Chirurgie Ophtalmologique
Cristalens

Cristalens Industrie
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22300 Lannion France
Tel:+33(0)2 96 48 92 92
Fax:+33(0)2 96 48 97 87

ANSM / Ministry of Health

OBJET/SUBJECT : PREAVIS DE RAPPEL DE LOTS VOLONTAIRE / VOLUNTARY RECALL PRE-ALERT.
FSCA ref : 2017.09.05.

Lannion, le 05 Septembre 2017,

Madame, Monsieur,

Il a été constaté une augmentation des échecs de poses de nos dispositifs médicaux, liée à l'injecteur, sur nos lentilles intraoculaires hydrophobes préchargées.
Nous avons pris la décision de rappeler les lots concernés pour une expertise plus poussée.

Veuillez trouver ci-joint l'avis de sécurité (FSN) que nous allons transmettre à nos distributeurs concernés, ainsi que le formulaire FSCA.

Veuillez agréer, Madame, Monsieur, l'expression de nos sincères salutations,

Mr Denis DELAGE
Président

Lannion, the 05th of September 2017,

Dear Sirs,

An increase of injection failures due to the injection system has been stated on our preloaded hydrophobic medical devices.
We have decided to recall the concerned batches for further analysis.

Please find enclosed the Field Safety Notice that we will send to our concerned distributors, as well as the FSCA formular.

Yours faithfully,

M. Denis DELAGE
CEO

Chirurgie Ophtalmologique
Cristalens

URGENT: FIELD SAFETY NOTICE: VOLUNTARY RECALL

Lannion, the 05th of September 2017,

Réf Cristalens: FE_01132, FSCA ref: 2017.09.05.
Concerned products: Preloaded hydrophobic intraocular lenses.

Dear Customer,

Cristalens Industrie has decided to proceed with a voluntary recall of several preloaded hydrophobic intraocular lenses batches. This action is initiated due to a risk of injection system malfunction only, which may lead to an intraocular lens block in the injector, during the surgery.
If the lens is forced into the injector tip, this may lead to damages on the lens and/or on the injector tip.

We inform you that the lenses of concerned batches, which have been already implanted, do not pose any additional risk for the patients (compare to a classic cataract surgery).

To guarantee optimum quality products to you, we proceed to the recall of the devices with enclosed serial numbers.

Please find our instructions for this recall below:

1. Check your stock without delay with the enclosed traceability form.
2. Send this notice to all persons which have to be informed of this notification in your company, and/or all other facilities where the concerned products have been sent.
3. Stop using immediately the concerned batches of medical devices.
4. Send us back the reply form and the traceability list signed and stamped without delay to: materiovigilance@cristalens.fr or by fax to + 33 2 96 48 97 87.
5. Contact your usual commercial department to organize the product return at Cristalens Industries' expense.

We inform you that the recall notification has been already sent to your local competent authorities.

Cristalens Industrie thanks you for your involvement in this recall, and is fully aware of the inconvenience caused. Cristalens Industrie remains determined to supply you, as well as your customers, high quality, secured and efficient products.

For any further query on this recall, please contact Cristalens Industrie:

- by phone + 33 2 96 48 92 92
- by fax + 33 2 96 48 97 87
- by mail materiovigilance@cristalens.fr

Best Regards,

M. Denis DELAGE
CEO

Encs : - Reply form
- Traceability list

REPLY CUSTOMER FORM FOR RECALL OF CRISTALENS INDUSTRIE PRODUCTS

Réf Cristalens: FE_01132, FSCA ref: 2017.09.05.
Concerned products: Preloaded hydrophobic intraocular lenses.

Date : 2017/05/09

Please fill-in and send us back this form without delay by mail to materiovigilance@cristalens.fr or by fax to: +33 2 96 48 97 87.

Please tick the appropriate case below:

☐ I have read the Field Safety Notice dated 2017/05/09 and have checked my stocks. I confirm that my company does not have any medical devices from enclosed traceability list.

☐ I have read the Field Safety Notice dated 2017/05/09 and have checked my stocks. Our company needs the medical devices marked in our filled-in traceability list to be returned.

The person in charge of this reply form, acknowledges receipt of the Field Safety Notice instructions to be applied and understand it,

Company name:

Mandatory name: Position:

Date:

Signature & Company stamp

Contact details for the person in charge of the recall follow-up in your company:
Name/position/mail/tel:

N° de lot	Model							
Batch Nr.	ARTIS E	ARTIS M	ARTIS T	ARTIS Y	ASE	EAZ-Y	LUXIOL60	NAVIGO
1612538	X							
1612629	X							
1612631	X							
1612635	X							
1612893	X							
1613109	X							
1613110	X							
1700425			X					
1700623	X							
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1700626	X							
1700647	X							
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