

URGENT: FIELD SAFETY NOTICE

Commercial Name of Affected Product: CENTURION[®] FMS (Fluidics Management System)
Pack for CENTURION[®] Vision System
Reference(s): 8065752180-8065752203; 8065752212-8065752217;
8065752244-8065752247; 8065752274-8065752275;
8065752479-8065752494; 8065752917-8065752920
FSCA Identifier: 2016.018
Type of Action: Medical Device Removal

April 29, 2016

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

Dear Valued Alcon Customer.

This letter is to advise you of a Voluntary Medical Device Removal being initiated by Alcon for the CENTURION[®] FMS (Fluidics Management System) Pack for the CENTURION[®] Vision System. Alcon is conducting this Voluntary Medical Device Removal for specific lots of its CENTURION[®] FMS packs due to the possible presence of a molding irregularity found within the aspiration luer which may result in a reduction of vacuum within the aspiration line. We have identified that you have recently received stock from one or more of the identified lot numbers listed in *Attachment 1* of this letter.

Details on Affected Device:

The CENTURION[®] Vision System is a Phacoemulsification Aspiration (P.E.A.) platform designed for use in anterior segment procedures that require simultaneous lens extraction, irrigation, aspiration, phacoemulsification, vitreous aspiration cutting, and bipolar coagulation, as well as automated IOL injection. The consumables CENTURION[®] FMS pack in conjunction with the console fluidics and irrigation modules controls irrigation and aspiration and is responsible for maintaining fluidics balance in the eye during cataract surgery.

Description of the Potential Condition:

Alcon is conducting this Voluntary Medical Device Removal for specific lots of its CENTURION[®] FMS packs due to the possible presence of a molding irregularity found within the aspiration luer which may result in a reduction of vacuum within the aspiration line. The use of products from the affected lots of Alcon CENTURION[®] FMS Pack may result in a small air leak and corresponding reduction in vacuum performance, leading to inability to achieve or reach maximum targeted vacuum and reduction of holding force at distal end of the phaco tip.

While the molding irregularity that causes this potential reduction in vacuum is most likely only to cause a reduction in the efficiency of removing the OVD and lens fragments from the eye resulting in a slightly longer surgical procedure. However, there is also a low likelihood of a patient harm to occur. Potential

foreseeable harms identified for this issue include, in descending order of clinical likelihood, the following: thermal injury, capsular bag tear, tissue damage, corneal endothelial cell damage, corneal edema, retinal tear/detachment, and endophthalmitis.

To date, there have been no harms reported resulting from this issue.

Actions to be taken by the Customer / User:

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

1. Review your inventory to determine if you have any affected CENTURION[®] FMS units
2. Stop the use of any affected CENTURION[®] FMS units immediately
3. Segregate the potentially-affected product to ensure it is not used
4. Contact Alcon Customer service to arrange replacement of affected units, if necessary
5. Forward notification to all departments or organizations affected
6. Please fill out and return the attached "*Response Form*" even if you have zero units in inventory
7. Return the attached "*Response Form*" via fax or email to Alcon. The completed response form should be immediately returned via fax or email to:

Fax: +44 1276 673971

Email: gb.medicaldepartment@alcon.com

Please Note: Replacement stock will be issued for units that are returned to Alcon. An Alcon Customer Service Representative will work with you to place a new order to replace the affected units. Please contact Alcon Customer Service to arrange for the return of your inventory.

Telephone: +44 1276 673556

Email: gb.customerservice@alcon.com

Transmission of this Voluntary Medical Device Removal:

Please immediately forward this information to professionals within your organization who may be using the CENTURION[®] Vision System and associated CENTURION[®] FMS Packs. Additionally, please ensure that a copy of this notification is provided to any other organizations to which the CENTURION[®] Vision System may have been transferred.

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 Alcon Medical Information at:

Telephone: +44 (0) 345 266 9363

Email: gb.medicaldepartment@alcon.com

Yours Sincerely,



James Comper

Regulatory Affairs Manager UK & Ireland

Park View, Watchmoor Park, Camberley, Surrey, GU15 3YL. United Kingdom

**Alcon CENTURION® Fluid Management System (FMS) Packs
RESPONSE FORM
MA# 2016.018**

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

Please follow these important steps:

1. Review your inventory to determine if you have any affected CENTURION® FMS units
2. Stop the use of any affected CENTURION® FMS units immediately
3. Segregate the potentially-affected product to ensure it is not used
4. Contact Alcon Customer service to arrange replacement of affected units, if necessary
5. Forward notification to all departments or organizations affected
6. Please fill out and return the attached "Response Form" even if you have zero (0) units in inventory
7. Return the attached "Response Form" via fax or email to Alcon Medical Information.

Fax: +44 1276 673971

Email: gb.medicaldepartment@alcon.com

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

Please contact Alcon Customer Service to arrange for the return of your inventory using the following contact details.

Telephone: +44 1276 673556

Email: gb.customerservice@alcon.com

Catalog Number	Lot Numbers in Inventory	Quantity in Inventory	Catalog Number	Lot Numbers in Inventory	Quantity in Inventory

Signature of Facility Representative:

Printed Name and Title:

Date:

Catalog #	Lot #	Product Description
8065752200	1802319H	CEN FMS PACK,ACT,,9U 30 BAL
8065752200	1802320H	CEN FMS PACK,ACT,,9U 30 BAL
8065752200	1804670H	CEN FMS PACK,ACT,,9U 30 BAL
8065752200	1804671H	CEN FMS PACK,ACT,,9U 30 BAL

Catalog #	Lot #	Product Description
8065752918	1794560H	CEN FMS PACK,ACT,,9 45 BAL
8065752918	1794561H	CEN FMS PACK,ACT,,9 45 BAL
8065752918	1794562H	CEN FMS PACK,ACT,,9 45 BAL
8065752918	1801714H	CEN FMS PACK,ACT,,9 45 BAL

Affected Custom Paks™

Catalog #	Lot #	Product Description
10772-26	1857679H	CATARACT PACK
11211-14	1850236H	CATARACT
11211-14	1855616H	CATARACT
14668-08	1852312H	PINK/45K MINI/DUOVISC
14668-08	1852313H	PINK/45K MINI/DUOVISC
14668-08	1858039H	PINK/45K MINI/DUOVISC
16072-02	1852102H	LENSX
1851-65	1856223H	OPHTHALMIC