VOLUNTARY FIELD SAFETY CORRECTIVE ACTION	
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

April 28, 2026

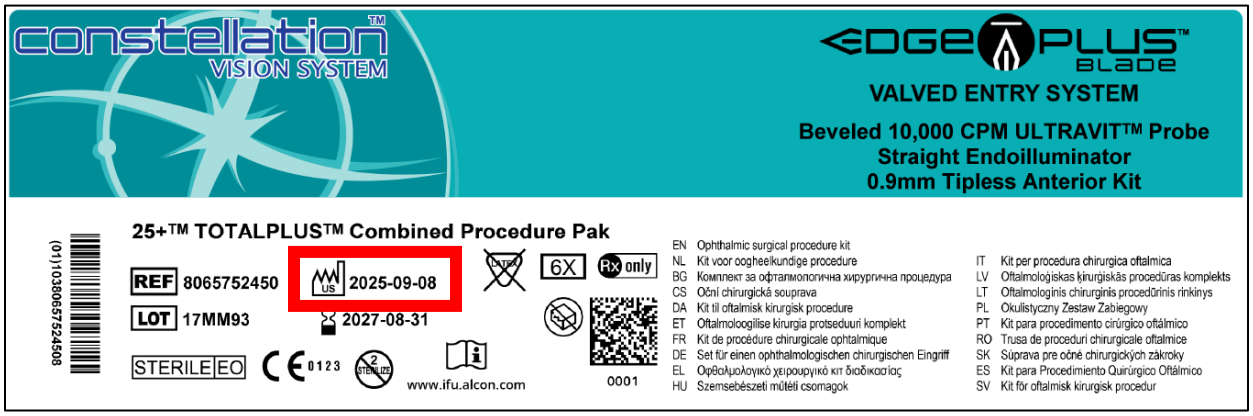
Medic d.o.o.

Dear partner,

This letter is a follow-up to the communication provided to you in September 2025, and is related to the **Voluntary Field Safety Correction for specific models of ULTRAVIT® and HYPERVIT® probes** intended for use with the CONSTELLATION® and Vitreoretinal Cataract Systems. As previously communicated, to prevent probe shortages and potential surgery cancellations due to initial inventory constraints, Alcon asked that you reduce the actuation rate of affected probe products to no more than 5000 actuations per minute, until sufficient unaffected probe inventory was available.

Alcon has made corrections to our ULTRAVIT® and HYPERVIT® probes and has ceased distribution to your facility of affected **standalone** ULTRAVIT® and HYPERVIT® probes, and FMS (Fluid Management System) Pak products.

Any ULTRAVIT® or HYPERVIT® probes and FMS Procedure Pak with these probes, that were manufactured on or after September 8, 2025 (indicated as **2025-09-08** on the label), include the correction, and can be used for all actuation speeds as indicated in their associated labeling or Instructions For Use (IFU). Please see image below to identify the manufacturing date on the label.



As previously communicated, reason for the 2025 Voluntary Field Safety Correction

Alcon detected an increased trend of complaints and adverse event (AE) reports associated with CONSTELLATION® ULTRAVIT® 10K probes related to unexpected failure to actuate and cut during use.

Our investigation of the complaint trend determined that a portion of Alcon vitrectomy probes were manufactured with a component received from a supplier that did not perform as intended, which could potentially lead to increased friction within the probe engine. The increased friction may cause premature actuation failure, resulting in failure to cut.

Potential patient impact

There is a remote chance that an adverse event may occur if an affected 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

ULTRAVIT® and HYPERVIT® probes, and FMS Pak products manufactured on or after September 8, 2025 (indicated as **2025-09-08** on the label) can be used for all actuation speeds as indicated in their associated labeling or IFU.

To acknowledge your receipt and understanding of this notification, please take the following steps:

1. Review your inventory to determine if you have any remaining affected standalone ULTRAVIT® probe, HYPERVIT® probe, FMS Pak products:
    - **For standalone ULTRAVIT® and HYPERVIT® probes and FMS Pak**: this is any product within your facility manufactured before **2025-09-08**. See ***Attachment 1*** for a list of probe models within the scope of the Voluntary Field Safety Correction.
2. Identify any remaining impacted inventory and continue reduced actuation rate of to no more than 5000 actuations per minute for these products.
3. Call Alcon Customer Service if you need help verifying affected lots in your inventory.
4. Post this notification letter near where affected products are stored to make facility personnel aware of this Voluntary Field Safety Correction and associated Alcon corrective action.
5. 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.
6. Once impacted inventory has been used, machine settings can be changed for use at actuation speeds as indicated in their associated labeling or Instructions For Use (IFU).
7. Respond to Alcon even if you have zero (0) units remaining in inventory by completing the attached *Response Form* and returning to Alcon.

