HAZARD ALERT / URGENT MEDICAL DEVICE RECALL*

LEVEL: Hospital

CLASS: Class II

REFERENCE: RC-2014-RN-01322-1

DATE AGREED: 17/12/2014

PRODUCT: **LENTIS HydroSmart Foldable Intraocular Lenses (IOL) in Glass Vials**

IOL Model Numbers: All starting with L-, LU-, or LS-

Serial Numbers: All starting with 20000

ARTG Number: 192478

(All Oculentis Intra Ocular Lens models packaged in a blister are not affected by this recall action.)

SPONSOR: Device Technologies Australia Pty Ltd

PHONE: 1800 429 551 - Device Technologies Australia

REASON: The manufacturer has received sporadic notifications of postoperative opacification of the LENTIS Hydrosmart Inta Ocular Lenses (IOL's) in glass vials 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. 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.

PROPOSED ACTION: Customers are requested to inspect their stock and quarantine any affected units in preparation for return to Device Technologies.

Surgeons are advised that if postoperative opacification is observed to evaluate visual acuity levels and consider surgical IOL replacement if visual acuity is compromised in face of the patient's individual conditions and needs. Intraocular lens replacement is the only recommended treatment for postoperative calcification of the IOL leading to compromise of visual acuity. In some cases postoperative opacification of the IOL may present bio-microscopic aspects similar to posterior capsule opacification. Practitioners are advised to carefully evaluate each case to determine the exact nature of

the cloudiness and avoid YAG laser capsulotomy in patients with an opacificied IOL since this procedure may affect the IOL replacement if needed in the future.

For further information please see http://www.tga.gov.au/alert/lentis-hydrosmart-intraocular-lenses-supplied-glass-vials .

The sponsor is expected to dispatch letters to all affected customers within two working days of the agreed date.

Product Distribution: 65 hospitals / day surgeries, eye clinics in NSW, QLD, TAS, VIC & WA

Product export status: New Zealand

This issue was first identified by the Sponsor

*For further details about Recall Actions, please refer to http://tga.gov.au/safety/recalls-about.htm

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Document 2

15th December 2014

Chief Executive Officer
«CUSTOMER»
«ADDRESS_1»
«ADDRESS_2»
«SUBURB» «STATE» «POSTCODE»

Hazard Alert & Urgent Medical Device Recall
Oculentis – LENTIS® HydroSmart foldable intraocular lenses in glass vials
Potential Postoperative Opacification ARTG: 192478

Attention: XXXXXXXXXXX

Dear Customer

Device Technologies Australia (DTA) in conjunction with the manufacturer, Oculentis GmbH, is issuing this medical device recall of the LENTIS® Hydrosmart foldable Intraocular lenses (IOL's) **packaged in glass vials**. All IOL models starting with L-, LU-, or LS- and with serial numbers starting with 20000 are affected. Device Technologies may have supplied your facility with one or more of these models.

All Oculentis IOL models packaged in a blister are not affected by this recall action.

Description and Background of the Problem

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. 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. This manufacturing process was ceased as of 31/12/2011 in favour of a new manufacturing process with blister packaging. **For all Oculentis IOL's produced after December 2011 and packaged in Blister packs, no reports of calcifications have been received.**

Action Required:

1. Read notice in full and distribute to all relevant personnel.
2. Inspect your stock and isolate any affected stock. See **Attachment 1** to assist in identifying affected stock.
3. Complete the Reply Fax Form attached to acknowledge receipt of this notification and advise stock quantity and quarantine all affected product.

   If you identify affected stock at your facility, Device Technologies will contact you with a Goods Return Authorisation (GRA) number and arrange collection as soon as possible.

4. In case postoperative opacification is observed, practitioners are advised to evaluate visual acuity levels and consider surgical IOL replacement if visual acuity is compromised in face of the patient's individual conditions and needs. Intraocular lens replacement is the only recommended treatment for postoperative calcification of the IOL leading to compromise of visual acuity.
5. Practitioners are advised that in some cases postoperative opacification of the IOL may present bio-microscopic aspects similar to posterior capsule opacification. Practitioners are advised to carefully evaluate each case to determine the exact nature of the cloudiness and **avoid YAG laser capsulotomy in patients with an opacificied IOL** since this procedure may affect the IOL replacement if needed in the future.
6. A revision of patients who have had this device implanted is recommended.
7. Practitioners are reminded to report without delay to Device Technologies Product Specialists any adverse events (including postoperative calcification or opacification) relating to Oculentis.

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

This notice is being issued following consultation with Therapeutic Goods Administration.

If you have any questions please contact Australasian Business Manager Jodie Coates on +61 419 239 225 or National Sales Manager George Loucas on +61 417 419 268.

