

URGENT: FIELD SAFETY NOTICE (FSN)

Lannion, on November 20th, 2019

Cristalens Industrie Reference: FSN_RC_00007

Subject: Field safety notice concerning the software for calculating characteristics of ARTIS T PL E preloaded hydrophobic intraocular lenses

Dear Cristalens Industrie Customers,

We inform you that a new version of the calculating software for toric intraocular lenses was made available on September 13th, 2019. This software version integrates calculations for the ARTIS SYMBIOSE TORIC preloaded hydrophobic intraocular lenses.

This new version, reference 4.0.1, includes the following improvements:

- 1/ Add a delay to the software module for printing. The printable version of the calculation is not possible until the image is available.
- 2/ Improve how the schema appears, with the schema resetting automatically if a new calculation is begun.
- 3/ Add the possibility for the user to fill in the keratometric axes values without a particular decimal requirement (either comma or period).

Improvements 1/ and 2/ correct an error that occurred when printing calculations with the previous software version (reference 3.0.1) which occurred when carrying out multiple calculations in a row with poor access to the server where the calculating software is located (a problem tied to poor internet connection). Indeed, an incident was reported in France in which two toric calculations were made in a row. The calculation sheet for the second lens showed the same orientation image as was calculated for the first toric lens rather than updating the image according to the second toric lens' axis indications. The ARTIS T PL E lens was implanted according to this incorrect orientation resulting in induced astigmatism.

Also, as precautionary measures, if you are led to use a calculation that was carried out **before September 13, 2019**, we recommend checking the implantation axis indicated on the calculation sheet. If in doubt, carry out the calculation with the version of the software currently available.

Please immediately transfer this warning to all people that may need to be informed in your establishment and all other establishments where the on-line calculator is used. We confirm that this notice has already been submitted to the competent national authorities.

While we fully understand the inconvenience caused, Cristalens Industrie remains determined to provide you and your clients with the highest quality, safest and most efficient products. Cristalens Industrie thanks you for your cooperation.

For questions concerning this information, please contact Cristalens Industrie:

- By telephone at +33 2 96 48 92 92,
- By fax at + 33 2 96 48 97 87,
- By e-mail at materiovigilance@cristalens.fr.

Dear Customer, we send you our kindest regards,

Mr. Denis DELAGE
CEO

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Attached: Reply slip

CRISTALENS INDUSTRIE CUSTOMER REPLY SLIP FOR SAFETY WARNING (FSN)

Cristalens Industrie Reference: FSN_RC_00007

Date: 20/11/2019

Subject: Field safety notice concerning the software for calculating characteristics of ARTIS T P L E preloaded hydrophobic intraocular lenses

Please complete the following form and return it immediately by e-mail to materiovigilance@cristalens.fr or by fax to +33 2 96 48 97 87.

Please check the box on the left to confirm the following:

I have taken into account the field safety notice sent by Cristalens Industrie, reference FSN_RC_00007 from 20/11/2019.

I immediately transferred the Cristalens Industrie field safety notice reference FSN_RC_00007 from 20/11/2019 to all those who ought to be informed of this notification in our establishment and/or all other establishments that use the calculating software concerned by the warning.

The person completing this form confirms having received and understood the measures to undertake following this warning, as indicated in the Cristalens Industrie field safety notice reference FSN_RC_00007 from 20/11/2019.

Company Name : _____

First & Last Name : _____ Position: _____

Date: _____

Signature & stamp

Contact information for the person to contact within your company for follow-up on this notice:

First & Last Name: _____ Position: _____

Email Address: _____ Telephone Number: _____