

MEDICAL DEVICE
SAFETY NOTICE

**Explosions and Fire in Aluminium
Oxygen Regulators**
IMB Safety Notice: SN2002(05)

MANUFACTURER/SUPPLIER

Various

TARGET GROUPS

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 Hospital

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,

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connected and serviced and that the device had been in service for over twelve months. **To date we have had no such reported incidents.**

BACKGROUND

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.

ACTION OR RECOMMENDATIONS

- 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.

ENQUIRIES

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: (01) 6764971
Fax: (01) 6767836
Email: medicaldevices@imb.ie
Website: www.imb.ie

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