Yours Sincerely

s22 [redacted]

Reply Fax Form

Please complete and return to fax s22 [redacted]

TO: s22 [redacted]
Device Technologies
FAX: s22 [redacted]
EMAIL: s22 [redacted] **@device.com.au**

SUBJECT: **Urgent Medical Device Recall: LENTIS® Hydrosmart foldable IOLs in glass vials**

CONTACT NAME: .....

INSTITUTION: .....

TELEPHONE: ..... FAX: .....

EMAIL: .....

I acknowledge receipt of this notice and:

❒ Confirm this facility does not have any of LENTIS® Hydrosmart foldable IOLs in glass vials with the serial numbers starting with number 20000 **(Refer to Attachment 1 to help identify affected IOLs).**

OR

❒ Confirm this facility has affected stock LENTIS® Hydrosmart foldable IOLs in glass vials with the serial numbers starting with number 20000 **(Refer to Attachment 1 to help identify affected IOLs).**

SERIAL NUMBER	

In this case:

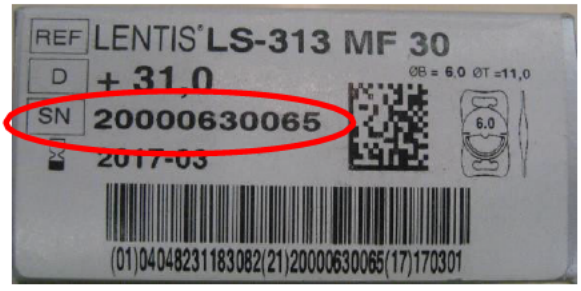
1. *A Device Technologies representative will contact you to provide a GRA*
2. *Write the GRA number on the outer packaging of the affected stock*
3. *Include a copy of your completed Reply Fax Form with the affected stock*
4. *Device Technologies will arrange collection as soon as possible*

Signature: ..... **Date:** .....

FAX THIS FORM TO: s22 [redacted]

Attachment 1: Difference between unaffected IOL and affected IOL

Unaffected IOL	Affected IOL
• Smaller packaging • Serial number does not start with 20000	• Larger packaging • Serial number starts with 20000.



R14 1239206 Customer Letter - TGA AMENDED.DOCX - Read-Only

Main document changes and comments

Page 1: Added s22 [redacted] **17/12/2014 10:47:00 AM**

Hazard Alert &

Page 1: Added s22 [redacted] **17/12/2014 10:48:00 AM**

Potential Postoperative Opacification

Page 3: Added s22 [redacted] **18/12/2014 5:13:00 PM**

1.

A revision of patients who have had this device implanted is recommended.

1.

Header and footer changes

Text Box changes

Header and footer text box changes

Footnote changes

Endnote changes

Customer	Suburb	Postcode
Ballina Day Surgery	Ballina	2478
Barton Private Hospital	Barton	2600
Bowen Hospital	Crofton Downs	6035
Bridgewater Day Surgery	Hamilton	3204
Broadmeadow Day Surgery P/L	Broadmeadow	2292
Cabrini Brighton	Brighton	3186
Castle Hill Day Surgery P/l	Castle Hill	2154
Central Coast Surgery Centre	Erina	2250
City East Specialist Day	Maroubra	2035
Como Private Hospital	Parkdale	3195
Dalcross Adventist Hospital	Killara	2071
Delmar Private Hospital	Dee Why	2099
Doncaster Eye Centre	Doncaster	3108
s22	s22	
s22		
s22		
s22		
s22		
s22		
s22		
Dubbo Private Hospital	Dubbo	2830
Epping Surgery Centre	Epping	2121
Epworth Hospital - Richmond	Abbotsford	3067
Eye-Tech Day Surgeries Spring Hill	Spring Hill	4000
Griffith Base Hospital Theatre	Griffith	2680
Ipswich Day Hospital	Ipswich	4305
s22	s22	
Laser Sight Centres	Cotton Tree	4558
Laser Sight Centres	Spring Hill	4000
Laser Sight Centres Aust. QLD	Eagle Farm	4558
Lingard Private Hospital	Merewether	2291
Lions Eye Surgery	Nedlands	6009
Liverpool Eye Surgery	Liverpool	2170
s22	s22	
Macquarie University Hospital	Macquarie University	2109
Marsden Eye Surgery Centre	Parramatta	2150
Mater (Bris) Adult Hospital Store	South Brisbane	4101
Melbourne Day Surgery	Caulfield	3162
Moreton Eye Group	Redcliffe	4020
National Day Surgery Sydney P/L	Kogarah	2217
Newcastley Eye Hospital P/L	Waratah	2298
NSW Eye Centre	Ashfield	2131
Ophthalmic Surgery Centre	Chatswood	2067
Orange Day Surgery Centre	Orange	2800
Parramatta Eye Centre Pty Ltd	Parramatta	2150
Peninsula Private Hospital	Kippa-Ring	4021
Perfect Vision - Hornsby	Hornsby	2077
Perth Eye Centre	West Perth	6005
Perth Eye Centre	Medindie	5081
Perth Laser Vision Centre	Murdoch	6150
Port Macquarie Ophthalmic Surgery	Port Macquarie	2444
President Private Hospital	Kirrawee	2232
Queensland Eye Hospital	Spring Hill	4000
Robina Procedure Centre	Robina	4230
Short Street Day Surgery	Southport	4215
Sight Foundation Theatre	Sydney	2000
South Coast Ophthalmic Supplies	Warrnambool	3280
St Andrews War Mem Hospital	Spring Hill	4000

