

Firesafe™ Cannula Valve

Making oxygen therapy safer for everyone

Rapidly developing structural fires are an unfortunate and all too common problem associated with oxygen therapy.

Firesafe™ devices reduce this risk by isolating the oxygen flow and extinguishing a fire tracking back along the oxygen delivery tubing.

Firesafe™ Cannula Valves are intended for in-line installation in oxygen delivery tubing. They can also be fitted at the interface with the oxygen supply equipment, providing the following potential benefits:

- Reduce the rate at which the fire spreads and the potential impact on other residents, patients or healthcare workers
- Prevent the fire reaching the oxygen supply source
- Minimise the size of the fire and the cost of restoration
- Buy valuable time to evacuate people from the scene

Compliance & Safety

EN ISO 80601-2-69:2014 concerning oxygen concentrators requires ‘...means to stop the flow of gas towards the patient in the case that the applied part becomes ignited.’ It also requires ‘...means to prevent the propagation of fire back through the outlet connector.’ Firesafe™ devices satisfy these requirements perfectly.

The UK Department of Health requires ‘firebreaks’ to be supplied as part of NHS home oxygen contracts and in Germany, BfArM’s recommendations mirror those given in the amendment to EN ISO 80601-2-69.

Technical Description

The Firesafe™ Cannula Valve is essentially a thermal fuse, comprising a spring loaded valve held open by a T-bar. The T-bar is situated downstream of the valve and supported by a fusible ledge of material.

The valve is actuated when the fusible ledge softens as a result of heat from an approaching fire in the oxygen delivery tubing. Upon actuation the valve probe moves forward and an o-ring seals the valve, thereby isolating the oxygen supply from the fire.



It is recommended that two Firesafe™ devices are fitted to each oxygen tubing set. The first, normally a Firesafe™ Nozzle, should be positioned at the interface with the oxygen supply source. A Firesafe™ Cannula Valve should then be fitted close to the point of oxygen delivery, normally adjacent to the patient’s sternum.

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⁽¹⁾ Maximum static pressure delivered by the gas supply source.

⁽²⁾ The Firesafe™ Cannula Valve can be safely used at lower flow rates but may not meet the internal leak rate of 10 ml/min when activated in the event of a fire.

SPECIFICATION

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| Gas Compatibility | Oxygen and oxygen enriched air |
| Maximum Operating Pressure ⁽¹⁾ | 450 kPa |
| Flow Rate ⁽²⁾ | 0.7 - 20 l/min ≤ 1 kPa at 2 l/min |
| Resistance to Flow | ≤ 2 kPa at 5 l/min ≤ 16 kPa at 15 l/min |
| Intended Life | 4 years after date of manufacture (engraved on device) |
| Application | Single patient use |
| Packaging | 100 units per box (5 bags per box, 20 units per bag) |
| Connections | EN 13544-2, 6 mm nominal tubing connection nominal |
| Environmental Transport and Storage Limits | Temperature: -20 °C (-4 °F) to 60 °C (140 °F) Humidity: 0 to 100 % RH |
| Environmental Limits for Operation | Temperature: 0 °C (32 °F) to 50 °C (122 °F) Humidity: 0 to 100 % RH |
| Regulatory | EC: MDD Class IIa Medical Device USA: FDA Class 1 Medical Device; 510(k) exempt Canada: Health Canada licence ref. 78173 Japan: PMDA Class 1 Medical Device Australia: Class IIa, ARTG Identifier 177167 GMDN Code and Term: 60391 – Fire safety valve |

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