

Intended Use

The OxySafe2™ Cannula Valve is a thermal fuse designed to extinguish an oxygen delivery tube fire and stop the flow of oxygen if the tube is accidentally ignited.

The OxySafe2™ Cannula Valve supplied with this instruction is bidirectional in operation and can be installed either way around in the oxygen delivery tubing. The bidirectional OxySafe2™ Cannula Valve is distinguishable from previous models because the label is fully laser engraved, previously models were printed. The flow direction engraved on the side indicates it can be oriented either way around in the supply tubing.

It is recommended that at least two OxySafe2™ devices be installed to each oxygen delivery circuit. The first should be positioned close to the patient and the second close to the source of supply, above ground level, as shown in figure 1. The OxySafe2™ Cannula Valve provides no protection if a fire burns through the oxygen delivery tubing upstream of the device.

WARNING

1. Read through this instruction before installing an OxySafe2™ Cannula Valve. As with all medical equipment, attempting to use or install this device without a thorough understanding of its operation and limitations may result in patient or user injury.
2. This device is intended for use with oxygen supply equipment with a delivery pressure not exceeding 87 psi with the outlet occluded. It must not be used for other applications.
3. Do not store or install this device near an open flame or near a source of excessive heat that is likely to exceed that stated in the Device Specification.
4. Keep this device free from oil, grease, dirt and other contaminants. Never lubricate the hose barb connectors.
5. Never administer oxygen or undertake oxygen therapy while smoking and / or within five feet of an open flame.
6. Additional risk control measures (e.g. SpO2 monitoring with an alarm) are essential for patients who might suffer injury or death in the event that their oxygen flow is stopped unexpectedly.
7. The device is intended for single patient use and should not be moved between installations due to the risk of cross contamination.
8. This device is designed for use in the delivery of oxygen or oxygen enriched air. Do not use the device with any other gas.

Cleaning

Clean the exterior surfaces of the device using an alcohol or disinfectant wipe. Do not immerse the device in any fluid or allow fluid to enter through the hose barb connections. The OxySafe2™ Cannula Valve can be used with bubble humidifiers and will not be affected by water condensing in the tubing.

Maintenance & Disposal

The OxySafe2™ Cannula Valve is maintenance free and has an intended life of 4 years. Dispose of any OxySafe2™ Cannula Valve 5 years after the manufacturing date stated on the device label. Once actuated, the OxySafe2™ Cannula Valve cannot be reset and must be replaced.

Device Specification

Flow Rate	0.25 to 25 l/min	*Maximum static pressure delivered by the gas supply source.
Maximum Operating Pressure*	87 psi	
Maximum internal leakage following activation	10 ml/min	
Maximum external leakage following activation	5 ml/min	
Operating Temperature	0 to 50 °C (32 to 122 °F)	
Transit & Storage Temperature range	-25 to 70 °C (-13 to 158 °F)	
Humidity Range	0 to 100% RH	
Gas type	Oxygen/oxygen enriched air	

Installation Instructions

WARNING When actuated, the OxySafe2™ Cannula Valve will stop the gas flow. The pressure upstream of the device will rise until it reaches the maximum output pressure of the supply system. In order to ensure that the connection between the OxySafe2™ Cannula Valve and the supply system can withstand this pressure, it is recommended that a test be carried out with each style of trumpet connector or cannula tubing used. This may be achieved by occluding the tubing downstream of the OxySafe2™ Cannula Valve with the oxygen flow turned on.

Note: Due to the differences in the flexibility of the materials used for tubing and trumpet connectors and variations of inner bore diameter, it is not possible to fully engage the third barb as shown in figure 2 unless large bore tubing is used.

Note: The resistance to gas flow of the OxySafe2™ Cannula Valve is negligible.



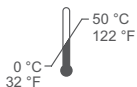
No Open Flames within 10' of Device or Container, 5' from Patient



No Smoking



Single Patient, Multiple Use



Operating Temperature Range

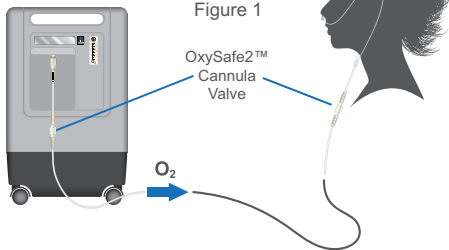
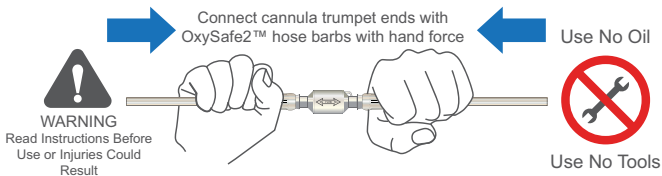
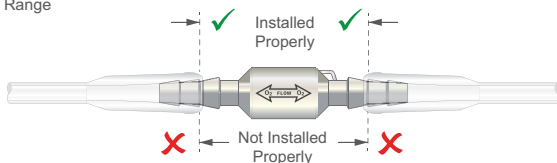


Figure 2
Recommended Installation



Caution: Federal law restricts this device to sale by or on the order of a physician.