IRISH MEDICINES BOARD

Notice Information: - Advisory
15 July 2011

Part 1. Product Information

a)	Title:	HARMONY LA, LC 500 and LA 700 SURGICAL LIGHTING and MEDIA SYSTEM
b)	Product Name/Type:	HARMONY LA, LC 500 and LA 700 SURGICAL LIGHTING and MEDIA SYSTEM
c)	Reference:	IMB Safety Notice: SN2011(17)
d)	Manufacturer/Supplier:	Manufacturer: STERIS Corporation Ltd. Distributed in Ireland by: ALLPHAR SERVICES 4045 Kingswood Road Citywest Business Campus Co. Dublin Contact Person: Laura Jacob Phone: + 353 1 468 8472

Part 2. Target Audience

a)	Target Audience:	Hospital Managers / CEOs Risk Managers Clinical Directors Clinical Engineers Surgeons Obstetricians and Gynaecologists Endoscopy units Theatre and Nursing Staff Purchasing Managers Nursing Managers Hospital personnel Medical device distributors

Part 3. Problem/Issue

a)	Problem/Issue:	Premature bulb failures due to loosening of wires and overheating of the lamp housing assemblies within the Harmony LA, LC 500 and LA 700 Surgical Lighting and Media Systems.

Part 4. Background Information

a) Background Information:

STERIS Corporation has learned that some customers may experience premature bulb failures due to loosening of wires and overheating of the lamp housing assemblies within the Harmony LA, LC 500 and LA 700 Surgical Lighting and Media Systems.

The affected devices are those bearing serial numbers 428102135 to 0430207104 produced from August 2002 to October 2007. The Irish Medicines Board (IMB) is aware that several affected devices have been placed on the Irish market and some of the users have not been identified by the distributor. The IMB is issuing this safety notice to ensure all users are aware of the potential problem.

STERIS Corporation issued a field safety notice (see attached) in February 2010 recommending that customers ensure that they are adhering to the Harmony LA, LC 500 and LA 700 Surgical Lighting and Media System Operator Manuals by:

- Not touching the glass portion of the lamp with bare fingers as this can cause deterioration of material, leading to possible failure of the bulbs;

- Using only STERIS replacement bulbs in the lighting system; use of other than those provided by STERIS may damage equipment;

- Placing the lighting system into STANDBY or OFF mode when not in use.

Part 5. Action to be taken

a) Action to be taken:

The IMB advise that you:

• Check if you have these devices in your institution.

• If you have any of these identified devices in your institution, contact ALLPHAR SERVICES to arrange an upgrade of the lamp housing assembly.

• Ensure that you adhere to the manufacturer's Operator Manual for use and maintenance of the product.

Part 6. Enquiries

a)	All enquiries should be made to:	Enquiries to the Irish distributor should be addressed to: ALLPHAR SERVICES 4045 Kingswood Road Citywest Business Campus Co. Dublin Contact Person: Laura Jacob Phone: + 353 1 468 8472 Enquiries to the manufacturer should be addressed to: STERIS Corporation Ltd. Chancery House, 190 Waterside Road, Hamilton Industrial Park, Leicester, LE5 1QZ, UK Contact person: Louisa Ballard Telephone: +44 (0) 116 276 8636 Fax: +44 (0) 116 276 8639 E-mail: Louisa_Ballard@steris.com All adverse incidents relating to a medical device should be reported to the: Irish Medicines Board Kevin O'Malley House Earlsfort Centre Earlsfort Ter

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

Please click here to download a pdf version of the safety notice

Please click here to download a pdf version of the Field Safety Notice