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

Adverse events or quality problems experienced with the use of this product may also be reported to 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
Senior Vice President, Chief Quality and Regulatory Affairs Officer

RESPONSE FORM	
Potential for ULTRAVIT® and HYPERVIT® probe to fail to actuate or cut during use MA# 2025.013	**Medic d.o.o.**

To acknowledge your receipt of this Voluntary Field Safety Correction notification, please take the following steps:

1. Review your inventory to determine if you have any remaining affected ULTRAVIT® probe, HYPERVIT® probe, FMS Pak products or Alcon Custom Pak® products:
    a. **For standalone ULTRAVIT® and HYPERVIT® probes and FMS Pak**: this is any product within your facility manufactured before **2025-09-08**. See ***Attachment 1*** for a list of probe models within the scope of the Voluntary Field Safety Correction.
2. Identify any remaining impacted inventory and continue reduced actuation rate of to no more than 5000 actuations per minute for these products.
3. Call Alcon Customer Service if you need help verifying affected lots in your inventory
4. Post this notification letter near where affected products are stored to make facility personnel aware of this Voluntary Field Safety Correction and associated Alcon corrective action.
5. 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.
6. Once impacted inventory has been used, machine settings can be changed for use at actuation speeds as indicated in their associated labeling or Instructions For Use (IFU).
7. **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.

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 the information in this notice.

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

Attachment 1: List of Affected Products

If you have any questions about lots in your inventory, please feel free to contact Alcon Customer Service or contact your Alcon Sales Representative.

Catalog Number	Production Description	Batch Number	Number of affected boxes
8065752448	**23G CMB PAK 10K CPM,V,STD 0.9**	16W3X3	0
8065752448	23G CMB PAK 10K CPM,V,STD 0.9	16W3X4	0
8065752448	23G CMB PAK 10K CPM,V,STD 0.9	16WLJW	0
8065752448	23G CMB PAK 10K CPM,V,STD 0.9	16YR69	0
8065752448	23G CMB PAK 10K CPM,V,STD 0.9	1702EU	0
8065752448	23G CMB PAK 10K CPM,V,STD 0.9	171U5H	0
8065752448	23G CMB PAK 10K CPM,V,STD 0.9	17260V	0
8065752448	23G CMB PAK 10K CPM,V,STD 0.9	176WUF	0
8065752448	23G CMB PAK 10K CPM,V,STD 0.9	1776AH	0
8065752448	23G CMB PAK 10K CPM,V,STD 0.9	1782J4	1
8065752448	23G CMB PAK 10K CPM,V,STD 0.9	178TA4	0
8065752448	23G CMB PAK 10K CPM,V,STD 0.9	17930J	0
8065752448	23G CMB PAK 10K CPM,V,STD 0.9	179EH3	1
8065752448	23G CMB PAK 10K CPM,V,STD 0.9	179TYL	0
8065752448	23G CMB PAK 10K CPM,V,STD 0.9	17C7F3	0
8065752448	23G CMB PAK 10K CPM,V,STD 0.9	17EEHU	43
8065752448	23G CMB PAK 10K CPM,V,STD 0.9	17F535	10
8065752448	23G CMB PAK 10K CPM,V,STD 0.9	17FLDE	0
8065752448	23G CMB PAK 10K CPM,V,STD 0.9	17FXEM	0
	TOTAL		**55**
8065752437	**TOTAL PLUS,25+,10K VALVE STD**	16NDXH	0
8065752437	TOTAL PLUS,25+,10K VALVE STD	170N0U	0
8065752437	TOTAL PLUS,25+,10K VALVE STD	17260N	0
8065752437	TOTAL PLUS,25+,10K VALVE STD	17260R	0
8065752437	TOTAL PLUS,25+,10K VALVE STD	178TD4	0
8065752437	TOTAL PLUS,25+,10K VALVE STD	17F52U	0
8065752437	TOTAL PLUS,25+,10K VALVE STD	17FLCP	6
	TOTAL:		**6**
8065752438	**TOTAL PLUS,25+,10K VALVE WD**	17174E	0

