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Alcon
a Novartis company

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**

May 05, 2016

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

Attention <<Enter Customer Information>>:

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. 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. 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.

Alcon has chosen to initiate this Voluntary Medical Device Removal after a quality review process showed that a specific lot of aspiration luers received from our vendor contained a molding irregularity. These luers are used on the aspiration line of the CENTURION® FMS packs. We are conducting this Voluntary Medical Device Removal due to the fact that the possibility exists for a reduction in vacuum during surgery which may cause the potential inability to achieve or reach maximum targeted vacuum.

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

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

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 at <<insert contact information>> to arrange for the return of your inventory.

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 at <<insert contact information>>

Alcon Representative,
Alcon affiliate name and address

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

<<Insert Alcon Affiliate contact information here>>

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

Please contact Alcon Customer Service at <<Insert Alcon Affiliate contact information here>> to arrange for the return of your inventory.

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:

Attachment 1: Affected Lot Numbers *(sorted by Catalog #, then Lot #)*

Catalog #	Lot #	Product Description
8065752180	1794101H	CENT FMS PACK,ACT,BASIC
8065752180	1794102H	CENT FMS PACK,ACT,BASIC
8065752180	1794103H	CENT FMS PACK,ACT,BASIC
8065752180	1794104H	CENT FMS PACK,ACT,BASIC
8065752180	1794105H	CENT FMS PACK,ACT,BASIC
8065752180	1794106H	CENT FMS PACK,ACT,BASIC
8065752180	1794107H	CENT FMS PACK,ACT,BASIC
8065752180	1794108H	CENT FMS PACK,ACT,BASIC
8065752180	1799220H	CENT FMS PACK,ACT,BASIC
8065752180	1799221H	CENT FMS PACK,ACT,BASIC
8065752180	1799222H	CENT FMS PACK,ACT,BASIC
8065752180	1799223H	CENT FMS PACK,ACT,BASIC
8065752180	1799224H	CENT FMS PACK,ACT,BASIC
8065752180	1799225H	CENT FMS PACK,ACT,BASIC
8065752180	1799226H	CENT FMS PACK,ACT,BASIC
8065752180	1799227H	CENT FMS PACK,ACT,BASIC
8065752180	1799228H	CENT FMS PACK,ACT,BASIC
8065752180	1799229H	CENT FMS PACK,ACT,BASIC
8065752180	1799230H	CENT FMS PACK,ACT,BASIC
8065752180	1799231H	CENT FMS PACK,ACT,BASIC
8065752180	1799232H	CENT FMS PACK,ACT,BASIC
8065752180	1799233H	CENT FMS PACK,ACT,BASIC
8065752180	1801725H	CENT FMS PACK,ACT,BASIC
8065752180	1801726H	CENT FMS PACK,ACT,BASIC
8065752180	1802250H	CENT FMS PACK,ACT,BASIC
8065752180	1802251H	CENT FMS PACK,ACT,BASIC
8065752180	1802252H	CENT FMS PACK,ACT,BASIC
8065752180	1802253H	CENT FMS PACK,ACT,BASIC
8065752180	1802254H	CENT FMS PACK,ACT,BASIC
8065752181	1799257H	CENT FMS PACK,ACT,0.9 TIPLESS
8065752181	1801716H	CENT FMS PACK,ACT,0.9 TIPLESS
8065752181	1801717H	CENT FMS PACK,ACT,0.9 TIPLESS
8065752181	1804658H	CENT FMS PACK,ACT,0.9 TIPLESS
8065752181	1804659H	CENT FMS PACK,ACT,0.9 TIPLESS
8065752181	1804660H	CENT FMS PACK,ACT,0.9 TIPLESS
8065752181	1804661H	CENT FMS PACK,ACT,0.9 TIPLESS
8065752181	1820467H	CENT FMS PACK,ACT,0.9 TIPLESS
8065752181	1820468H	CENT FMS PACK,ACT,0.9 TIPLESS
8065752182	1785989H	CENT FMS PACK,ACT,0.9U TIPLESS
8065752182	1785990H	CENT FMS PACK,ACT,0.9U TIPLESS
8065752182	1794544H	CENT FMS PACK,ACT,0.9U TIPLESS
8065752182	1794545H	CENT FMS PACK,ACT,0.9U TIPLESS
8065752182	1794546H	CENT FMS PACK,ACT,0.9U TIPLESS
8065752182	1794547H	CENT FMS PACK,ACT,0.9U TIPLESS
8065752182	1794548H	CENT FMS PACK,ACT,0.9U TIPLESS
8065752182	1794549H	CENT FMS PACK,ACT,0.9U TIPLESS
8065752182	1794550H	CENT FMS PACK,ACT,0.9U TIPLESS
8065752182	1794551H	CENT FMS PACK,ACT,0.9U TIPLESS
8065752182	1801720H	CENT FMS PACK,ACT,0.9U TIPLESS
8065752182	1801721H	CENT FMS PACK,ACT,0.9U TIPLESS
8065752182	1804665H	CENT FMS PACK,ACT,0.9U TIPLESS
8065752182	1804666H	CENT FMS PACK,ACT,0.9U TIPLESS
8065752182	1813648H	CENT FMS PACK,ACT,0.9U TIPLESS
8065752182	1822927H	CENT FMS PACK,ACT,0.9U TIPLESS
8065752183	1799248H	CEN FMS PACK,ACT,.9N
8065752183	1799249H	CEN FMS PACK,ACT,.9N
8065752183	1799250H	CEN FMS PACK,ACT,.9N
8065752183	1799251H	CEN FMS PACK,ACT,.9N
8065752183	1799252H	CEN FMS PACK,ACT,.9N

