«Account_Name»
«Salutation» «Degree» «First_Name»
«Last_Name»
«Account_Street_Address»
«Account_Postal_Code» «Account_City»

Name: Dr. Benjamin Baur
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Date: 22 July 2016

Corrective Action, Recall of
Alcon AcrySof® IQ IOL with UltraSert® Implantation System

Dear <<Enter Customer Information>>,

with this letter we inform you that Alcon is initiating a recall for specific lots of the AcrySof® IQ Intraocular Lens (IOL) with ULTRASERT™ Implantation System. We are initiating this recall because we have determined the ULTRASERT™ Implantation System from certain lots have an interior surface characteristic that could result in the IOL becoming lodged in the ULTRASERT™ Implantation System. Most likely if this event happens the lens would not be implanted 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™ Implantation 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 of the potentially-affected products.

Details for the affected products:

The AcrySof® IQ IOL with ULTRASERT™ Implantation 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 Implantation System for a convenient, controlled means to reliably place these lenses into the capsular bag.

Description of the potential problem:

The ULTRASERT™ Implantation Systems from certain lots have an interior surface characteristic that could result in the IOL becoming lodged in the ULTRASERT™ Implantation 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.
Our records indicate that you have purchased this product from Alcon and may have some quantity at your facility that must be returned. Specific product being removed from the market is summarize in the following table:

Model	Product Description	Lot Number(s)	Expiry Date
AU00T0.175	SN60WF IN ULTRASERT DELIVERY SYSTEM	12407022	09/30/17
AU00T0.195	SN60WF IN ULTRASERT DELIVERY SYSTEM	12407085	
AU00T0.195	SN60WF IN ULTRASERT DELIVERY SYSTEM	12407087	
AU00T0.220	SN60WF IN ULTRASERT DELIVERY SYSTEM	12409013	
AU00T0.220	SN60WF IN ULTRASERT DELIVERY SYSTEM	12409024	
AU00T0.220	SN60WF IN ULTRASERT DELIVERY SYSTEM	12409026	
AU00T0.220	SN60WF IN ULTRASERT DELIVERY SYSTEM	12409028	

Advise on Action to be Taken by the User:

Please support Alcon at this recall by following the mentioned steps:

1. Review your inventory to determine if you have any affected Alcon AcrySof® IQ IOL with UltraSert® Implantation Systems.

2. Please stop using the affected Alcon AcrySof® IQ IOL with UltraSert® Implantation Systems immediately.

3. Separate the affected products to assure that they are not used any more.

4. Please confirm with your signature on the response form that you have received, read and understood the information and the necessary actions.

5. Please fill out, sign and return the attached "*Response Form*" to: Fax: 0761 / 1304-99338. **Please fill out and return the attached "Response Form" even if you have zero units in inventory.**

6. 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.

Forwarding of this information:

Please immediately forward this information to all departments within your organization who may be using the AcrySof® IQ IOL with ULTRASERT™ Implantation 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.

Contact Information:

If you have any questions concerning the replacement products or need additional assistance please contact the

Alcon Costumer Service under 0761/1304 – 400 or your responsible Alcon associate.

If you have further questions please contact:

Mr. Dr. Benjamin Baur unter der Telefon-Nr.: 0761 / 1304 - 218
Mrs. Dr. Verena Kollek unter der Telefon-Nr.: 0761 / 1304 - 338

With best Regards

Alcon Pharma GmbH

b.o.

[redacted]

Dr. Verena Kollek
Quality Assurance Manager

b.o.

[redacted]

Dr. Benjamin Baur
Quality Assurance Specialist

Attachment : Field Safety Notice Response Form

Response Form

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   Fax-Number: 0761 / 1304-99338.

   Please fill out and return the attached "Response Form" even if you have zero units in inventory.

6. Please send the affected products together with a copy of the response form to:

   GLG- Grieshaber Logistic Group

   Retourenabteilung
   Warmbacherstr. 80
   79618 Rheinfelden

Model	Lot	Number

Signature of Facility Representative:

Printed Name and Title:

Date:

«Account_Name»
«Salutation» «Degree» «First_Name» «Last_Name»
«Account_Street_Address»
«Account_Postal_Code»