8065752438	TOTAL PLUS,25+,10K VALVE WD	1776AD	1
8065752438	TOTAL PLUS,25+,10K VALVE WD	17FLDC	5
8065752438	TOTAL PLUS,25+,10K VALVE WD	17H951	3
	TOTAL:		**9**
8065752450	**25+ CMB PAK 10K CPM,V,STD 0.9**	16MV19	0
8065752450	25+ CMB PAK 10K CPM,V,STD 0.9	16PJ1Y	0
8065752450	25+ CMB PAK 10K CPM,V,STD 0.9	16UUEK	0
8065752450	25+ CMB PAK 10K CPM,V,STD 0.9	16V4Y0	0
8065752450	25+ CMB PAK 10K CPM,V,STD 0.9	16Y10H	0
8065752450	25+ CMB PAK 10K CPM,V,STD 0.9	1707N2	0
8065752450	25+ CMB PAK 10K CPM,V,STD 0.9	172NVU	0
8065752450	25+ CMB PAK 10K CPM,V,STD 0.9	1732C3	0
8065752450	25+ CMB PAK 10K CPM,V,STD 0.9	173DV7	0
8065752450	25+ CMB PAK 10K CPM,V,STD 0.9	1754P1	0
8065752450	25+ CMB PAK 10K CPM,V,STD 0.9	176CCX	0
8065752450	25+ CMB PAK 10K CPM,V,STD 0.9	1776CF	0
8065752450	25+ CMB PAK 10K CPM,V,STD 0.9	177FDV	0
8065752450	25+ CMB PAK 10K CPM,V,STD 0.9	1782J7	0
8065752450	25+ CMB PAK 10K CPM,V,STD 0.9	17AFXM	0
8065752450	25+ CMB PAK 10K CPM,V,STD 0.9	17AVMF	0
8065752450	25+ CMB PAK 10K CPM,V,STD 0.9	17ET0E	0
8065752450	25+ CMB PAK 10K CPM,V,STD 0.9	17FXET	0
8065752450	25+ CMB PAK 10K CPM,V,STD 0.9	17HJL9	1
	TOTAL:		**1**
8065752451	**25+ CMB PAK 10K CPM,V,WA 0.9**	172NW4	0
8065752439	**TOTAL PLUS,27+,10K VALVE STD**	16X5V5	0
8065752439	TOTAL PLUS,27+,10K VALVE STD	17DRAD	0
	TOTAL		**0**
8065752452	**27+ CMB PAK 10K CPM,V,STD 0.9**	16Y10U	0
8065752452	27+ CMB PAK 10K CPM,V,STD 0.9	1776CR	0
8065752452	27+ CMB PAK 10K CPM,V,STD 0.9	178DEV	2
8065752452	27+ CMB PAK 10K CPM,V,STD 0.9	17CNV1	0
8065752452	27+ CMB PAK 10K CPM,V,STD 0.9	16NRWP	0
	TOTAL		**2**
8065752435	**TOTAL PLUS,23G,10K VALVE STD**	16RRL3	0
8065752435	TOTAL PLUS,23G,10K VALVE STD	16T7U6	0
8065752435	TOTAL PLUS,23G,10K VALVE STD	16X5HC	0

8065752435	TOTAL PLUS,23G,10K VALVE STD	16Y107	0
8065752435	TOTAL PLUS,23G,10K VALVE STD	17260H	0
8065752435	TOTAL PLUS,23G,10K VALVE STD	172H57	0
8065752435	TOTAL PLUS,23G,10K VALVE STD	176CCJ	0
8065752435	TOTAL PLUS,23G,10K VALVE STD	1782HN	0
8065752435	TOTAL PLUS,23G,10K VALVE STD	179TY4	4
8065752435	TOTAL PLUS,23G,10K VALVE STD	17CNUP	3
8065752435	TOTAL PLUS,23G,10K VALVE STD	17E13A	27
8065752435	TOTAL PLUS,23G,10K VALVE STD	17F52P	15
8065752435	TOTAL PLUS,23G,10K VALVE STD	17HJKW	7
8065752435	TOTAL PLUS,23G,10K VALVE STD	17HJKX	2
8065752435	TOTAL PLUS,23G,10K VALVE STD	17MAKN	18
	TOTAL		**76**
8065752436	**TOTAL PLUS,23GA,10K VALVE WD**	17FLC9	2
8065752436	TOTAL PLUS,23GA,10K VALVE WD	17KCWU	2
	TOTAL		**4**
8065753106	**25+TTLPL VPK 20000CPM BEV VAL**	173DVU	**0**
8065753109	**27+TTLPL VPK 20000CPM BEV VL**	171U1P	**0**
8065000095	**25+ TOTALPLUS CP PAK 20K CPM BV .9 IU**	1742TV	0
8065000095	25+ TOTALPLUS CP PAK 20K CPM BV .9 IU	177TV6	0
8065000095	25+ TOTALPLUS CP PAK 20K CPM BV .9 IU	172625	0
8065000095	25+ TOTALPLUS CP PAK 20K CPM BV .9 IU	1776D7	0
	TOTAL		**0**