Field Safety Notice

DORC Directional Laser Probes
7220.xxx, 7223.xxx, 7225.xxx and 7227.xxx

FAN Identifier: 2023-0023

Att: <name distributor>
<address distributor>
<postal code, city>
<country>

Dear DORC distributor,

The purpose of this letter is to inform you about a potential safety risk concerning some of the products of D.O.R.C. Dutch Ophthalmic Research Center (International) B.V.

This letter concerns DORC Directional Laser Probes, which were manufactured between June and December 2023. The impacted product codes are 7220.xxx, 7223.xxx, 7225.xxx and 7227.xxx, where xxx can be ALC, DORC, or IRI.

According to our information you have received one or more boxes of directional laser probes that were produced in this period.

Please review this information with relevant members of your staff and decide how you will inform all customers and organizations who might have received this product from you. Also decide how to organize the return to your warehouse of the affected products.

You are allowed to make a local translation of the FSN attached, and adopt the last two bullets of section 3.1 and the FSN attachment on how to confirm receipt and return products attachment.

After you have informed your customers and collected the returned products, please confirm this by following the instructions provided on the attachment of the Field Safety Notice. A label for shipment of returned products will then be provided by our recall management service provider.

If you need any further information or support concerning this issue, please contact your local DORC representative, call our Customer Technical Service Center at +31 181 45 80 80, or send an email to TSC@dorcglobal.com.

D.O.R.C. Dutch Ophthalmic Research Center (International) B.V. apologizes for any inconvenience caused by this problem.

Kind regards,

Cornelis den Besten
Chief Compliance Officer
D.O.R.C. Dutch Ophthalmic Research Center (International) B.V
Thursday, 05 January 2023

Field Safety Notice (FSN)

DORC Directional Laser Probes

Inconsistent Laser Fiber Movement

1. Information on Affected Devices	
1.1. Device Type(s)	Ophthalmic laser system beam guide
1.2. Commercial name(s)	DORC Directional Laser Probe
1.3. Clinical Purpose	Intended to be used in conjunction with an ophthalmic laser system during ophthalmic surgery to invasively direct and deliver laser energy to treat non-refractive conditions (e.g., to repair a retinal tear)
1.4. Product Code(s)	7220.ALC, 7220.DORC, 7220.IRI 7223.ALC, 7223.DORC, 7223.IRI 7225.ALC, 7225.DORC, 7225.IRI 7227.ALC, 7227.DORC, 7227.IRI
1.5. Affected lot number range	Affected lots range starts with a number between 2470 and 18705. E.g. LOT 4330-*-*-1

2. Reason for Field Safety Corrective Action (FSCA)	
2.1. Description of the product problem	User may experience difficulties to extend or retract the laser fiber, and in some occasions may also have difficulties to direct the laser fiber tip precisely.
2.2. Hazard giving rise to the FSCA	Worst-case a potential risk to patient safety could be macular edema when a misdirected laser fiber tip is unnoticed at the time of laser firing
2.3. Probability of problem arising	To date 33 complaints have been received on approximately 26.000 products sold. No reports of patient harm have been received.
2.4. Background on Issue	Complaint investigation concluded that a mold repair at a supplier caused stress in the invisible part of the slider that moves the laser fiber. As a result cracks may develop in the area that holds the laser fiber, which could lead to inconsistent laser fiber movements.

3. TYPE OF ACTION TO MITIGATE THE RISK	
3.1. Actions to take by the User	• Pass this FSN on to all those who need to be aware within your organisation and/or to any organisation where the potentially affected devices have been transferred to. • Verify whether you have any unopened boxes, or individual pouches of the affected DORC directional laser probes in your inventory. • Remove any remaining boxes and individual Products from your inventory and return the impacted Product to DORC following the instructions in the attachment. • Complete, even if you do not return the Product, the on-line reply form per instructions in the attachment. • Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Authority, if appropriate.
3.2. Action Being Taken by the Manufacturer	• We conduct this voluntary FSCA to inform customers and to remove the potentially affected product from the market. • We have identified the root cause and are in the process of implementing corrective actions to prevent reoccurrence.

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	See: www.dorcglobal.com
4.4. Contact in case of questions	• Contact your local DORC representative, or • Call the DORC Customer Technical Service Center at +31 181 45 80 80, or • Send an email to TSC@dorcglobal.com
4.5. Authority Notification	The responsible competent authority of your country has been informed about this communication to customers.

Attachment: Instructions for completion of Reply Form and Product return

Instructions for completion of Reply Form and Product return

Completion of Reply Form:

Please complete the Online Acknowledgement Form on behalf of yourself and your customer(s) within **three (3) business days** upon receipt of this notification**. This online acknowledgement form MUST be completed on all occasions.**

	STEP 1 Scan the QR Code or visit the link below to access the online response form https://iqvia-response.my.site.com/mt/fca?cid=DDLP24
	STEP 2 Enter your Unique Identifier: Your Unique Identifier - **XXXXX**
	STEP 3 Acknowledge the receipt of this notice & complete the form online *Call IQVIA MedTech for any questions/concerns with response form* Ph: +44 1706 619937 E: Recall-DORC@iqvia.com

D.O.R.C. has partnered with IQVIA MedTech to assist in this action. For any assistance regarding online response processing please contact IQVIA MedTech using the information above.

Product Return:

- Should you need to return product that you or your customers have then please complete the online response form and ensure you select the box regarding returns. This can be found in the Customer Acknowledgement section.
- You will then be contacted to arrange the return.
- Where your customer(s) wish to return product, please collate all product before arranging the return.