Rev 1: September 2018

FINNSUSP

FSN Ref: LP007058 FSCA Ref: Manufacturer's ref number LP007058

Date: 20.07.2026

Urgent Field Safety Notice

The Eye Doctor Advanced Triple Action Eye Drops

For Attention of*:The Body Doctor Ltd, UK, and its distribution chain

Contact details of local representative (name, e-mail, telephone, address etc.)*
The manufacturer: Oy Finnsusp Ab, Quality Director Heidi Hirviniemi, Pääskykalliontie 5, 21420 Lieto, Finland. e-mail: quality@piiloset.fi. Tel. +358503723787.

Urgent Field Safety Notice (FSN)
The Eye Doctor Advanced Triple Action Eye Drops
Theft of Batch A1127 – Risk of Unauthorised Distribution and Use

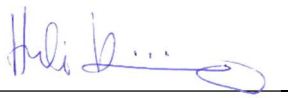
1. Information on Affected Devices*	
1.	1. Device Type(s)*
	The product is a sterile, preservative-free lipid microemulsion eye drop for the treatment and prevention of signs and symptoms of moderate to severe dry eye, filled in a 10 mL multidose bottle.
1.	2. Commercial name(s)
	The Eye Doctor Advanced Triple Action Eye Drops
1.	3. Unique Device Identifier(s) (UDI-DI)
	Complete when this becomes available.
1.	4. Primary clinical purpose of device(s)*
	Eye drop intended to treat and prevent signs and symptoms of moderate to severe dry eye
1.	5. Device Model/Catalogue/part number(s)*
	Medical device identifying type number F0017
1.	6. Software version
	Only where relevant.
1.	7. Affected serial or lot number range
	Lot/batch A1127
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*
	The manufacturer is issuing this Field Safety Notice following the confirmed theft of an entire shipment of the above medical device lot/batch A1127 during transportation. The affected shipment has not reached the authorised distributor and its current whereabouts are unknown. As the products are outside the manufacturer's controlled distribution chain, their storage conditions, handling, transportation and possible subsequent distribution cannot be verified. Consequently, the manufacturer cannot guarantee that the affected products continue to comply with the specified quality, safety and performance requirements. This FSN is intended to prevent the use or distribution of products originating from the stolen shipment.
2.	2. Hazard giving rise to the FSCA*
	Products originating from the stolen shipment may have been exposed to uncontrolled transportation or storage conditions. Potential hazards associated with the affected products: 1. Unknown storage conditions may result in reduced product quality or performance and local ocular irritation or discomfort. 2. Use beyond the recommended discard period may cause local irritation or discomfort or, in rare cases, eye infection due to microbial contamination of the contents. 3. Manipulation or tampering of the primary package may lead to eye infection due to microbial contamination of the contents. 4. Off-label or non-compliant use may delay the diagnosis and treatment of an underlying ophthalmic condition, as symptom relief may mask disease progression.
	3. Probability of problem arising

2.	1. Probable, 2. Probable, remote, 3. Occasional, 4. Occasional
2.	4. Predicted risk to patient/users
	The risks identified for the stolen batch, should it be placed on the market outside the authorised distribution network, all fall within the investigate-further-risk-reduction (IFRR) area, with the exception of off-label use, which remains at an acceptable level. To mitigate these risks, the FSN has been issued to prevent the unauthorised distribution and use of batch A1127.
2.	5. Further information to help characterise the problem
	Any product obtained outside the authorised distribution network should be considered potentially compromised. The stolen batch can be identified by lot number A1127, which appears on the bottle label, the carton box, the 10-piece plastic bundle label, and the wholesale carton boxes.
2.	6. Background on Issue
	The transportation company has informed on the theft of the entire shipment.
2.	7. Other information relevant to FSCA
	The complete shipment consisting of 24,230 units from the affected batch was dispatched from the manufacturer on 4 June 2026. According to information subsequently received from the transportation company, the shipment was stolen in the United Kingdom before delivery to the authorised distributor. The products were transported on wooden pallets. During the theft, the complete wholesale boxes were removed from the pallets and stolen intact. The whole batch was dispatched to and intended to be distributed by The Body Doctor Ltd in the territory of UK and Ireland. The batch has not been distributed elsewhere.

	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 Customers, distributors and healthcare professionals are requested to: 1. Verify whether they possess products from the affected lot. 2. Do not use, distribute or supply products from the affected batch, since their origin cannot be confirmed through the authorised distribution chain. 3. Do not purchase products from unofficial sources or online marketplaces if the origin cannot be verified. 4. Immediately quarantine any affected products. If possible, quarantine the affected lot in advance in the ERP system or similar, although not possessing the products. 5. Notify the manufacturer immediately if products from the affected lot are identified. 6. Report any suspected adverse events associated with the affected products according to local vigilance requirements.	
3.	2. By when should the action be completed?	Potentially the stolen batch can unauthorisedly be placed on the market until the expiry date of the batch, i.e. April 2028. 01.05.2028.

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)	Yes
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None Communication to the relevant Competent Authorities, Notified Body, UKRP and the customer on the theft of the batch A1127. Evaluation of the logistics process. Post-market-surveillance and possible vigilance reporting concerning the batch A1127.	
3	6. By when should the action be completed?	The batch expiry date is until 04 / 2028.
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
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.	

	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, the Finnish Competent Authority Fimea was informed 03.07.2026.	
4.	9. List of attachments/appendices:	If extensive consider providing web-link instead.
4.	10. Name/Signature	**Heidi Hirviniemi,** **Quality Director** 

	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.