

Urgent Field Safety Notice
Senso Mini Sclera PT & Senso Sclera Easy

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 Scleral Lenses listed in the attachment.

Details on affected devices: See attachment II for the list of 87 affected scleral lenses.

Description of the problem: The ERP did not calculate the production sagitta for scleral lenses because the ERP-option (flag) for default sagitta was inadvertently checked. As a result of the incorrect ERP-flag the default minimal sagitta has been manufactured. The default minimal sagitta only offers a minimal distance between cornea and scleral lens and is less than the ordered sagittal height. The risk of this incorrect sagittal height is that some of the scleral lenses will contact the cornea.

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.

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 scleral 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: Reply form FSN 202002_EN

Please add this form to the return shipment and add the batchnumber

Batchnr

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

Attachment II: List of 87 Scleral lenses with incorrect sagitta

Medical Device Name : Senso Mini Sclera PT & Senso Sclera Easy
List of scleral lenses with incorrect sagitta:

Item number	Product Name	Lot Number
P21502	Senso Mini Sclera PT	SO00001409
P21502	Senso Mini Sclera PT	SO00002287
P21502	Senso Mini Sclera PT	SO00002304
P21502	Senso Mini Sclera PT	SO00002304
P21502	Senso Mini Sclera PT	SO00002310
P21502	Senso Mini Sclera PT	SO00002310
P21502	Senso Mini Sclera PT	SO00002321
P21502	Senso Mini Sclera PT	SO00007011
P21502	Senso Mini Sclera PT	SO00008590
P21502	Senso Mini Sclera PT	SO00011264
P21502	Senso Mini Sclera PT	SO00011507
P21502	Senso Mini Sclera PT	SO00011557
P21502	Senso Mini Sclera PT	SO00011569
P21502	Senso Mini Sclera PT	SO00011880
P21502	Senso Mini Sclera PT	SO00011881
P21502	Senso Mini Sclera PT	SO00011882
P21502	Senso Mini Sclera PT	SO00011913
P21502	Senso Mini Sclera PT	SO00012734
P21502	Senso Mini Sclera PT	SO00014781
P21502	Senso Mini Sclera PT	SO00014882
P21502	Senso Mini Sclera PT	SO00014884
P21502	Senso Mini Sclera PT	SO00014915
P21502	Senso Mini Sclera PT	SO00014930
P21502	Senso Mini Sclera PT	SO00014942
P21502	Senso Mini Sclera PT	SO00014942
P21502	Senso Mini Sclera PT	SO00015185
P21502	Senso Mini Sclera PT	SO00015197
P21502	Senso Mini Sclera PT	SO00015218
P21502	Senso Mini Sclera PT	SO00015227
P21502	Senso Mini Sclera PT	SO00015296
P21502	Senso Mini Sclera PT	SO00015631
P21502	Senso Mini Sclera PT	SO00016011
P21502	Senso Mini Sclera PT	SO00016298
P21502	Senso Mini Sclera PT	SO00016348
P21502	Senso Mini Sclera PT	SO00016393
P21502	Senso Mini Sclera PT	SO00016683
P21502	Senso Mini Sclera PT	SO00017925
P21502	Senso Mini Sclera PT	SO00017925
P21502	Senso Mini Sclera PT	SO00017977
P21502	Senso Mini Sclera PT	SO00017977

P21400	Senso Sclera Easy	SO00017978
P21502	Senso Mini Sclera PT	SO00017988
P21502	Senso Mini Sclera PT	SO00017988
P21502	Senso Mini Sclera PT	SO00018087
P21502	Senso Mini Sclera PT	SO00018087
P21502	Senso Mini Sclera PT	SO00018114
P21502	Senso Mini Sclera PT	SO00018380
P21502	Senso Mini Sclera PT	SO00018497
P21502	Senso Mini Sclera PT	SO00018520
P21502	Senso Mini Sclera PT	SO00018588
P21502	Senso Mini Sclera PT	SO00018630
P21502	Senso Mini Sclera PT	SO00018630
P21502	Senso Mini Sclera PT	SO00018633
P21502	Senso Mini Sclera PT	SO00018650
P21502	Senso Mini Sclera PT	SO00019041
P21502	Senso Mini Sclera PT	SO00019041
P21502	Senso Mini Sclera PT	SO00019970
P21502	Senso Mini Sclera PT	SO00020026
P21502	Senso Mini Sclera PT	SO00020602
P21502	Senso Mini Sclera PT	SO00020604
P21502	Senso Mini Sclera PT	SO00020605
P21502	Senso Mini Sclera PT	SO00020645
P21502	Senso Mini Sclera PT	SO00020649
P21502	Senso Mini Sclera PT	SO00020657
P21502	Senso Mini Sclera PT	SO00020657
P21502	Senso Mini Sclera PT	SO00020658
P21502	Senso Mini Sclera PT	SO00020759
P21502	Senso Mini Sclera PT	SO00020759
P21502	Senso Mini Sclera PT	SO00020761
P21502	Senso Mini Sclera PT	SO00020761
P21502	Senso Mini Sclera PT	SO00020764
P21502	Senso Mini Sclera PT	SO00020765
P21502	Senso Mini Sclera PT	SO00023351
P21502	Senso Mini Sclera PT	SO00023381
P21502	Senso Mini Sclera PT	SO00023383
P21502	Senso Mini Sclera PT	SO00023385
P21502	Senso Mini Sclera PT	SO00023387
P21502	Senso Mini Sclera PT	SO00023899
P21502	Senso Mini Sclera PT	SO00023899
P21502	Senso Mini Sclera PT	SO00023913
P21502	Senso Mini Sclera PT	SO00023913
P21502	Senso Mini Sclera PT	SO00011425
P21502	Senso Mini Sclera PT	SO00024447
P21502	Senso Mini Sclera PT	SO00028603

P21502	Senso Mini Sclera PT	SO00028605
P21502	Senso Mini Sclera PT	SO00028619
P21400	Senso Sclera Easy	SO00029059
P21502	Senso Mini Sclera PT	SO00030640
P21502	Senso Mini Sclera PT	SO00031031
P21502	Senso Mini Sclera PT	SO00031341
P21502	Senso Mini Sclera PT	SO00031411
P21502	Senso Mini Sclera PT	SO00031638
P21502	Senso Mini Sclera PT	SO00032408
P21502	Senso Mini Sclera PT	SO00032410
P21502	Senso Mini Sclera PT	SO00032424
P21502	Senso Mini Sclera PT	SO00032937
P21502	Senso Mini Sclera PT	SO00032946
P21502	Senso Mini Sclera PT	SO00032947
P21502	Senso Mini Sclera PT	SO00033600
P21502	Senso Mini Sclera PT	SO00033601
P21502	Senso Mini Sclera PT	SO00033601

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