Catalog #	Lot #	Product Description
8065752200	1804846H	CEN FMS PACK,ACT,.9U 30 BAL
8065752200	1804847H	CEN FMS PACK,ACT,.9U 30 BAL
8065752200	1804848H	CEN FMS PACK,ACT,.9U 30 BAL
8065752200	1804849H	CEN FMS PACK,ACT,.9U 30 BAL
8065752200	1810821H	CEN FMS PACK,ACT,.9U 30 BAL
8065752200	1810822H	CEN FMS PACK,ACT,.9U 30 BAL
8065752200	1810823H	CEN FMS PACK,ACT,.9U 30 BAL
8065752200	1822928H	CEN FMS PACK,ACT,.9U 30 BAL
8065752201	1786004H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1786005H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1786006H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1786007H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1791520H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1791521H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1791522H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1791523H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1791524H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1791525H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1791526H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1791527H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1791528H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1791529H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1794153H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1794154H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1794155H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1794156H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1794157H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1794158H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1794159H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1794160H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1794161H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1794162H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1794163H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1794164H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1794165H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1794166H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1794167H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1794168H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1799344H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1799345H	CEN FMS PACK,ACT,.9U 45 BAL
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8065752201	1799583H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1799584H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1799585H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1799586H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1799587H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1799588H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1799589H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1799590H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1799591H	CEN FMS PACK,ACT,.9U 45 BAL

