Urgent Field Safety Notice to concerned Customers

Commercial name of the affected product: **MeniCare Soft 70ML**
FSCA-identifier (e.g. date): **FSCA (MCSoft) 2018-01-04**
Type of action: **Instruction to return the product, RECALL**

Date: 2018-01-04

Dear Customer/Distributor [*insert the individual customer name & address*]

this Field Safety Notice is exclusively related to "MeniCare Soft 70ML" and concerns following Lot numbers:

Lot No. (Box)	Lot No. (Bottle)
MP17288	703061
MP17350	703061

Caution: Lot numbers printed on a box and a bottle are different.

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. (Box)	Lot No. (Bottle)	Quantity
MeniCare Soft 70ML	MP17288*	703061	*insert received quantity*
MeniCare Soft 70ML	MP17350**	703061	*insert received quantity*

*distributed by Menicon SAS
**distributed by Menicon Ltd.

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 MeniCare Soft is *insert received quantity* units respectively, 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 MeniCare Soft 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?
MeniCare Soft 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 MeniCare Soft 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 MeniCare Soft to you:

For [*insert country*], please send it to

[*insert the concerned national address, contact person, phone & Fax number, Email*]

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 [*insert country*]

[*insert the concerned national contact person, phone & Fax number, Email*]

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 Hideshi Nomura

Signature [redacted]