



**Menicon Singapore Sales Pte. Ltd.**

8 International Business Park

Singapore 609925

Tel: (65) 6411 4778 Fax: (65) 6411 4768

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## **Urgent Field Safety Notice to concerned Customers**

**Commercial name of the affected product:**

**Menicon O2 CARE**

**FSCA-identifier (e.g. date):**

**FSCA 2018-01-04**

**Type of action:**

**Instruction to return the product, RECALL**

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Date: 2018-01-04

Dear Customer/Distributor

this Field Safety Notice is exclusively related to "Menicon O2 CARE" and concerns following Lot numbers:

Lot No.	705091
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### Details on affected devices:

Out of that range and based on our records, we identified that you have received the following products related to that Urgent Field Safety Notice:

Product name	Lot No.	Quantity
Menicon O2 CARE	705091	

### Description of the problem:

Process simulation (media fill testing) in manufacturing process line was conducted and the result was failed. In regard to the manufacturing line, we have confirmed the suitability of sterility guarantee on a regular basis. As the result of last validation was passed, we have confirmed that there is no influence on the sterility of products produced until last validation. Furthermore, no reports of damage to health have been received to date. However, we have decided to recall products manufactured after the validation as it is difficult to guarantee sterility completely.

### How many products are affected?

Although the number of affected Menicon O2 CARE is [insert received quantity] units, the sterility tests performed for each manufactured lot were passed, so the possibility of any damage to health is thought to be extremely low; however, Menicon voluntarily decided to issue this Field Safety Notice as corrective action and to prevent any possible impact on user's health.

### What to do with affected products already used?

If users already have used Menicon O2 CARE of the affected Lot numbers the affected product should be replaced with new one. If users have symptoms like red eye, eye pain or any discomfort, he/she should remove lenses and contact his/her eye care professional.

### What to do with products not affected?

Menicon O2 CARE not related to the affected Lot numbers can be safely continued to be used.

### Advise on action to be taken by the user:

1) identify and quarantine the device(s) based on the affected Lot numbers

2) return any Menicon O2 CARE if you still have any of the affected Lot numbers in your stock or shelf. In that case, please use the "Acknowledgement and Conformation Form" attached hereto and indicate the status of the concerned product and confirm the Lot numbers you have returned

3) please return that "Acknowledgement and Conformation Form" within 7 days after receiving to the national Menicon organization which supplied the Menicon O2 CARE to you:

For *Singapore*, please send it to

Menicon Singapore Sales Pte. Ltd.  
8 International Business Park, Singapore 609925  
Tel: 6411 4778  
Fax: 6411 4768  
Contact Person: Hiroshi Suzuki  
Email address: [enquiry@menicon.com.sg](mailto:enquiry@menicon.com.sg)

and as applicable, please return such products to the above mentioned address. Menicon will bear and compensate for all costs to return the products, evidently returned products will be credited to you.

Transmission of this Field Safety Notice:

Please forward this notice to all those who need to be aware within your organization or to any organization where the affected devices have been transferred by you. Please contact and inform concerned customers /users of this notice.

Contact reference person:

For any question, please us following contacts:

For *Singapore*,

Menicon Singapore Sales Pte. Ltd.  
8 International Business Park, Singapore 609925  
Tel: 6411 4778  
Fax: 6411 4768  
Contact Person: Hiroshi Suzuki  
Email address: [enquiry@menicon.com.sg](mailto:enquiry@menicon.com.sg)

Menicon deeply apologize for all inconvenience this subject has caused to you, or to your users. We trust on your full cooperation and awareness for an appropriate period to ensure effectiveness of the corrective action. Please fill out and return the "Acknowledgement and Conformation Form" to your national Menicon organization as described above (see next page for the Form).

The undersign confirms that this notice has been notified to the appropriate Regulatory Authorities.

Name Hiroshi Suzuki

Signature

※Please put company stamp as well. Thank you.

## Acknowledgement and Confirmation Form

(to ensure effective corrective action, returning of that Form is required by the Regulatory Authorities)

Please fill out, date, sign and return by Fax, Email or Post to

For Singapore,

Menicon Singapore Sales Pte. Ltd.  
8 International Business Park, Singapore 609925  
Tel: 6411 4778  
Fax: 6411 4768  
Contact Person: Hiroshi Suzuki  
Email address: [enquiry@menicon.com.sg](mailto:enquiry@menicon.com.sg)

Customer Number	
Customer name & address	

### Status of the concerned product

☐ no more Menicon O2 CARE from the affected Lots exists in our stock

Following of the affected Menicon O2 CARE were found in our stock and were

☐ returned \* to the above named Menicon organization

\* please describe the Lot number and Quantity below table as these products will be credited to you

Lot number	Quantity
705091	

Date \_\_\_\_\_

Name \_\_\_\_\_

Signature \_\_\_\_\_

※Please put the company stamp as well. Thank you.