Catalog #	Lot #	Product Description
8065752183	1799253H	CEN FMS PACK,ACT,.9N
8065752183	1799254H	CEN FMS PACK,ACT,.9N
8065752183	1799255H	CEN FMS PACK,ACT,.9N
8065752183	1799256H	CEN FMS PACK,ACT,.9N
8065752192	1794552H	CEN FMS PACK,ACT,.9U 30K MF
8065752192	1799259H	CEN FMS PACK,ACT,.9U 30K MF
8065752192	1799260H	CEN FMS PACK,ACT,.9U 30K MF
8065752192	1799548H	CEN FMS PACK,ACT,.9U 30K MF
8065752192	1802422H	CEN FMS PACK,ACT,.9U 30K MF
8065752192	1810810H	CEN FMS PACK,ACT,.9U 30K MF
8065752192	1810811H	CEN FMS PACK,ACT,.9U 30K MF
8065752193	1791845H	CEN FMS PACK,ACT,.9U 45K MF
8065752193	1791846H	CEN FMS PACK,ACT,.9U 45K MF
8065752193	1796505H	CEN FMS PACK,ACT,.9U 45K MF 6
8065752193	1796506H	CEN FMS PACK,ACT,.9U 45K MF 7
8065752193	1799333H	CEN FMS PACK,ACT,.9U 45K MF
8065752193	1799334H	CEN FMS PACK,ACT,.9U 45K MF
8065752193	1802314H	CEN FMS PACK,ACT,.9U 45K MF
8065752193	1810816H	CEN FMS PACK,ACT,.9U 45K MF
8065752200	1793706H	CEN FMS PACK,ACT,.9U 30 BAL
8065752200	1793707H	CEN FMS PACK,ACT,.9U 30 BAL
8065752200	1793709H	CEN FMS PACK,ACT,.9U 30 BAL
8065752200	1793710H	CEN FMS PACK,ACT,.9U 30 BAL
8065752200	1793711H	CEN FMS PACK,ACT,.9U 30 BAL
8065752200	1793712H	CEN FMS PACK,ACT,.9U 30 BAL
8065752200	1793713H	CEN FMS PACK,ACT,.9U 30 BAL
8065752200	1793714H	CEN FMS PACK,ACT,.9U 30 BAL
8065752200	1793715H	CEN FMS PACK,ACT,.9U 30 BAL
8065752200	1793716H	CEN FMS PACK,ACT,.9U 30 BAL
8065752200	1794563H	CEN FMS PACK,ACT,.9U 30 BAL
8065752200	1794564H	CEN FMS PACK,ACT,.9U 30 BAL
8065752200	1794565H	CEN FMS PACK,ACT,.9U 30 BAL
8065752200	1794566H	CEN FMS PACK,ACT,.9U 30 BAL
8065752200	1794567H	CEN FMS PACK,ACT,.9U 30 BAL
8065752200	1794568H	CEN FMS PACK,ACT,.9U 30 BAL
8065752200	1794569H	CEN FMS PACK,ACT,.9U 30 BAL
8065752200	1794570H	CEN FMS PACK,ACT,.9U 30 BAL
8065752200	1794571H	CEN FMS PACK,ACT,.9U 30 BAL
8065752200	1794572H	CEN FMS PACK,ACT,.9U 30 BAL
8065752200	1799595H	CEN FMS PACK,ACT,.9U 30 BAL
8065752200	1799596H	CEN FMS PACK,ACT,.9U 30 BAL
8065752200	1799597H	CEN FMS PACK,ACT,.9U 30 BAL
8065752200	1799598H	CEN FMS PACK,ACT,.9U 30 BAL
8065752200	1799599H	CEN FMS PACK,ACT,.9U 30 BAL
8065752200	1799600H	CEN FMS PACK,ACT,.9U 30 BAL
8065752200	1799601H	CEN FMS PACK,ACT,.9U 30 BAL
8065752200	1799602H	CEN FMS PACK,ACT,.9U 30 BAL
8065752200	1799603H	CEN FMS PACK,ACT,.9U 30 BAL
8065752200	1799604H	CEN FMS PACK,ACT,.9U 30 BAL
8065752200	1799605H	CEN FMS PACK,ACT,.9U 30 BAL
8065752200	1799606H	CEN FMS PACK,ACT,.9U 30 BAL
8065752200	1799609H	CEN FMS PACK,ACT,.9U 30 BAL
8065752200	1799610H	CEN FMS PACK,ACT,.9U 30 BAL
8065752200	1799611H	CEN FMS PACK,ACT,.9U 30 BAL
8065752200	1799612H	CEN FMS PACK,ACT,.9U 30 BAL
8065752200	1799613H	CEN FMS PACK,ACT,.9U 30 BAL
8065752200	1799614H	CEN FMS PACK,ACT,.9U 30 BAL
8065752200	1799615H	CEN FMS PACK,ACT,.9U 30 BAL
8065752200	1799616H	CEN FMS PACK,ACT,.9U 30 BAL
8065752200	1802316H	CEN FMS PACK,ACT,.9U 30 BAL
8065752200	1802317H	CEN FMS PACK,ACT,.9U 30 BAL
8065752200	1802318H	CEN FMS PACK,ACT,.9U 30 BAL

