

June 01, 2017

Sundhedsstyrelsen
Axel Heides Gade 1
2300 Kbh S
Denmark

Re: ***Alcon Lux OR™ LX3 Microscope Floor Stand***
Model: LX3

Dear Sir/Madam:

Alcon is providing the Sundhedsstyrelsen with the attached communication/report regarding the voluntary medical device correction of its Alcon LX3 Microscope Floor Stand. This floor stand is used in conjunction with the LuxOR™ LX3 Ophthalmic Microscope and LuxOR™ LX3 Ophthalmic Microscope with Q-VUE™ 3-D Assistant Visualization used for low magnification visualization during ophthalmic surgical procedures for cataract, retina and cornea.

Alcon is conducting a voluntary medical device correction for the LX3 Microscope Floor Stands. Through our monitoring process, 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 cause 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, the unit may tip if the microscope arm is extended 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 retrofitting LuxOR / LX3 units with new bases for those demonstration units in which multiple shipments have occurred. Demonstration units include units used for training, trade shows, and on location demonstration. There have been no incidents of caster breakage occurring for single shipment units. Although there have been no incidents of caster breakage occurring for single shipment units, these units will be inspected and retrofitted with a new base and / or an updated caster configuration.

The purpose of this communication is to inform the Sundhedsstyrelsen that Alcon has initiated a voluntary medical device correction for the LuxOR /LX3 Microscope Floor Stand in Denmark.

If you have any questions regarding this matter, please contact Rubia Gilbert, using the following email address: ga.nordic@alcon.com

Sincerely,

Rúbia Cristina Gilbert Poulsen
Nordic Quality Manager