

Urgent Field Safety Notice

Commercial name of the device: Crystalens® AO (PMA P030002) Intra Ocular Lens.

FSCA-identifier : 2015.02.02

Type of FSCA : Advice given by manufacturer regarding the use of the device

Date: 02 February, 2015

Dear customers of Bausch&Lomb!

Bausch&Lomb company voluntarily publishes the present safety notice for the use of intraocular lenses Crystalens® AO.

Please read carefully the contents of this announcement in order to understand the problem and to ensure the continued safe use of the product.

Details on affected devices: Crystalens® AO (PMA P030002) Intra Ocular Lens.

Description of the problem

Crystalens® AO Intraocular Lenses are designed to provide an increased range of vision through dynamic movement of the lens optic. Prior to 2014 in USA market, the reported incidence rate of vaults was approximately 1-2 per 1,000 implants of Crystalens. The reported incidence of symmetric and asymmetric lens vaults between January 1st and November 30th of this year was approximately 6.3 per 1,000 implants for Crystalens. These current vault complaint rates, are comparable to the vault rate reported in its clinical trial.

Our extensive investigation has not identified any product nor process nonconformities that would account for the observed increase in vault related complaints. We continue to monitor the situation in USA and Europe and will provide updates as warranted.

We consistently listen to our customers insights and experiences to maximize patient outcomes with our technologies.

Information and data collected through surveys and various forums suggests that strict adherence to Crystalens product labeling, and all of the clinical recommendations in that labeling, will help reduce the potential for lens vaults.

Advise on action to be taken by the user:

We encourage you to carefully review and adhere to the product labeling sections on “**Warnings**”, “**Precautions**” and “**Optimizing Patient Outcomes**” to minimize the potential for vaults. We wish to call-out the following directions for immediate reminder:

- 1. Ensure proper IOL placement through rotation and visual inspection**
- 2. Carefully clean the capsule to remove all residual lens material**

3. **Ensure all incisions are watertight and do not leak**
4. **Carefully monitor patients post-operatively to ensure control of inflammation and to detect early signs of capsular fibrosis.**

Customers that have reported lens vaults will be contacted by our team of Clinical Outcome Specialists to schedule in-service training. The training will underscore the importance of strict adherence to the product labeling to help minimize the potential for vaults. We will also be offering training opportunities for all Crystalens® AO Intraocular Lenses customers through scheduled webinars, videos and other materials. Additional information concerning these training opportunities will be forthcoming. In-service training will be made available to all customers upon request.

For your convenience, a copy of the product labeling has been attached.

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person:

If you have any questions or complaints, please contact us.

If you wish to arrange in-service training, or to speak with our panel of experienced surgeons please contact your Clinical Outcome Specialist or the Clinical Outcome Specialist Team at Mrs. Marion Bastier Tel. +33 467 12 3345, Mobile: +33 610 61 2934, e-mail: marion.bastier@bausch.com.

Should you wish to report an adverse event regarding these products, including a lens vault, please contact us at Mrs. Marion Bastier tel +33 467 12 3345, Mobile +33 610 61 2934, e-mail: marion.bastier@bausch.com.

For inquiries specifically concerning this notification, please contact us at Elzbieta Weston tel. Tel: +4822/5374277, Mobile: +48 510017071,

e-mail: Elzbieta.weston@valeant.com

As a valued Crystalens AO customer, we want to thank you for using these Bausch + Lomb IOL technologies. The Crystalens® IOL has served the market for over 10 years while maintaining a low product complaint rate. Our goal at Bausch + Lomb is to provide you with surgical technologies that are safe, effective and beneficial to your patients. We continually evaluate our products and processes to ensure that we provide our customers with products that consistently meet high quality standards.

Thank you for your continued support of our Crystalens products.

Sincerely,



Elzbieta Weston

Director

Food Supplement

Cosmetics & Medical Devices

Valeant EMEA