Urgent Field Safety Notice (FSN) UPDATED****
SP EYE Ref SPY 712
FSN Ref: FSN2024-001 **FSCA Ref: FSCA2024-001**

Date: 29 July 2024

Urgent Field Safety Notice (FSN) ** UPDATED**
SP EYE Ref SPY 712
– Sharps Safe Intravitreal Injection Needle

MHRA Ref: 2024/007/004/601/064

For Attention of*: Distributors and Users

****Updates: Section 2.2: Added in further information related to 'Hazard giving rise to the FSCA'. Section 2.3: Amended risk matrix probability/severity nomenclature and criteria. Section 2.6: Added in further details of users who reported device issues, and clarified what is meant by operational issues at the subcontractor. Section 2.7: Added in further details of the rationale for recall of lot N011169. Section 3.5: Added new text 'Devices from the affected lot N011169, which have been subject to 100% inspection and are suitable for clinical use, will be re-labelled as lot N011169R'. General: Corrected typographical errors. New appendices: Field Safety Notice Customer Reply Form and Field Safety Notice Distributor/Importer Reply Form**.**

Contact details of local representative (name, e-mail, telephone, address etc.)*
Andersen Caledonia, Caledonia House, Strathclyde Business Park, Bellshill ML4 3NJ United Kingdon +44 1698 844476 jlintott@andersencaledonia.com regulatory@andersencaledonia.co.uk

Urgent Field Safety Notice (FSN) UPDATED****

SP EYE Ref SPY 712

FSN Ref: FSN2024-001 **FSCA Ref: FSCA2024-001**

Risk addressed by FSN
– Use of affected device may result in failure to control injection

1.	**Information on Affected Devices***	
1	Device Type(s)*	Sharps Safe Intravitreal Injection Needle Class IIa Medical Device Single use sterile device
2	Commercial name(s)	SP.Eye device SPY 712
3	Unique Device Identifier(s) (UDI-DI)	05060544340005 (Blister pack) 15060544340002 (Box of 100)
4	Primary clinical purpose of device(s)*	SP.Eye device is indicated for use for general adult population who require an intravitreal eye injection, predominantly those with macular degeneration
5	Device Model/Catalogue/part number(s)*	SPY 712 (QRG30993SC198)
6	Software version	Not Applicable
7	Affected serial or lot number range	Lot N011169 expiration date 2026-10-28 (28th October 2026)
8	Associated devices	Not Applicable

Urgent Field Safety Notice (FSN) UPDATED****

SP EYE Ref SPY 712

FSN Ref: FSN2024-001 **FSCA Ref: FSCA2024-001**

2	**Reason for Field Safety Corrective Action (FSCA)***	
1	Description of the product problem*	Excess glue on the shaft of the needle and spontaneous disassembly
2	Hazard giving rise to the FSCA*	Risks fall into three categories: 1. Failure to control depth of injection 2. Failure to control position of injection 3. Failure to control angle of injection The non-conformities discussed herein are generally of low clinical risk, however they are understandably a potential cause for concern and loss of confidence in the device by that user. The most significant risk is to the patient - the throw of the needle being limited such that the injection depth is inappropriately limited, which, in the worst case, might cause drug to be delivered into the choroidal or scleral spaces - this could potentially lead to sight threatening complications, but more likely would induce unnecessary pain. A minor limitation of needle throw will still deliver the drug into the vitreous cavity and will not cause any adverse events. **Non-conformity Risk Assessment:** **Glue on shaft limiting throw** Severity* score 9 (hazardous severity) **Spontaneous disassembly** Severity* score – 5 (moderate severity) **Risk matrix* *Severity score range: 1-10 (1 = none - no effect; 10 = catastrophic – very high severity)*

