

URGENT: FIELD SAFETY NOTICE

Commercial Name of Affected Product: LX3 Microscope Floor Stand
Reference(s): 8065752560
FSCA Identifier: 2017.041-ITC
Type of Action: Voluntary Medical Device Correction

May XX, 2017

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

Attention <<Enter Customer Information>>:

Dear Valued Alcon Customer,

This letter is to advise you of a Field Safety Corrective Action being initiated by Alcon for the LX3 Microscope Floor Stand used with the LuxOR™ Ophthalmic Microscope and LuxOR™ Ophthalmic Microscope with Q-VUE™ 3D Assistant Visualization for low magnification visualization during ophthalmic surgical procedures for cataract, retina and cornea. Alcon has identified the following impacted floor stand(s) within your facility.

Affected Product(s):

| Product | Catalog Number | Serial Number |
|----------------------------|----------------|------------------------|
| LX3 Microscope Floor Stand | 8065752560 | <<insert information>> |

Description of the potential condition:

Alcon has observed that multiple shipments or forceful impact to a caster on a LuxOR/LX3 microscope may stress the microscope base, which could contribute to a caster breaking or detaching from the base.

During in-facility transfer, should a caster break or detach from the base while the microscope arm is not in the most inward locked position (as shown in Figure 1), the unit may tip if the microscope arm is extended (as shown in Figure 2) over the location of the broken caster. This may lead to the potential for physical injury from the microscope tipping or falling. Two incidents of physical injury have been reported in conjunction with this issue.

As a precaution, we are voluntarily inspecting and retrofitting LuxOR / LX3 units with new bases and / or an updated caster configuration.

Action to be taken by the user:

Our records indicate you have a LuxOR / LX3 unit within your facility. Alcon will contact you to schedule an appointment for one of our Field Service Engineers to inspect and replace your unit's base and / or provide an update of the caster configuration, at your convenience.

While awaiting this intervention, please respect following instructions for transporting the Ophthalmic Microscope

During in-facility transfer, please ensure the articulating microscope arm is placed in a stowed and locked position over the microscope base (as shown in Figure 1) and protect the casters from forceful impact. This will distribute the LuxOR / LX3 unit weight evenly amongst all of the casters to reduce the potential for the units to tip or fall in the event that a caster breaks. If you need to transport your unit to an off-site location such as a different building or have immediate concerns about your unit, please contact your Alcon technical representative for professional support.



Figure 1
Articulating microscope arm
in stowed and locked position



Figure 2
Articulating microscope
arm in extended position

Please sign and return the attached Acknowledgement Form to confirm that you understand the potential condition and actions to be taken.

To assist us in this voluntary medical device correction, please take the following steps:

1. During in-facility transfer, please ensure the articulating microscope arm is placed in a stowed and locked position over the microscope base (as shown in Figure 1 above) and protect casters from forceful impact during transfer..
2. Forward this information immediately to all departments within your organization who may be using the LX3 Microscope Floor Stand unit.
3. Provide a copy of this notification to any other organization / location to which the LuxOR / LX3 has been transported.
4. Return the attached Response Form via fax or email to Alcon.

Transmission of this Voluntary Medical Device Correction:

Please immediately forward this information to all departments within your organization who may be using the LX3 Microscope Floor Stand unit. If you have transported your LuxOR / LX3 unit to another location, please provide a copy of this notification to the recipient(s) so they may contact Alcon to schedule their retrofitting appointment.

Contact reference person:

We appreciate your cooperation and sincerely regret any inconvenience that this may cause you.

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 LX3 Microscope Floor Stand
ACKNOWLEDGEMENT Form
MA# 2017.041- ITC**

Please follow these important steps:

- 1) During in-facility transfer, please ensure the articulating microscope arm is placed in a stowed and locked position over the microscope base as shown in Figure 1 above and protect casters from forceful impact.
- 2) Please forward this information immediately to all departments within your organization who may be using the LX3 Microscope Floor Stand unit.
- 3) Additionally, please ensure that a copy of this notification is provided to any other organization / location to which the LuxOR / LX3 has been transported.
- 4) 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 this Alcon medical device correction.

Signature of Facility Representative:

Printed Name and Title:

Date:

<<Enter Customer Information>>
<<Enter Customer Information>>
<<Enter Customer Information>>
<<Customer number>>