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URGENT: FIELD SAFETY NOTICE

Date:	**29 July 2016**
Commercial Name of Product:	**AcrySof® IQ IOL with ULTRASERT™ Delivery System**
FSCA Identifier:	**2016.069**
Type of Action:	**Medical Device Removal**

Attention:
«Account_Name»
«Account_Address»
«Contact_Name»

Dear Valued Alcon Customer:

Alcon is initiating a Medical Device Removal for specific lots of the AcrySof® IQ Intraocular Lens (IOL) with ULTRASERT™ Delivery System. We are initiating this voluntary removal because we have determined the ULTRASERT™ Delivery Systems from certain lots have an interior surface characteristic that could result in the IOL becoming lodged in the ULTRASERT™ Delivery System. Most likely if this happens the lens would not be delivered and the surgery could be completed with a standby lens; however, if the lens is forced through the nozzle this could result in damage to the lens and/or nozzle, possibly injuring the patient.

Please note that this event affects only a small portion of the ULTRASERT™ Delivery Systems within the specified production lots. National Competent Authorities have been notified of this action.

Below please find the full details on this matter and directions for handling potentially-affected product in your practice.

Details on Affected Device:

The AcrySof® IQ IOL with ULTRASERT™ Delivery System is a CE marked medical device. The Alcon AcrySof® IQ IOL is an acrylic foldable single-piece posterior chamber lens for the replacement of the human crystalline lens in the visual correction of aphakia in adult patients following cataract surgery. The AcrySof® IQ IOLs are provided in the ULTRASERT™ Pre-loaded Delivery System for a convenient, controlled means to reliably place these lenses into the capsular bag.

Specific product being removed from the market is summarized in the following table:

Model	Product Description	Lot Number(s)	Expiry Date
AU00T0.220	SN60WF IN ULTRASERT DELIVERY SYSTEM	12409026	30-Sep-17
AU00T0.220	SN60WF IN ULTRASERT DELIVERY SYSTEM	12409028	

Description of the Potential Condition:

ULTRASERT™ Delivery Systems from the identified lots have an interior surface characteristic that could result in the IOL becoming lodged in the ULTRASERT™ Delivery System. Most likely if this happens the lens would not be delivered and the surgery could be completed with a standby lens; however, if the lens is forced through the nozzle this could result in damage to the lens and/or nozzle, possibly injuring the patient.

Advice on Action to be Taken by the User:

Our records indicate that you have purchased this product from Alcon and may have some quantity at your facility that must be returned. Please follow these steps as part of this medical device removal:

1. Check your inventory and segregate any product being recalled as listed in the above table.
2. Complete and return the Field Safety Notice Response Form to Alcon. The completed response form should be immediately returned via fax or email to:
   [redacted]
   (Please reply even if you do not have any inventory to be returned.)
3. Alcon will contact you to arrange for the return of product at no charge to you and replacement product can be ordered at this time.

Transmission of this Medical Device Removal:

Please immediately forward this information to all departments within your organization who may be using the AcrySof® IQ IOL with ULTRASERT™ Delivery System. Additionally, please ensure that a copy of this notification is provided to any other organizations to which the product may have been transferred.

We appreciate your cooperation and sincerely regret any inconvenience that this may cause you. We have decided to take this action out of precaution and to provide you with the highest quality surgical ophthalmic products for you and your patients.

Should you have any questions or concerns about this matter, please contact Alcon Medical Information at:

[redacted]

Field Safety Notice Response Form

Date:	**29 July 2016**
Commercial Name of Product:	**AcrySof® IQ IOL with ULTRASERT™ Delivery System**
FSCA Identifier:	**2016.069**
Type of Action:	**Medical Device Removal**

☐ I have read the attached Medical Device Removal letter, checked our inventory, and noted that our facility does not have any of the specified AcrySof® IQ IOL with ULTRASERT™ Delivery Systems in our inventory.

☐ I have read the attached Medical Device Removal letter and checked our inventory. Our facility needs to arrange the return of the below product.

Model	Product Description	Lot Number(s)	Quantity to Return
AU00T0.220	SN60WF IN ULTRASERT DELIVERY SYSTEM	12409026	
AU00T0.220	SN60WF IN ULTRASERT DELIVERY SYSTEM	12409028	

Name (Please Print) Date Customer's Signature

<<Contact Name>>
<<Account Name>>
<<Account Address>>