Alcon
a Novartis company

URGENT: FIELD SAFETY NOTICE

Commercial Name of Affected Product:	**ACCURUS® 2500 STAND-ALONE VITREOUS PROBE** **ACCURUS® 23 GA STANDALONE VITREOUS PROBE** **ACCURUS® 25+ 2500 CPM STAND-ALONE VITREOUS PROBE** **ANTERIOR ACCURUS® PROBE WITH INFUSION NEEDLE**
Reference(s):	**8065741018** **8065750821** **8065751122** **8065803650**
FSCA Identifier:	**2015.026**
Type of Action:	**Medical Device Recall**

June 3, 2015

«Account_Name»
«Account_Address»
«City», «State» «Zip_Code»
«Contact_Name»

Dear Valued Alcon Customer,

Alcon has discovered that the specific single-use standalone Accurus® Vitrectomy Probe lots listed below may have an insufficient primary seal on the outside packaging, potentially affecting the sterility of the product.

Reason for the Voluntary Recall:

Alcon is conducting a voluntary medical device recall for specific lots of its single-use standalone Accurus® Vitrectomy Probes after discovering an insufficient seal on the outside packaging that could potentially affect the sterility of the product. The use of non-sterile vitrectomy probes in surgery has the potential to result in patient infection or inflammation.

Details on Affected Device:

The single-use standalone Accurus® Probe is intended to provide the surgeon with a single-use probe for performing vitrectomy surgical procedures while using the Alcon Accurus® vitrectomy console.

This medical device recall is for specific lots of single use Accurus® vitrectomy probes. The standalone product lots affected by this recall are included in Table 1, next page.

Alcon
a Novartis company

Table 1: Standalone Product Lots Affected by this Medical Device Recall

Catalog # 8065741018	Catalog # 8065750821	Catalog # 8065751122	Catalog # 8065803650
Lot Numbers	Lot Numbers	Lot Numbers	Lot Numbers
14014738X	14010428X	14010429X	14010430X
14017452X	14012987X	14012985X	14012984X
14020246X	14014736X	14014737X	14014739X
14022921X	14016577X	14016477X	14017451X
14026030X	14017912X	14018320X	14020283X
14028440X	14020280X	14020282X	14022923X
14031263X	14022920X	14022922X	14024219X
14033833X	14024168X	14026032X	14026034X
14036297X	14026031X	14028554X	14028555X
15010056X	14028553X	14033831X	14031264X
15012798X	14029477X	14036315X	14033832X
15014227X	14033830X	15010058X	14036319X
15015746X	14036306X	15013290X	14038094X
	15010057X		15010059X
	15012799X		15013291X
	15015699X		

Description of the Problem:

Alcon is conducting a voluntary medical device recall for specific lots of its single-use standalone Accurus® Vitrectomy Probe after discovering an insufficient seal on the outside packaging that could potentially affect the sterility of the product.

At this time, no adverse events or complaints have been confirmed related to the Accurus Vitrectomy Probe lots impacted by this voluntary recall. Regular post-operative patient follow-up may enable the surgeon to detect early potential abnormal inflammatory reaction and/or infection, which may reduce the severity of the ensuing event.

Actions to be Taken by the Customer/User:

To assist us in this voluntary recall, please take the following steps:

1. Immediately stop further use of the affected lots of Accurus probes.
2. Review your inventory to determine if you have any affected units.
3. Segregate the potentially-affected product to ensure it is not used.
4. Return the attached Response Form via fax or email to Alcon.
5. **Please fill out and return the attached "Response Form" even if you have zero (0) units in inventory.**

Alcon
a Novartis company

Please Note: Replacement stock will be issued for catalog numbers 8065741018, 8065750821, 8065751122 and 8065803650 that are returned to Alcon. An Alcon Representative will work with you to place a new order and replace the affected units. Please contact Sarah Furrer at 079 800 19 95 to arrange for the return of your inventory.

Transmission of this Notice:

Please immediately forward this information to all departments within your organization who may be using or ordering the single-use standalone Accurus® probe. Additionally, please ensure that a copy of this notification is provided to any other organizations to which the affected device lots have been transferred.

Contact Reference Person:

We appreciate your 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 matter, please contact Sarah Furrer at 079 800 19 95.

Sincerely,

i.V.

Markus Reut
Head of Market Access & Regulatory Affairs
Alcon Switzerland SA
Suurstoffi 14, CH-6343 Rotkreuz, Switzerland
T +41 41 763 7740 | Fax +41 58 911 37 04 | M +41 79 848 60 65
markus.reut@alcon.com

Alcon
a Novartis company

ACCURUS® PROBES
RESPONSE FORM
MA 2015.026

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

Catalogue Number	Description
8065741018	ACCURUS® 2500 STAND-ALONE VITREOUS PROBE
8065750821	ACCURUS® 23 GA STANDALONE VITREOUS PROBE
8065751122	ACCURUS® 25+ 2500 CPM STAND-ALONE VITREOUS PROBE
8065803650	ANTERIOR ACCURUS® PROBE WITH INFUSION NEEDLE

Please follow these important steps:

1. **Immediately stop further use of the affected lots of Accurus Probe**
2. Review your inventory to determine if you have any affected units
3. Segregate the potentially-affected product to ensure it is not used
4. Return the attached Response Form via fax or email to Alcon
5. **Please fill out and return the attached "Response Form" even if you have zero (0) units in inventory**

Fax +41 58 911 37 95
Email: christoph.morger@alcon.com

Please return the Response Form even if you do not have any inventory from these lots. Your signature bellow attests that you have read and understood Alcon's request and instructions.

Please contact Sarah Furrer at 079 800 19 95 to arrange for the return of your inventory.

Catalog Number	Lot ID Number	# Units in Inventory

Signature of Facility Representative:

Printed Name and Title:

Date: