

FIELD SAFETY NOTICE

Template ID 010-12-08

010-12-08-2201

Revision Index 01

Effective Date 2022-06-04

FSN Ref: 010-12-08-2201

FSCA Ref: N/A

Date: 04.07.2022

Date: 04.07.2022



Urgent Field Safety Notice

IOLMATIC injector system

For Attention of intraocular lens manufacturers who distribute the IOMATIC injector system together with compatible intraocular lenses

Contact details of local representative (name, e-mail, telephone, address etc.)*

**UK Responsible Person: Qserve Group UK, Ltd., globalreg@qservegroup.com,
+44 7408 830172, 49 Greek Street, Soho, London W1D 4EG**

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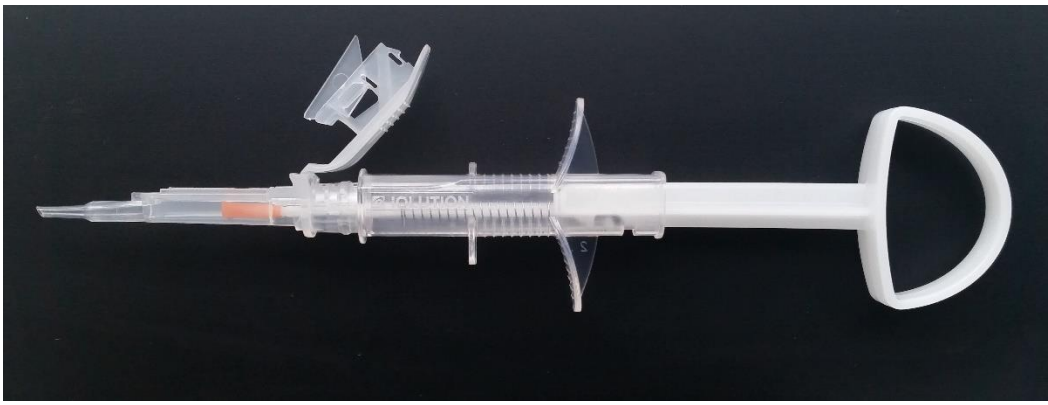
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Urgent Field Safety Notice (FSN)
IOLMATIC injector system
Injection behaviour at uncommonly low temperature

1. Information on Affected Devices*	
1	1. Device Type(s)*
.	Single use sterile injector system for implantation of compatible intraocular lenses
	
1	2. Commercial name(s)
.	IOLMATIC injector system
1	3. Unique Device Identifier(s) (UDI-DI)
.	4260676610057
1	4. Primary clinical purpose of device(s)*
.	Implantation of qualified foldable intraocular lenses into the eye following cataract removal
1	5. Device Model/Catalogue/part number(s)*
.	200-12-203-0020401
1	6. Affected serial or lot number range
.	See attachment 1 Lot number table
1	7. Associated devices
.	Softec HD Click (Intraocular lens manufactured by Lenstec Inc.)

2 Reason for Field Safety Corrective Action (FSCA)*	
2	1. Description of the product problem*
.	N/A (FSN is to reinforce instructions for use)
2	2. Hazard giving rise to the FSCA*
.	Using the device at uncommonly low room temperatures outside of the temperature range the intraocular lens manufacturer has evaluated to be safe during compatibility testing may lead to uncontrolled injection behaviour and/or damaged intraocular lenses and/or prolonged surgical procedures

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3. Type of Action to mitigate the risk*	
3. 1. Action To Be Taken by the User*	<p> <input type="checkbox"/> Identify Device <input type="checkbox"/> Quarantine Device <input type="checkbox"/> Return Device <input type="checkbox"/> Destroy Device <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Follow patient management recommendations <input checked="" type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU) <input type="checkbox"/> Other <input type="checkbox"/> None </p> <p>Instruction for Use of the IOLMATIC injector system has been amended in its current version: “The device shall be used in a controlled environment (hospital environment) at controlled room temperature. For details on safe temperature range, always follow the instructions of the lens manufacturer.”</p> <p>All intraocular lens manufacturers that distribute the IOLMATIC injector system together with compatible lenses are requested to check if they explicitly state a safe to use temperature range in their respective Instructions for Use and add this information if not already present. IOLUTION will contact any associated lens manufactures directly in this regard</p>
3. 2. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	No
3. 3. Action Being Taken by the Manufacturer	<p> <input type="checkbox"/> Product Removal <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Software upgrade <input checked="" type="checkbox"/> IFU or labelling change <input type="checkbox"/> Other <input type="checkbox"/> None </p> <p>See above</p>

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4. General Information*	
4.	1. FSN Type* New
4.	2. Further advice or information already expected in follow-up FSN? * No
4.	3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)
	a. Company Name IOLUTION GmbH
	b. Address Ruhrstrasse 13, 22761 Hamburg, Germany
	c. Website address www.iolution.com
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *
4.	5. List of attachments/appendices: Attachment 1 Lot number table
4.	6. Name/Signature

Transmission of the Field Safety Notice	
	<p>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)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>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..*</p>

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Attachment 1

Lot number table

Device Model	Lot Number
200-12-203-0020401	1.32448.1
200-12-203-0020401	1.32528.1
200-12-203-0020401	1.32528.1
200-12-203-0020401	1.32939.1
200-12-203-0020401	1.32528.1
200-12-203-0020401	1.32939.1
200-12-203-0020401	1.32939.1
200-12-203-0020401	1.33049.1
200-12-203-0020401	P200220309C



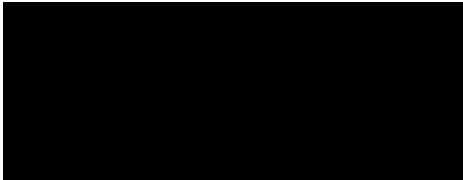
Airport Commercial Centre, Pilgrim Road, Christ Church, BARBADOS BB17092
Telephone: (246) 420-6795 • Fax: (246) 420-6797 • Email: lenstecbarbados@lenstec.com

Distributor / User Notice

1. Please refer to the field safety notice from the manufacturer of the Click Injector;
2. Please note the recommended operating temperature (18°C – 22°C);
3. Please distribute this notice to all facilities / users to whom you would have shipped the Click Injector;
4. Please send confirmation that the information has been received and sent to the facilities / users who received the Click Injector.

Prepared by:

Date: 31st August 22



Reviewed by:

Date: 31st August 22

