



Oculentis GmbH · Am Borsigturm 58 · 13507 Berlin · GERMANY

Oculentis GmbH  
Am Borsigturm 58  
13507 Berlin Germany  
Tel. +49 (0)30 430955-0  
Fax +49 (0)30 430955-11  
info@oculentis.com

[ Firma ]  
[ Anrede, Amtsbezeichnungen ]  
[ ggf. Akademische Grade, Name ]  
[ Straße Hausnummer, Postfach ]  
[ Postleitzahl und Ort, bei Ausland gross ]  
[ LAND ]

Urgent Field Safety Notification Oculentis GmbH 2014-001  
Voluntary recall LENTIS HydroSmart foldable Intraocular lenses  
in glass vials (CE1275)

2014-12-05

Identification of the medical devices involved:

LENTIS HydroSmart foldable Intraocular lenses (IOL), with CE mark CE 1275 packaged in glass vials, production date until 31/12/2011. All IOL models, starting with L-, LU- or LS- and with serial numbers starting with 20000.

All Lentis IOL models packaged in a blister are not affected by this Field Safety Notice.

Background information and details on the actions taken:

Oculentis GmbH issues a voluntary recall for all Lentis Hydrosmart foldable IOL's in glass vials carrying the CE1275 number due to some reports of postoperative opacification predominantly with the L-402 3-piece model. The production of all IOL models stored in glass vials was ceased by December 2011. The purpose of this Field Safety Notice is to voluntarily recall all possibly affected remaining lots of IOL's stored in glass vials. Based on the change of the production to facilitate the current blister packaging, Lentis Hydrosmart IOL's produced after these dates are not affected by this notice.

Oculentis GmbH has received sporadic notifications of postoperative opacification of the LENTIS HydroSmart IOL's in glass vials, resulting in a reported occurrence rate of 0.011% of all implanted Hydrosmart IOL's since 2006. Analysis suggests a possible interaction between phosphate crystals originating from the hydration process of the IOL material and the fluctuating, batch related presence of silicone residues on some IOL's. According to relevant literature, such residues may potentially change the IOL surface properties, making it under certain medical conditions more prone to deposition of calcium phosphate from the aqueous humor in predisposed patients. These deposits may compromise the optical transparency of the IOL, potentially leading to a reduction in the patient's visual acuity. For all Oculentis IOL's produced after December 2011 and packaged in Blister, no reports of calcifications have been received.



Recommended Actions:

- In case postoperative opacification is observed, practioners are advised to evaluate visual acuity levels and consider surgical IOL exchange if visual acuity is compromised in face of the patient's individual conditions and needs. Intraocular lens exchange is the only recommended treatment for postoperative calcification of the IOL leading to compromise of visual acuity.
- Practioners are advised that in some cases postoperative opacification of the IOL may present biomicroscopic aspects similar to posterior capsule opacification. Practioners are advised to carefully evaluate each case to determine the exact nature of the cloudiness and avoid YAG laser capsulotomy in patients with a opacified IOL since this procedure may affect the IOL exchange if needed in the future.
- Practioners are advised to report without delay any adverse event to Oculentis and local competent authorities.
- Oculentis has established a program through which a replacement IOL and ophthalmic viscosurgical device may be provided at no charge to practioners.
- In case the affected IOL's of the identified models in glass bottles are in your possession, ship these back to Oculentis or your local representative.

Forwarding the information in this FSN:

Please forward this notice to all those who need to be aware within your organization. If the potentially affected devices have been transferred to any other organizations, please forward this notice to the third party or inform the contact person below.

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 ensure that our product meets your expectations.

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

Please save this information for at least the timeframe of the closure of the actions. The Compentent Authority in your country has received a copy of this Field Safety Notice.

Name of the distributor

Name / organization, address, contact details.

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

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Name and signature of the recipient.