

## Urgent Field Safety Notice RGP Contact Lenses

Date: 23-12-2020

Attention: - Practitioners dispensing Contact Lenses with the below listed batchnumber  
- Any customer having received contact lenses with the below listed batchnumber

Dear Sir of Madam,

hereby we would like to inform you about a safety-relevant information which is being made voluntarily by Procornea Nederland BV for the RGP Contact Lenses listed in the attachment.

*Details on affected devices:* See attachment I for the list of 22 affected contact lenses.

*Description of the problem:* The RGP Contact Lenses listed in attachment I are labelled without expiry date and a possible reversible health impact might occur if the use of these made-to-order products starts after the actual expiry date.

*Advise on action to be taken by the user:* Please refer to the batchnumber on the label and check with the batchnumber in the attachment. If the batchnumber is listed in the attachment, then please return the product to manufacturer directly or via your practitioner. There is no safety or health risk if the contact lens has already been taken into use.

*Transmission of the Field Safety Notice:* This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. In case the contact lens has been handed to the customer in a closed packaging then please contact the customer.

*Contact reference person:* Benno Schreurs, Procornea Nederland BV, QA/RA manager

The undersigned confirms that this Field Safety Notice has been notified to the National Competent Authority. We regret the inconvenience cause and fully appreciate your prompt cooperation in addressing this situation. If you require additional information, then please do not hesitate to contact us directly.

Sincerely,

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Procornea Nederland BV  
Tel +31 (0) 313 677 677

### Attachment I: List of Batches without Expiry Date

List of 22 contact lenses without Expiry Date on the label. Note: Actual expiry date is 12-2022

Item number	Product Name	Lot Number
P1038	Sclera PFT-II	S9003205
P21504	Senso Mini Sclera PFT	S9009281
P21504	Senso Mini Sclera PFT	S9009282
P21402	Senso Sclera Easy PT	S9009314
P7700	DreamLite TRX	S9011371
P7700	DreamLite TRX	S9011372
P21404	Senso Sclera Easy PFT	S9014395
P21502	Senso Mini Sclera PT	S9014555
P21502	Senso Mini Sclera PT	S9014556
P21502	Senso Mini Sclera PT	S9014883
P1038	Sclera PFT-II	S9016161
P1037	Sclera PT-II	S9016301
P1037	Sclera PT-II	S9016302
P7700	DreamLite TRX	S9018684
P400	F Ellips	S9019832
P400	F Ellips	S9019834
P400	F Ellips	S9019885
P400	F Ellips	S9019886
P7405	DreamLite MC	S9022567
P7700	DreamLite	S9022630
P21504	Sclera	S9013356
P21504	Sclera	S9014112

**Attachment II: Reply form FSN 202001\_EN**

Batchnr.	Date Contact	Time Contact	Expiry Date Printed on Label ?	Option*
			Yes / No / Not possible to verify	1 / 2 / 3
			Yes / No / Not possible to verify	1 / 2 / 3
			Yes / No / Not possible to verify	1 / 2 / 3
			Yes / No / Not possible to verify	1 / 2 / 3
			Yes / No / Not possible to verify	1 / 2 / 3
			Yes / No / Not possible to verify	1 / 2 / 3
<p><b>*Please select on of the following options 1, 2 of 3</b></p> <ul style="list-style-type: none"> <li>- 1. Contact Lens is already in use (no safety concern)</li> <li>- 2. The customer has been contacted at the indicated time and date and the customer confirms that the contact lens is already in use. (no safety concern)</li> <li>- 3. The customer has been contacted and the customer has confirmed that the contact lens will be returned.</li> </ul>				

I herewith acknowledge the receipt of your Field Safety Notice. Further I confirm that I have transferred the content of the attached FSN and attachments to all relevant colleagues, departments or affiliates on which this action has an impact.

Name (Signature) \_\_\_\_\_

Name (Print) \_\_\_\_\_

Position \_\_\_\_\_

Please Email a scan of this document to [ra@procornea.nl](mailto:ra@procornea.nl)