Lentis Intraocular lenses FSN 2017-001-IE 2017-09-21

Supplemental Urgent - Field Safety Notice
Recall Lentis foldable Intraocular lenses

Dear Customer,

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 supplemental Field Safety Notice is to provide you with additional information as requested by the Irish health authority HPRA, 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,

Peter van Geffen

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 **2017-01** until **2020-05**
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. Incident rate is 0.07% mean incubation time 38 Months with a standard deviation of 9 months. For Ireland, no cases have been reported.
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	• Considering each individual patients' current risk-benefit ratio there is no need for calling patients back and screening all patients that have been implanted with affected IOL's. Intensifying routine patient follow-up may be adopted if the risk-benefit ratio changes considerably • 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. • Please be aware of this notice and resulting action for an appropriate period of time to ensure effectiveness of the corrective action.
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: **2017-01** until **2020-05** 
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	If you need any further information or support concerning this issue, please contact Oculentis or your Irish local Oculentis representative.

Irish specific contact details:
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