IRISH MEDICINES BOARD

Notice Information: - Advisory
18 February 2010

Part 1. Product Information

a)	Title:	Wallach LL100 Cryosurgical System CO2 and Accessories
b)	Product Name/Type:	Wallach LL100 Cryosurgical System CO2 and Accessories
c)	Reference:	SN2010(01)
d)	Manufacturer/Supplier:	Wallach Surgical Devices / Cooper Surgical Inc.

Part 2. Target Audience

a) Target Audience:

General Practitioners

Practice Nurses

Hospital risk managers

Clinical Nurse Specialists

Hospital consultants including:

Dermatologists

Plastic surgeons

Public health consultants

Genito-Urinary medicine

General surgical consultants

Gynaecologists

Infectious disease specialists

Part 3. Problem/Issue

a)	Problem/Issue:	A manufacturing problem has been detected where under certain circumstances a restriction of the flow of carbon dioxide gas within the handle may result in a less than optimum temperature delivery to the treatment site.

Part 4. Background Information

a)	Background Information:	During September 2009, Wallach Cryosurgical issued a field safety notice (FSN) to advise customers of the recall of Wallach Surgical CO2 based Cryosurgical Instruments due to a manufacturing problem which was identified during internal testing. The manufacturer confirmed that Nitrous Oxide (N2O) Cryosurgery Devices are not affected and should continue to be used. The Irish Medicines Board (IMB) is aware that these cryosurgical units have been placed on the market in Ireland and while it is believed that Irish customers use nitrous oxide in the operation of the cryosurgical system, which is unaffected by this issue, the IMB is issuing this safety notice to ensure all Wallach Surgical cryosurgical system users are aware of the issue as described in the attached FSN.

Part 5. Action to be taken

a)	Action to be taken:	1) Ensure the appropriate personnel are made aware of this notice. 2) Identify the location of all Wallach LL100 Cryosurgical System CO2 and Accessories. 3) Follow the instructions outlined in the attached FSN from Wallach Surgical regarding this action.

Part 6. Enquiries

a)	All enquiries should be made to:	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 Enquiries to the manufacturer should be addressed to: Manufacturer - Wallach Surgical Devices 235 Edison Road Orange, CT 06477 USA Telephone: +1-203-799-2000 Fax: +1-203-799-2002 E-mail: CO2@wallachsurgical.com Website: www.wallachsurgical.com/CO2 Or Authorized European representa

Or

Authorized European representative:

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Telephone: +49-30-319-009-53

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E-mail: CO2@wallachsurgical.com

Contact person: Mr. Norman Popp-Lange

Download: Field Safety Notice