

**Notice Information: Medical Devices - Advisory  
19 November 2002**

**Part 1. Product Information**

- a) Title: Explosions and Fire in Aluminium Oxygen Regulators
- b) Product Name/Type: Explosions and Fire in Aluminium Oxygen Regulators
- c) Reference: SN2002(05)
- d) Manufacturer/Supplier: Various

**Part 2. Target Audience**

- a) Target Audience: *Hospitals:* Chief Executive Officers; Medical Directors; Ambulance Departments; Pharmacists Medical; Nursing; Technical and Portering Staff in all Wards and Departments *Health Boards:* General Medical Practitioners; Community Nursing Services; Practice Nurses; Nursing Homes; Hospices; Private Hospitals

**Part 3. Problem/Issue**

- a) Problem/Issue: Over the past nine years, FDA and several EU Member States have received reports of aluminium regulators used with oxygen cylinders burning or exploding. Several of these incidents caused burns in patients and healthcare workers. The FDA and the National Institute for Occupational Safety and Health in the US indicated in a Safety Notice that they published in February 1999 that they believed that the aluminium in these regulators was a major factor in both the ignition and the severity of the fires. They also included that there were also other likely contributing factors. Indications from European investigations indicate that high levels of contamination were present within the areas where the regulators had been used, connected and serviced and that the device had been in service for over twelve months. To date we have had no such reported incidents.

**Part 4. Background Information**

a) Background Information:

Most oxygen regulators are made of brass or aluminium. Aluminium and its alloys are more likely to ignite than brass. In standard tests, aluminium can burn vigorously at pressures as low as 25 pounds per square inch (psi), while brass does not burn at pressures below 10,000 psi.

## Part 5. Action to be taken

a) Action to be taken:

Oxygen Regulators incorporating aluminium components within the high-pressure gas path should only be used if the cleanliness of the items can be maintained to an acceptable standard. All persons involved in the use and handling of medical gas cylinders should receive training from their employer or the cylinder supplier to ensure: Cleanliness when storing, transporting or connecting medical gas cylinders to regulators or other medical devices That users open medical gas cylinders slowly That if resistance to opening of the cylinder is excessive the cylinder should not be used and should be returned to the manufacturer / supplier with a label to indicate the problem That users read, understand and follow all instructions and labelling provided by the manufacturer / supplier. Further precautions are described in the addendum. For future purchases consider the purchase of regulators with brass components.

## Part 6. Enquiries

a) All enquiries should be made to:

All adverse incidents relating to a medical device should be reported to the: Medical Devices Department Irish Medicines Board Earlsfort Centre Earlsfort Terrace Dublin 2 If you have any enquiries, you may contact the Medical Devices Department at: Telephone: +353-1-6764971 Fax: +353-1-6767836 Email: vigilance@imb.ie Website: www.imb.ie SN2002(05): Explosions and Fire in Aluminium Oxygen Regulators SN2002(05): Explosions and Fire in Aluminium Oxygen Regulators - Appendix 1

## Part 7. Keywords

a) Keywords:

Explosions and Fire in Aluminium Oxygen Regulators