

URGENT: FIELD SAFETY NOTICE

Commercial Name of Affected Product: LenSx[®] Laser with Corneal Flap Capability
Reference(s): 8065998162
FSCA Identifier: 2016.010
Type of Action: Medical Device Correction

April XX, 2016

«Account_Name»
«Account_Address»
«City», «State» «Zip_Code»
«Contact_Name»

Attention <<Enter Customer Information>>:

This letter is to advise you of a Voluntary Medical Device Correction being initiated by Alcon for the LenSx[®] Laser with Corneal Flap Capability. This voluntary medical device correction only applies to LenSx[®] Laser systems used for creation of corneal flaps in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea.

Alcon has identified the following product within your facility:

Product	Catalog Number
LenSx [®] Laser with Corneal Flap Capability	8065998162

Description of the potential condition:

Alcon is conducting a voluntary medical device correction of all LenSx[®] Laser with Corneal Flap Capability after receiving reports concerning incomplete corneal flap creation, which manifests as un-dissected area(s) within the side cut. If an un-dissected area in the side cut is observed, it may cause difficulty lifting the flap, potentially resulting in corneal tear, irregular stromal bed, or a corneal epithelial defect. This issue has been confirmed to manifest in only a small number of systems through the normal installation setup and optimization process; however, we are informing all corneal flap capability users of this potential issue and will be upgrading the software on all LenSx[®] Laser systems that are being used to create corneal flaps to minimize the frequency of potential incomplete areas within the side cut. An Alcon Service Engineer will

contact you once the upgrade is available. Be assured, we are working to resolve this issue as soon as possible.

Action to be taken by the user:

Incomplete flap cuts are known to occur during LASIK procedures and proper handling of them is part of LASIK training. Please exercise your professional medical judgment when determining your comfort level with management of the potential side cut issues that may occur as a result of your continued use of the LenSx[®] Laser for creation of corneal flaps.

As stated in the LenSx[®] Laser System Operators Manual, in the case of an incomplete laser treatment during flap creation procedure, whether a side cut has been created or not, it is advisable not to lift the corneal flap. The surgeon is advised to consider other medical options best suited to complete the refractive treatment.

Please sign and return the attached Acknowledgement Form for confirmation that you have read this Voluntary Medical Device Correction, understand the potential condition and actions to be taken.

Transmission of this Voluntary Medical Device Correction:

Please immediately forward this information to professionals within your organization who may be using the LenSx[®] Laser for creation of corneal flaps to be used for LASIK procedures. Additionally, please ensure that a copy of this notification is provided to any other organizations to which the affected LenSx[®] Laser has been transferred.

Contact reference person:

We appreciate your cooperation and sincerely regret any inconvenience that this may cause you. We hope this action reassures you of our commitment to provide you with the highest quality vision care products and continued quality excellence for you and your patients.

Should you have any questions or concerns about this matter, please contact Alcon at <<insert contact information>>

Alcon Representative,
Alcon affiliate name and address

**Alcon LenSx[®] Laser with Corneal Flap Capability
ACKNOWLEDGEMENT Form
MA# 2016.010**

Please follow these important steps:

- 1) Return the completed Acknowledgement Form via fax or email to Alcon.

<<Affiliate to add fax and/or email contact>>

Your signature below attests that you have read and understood Alcon's medical device correction.

Signature of Facility Representative:

Printed Name and Title:

Date:

<<Account Name>>

<<Account_Address>>

<<City>>, <<State>> <<Zip_code>>

<<Contact Name>>