3	Probability of problem arising	**Non-conformity Risk Assessment:** **Glue on shaft limiting throw** – Probability* score - 8 (repeated failures, 1 in 8 probability) **Spontaneous disassembly** – Probability* score - 1 (failure is unlikely, <1 in 1,500,000 probability) **Risk matrix* *Probability score range: 1-10 (1 = remote probability - failure unlikely; 10 = very high probability – failure is almost inevitable*
4	Predicted risk to patient/users	**Risk Categories** 1. Probability and severity of failure to control depth. Depth may not be controlled adequately if glue on the shaft of the needle prevents full compression of the spring. Injection at any depth within the vitreous cavity is acceptable, however injection prior to penetration into this cavity would result in drug delivery to the wrong area, with the potential risk of embolisation of the choroidal vessels, pain or failure to deliver a therapeutic dose. The thickness of the sclera and choroid is approximately 220-550um, thus, providing the spring throw exceeds this distance, the risk of inadvertent injection into this space is low. The designed throw of the needle is 6.5mm. 2. Probability and severity of failure to control position. The most likely scenario in which this non-conformity might cause a failure of positional control, with respect to the limbus would be if there was no glue present and the assembly came apart from the

		needle itself. This would either occur prior to the device being addressed to the eye - when the correct position of injection had not yet been established, or after securing the device on the globe. In the former scenario it would not be possible to use the device effectively and so its role in establishing the correct position with respect to the limbus would be lost - the injector would then be carrying out an unguided injection with high risk of inadvertent injury to the patient. In the latter scenario, the correct position would already have been established, regardless of the subsequent disassembly of the device - and the risk of incorrect placement would be negligible. Incorrectly placing the needle too anteriorly may cause lens strike (needle hitting the crystalline, or pseudophakic lens) which would be likely to require surgery to correct and may affect long term vision. Furthermore, placing the needle too posteriorly may cause retinal detachment or injury which may lead to further surgery and (in rare cases) permanent loss of vision. 3. Probability and severity of failure to control angle. The most likely scenario in which this non-conformity might cause a failure of angle control would be if there was no glue present and the assembly came apart from the needle itself. This would either occur prior to the device being addressed to the eye - when the correct angle of injection had not yet been established, or after securing the device on the globe. In the former scenario it would not be possible to use the device effectively and so its role in establishing the correct angle would be lost - the injector would then be carrying out an unguided injection with high risk of inadvertent injury to the patient. In the latter scenario, the correct angle would already have been established, regardless of the subsequent disassembly of the device - and the risk of incorrect placement would be negligible. Were the angle of injection to be too flat, this could cause lens strike (needle hitting the crystalline, or pseudophakic lens) which would be likely to require surgery to correct and may affect long term vision. Furthermore, were the angle to be too acute, there is a remote risk of damaging the retina which may lead to further surgery and (in rare cases) permanent loss of vision.
5	Further information to help characterise the problem	Not Applicable

6	Background on Issue	Manufacturer was made aware of the issue by two users (distributors) of the device on 11 June 2024. An investigation was initiated and has established that the root cause of the issue was operational failures (i.e. lack of manufacturing controls, including In Process/QC checks) at the contract manufacturer (Manufacturer's sub-contractor). Risk information can be found above.
7	Other information relevant to FSCA	As stated above, the non-conformities discussed herein are generally of low clinical risk, however they are understandably a potential cause for concern and loss of confidence in the device by the user. These non-conformities can easily be detected visually (by the naked eye) on the device, thus a Field Safety Notice and recall was initiated solely for Lot N011169 expiration date 2026-10-28 (28th October 2026), since this batch is with customers in the field and requires 100% visual inspection. Other SP:EYE batches in the field have either had no reported issues or have been subject to 100% inspection prior to dispatch to the user and are therefore not included within this Field Safety Notice.

3. Type of Action to mitigate the risk*

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	
	Further details of actions identified	User and distributor to complete the distributor/customer reply form and return to Andersen Caledonia as instructed by the form
2	By when should the action be completed?	One month after receiving FSN

