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Alcon
a Novartis company

ALCON NORDIC A/S

August 12, 2016

Sundhedsstyrelsen
Axel Heides Gade 1
2300 Kbh S
Denmark

Re: Field Safety Corrective Action for Specific Lots of the Alcon AcrySof® IQ IOL with ULTRASERT™ Delivery System

Dear Sir/Madam,

Alcon is submitting the following Field Safety Corrective Action Report and Annexes (including the Field Safety Notice) for your attention and review.

The Alcon AcrySof® IQ Intraocular Lens (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. Alcon has learned that a subset of the ULTRASERT™ Delivery Systems from specific manufacturing lots may not have received a complete coating on the interior surface of the delivery system. The coating is to facilitate the smooth release of the lens from the delivery system and an incomplete coating 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. Alcon has determined this event affects only a subset of the ULTRASERT™ Delivery Systems within the specified production lots.

Although Alcon's assessment determined that an IOL becoming lodged in the ULTRASERT™ Delivery System should not pose a risk to patient health and surgeries can be completed with a standby lens, Alcon is conducting a voluntary recall for the identified specific production lots.

If you have any questions regarding this matter, please contact us using the email address:
qa.nordic@alcon.com

Sincerely,

Gilbert Poulsen Rubia Cristina

Digitally signed by Gilbert Poulsen Rubia Cristina
DN: SERIALNUMBER=1824040 + CN=Gilbert Poulsen Rubia Cristina, OU=AL, OU=people, DC=novartis, DC=com
Reason: I have reviewed this document.
Date: 2016.08.12 14:01:15 +02:00

Rúbia Cristina Gilbert Poulsen
Nordic Quality Manager