

«Hospital_Name»
«Users_Name»
«Department»
«Customer_Address»
«Zip_Code» «City»
«Country_name»

<Reference: 92504179-FA>

30 March 2020

Urgent Field Safety Notice - Product Advisory GreenLight MoXy™ Laser Fiber

Dear «Users_Name»,

Boston Scientific (BSC) is initiating a Product Advisory for the GreenLight MoXy™ Laser Fibers to reinforce existing instructions within the Directions for Use (DFU) and provide further guidance which will be added to the DFU that may reduce the likelihood of metal cap and fiber tip break temperature related complaints. Internal bench testing has determined that an increased irrigation flow may increase the liquid cooling effect and may reduce temperature related complaints.

The most common reasonably foreseeable consequence of the identified thermal related issues as identified in the complaints is a clinically minor procedural delay due to the need to exchange the fiber for another. The most serious injury that could potentially occur as result of any of the thermal issues identified is a severe burn. A severe burn could happen if the side firing laser converts to an end firing laser due to damage to the laser tip and the laser beam is directed at tissue that is not intended to be vaporized, however, the probability is remote.

Note that some products in scope of this Product Advisory have AMS branding on the box and product label.

Our records indicate that your facility received some of the concerned product. **The table below provides a complete list of all affected products**, including Product Description, Material Number (UPN) and GTIN number. Please note that **only the devices listed below are affected. No other Boston Scientific product is involved in this Field Safety Notice.**

Product Description	Material Number (UPN)	GTIN
MoXy™ Laser Fiber	0010-2400	00878953005515

NO product is being recalled and you are NOT required to return product to Boston Scientific.

NOTE: this Advisory has no bearing upon previously completed procedures using MoXy Laser Fibers (i.e. patient follow-up should simply follow the normal course).

Existing MoXy™ laser fiber Direction for Use to be Reinforced

- 1- Ensure the distance from the fiber to the tissue is approximately 2mm (1 to 3 mm). Reference: Table 2. Troubleshooting and Procedural Considerations in product DFU.
- 2- Do not bury the tip of the fiber into the tissue. Reduced irrigation flow may result in damage to the fiber. Reference: Caution in page 3 of product DFU.
- 3- Failure to position the saline solution at least 106cm or not opening the flow valve will decrease the amount of fluid across the fiber end. Decreased fluid flow may limit the lasing time of the fiber. Reference: Caution in page 3 of product DFU.

Updated Direction for Use

Section 8.3 of the MoXy™ Laser Fiber DFU has been updated to recommend an increased irrigation flow to increase the liquid cooling effect. The additions to the current DFU are highlighted in blue:

8.3 Performing the Procedure

1. Ensure user, patient, and personnel in the room are wearing appropriate protective eyewear before using the laser.

WARNING: Do not press the footswitch without having the appropriate protective eyewear. Pressing the footswitch may activate the laser beam. Activation of the laser beam when not wearing protective eyewear may result in eye injury to the user, personnel in the room, or the patient.

2. Connect the tubing from the sterile saline for irrigation solution to the fiber luer lock connector. Position the saline solution at least 106 cm higher than the level of the endoscope/cystoscope.

Increased irrigation flow by means of a saline pressure bag (set to 250 mmHg – 300 mmHg) will further increase liquid cooling effect and may reduce fiber tip damage.

INSTRUCTIONS:

- 1- Please read this notice and the instructions attached to this letter.
- 2- **Please complete the attached Acknowledgement Form** even if you do not have any affected product.
- 3- **When completed, please return the Acknowledgement Form to your Boston Scientific office** for the attention of «Customer_Service_Fax_Number» on or before **31 May 2020**.
- 4- Please pass on this notice to any healthcare professional from your organization that need to be aware and to any organization where the potentially affected devices have been transferred (If appropriate). Please provide Boston Scientific with details of any affected devices that have been transferred to other organizations (if appropriate).

Although Boston Scientific is not physically recalling any product, your Competent Authority is being notified of this Field Safety Notice.

We regret any inconvenience that this action may cause, and we appreciate your understanding as we act to ensure patient safety and customer satisfaction.

If you have any questions or would like assistance with this Field Safety Notice, please contact your local Sales Representative.

Yours sincerely,

xxx
Boston Scientific International S.A.

Attachment: Acknowledgement Form



Please complete the form & Send it to:
«Customer_Service_Fax_Number»

«Sold_to» - «Hospital_Name» - «City» - «Country_name»

Acknowledgement Form – Product Advisory

GreenLight MoXy™ Laser Fiber

92504179-FA

By signing this form, I confirm that

I have read and understood
the Boston Scientific Field Safety Notice

dated 30 March 2020

for GreenLight MoXy™ Laser Fiber.

NAME* _____ **Title** _____

Telephone _____ **Email** _____

Customer' SIGNATURE* _____ **DATE*** _____
* Required field dd/mm/yyyy