Rev 1: September 2018
FSN Ref: 1-2023 FSCA Ref: 1-2023

Date: 2023-11-28

Urgent Field Safety Notice
Device Commercial Name

For Attention of*: DISTRIBUTORS OF THE CONTACT LENS DISINFECTION SYSTEM “iWear dynamic 250ml” (PEROXIDE SOLUTION) IDENTIFIED BY THE LOT NUMBER 238145

Contact details of local representative (name, e-mail, telephone, address etc.)*
Not applicable

Soleko Spa
Via Ravano, snc - 03037 Pontecorvo (FR) Italia | Tel. +39 0776 77091 | Fax +39 0776 770952
Via Casilina, 110b - 00182 Roma (RM) Italia | Tel. +39 06 4395508 | Fax +39 06 4395486
P.IVA 00216880609 | E-mail info@soleko.it | www.soleko.it | www.menicon.it

Rev 1: September 2018
FSN Ref: 1-2023 FSCA Ref: 1-2023

Urgent Field Safety Notice (FSN)
Device Commercial Name
Risk addressed by FSN

	1. **Information on Affected Devices***
1.	1. Device Type(s)*
	Peroxide solution indicated for the disinfection of all contact lenses with the exception of coloured/cosmetic ones.
1.	2. Commercial name(s)
	iWear dynamic 250ml
1.	3. Unique Device Identifier(s) (UDI-DI)
	Complete when this becomes available.
1.	4. Primary clinical purpose of device(s)*
	Peroxide solution indicated for the disinfection of all contact lenses with the exception of coloured/cosmetic ones.
1.	5. Device Model/Catalogue/part number(s)*
	PER250 IWF
1.	6. Software version
	Only where relevant.
1.	7. Affected serial or lot number range
	LOT 238145
1.	8. Associated devices
	Within context of the FSCA eg for IVD reagents and platforms.

	2 **Reason for Field Safety Corrective Action (FSCA)***
2.	1. Description of the product problem*
	During our normal routine control, we discovered that some cross contamination occurred in LOT 238145 of Soleko iWear dynamic 250ml. This happened due to some accidental and partial mixing with a multipurpose solution during the compounding operation.
2.	2. Hazard giving rise to the FSCA*
	We carried out further testing which indicated that the Peroxide solution efficacy and microbiological performance of the product was not affected by the contamination and would still be safe to use. However, given the composition of this Peroxide lot does not correspond to the declared specifications on the label and the patient IFU we have therefore decided to withdraw LOT 238145 from your warehouse.
2.	3. Probability of problem arising
	-
2.	4. Predicted risk to patient/users
	-
2.	5. Further information to help characterise the problem
	-
	6. Background on Issue

Soleko Spa
Via Ravano, snc - 03037 Pontecorvo (FR) Italia | Tel. +39 0776 77091 | Fax +39 0776 770952
Via Casilina, 110b - 00182 Roma (RM) Italia | Tel. +39 06 4395508 | Fax +39 06 4395486
P.IVA 00216880609 | E-mail info@soleko.it | www.soleko.it | www.menicon.it

2.	-
2.	7. Other information relevant to FSCA This field may only contain additional information that is deemed necessary by the manufacturer to supplement information relevant to the FSCA.

3. Type of Action to mitigate the risk*

3. 1. Action To Be Taken by the User*

☒ Identify Device ☒ Quarantine Device ☒ Return Device ☐ Destroy Device

☐ On-site device modification/inspection

☐ Follow patient management recommendations

☐ Take note of amendment/reinforcement of Instructions For Use (IFU)

☐ Other ☐ None

Provide further details of the action(s) identified.

3.	2. By when should the action be completed?	Specify where critical to patient/end user safety

3. 3. Particular considerations for: Choose an item.

Is follow-up of patients or review of patients' previous results recommended?
Choose an item.

Provide further details of patient-level follow-up if required or a justification why none is required

3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	No

3. 5. Action Being Taken by the Manufacturer

☒ Product Removal ☐ On-site device modification/inspection
☐ Software upgrade ☐ IFU or labelling change
☐ Other ☐ None

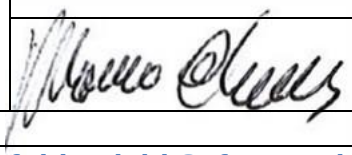
Provide further details of the action(s) identified.

3	6. By when should the action be completed?	Specify where critical to patient/end user safety
3.	7. Is the FSN required to be communicated to the patient /lay user?	Choose an item.

Soleko Spa
Via Ravano, snc - 03037 Pontecorvo (FR) Italia | Tel. +39 0776 77091 | Fax +39 0776 770952
Via Casilina, 110b - 00182 Roma (RM) Italia | Tel. +39 06 4395508 | Fax +39 06 4395486
P.IVA 00216880609 | E-mail info@soleko.it | www.soleko.it | www.menicon.it

3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	Choose an item.	Choose an item.

Soleko Spa
Via Ravano, snc - 03037 Pontecorvo (FR) Italia | Tel. +39 0776 77091 | Fax +39 0776 770952
Via Casilina, 110b - 00182 Roma (RM) Italia | Tel. +39 06 4395508 | Fax +39 06 4395486
P.IVA 00216880609 | E-mail info@soleko.it | www.soleko.it | www.menicon.it

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	Provide reference and date of previous FSN if relevant
4.	**3.** For Updated FSN, key new information as follows:	
	Summarise any key difference in devices affected and/or action to be taken.	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	Eg patient management, device modifications etc	
4	6. Anticipated timescale for follow-up FSN	For provision of updated advice.
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Only necessary if not evident on letter-head.
	b. Address	Only necessary if not evident on letter-head.
	c. Website address	Only necessary if not evident on letter-head.
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * Yes	
4.	9. List of attachments/appendices:	If extensive consider providing web-link instead.
4.	10. Name/Signature	**Massimo Carbone, C.E.O. and PRRC**
		

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.