Urgent Field Safety Notice (FSN) UPDATED****

SP EYE Ref SPY 712

FSN Ref: FSN2024-001 **FSCA Ref: FSCA2024-001**

3.	Particular considerations for:	Not applicable
	Is follow-up of patients or review of patients' previous results recommended?	Not Applicable
4.	Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
5	**Action Being Taken by the Manufacturer** ☐ Product Removal ☒ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None	
	Further details of actions identified	100% inspection for all batches to be implemented by manufacturer for non-conforming batch, and current batches in stock. Supplier Non-Conformance raised with contract manufacturer and corrective actions are underway including 100% inspection for all future batch manufacturing. **Devices from the non-conforming lot N011169, which have been subject to 100% inspection and are suitable for clinical use, will be re-labelled as lot N011169R.**
6	By when should the action be completed?	One month from date that recalled product was returned to manufacturer. Immediate action by contract manufacturer for future batch manufacturing.
7	Is the FSN required to be communicated to the patient /lay user?	No
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?	Not Applicable

Urgent Field Safety Notice (FSN) UPDATED****

SP EYE Ref SPY 712

FSN Ref: FSN2024-001 **FSCA Ref: FSCA2024-001**

4. General Information*		
1	FSN Type*	Update
2	For updated FSN, reference number and date of previous FSN	FSN2024-001 17 July 2024
3	For Updated FSN, key new information as follows:	**Updates: Section 2.2: Added in further information related to 'Hazard giving rise to the FSCA'. Section 2.3: Amended risk matrix probability/severity nomenclature and criteria. Section 2.6: Added in further details of users who reported device issues, and clarified what is meant by operational issues at the subcontractor. Section 2.7: Added in further details of the rationale for recall of lot N011169. Section 3.5: Added new text 'Devices from the affected lot N011169, which have been subject to 100% inspection and are suitable for clinical use, will be re-labelled as lot N011169R'. General: Corrected typographical errors. New appendices: Field Safety Notice Customer Reply Form and Field Safety Notice Distributor/Importer Reply Form**.
4	Further advice or information already expected in follow-up FSN? *	31 Aug 2024
5	If follow-up FSN expected, what is the further advice expected to relate to:	Clinical Risk Assessment Report, Recall Plan Status Update, Root Cause Analysis Investigation report and Corrective Actions Plan
6	Anticipated timescale for follow-up FSN	31 Aug 2024
7	Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	Company Name	Andersen Caledonia
	Address	Caledonian House, Strathclyde Business Park, Bellshill, ML4 3NJ United Kingdom
	Website address	www.andersencaledonia.com
8	The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	Yes
9	List of attachments/appendices:	Appendix 1 - Field Safety Notice Customer Reply Form Appendix 2 - Field Safety Notice Distributor/Importer Reply Form
10	Name & Job Title	Jonathan Lintott Managing Director
	Signature	

Urgent Field Safety Notice (FSN) UPDATED****

SP EYE Ref SPY 712

FSN Ref: FSN2024-001 **FSCA Ref: FSCA2024-001**

	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.

Appendix 1 - Field Safety Notice Customer Reply Form

Urgent Field Safety Notice (FSN)** UPDATED**

SP EYE Ref SPY 712

FSN Ref: FSN2024-001 **FSCA Ref: FSCA2024-001**

ANDERSEN CALEDONIA	Field Safety Notice Customer Reply Form	3556 REV: A DCO#: 24327

1. Field Safety Notice (FSN) information	
FSN Reference number*	FSN2024-001
FSN Date*	16 July 2024
Product/ Device name*	SP.Eye Sharps Safe Intravitreal Injection Needle
Product Code(s)	SPY 712 (QRG30993SC198)
Batch/Serial Number (s)	Lot N011169 Expiration date 2026-10-28 (28th October 2026)

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Andersen Caledonia Ltd				
☐	I confirm receipt of the Field Safety Notice and that I have read and understood its content.	Comments (if none, enter N/A):		
☐	I have performed all actions requested by the FSN.	Comments (if none, enter N/A):		
☐	The information and required actions have been brought to the attention of all relevant users and executed.	Comments (if none, enter N/A):		
☐	I have returned affected devices - enter number of devices returned and date complete.	Qty:	Lot/Serial Number:	Date Returned (DD/MM/YYYY):
		Qty:	Lot/Serial Number:	Date Returned (DD/MM/YYYY):
		Comments:		

