

Bidirectional Firesafe™ Cannula Valve (Mk.II)

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 8359:2009/AMD1 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. ISO 80601-2-69 has similar requirements.

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 8359 and ISO 80601-2-69.

Technical Description

The Firesafe™ Cannula Valve is essentially a thermal fuse, comprising a spring loaded valve held open by a fusible support.

The valve is actuated when the fusible support is heated by 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.



The Mk.II Firesafe™ Cannula Valve has a valve at both ends, so can be fitted either way in the tubing (bidirectional), preventing the risk of incorrect installation. It is the smallest Firesafe™ Cannula Valve to date, with exceptionally low resistance to flow, and has an intended life of up to five years.

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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

Gas Compatibility	Oxygen and oxygen enriched air
Maximum Operating Pressure ⁽¹⁾	600 kPa
Flow Rate ⁽²⁾	0.25 - 25 l/min
Resistance to Flow	≤ 0.009 kPa at 0.5 L/min
	≤ 0.022 kPa at 1 L/min
	≤ 0.068 kPa at 2 L/min
	≤ 0.29 kPa at 5 l/min
	≤ 0.99 kPa at 10 l/min
	≤ 4.7 kPa at 25 l/min
Intended Life	5 years (expiry date engraved on device)
Application	Single patient, multiple 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: -25 °C (-13 °F) to 70 °C (158 °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
	GMDN Code and Term: 60391 – Fire safety valve

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