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; these cracks 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 rootcause 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.