Lannion, April 23, 2024 Reference: FSN_RC_00716_RC_00717

URGENT: SAFETY NOTICE (FSN) - DEVICE RECALL

Medical devices concerned: Preloaded hydrophobic acrylic intraocular lenses ARTIS SYMBIOSE, ARTIS PL E

Dear Cristalens Industrie Customer,

We hereby inform you that we are carrying out a batch recall as a precautionary measure.

Cristalens Industrie has been informed of 2 cases of intraocular lenses with unexpected refractive error.

As a precaution, Cristalens Industrie is recalling the batches potentially involved.

Users of batches concerned by the recall have already been informed.

Hazard description: Risk of unsatisfactory post-operative refractive results.

In appendix 1, you will find the references of the intraocular lenses concerned by this notice.

Please follow the instructions below:

1- Cristalens has identified that affected devices have been provided to your establishment. Check your stock management systems and your customers' warehouses: Please do not use intraocular lenses with the serial numbers shown in Appendix 1. Please return intraocular lenses with the serial numbers shown in Appendix 1. Please provide us with the references of the intraocular lenses with the serial numbers shown in Appendix 1 that have been fitted and the date of implantation.
2- Immediately transmit this notice to all persons who should be informed of this notice in your establishment, and/or to any other establishment where the affected products have been transferred.
3- Return the duly completed, stamped and signed reply form below without delay to the following address: materiovigilance@cristalens.fr
4- Contact your usual customer service department at export.ci@cristalens.fr if you have any questions.
5- Any correspondence or discussions relating to this notice must mention the following reference: FSN_RC_00716_RC_00717

We inform you that this notice has been communicated to the competent national authorities.

Committed to providing you and your customers with the highest quality products, Cristalens Industrie thanks you for your cooperation and is fully aware of the inconvenience caused.

If you have any questions concerning this information, please contact Cristalens Industrie :
By telephone at + 33 2 96 48 92 92, or by e-mail at materiovigilance@cristalens.fr

Yours sincerely
Mr Denis DELAGE
Chairman

Appendix 1: List of medical devices concerned by this safety notice
Appendix 2: Response form must be completed, stamped and signed.

Appendix 1: List of medical devices concerned by this safety notice - reference: FSN_RC_00716_RC_00717

Preloaded hydrophobic acrylic intraocular lens model ARTIS SYMBIOSE

ARTIS SYMBIOSE PLUS D20.5 Cyl 3.00 - Batch 2308048

2308048001	2308048006

ARTIS SYMBIOSE MID D24.0 Cyl 2.25 - Batch 2308158

2308158002	2308158003	2308158004

ARTIS SYMBIOSE MID D26.0 Cyl 2.25 - Batch 2312032

2312032004	2312032006

Preloaded hydrophobic acrylic intraocular lens model ARTIS PL E

ARTIS PL E D7- Batch 2320478

2320478001	2320478009	2320478016	2320478021	2320478025	2320478029
2320478002	2320478011	2320478017	2320478022	2320478026	2320478030
2320478004	2320478012	2320478018	2320478023	2320478027	2320478031
2320478008	2320478015	2320478019	2320478024	2320478028	

ARTIS PL E D24 - Batch 2320202

2320202007	2320202010

ARTIS PL E D23.5 - Batch 2322065

2322065001	2322065003	2322065006

ARTIS PL E D23 - Batch 2321301

2321301001	2321301002

ARTIS PL E D23 - Batch 2322115

2322115001

Appendix 2 :

CUSTOMER RESPONSE FORM - SAFETY NOTICE - CRISTALENS INDUSTRIE

Reference: FSN_RC_00716_RC_00717 Date: April 23, 2024

Medical devices concerned: Preloaded hydrophobic acrylic intraocular lenses ARTIS SYMBIOSE, ARTIS PL E

Please complete and return this form immediately by e-mail to materiovigilance@cristalens.fr.

- I have read the safety notice dated April 23, 2024 and checked my stock. We will return the affected medical devices as soon as possible.

- I have read the safety notice of April 23, 2024 and checked my stock. I confirm that my establishment has no medical devices concerned by this safety notice.

Signing this document confirms that you have read and understood the information contained in this communication.

Company name:

Name and surname of manager:

Position:

Date:

Signature & company stamp :
