

Lentis Intraocular lenses

FSN 2017-001

2017-09-12

Urgent - Field Safety Notice
Recall Lentis foldable Intraocular lenses



Dear Customer,
cc to Chairman Medical Board and relevant Head of Departments,

Oculentis has received notifications of sporadic late postoperative opacification of LENTIS IOL's that may compromise the optical transparency of the IOL, potentially leading to a slow reduction in the patient's visual acuity. It is generally known from the relevant literature that opacification might sometimes occur and can have multifactorial causes. Oculentis has carried out a study as to the possible causes of such opacification in relation to its product. Subsequently Oculentis decided to voluntary recall its product in order to prevent any potential risk for patients.

This Field Safety Notice is intended to inform you of the voluntary recall issued by Oculentis, the cause and the actions that should be taken by you. (see the next page of this letter for all details).

Forwarding the information in this FSN:

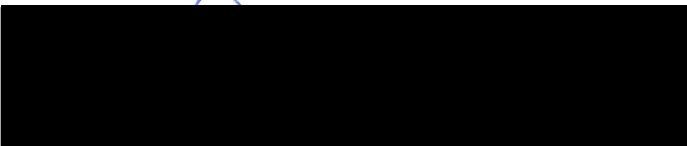
This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected product has been transferred. Please be aware of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Oculentis puts your patient's wellbeing first and takes its obligation to deliver the highest quality products very seriously. This voluntary recall is an expression of our commitment to meet the highest quality standards and to exclude any potential risk for patients, although opacification sporadically occurs and does not have to be the result of the cause identified.

We are aware that this voluntary recall is of inconvenience for you and we would like to thank you in advance for your cooperation.

Oculentis confirms that the voluntary recall has been notified to the appropriate National Regulatory Authority who also received a copy of this Field Safety Notice.

Sincerely,


Oculentis BV
Sr. Manager Quality and Regulatory

Please sign this Field Safety Notice and confirm the receipt by sending a fax or email pdf of this page to your local contact. In case of questions, please ask your local contact person.

Name (in block letters), date and signature of the recipient.

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AFFECTED PRODUCTS	LENTIS foldable Intraocular lenses with model numbers starting with L-, LU- or LS- and having an expiry date between <u>2017-01</u> and <u>2020-05</u>
PROBLEM DESCRIPTION	Possible sporadic opacification of the IOL. Studies by the manufacturer have indicated that surface calcification could possibly be the result of phosphate remnants originating from a detergent previously used in the cleaning process of the IOL. Although the cause of IOL opacification is multifactorial, remnants could make the IOL under certain conditions more prone to opacification.
HAZARD INVOLVED	The opacification may compromise the optical transparency of the IOL in time, potentially leading to a slow reduction in the patient's visual acuity.
ACTION TO BE TAKEN BY THE CUSTOMER/USER	• There is no need for recalling or review of patients. • In some cases, postoperative opacification of the IOL may present biomicroscopic aspects similar to posterior capsule opacification. Practitioners are advised to carefully evaluate each case to determine the exact nature of the cloudiness. • IOL exchange is the only recommended treatment for postoperative opacification if the visual acuity is compromised in face of the patient's individual conditions and needs. • In case affected IOL's of the identified expiry dates are in your possession, please isolate them and ship these back to Oculentis or your local representative.
HOW TO IDENTIFY AFFECTED PRODUCTS	If you have potentially affected unused products, identify the expiry date on the label at the top of the outer box. Potentially affected products carry an expiry date between: <u>2017-01 and 2020-05</u> 
ACTIONS BY OCULENTIS	Oculentis has established a program through which a replacement IOL and ophthalmic visco-surgical device may be provided at no charge to practitioners.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Oculentis representative.