Urgent Field Safety Notice (FSN) UPDATED****

SP EYE Ref SPY 712

FSN Ref: FSN2024-001 **FSCA Ref: FSCA2024-001**

ANDERSEN CALEDONIA	Field Safety Notice Customer Reply Form	3556 REV: A DCO#: 24327

☐	I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Lot/Serial Number:	Date Destroyed (DD/MM/YYYY):
		Qty	Lot/Serial Number:	Date Destroyed (DD/MM/YYYY):
		Comments:		
☐	No affected devices are available for return/ destruction	Comments (if none, enter N/A):		
☐	Other Action (Define):	Comments (if none, enter N/A):		
☐	I do not have any affected devices.	Comments (if none, enter N/A):		
☐	I have a query please contact me (e.g. need for replacement product).	Comments (if none, enter N/A):		
Print Name*				
Signature*				
Date*				

4. Return acknowledgement to sender	
Email	regulatory@andersencaledonia.co.uk
Customer Helpline	+44 (0)1698 844476
Postal Address	Caledonian House, Strathclyde Business Park, Bellshill, ML4 3NJ, United Kingdom
Web Portal	www.andersencaledonia.com
Deadline for returning the customer reply form*	09 August 2024

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

Appendix 2 - Field Safety Notice Distributor/Importer Reply Form

Urgent Field Safety Notice (FSN) UPDATED****

SP EYE Ref SPY 712

FSN Ref: FSN2024-001 **FSCA Ref: FSCA2024-001**

ANDERSEN CALEDONIA	Field Safety Notice Distributor/Importer Reply Form	3557 REV: A DCO#: 24328

1. Field Safety Notice (FSN) information	
FSN Reference number*	FSN2024-001
FSN Date*	16 July 2024
Product/ Device name*	SP.Eye Sharps Safe Intravitreal Injection Needle
Product Code(s)	SPY 712 (QRG30993SC198)
Batch/Serial Number (s)	Lot N011169 Expiration date 2026-10-28 (28th October 2026)

2. Distributor/Importer Details	
Company Name*	
Account Number	
Address*	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Distributors/Importers (Tick all that apply)				
☐	*I confirm the receipt, the reading and understanding of the Field Safety Notice.	Comments (if none, enter N/A):		
☐	I have checked my stock and quarantined inventory	Qty:	Lot/Serial Number:	Date Quarantined (DD/MM/YYYY):
		Qty:	Lot/Serial Number:	Date Quarantined (DD/MM/YYYY):
		Comments:		
☐	I have identified customers that received or may have received this device	Comments (if none, enter N/A):		
☐	I have attached a customer list	Comments (if none, enter N/A):		
☐	I have informed the identified customers of this FSN	Date of communication:		
☐	I have received confirmation of reply from all identified customers	Comments (if none, enter N/A):		
☐	I have returned affected devices - enter number of devices returned	Qty:	Lot/Serial Number:	Date Returned (DD/MM/YYYY):

Urgent Field Safety Notice (FSN) UPDATED****

SP EYE Ref SPY 712

FSN Ref: FSN2024-001 **FSCA Ref: FSCA2024-001**

ANDERSEN CALEDONIA	Field Safety Notice Distributor/Importer Reply Form	3557 REV: A DCO#: 24328

	and date complete.			
		Qty:	Lot/Serial Number:	Date Returned (DD/MM/YYYY):
		Comments:		
☐	I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Lot/Serial Number:	Date Destroyed (DD/MM/YYYY):
		Qty:	Lot/Serial Number:	Date Destroyed (DD/MM/YYYY):
		Comments:		
☐	Neither I nor any of my customers have any affected devices in inventory	Comments (if none, enter N/A):		
Print Name*				
Signature*				
Date *				

4. Return acknowledgement to Sender	
Email	regulatory@andersencaledonia.co.uk
Distributor/Importer Helpline	+44 (0)1698 844476
Postal Address	Caledonian House, Strathclyde Business Park, Bellshill, ML4 3NJ, United Kingdom
Web Portal	www.andersencaledonia.com
Deadline for returning the Distributor/Importer reply form*	09 August 2024

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.