1stQ GmbH .

FSN Ref: FNS22AA FSCA Ref: FSCA22AA

Date: 2022.10.18

Field Safety Notice
IOL

For Attention of*:1stQ GmbH Distributors / Customers

Contact details of local representative (name, e-mail, telephone, address etc.)*
This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages.

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Field Safety Notice (FSN)
IOL
Possible loss of Sterile Barrier

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Intraocular lens supplied sterile.
1.	2. Commercial name(s)*
	Please refer to the attached Field Safety Response Form.
1.	3. Unique Device Identifier(s) (UDI-DI)
	Please refer to the attached Field Safety Response Form.
1.	4. Primary clinical purpose of device(s)*
	Posterior chamber intraocular lenses: posterior chamber intraocular lenses are intended for primary implantation into the capsular bag in the posterior chamber of the eye to replace the human crystalline lens in adult patients. AddOn intraocular lenses: supplementary (AddOn) intraocular lenses are posterior chamber intraocular lenses intended for implantation into the ciliary sulcus in the posterior chamber of pseudophakic patients with a primary intraocular lens implanted in the capsular bag.
1.	5. Device Model/Catalogue/part number(s)*
	Please see on the attached Field Safety Response Form.
1.	6. Software version
	Not relevant.
1.	7. Affected serial or lot number range
	Please refer to the attached Field Safety Response Form.
1.	8. Associated devices
	Not relevant.

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	1stQ has detected a nonconformity within the production of intraocular lenses concerning one of the blistering machines, which may have caused an unstable welding line.
2.	2. Hazard giving rise to the FSCA*
	The blister might lose its sterile barrier function, allowing contamination from the environment. The contamination might get transferred to the operating theatre and to the patient.
2.	3. Probability of problem arising
	According to probability calculations 2,6% of the suspicious products can have an improper welding line.
2.	4. Predicted risk to patient/users
	The chance of contamination through the inhomogeneous welding is highly unlikely, but to test this would take a very long time, therefore we chose to recall the products. The sterility of the IOL is not affected, because it is located in a leak-free container within the blister.
2.	5. Further information to help characterise the problem
	Include any further relevant statistics to help convey the seriousness of the issue.
2.	6. Background on Issue
	The unusual inhomogeneity of the welding line has been detected during the 100% final visual inspection. After checking the blistering machines one of them had a stuck sealing foil sheet to the upper tool. Not all products blistered with this machine show visible signs of inhomogeneous welding, but all are treated as possibly affected. The other blistering machines are not affected.
2.	7. Other information relevant to FSCA
	As of October 18, 2022, there have been no product complaints, and no incidents, associated with this issue.

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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?	Two weeks from receipt of this document.
3.	3. Particular considerations for: Implantable device Is follow-up of patients or review of patients' previous results recommended? Yes Review patient results, check if any incident has been recorded.	
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 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?	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.	

FSN Ref: FNS22AA FSCA Ref: FSCA22AA

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	Not relevant.
4.	3. For Updated FSN, key new information as follows:	
	N/A	
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:	
	N/A	
4.	6. Anticipated timescale for follow-up FSN	N/A
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	1stQ GmbH
	b. Address	Konrad-Zuse-Ring 23, 68163 Mannheim
	c. Website address	www.1stq.de
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	If extensive consider providing web-link instead.
4.	10. Name/Signature	Ahmad Khalil, Senior Manager, QM/RA

	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.

1stQ GmbH

Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	FSN22AA
FSN Date*	2022. October 18
Product/ Device name*	Intraocular lens supplied sterile
Product Code(s)	Please refer to the attachment
Batch/Serial Number (s)	Please refer to the attachment

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 Healthcare Organisation				
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A		
☐	I performed all actions requested by the FSN.	Customer to complete or enter N/A		
☐	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A		
☐	I have returned affected devices - enter number of devices returned and date complete. Please refer to the **attachment** at the end of this document.	Qty:	Serial Number:	Date Returned (DD/MM/YY):
		Comments:		
☐	No affected devices are available for return/ destruction	Customer to complete or enter N/A		
☐	Other Action (Define):	Customer to complete or enter N/A		
☐	I do not have any affected devices.	Customer to complete or enter N/A		

☐	I have a query please contact me (e.g. need for replacement of the product).	Customer to enter contact details if different from above and brief description of query
Print Name*		
Signature*		
Date*		

Deadline for returning the customer reply form*	2 weeks from receival of Field Safety Notice

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.

Attachment

Model	Serial number	UDI-DI	Implanted
			yes ☐ no ☐
			yes ☐ no ☐

Was there any incident regarding the implanted intraocular lens?

yes ☐ no ☐

In case the product has already been implanted and an incident has been recorded, please send the following data for each case as soon as possible:

Serial number	Description of the incident	Outcome of the incident
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.