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Urgent Field Safety Notice

Marus Ref: 28 July-11

Marus brand LuxStar dental lights

28 July 2011

Dear Customer:

Details on affected devices:

This Field Safety Notice is applicable to the Marus brand LuxStar dental lights (model OL1000) with the following serial numbers: 4714B, 165569B, 12657B & 150179B

Description of the problem:

Marus would like to inform you of a field corrective action regarding the Marus brand LuxStar dental lights to improve the overall safety of the device. The lens heat (bulb) shield (birdcage) on the Marus LuxStar dental lights, model OL1000, may potentially fall off the dental light if not properly installed after replacing the light bulb or if not properly maintained. This improper installation or maintenance could result in potential injury to either the patient or the clinician.

Advice on action to be taken by the user:

Our self-install kit, part number 30792, has been developed to contain the required instructions and tools to allow easy installation by the staff within your office.

Contact reference person:

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Marus sincerely apologizes for the inconvenience this situation causes you and your patients.

Thank you for your patience and support.

Sincerely Yours,

Bonnie Dundas
Quality Assurance & Regulatory Affairs Manager,
Marus