understood Alcon's request and instructions.

Signature of Representative:	**Date:**
Name and Title:	**Units on Hand/Disposed:**