Catalog #	Lot #	Product Description
8065752201	1799592H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1799593H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1799594H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1799607H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1799608H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1802296H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1802297H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1802298H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1802299H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1802300H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1802301H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1804687H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1804688H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1804689H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1804690H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1804691H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1804692H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1804693H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1804696H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1804697H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1804698H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1804699H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1810866H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1810868H	CEN FMS PACK,ACT,.9U 45 BAL
8065752201	1822929H	CEN FMS PACK,ACT,.9U 45 BAL
8065752202	1810819H	CEN FMS PACK,ACT,.9N 30 BAL
8065752203	1793690H	CEN FMS PACK,ACT,.9N 45 BAL
8065752203	1799505H	CEN FMS PACK,ACT,.9N 45 BAL
8065752203	1799506H	CEN FMS PACK,ACT,.9N 45 BAL
8065752203	1801723H	CEN FMS PACK,ACT,.9N 45 BAL
8065752203	1802307H	CEN FMS PACK,ACT,.9N 45 BAL 6
8065752212	1794175H	CEN FMS PACK,GRV,BASIC TIPLESS
8065752212	1794176H	CEN FMS PACK,GRV,BASIC TIPLESS
8065752216	1794169H	CEN FMS PACK,GRV,.9U 30BAL
8065752216	1799838H	CEN FMS PACK,GRV,.9U 30BAL
8065752216	1805300H	CEN FMS PACK,GRV,.9U 30BAL
8065752245	1799297H	CEN FMS PACK,ACT,.9U 45K MI
8065752245	1804906H	CEN FMS PACK,ACT,.9U 45K MI
8065752245	1810778H	CEN FMS PACK,ACT,.9U 45K MI
8065752917	1799335H	CEN FMS PACK,ACT,.9 30 BAL
8065752917	1799336H	CEN FMS PACK,ACT,.9 30 BAL
8065752917	1799337H	CEN FMS PACK,ACT,.9 30 BAL
8065752917	1799338H	CEN FMS PACK,ACT,.9 30 BAL
8065752917	1799339H	CEN FMS PACK,ACT,.9 30 BAL
8065752917	1799340H	CEN FMS PACK,ACT,.9 30 BAL
8065752917	1799341H	CEN FMS PACK,ACT,.9 30 BAL
8065752917	1799342H	CEN FMS PACK,ACT,.9 30 BAL
8065752917	1802309H	CEN FMS PACK,ACT,.9 30 BAL
8065752917	1802310H	CEN FMS PACK,ACT,.9 30 BAL
8065752917	1802311H	CEN FMS PACK,ACT,.9 30 BAL
8065752917	1804668H	CEN FMS PACK,ACT,.9 30 BAL
8065752917	1807851H	CEN FMS PACK,ACT,.9 30 BAL
8065752917	1810784H	CEN FMS PACK,ACT,.9 30 BAL
8065752917	1810785H	CEN FMS PACK,ACT,.9 30 BAL
8065752917	1810786H	CEN FMS PACK,ACT,.9 30 BAL
8065752918	1794553H	CEN FMS PACK,ACT,.9 45 BAL
8065752918	1794554H	CEN FMS PACK,ACT,.9 45 BAL
8065752918	1794555H	CEN FMS PACK,ACT,.9 45 BAL
8065752918	1794556H	CEN FMS PACK,ACT,.9 45 BAL
8065752918	1794557H	CEN FMS PACK,ACT,.9 45 BAL
8065752918	1794558H	CEN FMS PACK,ACT,.9 45 BAL
8065752918	1794559H	CEN FMS PACK,ACT,.9 45 BAL

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