St John of God Hospital - Geelong	Bendigo	3550
St John of God Hospital - Geelong	Geelong	3220
St John of God Hospital - Subiaco	Subiaco	6008
St John of God Hospital - Subiaco	Medindie	5081
St John of God Hospital - Murdoch	Murdoch	6150
St Luke's Hospital Sydney Stores	Potts Point	2011
The Avenue Private Hospital	Windsor	3181
The Eye Hospital	Launceston	7250
The NSW Eye Centre	Ashfield	2131
The Sydney Private Hospital	Ashfield	2131
Toronto Private Hospital	Toronto	2283
Victoria Parade Surgery Centre	East Melbourne	3002
Vision Eye Institute - River City	Bondi Junction	2022
Vision Eye Institute - Auchenflower	Auchenflower	4066
Vision Eye Institute - Hurstville	Hurstville	2220
Visionary Eye Specialists P/l	Hurstville	2220

NOT FOR FURTHER DISTRIBUTION

Customer list for recall action RC-2014-RN-01322-1

Summary: 65 hospitals / day surgeries, eye clinics in NSW, QLD, TAS, VIC & WA

SPONSOR: Device Technologies Australia Pty Ltd

State:	Customer:
NSW	Ballina Day Surgery
	Barton Private Hospital
	Broadmeadow Day Surgery
	Castle Hill Day Surgery
	Central Coast Surgery Centre, Erina
	City East Specialist Day Hospital
	Dalcross Adventist Hospital
	Delmar Private Hospital
	Dubbo Private Hospital
	Epping Surgery Centre
	Griffith Base Hospital
	Lingard Private Hospital
	Liverpool Eye Surgery
	Macquarie University Hospital
	Marsden Eye Surgery Centre, Parramatta
	National Day Surgery, Kogarah
	Newcastle Eye Hospital
	NSW Eye Centre
	Ophthalmic Surgery Centre
	Orange Day Surgery Centre
	Parramatta Eye Centre
	Perfect Vision, Hornsby
	Port Macquarie Ophthalmic Surgery
	President Private Hospital
	Sight Foundation Theatre, Sydney
	St Luke's Hospital
	The NSW Eye Centre, Ashfield
	The Sydney Private Hospital
	Toronto Private Hospital
	Vision Eye Institute, Bondi Junction
	Vision Eye Institute, Hurstville
	Visionary Eye Specialists, Hurstville

QLD	Eye-Tech Day Surgeries, Spring Hill
	Ipswich Day Hospital
	Laser Sight Centres, Cotton Tree
	Laser Sight Centres, Spring Hill
	Laser Sight Centres, Eagle Farm
	Mater Brisbane Adult Hospital
	Moreton Eye Group, Redcliffe
	Peninsula Private Hospital
	Queensland Eye Hospital
	Robina Procedure Centre
	Short Street Day Surgery, Southport
	St Andrews War Memorial Hospital
	Vision Eye Institute, Auchenflower
TAS	The Eye Hospital, Launceston
VIC	Cabrini Brighton Hospital
	Como Private Hospital
	Doncaster Eye Centre
	Bendigo Eye Clinic
	Epworth Hospital
	Melbourne Day Surgery, Caulfield
	South Coast Ophthalmic Supplies, Warrnambool
	St John of God Bendigo Hospital
	St John of God Geelong Hospital
	The Avenue Private Hospital
	Victoria Parade Surgery Centre, East Melbourne
WA	Bowen Hospital
	Lions Eye Surgery, Nedlands
	Perth Eye Centre, West Perth
	Perth Eye Centre, Medindie
	Perth Laser Vision Centre, Murdoch
	St John of God Subiaco Hospital
	St John of God Medindie Hospital
	St John of God Murdoch Hospital