



S
A
F
E
T
Y

NOTICE

Marus Brand LuxStar Dental Lights

IMB Safety Notice: SN2011(26)

Circulation Date: 16 November 2011

MANUFACTURER/SUPPLIER

Marus, USA

TARGET GROUPS

Dental Practitioners
Distributors

ISSUE

Marus has become aware that 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.

BACKGROUND

Marus has issued a field safety notice (see attached) and has developed a self install kit, which will mitigate the risks associated with this issue.

ACTION OR RECOMMENDATIONS

Marus has been unsuccessful in their attempts to locate all devices affected by this field safety corrective action (FSCA), as one of the distributors in Ireland, Dacus Dental, has ceased trading. The serial numbers of the devices provided to Dacus Dental are 4714B and 165569B.

The IMB advises that users:

- Identify the affected devices in your facility.
- Ensure the appropriate personnel are made aware of this notice.
- If you (or your facility) have affected devices, follow the recommendations outlined in the attached Field Safety Notice and contact Marus to obtain the self-installation kit.

ENQUIRIES

Enquiries to the Manufacturer / European authorised representative should be addressed to:

S A F E T Y

NOTICE

Ms. Bonnie Dundas
Quality Assurance and Regulatory Affairs Manager
Marus
705 S. Springbrook Rd., Building C
Newberg, OR 97132
U.S.A.

Telephone: +1 503 537 3602
Fax: +1 503 537 3617
E-mail: bonnie.dundas@marus.com

Ms. Lorna Sanderson
Medical Device & QA Services Ltd.
76, Stockport Road
Timperley, Cheshire
WA15 7SN
United Kingdom

Telephone: +44 161 870 6751
Fax: +44 161 903 9787
E-mail: lorna@mdqa.co.uk

All adverse incidents relating to a medical device should be reported to the:

Irish Medicines Board
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: vigilance@imb.ie
Website: www.imb.ie