
Urgent Field Safety Notice to concerned Customers

Commercial name of the affected product: **Menicon soft 72**
FSCA-identifier (e.g. date): **FSCA 2017-02-13**
Type of action: **Instruction to return the product, RECALL**

Date: 2017-02-13

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

this Field Safety Notice is exclusively related to "Menicon soft 72 soft hydrophilic contact lenses" and concerns following Lot numbers:

16375331	16375454	16376215	16376216	16376225	16376227	16376256
16376257	16376383	16376385	16376904	16376906	16376939	16376940
16376979	16377169	16377309	16377510	16377519	16377621	16377622
16377623	16377624	16377625	16377836	16377838	16377945	16377946
16378434	16378435	16379224	16375729	16376419	16376463	16376907
16377409	16375462	16376419	16376463	16376907	16377409	

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:

Lot	Order no.	Brand name	Shipped to you on	Delivery note no.	Patient, Reference	BC	Power	Dia.
16375331	xyz	Menicon Soft72	23. Nov. 2016	XYZ123	7089880 - 311931	8.60	-3.00	14.00
...

Description of the problem:

A serious problem was found in the manufacturing process of Menicon soft 72 contact lenses as manufactured on 21. November 2016.

Instead of using the regular saline solution, we have grounds to suspect that for some Menicon soft 72 contact lenses, peroxide solution was wrongly used as shipping solution in the contact lens packaging process.

How many products are affected?

At time, the known risk for Menicon soft 72 contact lenses containing the wrong shipping solution for that manufacturing date is calculated as less than 10 percent; however Menicon voluntarily decided to issue this Field Safety Notice as corrective action and to prevent any possible impact on patient's health.

What can happen?

If patients insert such a lens directly from the shipping container onto the eye, immediately an eye irritation, eye pain and a red eye effect may occur.

What to do if it happens?

To escape from such effects, the lens shall be immediately removed from the eye, and the eye shall be rinsed straight away and thoroughly with a large amount of water or sterile saline. If any patient already experienced such symptoms, the lens shall be rejected and not used again.

How to prevent that it happens?

Do not use and do not insert onto the eye any Menicon soft 72 contact lens from the affected Lot numbers, if such lenses are still in the original and unopened packaging. Otherwise there is a potential risk to get a severe eye irritation and eye pain which may result in a serious deterioration of health!

What to do with affected products already used?

If patients already have used Menicon soft 72 contact lens from the affected Lot numbers, but no such symptom occurred when the lens was initially put onto the eye, then the lens can be safely worn. However, concerned lens should be replaced with new one.

If patients feel a sense of discomfort, he/she should remove lenses and contact his/her eye care professional.

What to do with products not affected?

Menicon soft 72 contact lenses 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 soft 72 contact lens 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 rejected or returned.

3) Please return that "Acknowledgement and Conformation Form" within 7 days after receiving to the national Menicon organization which supplied the Menicon soft 72 contact lenses to you:

For [**Germany, Great Britain, France**], 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 rejected/returned lenses 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 patients if you believe that the affected Menicon soft 72 contact lenses might still have not being used by the concerned patient.

Contact reference person:

For any question, please us following contacts:

For [**Germany, Great Britain, France**]

[**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 patients. 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 _____

Signature _____

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 [**Germany, Great Britain, France**]

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

Customer Number	
Customer name & address	

Status of the concerned product

no more Menicon soft 72 lenses from the affected Lots exists in our stock

Following of the affected Menicon soft 72 lenses were found in our stock and were

rejected *

returned * to the above named Menicon organization

*** please describe the Lot numbers in below table as these lenses will be credited to you**

Date _____

Name _____

Signature _____