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

URGENT MEDICAL DEVICE CORRECTION	
Description	Potential for specific models of ULTRAVIT® and HYPERVIT® probe to fail to actuate and cut during use
Product Reference	CONSTELLATION® ULTRAVIT® 10K CONSTELLATION® HYPERVIT® 20K
Market Action Identifier	2025.013

September 11, 2025

«Account_Name»
«Account_Address»
«City», «State» «Zip_Code»
«Account #»

Dear «Account_Name»,

This letter is to notify you that Alcon has initiated a **Medical Device Correction for specific models of ULTRAVIT® and HYPERVIT® probes** intended for use with the CONSTELLATION® Vision System and packs or kits containing those probes.

Alcon is conducting this Medical Device Correction as **there is potential for some probes to unexpectedly fail to actuate and cut during use**. This letter provides guidance to mitigate patient risk associated with these potential unexpected events during probe use.

Inventory of ULTRAVIT® and HYPERVIT® probes is limited, and sufficient inventory of alternative probes is currently not available to support emergent procedures. To prevent a probe shortage and the resulting risk of cancelling emergency and time-sensitive posterior segment surgeries, Alcon will continue to ship probes until non-affected probe inventory is available. We have identified the root cause of this issue and are actively working to build unaffected inventory.

Alcon provides ULTRAVIT® and HYPERVIT® in multiple product configurations, including within procedure packs and CUSTOM PAK®. Please see Attachment 1 for a list of affected probe models.

Reason for the medical device correction

Alcon has received complaints of CONSTELLATION® ULTRAVIT® (10K) and HYPERVIT® (20K) probes that unexpectedly failed to actuate and cut during use. Globally, reports of CONSTELLATION® ULTRAVIT® 10K and HYPERVIT® 20K failing to actuate and cut during use represent less than 1% of CONSTELLATION® ULTRAVIT® and HYPERVIT® probes sold from January through August 2025.

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Our investigation determined that a portion of ULTRAVIT® and HYPERVIT® probes were manufactured with a component received from a supplier that did not perform as intended, which can lead to increased friction within the probe engine. The increased friction may cause premature actuation failure, resulting in failure to cut.

Alcon detected an increased trend of adverse event (AE) reports associated with CONSTELLATION® ULTRAVIT® 10K probes related to this issue. From January 2025 through September 1, 2025, Alcon has received a global total of 10 complaints associated with CONSTELLATION® ULTRAVIT® 10K probes for failure to cut that included adverse events (AEs). There is no increase in reported adverse events related to CONSTELLATION® HYPERVIT® 20K probes.

Potential patient impact

There is a remote chance that an adverse event may occur if a probe unexpectedly fails to actuate and cut during surgery. Depending on the position of the cutter when the issue occurs and the amount of suction pressure applied by the probe, there is a potential for increased traction on the vitreous and/or retina that could lead to retinal detachment, holes, or tears.

Actions to be taken by the customer / user

A. To mitigate the potential risk associated with unexpected cut stoppage during surgery, Alcon is advising customers to take the following precautions:
   1. Strictly adhere to the Instructions for Use (IFU) regarding limitations, including maximum use time and single use only.
   2. **When using a probe model identified as within the scope of the Medical Device Correction:**
      a. **Reduce the actuation rate to no more than 5000 actuations per minute**
      b. **Adjust other related console settings as needed to accommodate the reduced cutting/actuation rate**
      c. **If a reduction of cutting capability or failure to actuate is observed during the surgical procedure, stop immediately. Take all necessary surgical precautions to remove the probe and replace it with an unused probe.**

B. To acknowledge your receipt of this Medical Device Correction notification, please take the following steps:
   1. Review your inventory to determine if you have affected product within your facility. See Attachment 1 for a list of probe models within the scope of the Medical Device Correction.
   2. Follow the risk mitigation precautions provided in this notice when using identified models of ULTRAVIT® and HYPERVIT® probes.
   3. Post this notification letter near where affected products are stored to make facility personnel aware of this Medical Device Correction and associated Alcon corrective action.

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4. 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.
5. Respond to Alcon indicating your understanding of these instructions **even if you have zero (0) units remaining in inventory** by completing the attached Response Form and returning to Alcon via email or fax.

Alcon will notify customers regarding replacement inventory as soon as adequate inventory of new, non-affected probes is available.

In the event you have experienced adverse events or product quality issues related to this communication, please contact Alcon at [insert local complaint intake details].

Adverse events or quality problems experienced with the use of this product may also be reported to [insert local health authority complaint reporting details, if required].

Should you have any questions or concerns about this matter, please feel free to call our Customer Service at [contact number] or contact your Alcon Sales Representative.

Sincerely,

Heather Attra
Senior Vice President, Chief Quality and Regulatory Affairs Officer

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RESPONSE FORM

Potential for specific models of ULTRAVIT® and HYPERVIT® probe to fail to actuate or cut during use
MA# 2025.013

«Account_Name»
«Account_Address»
«City», «State» «Zip_Code»
Account# «Account #»

To acknowledge your receipt of this Medical Device Correction notification, please take the following steps:

1. Review your inventory to determine if you have affected product within your facility. See Attachment 1 for a list of probe models within the scope of the Medical Device Correction.
2. Follow the risk mitigation precautions provided in this notice when using identified models of ULTRAVIT® and HYPERVIT® probes.
3. Post this notification letter near where affected products are stored to make facility personnel aware of this Medical Device Correction and associated Alcon corrective action.
4. 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.
5. Respond to Alcon indicating your understanding of these instructions **even if you have zero (0) units remaining in inventory** by completing the attached Response Form and returning to Alcon via email or fax.

Please return this Response Form via fax or email to Alcon:
Fax: [local fax] Email: [local contact]

Your signature below attests that you have read and understood the information in this notice.

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

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Attachment 1: List of relevant products and catalog numbers

CONSTELLATION® ULTRAVIT® (10K) and HYPERVIT® (20K) probes and any packs containing these probes which remain within their labeled expiration date are affected by this Medical Device Correction. This includes all lots of the part numbers listed below, including lots in shipments you may receive in the future. Alcon will notify customers regarding replacement products as soon as adequate inventory of new, non-affected probes is available.

If you have any questions about Alcon products, please feel free to call our Customer Service at [local number] or contact your Alcon Sales Representative.

Catalog Number	Item Description

Catalog Number	Item Description