

Passy-Muir® Valve Oxygen Adapter (PMA® 2000)

Instructions For Use



Passy-Muir® Valve Oxygen Adapter (PMA® 2000)

for use with PMV® 2000 (clear) and PMV® 2001 (Purple Color™)
Low Profile Tracheostomy & Ventilator
Swallowing and Speaking Valves

For technical questions regarding utilization of the PMA 2000 Adapter or to receive our free research literature packet, "Physiological Benefits" CD-ROM and clinical inservice DVD, please contact our respiratory and speech clinical specialists.

Touching Lives and Advancing Patient Care Through Education

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One (1) PMA[®] 2000 Adapter and PMA 2000 Adapter Instructions. Contents of this package are nonsterile and not made with natural rubber latex. Product Code Number: PMA 2000.

Read all Warnings, Precautions and Instructions Carefully Prior to Use.

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

CAUTION: For use with the PMV[®] 2000 (clear) and PMV[®] 2001 (Purple Color™) Low Profile Tracheostomy & Ventilator Swallowing and Speaking Valves only.

WARNING: SINGLE PATIENT USE ONLY. THIS DEVICE IS NOT DESIGNED, SOLD, OR INTENDED FOR USES EXCEPT AS INDICATED.

WARNING: PATIENTS USING THE PMA 2000 ADAPTER MUST BE OBSERVED AND/OR MONITORED PER PHYSICIAN DIRECTION.

WARNING: NOT INTENDED FOR USE IN-LINE DURING MECHANICAL VENTILATION.

DESCRIPTION:

The PMA 2000 Adapter is small, lightweight, clear in color and readily snaps onto the PMV 2000 (clear) and PMV 2001 (Purple Color™) Low Profile Tracheostomy & Ventilator Swallowing and Speaking Valves. The PMA 2000 Adapter is easily removed when not in use. The PMA 2000 Adapter allows for improved mobility and comfort of those patients requiring a tracheostomy tube, speaking valve, and low flow supplemental oxygen and humidity.

BENEFITS:

- Delivery of oxygen up to 6L/min.
- Oxygen is delivered *in front* of the diaphragm of the Passy-Muir[®] Valve. This avoids complications that may be associated with providing continuous flow *behind* the diaphragm of a speaking valve, which may include air trapping, drying of secretions and possible cilia damage.
- Allows for improved mobility of patients requiring low flow, supplemental oxygen and humidity.
- Small, lightweight design.
- Simple snap-on attachment that is easily removed when not in use.

INDICATIONS:

- Designed for use with the companion Passy-Muir PMV 2000 (clear) and PMV 2001 (Purple Color™) Low Profile Tracheostomy & Ventilator Swallowing and Speaking Valves. It is not indicated for any other use or with any other speaking valve.

- Tracheostomized patients utilizing the PMV[®] 2000 (clear) and PMV[®] 2001 (Purple Color™) Low Profile Tracheostomy & Ventilator Swallowing and Speaking Valves and requiring portable, low flow, supplemental oxygen ($\leq 6L/min$).
- Mechanically ventilated patients during periods of time they are **off** the ventilator and requiring portable, low flow, supplemental oxygen ($\leq 6L/min$).

CONTRAINDICATIONS:

- Patients requiring oxygen flows > 6L/min.
- Patients requiring high humidity levels are not candidates for use of the PMA[®] 2000 Adapter, as use of this device limits the amount of humidity that can be delivered through the O₂ port. A decreased amount of humidity in the airway may affect the viscosity of secretions.
- Oxygen conservation devices that require flow triggering cannot be used with the PMA 2000 Adapter, as it may not allow the patient to properly trigger the gas source, thereby decreasing the amount of oxygen delivered to the patient.
- Do not use in-line during mechanical ventilation.
- Do not use with devices other than the PMV 2000 (clear) and PMV 2001 (Purple Color™) Low Profile Tracheostomy & Ventilator Swallowing and Speaking Valves.

PLACEMENT:

The following instructions are for the PMA 2000 Adapter *only*. Refer to clinical instructions for the PMV 2000 (clear) and PMV 2001 (Purple Color™) valves, in the *Passy-Muir[®] Valve Instruction Booklet*.

- Prior to placing the Passy-Muir Valve on the tracheostomy tube, place the oxygen tubing firmly onto the side port connector (Fig. 1A) that protrudes from the side of the PMA 2000 Adapter to ensure a secure attachment.

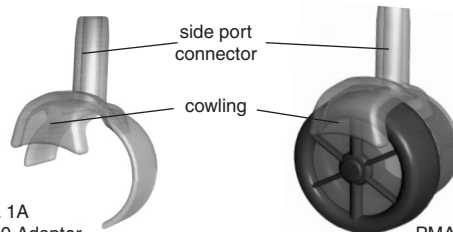


Fig. 1A
PMA[®] 2000 Adapter

Fig. 1B
PMA[®] 2000 Adapter
with PMV[®] 2001

- Snap the PMA[®] 2000 Adapter gently into place on the side of either the PMV[®] 2000 (clear) or PMV[®] 2001 (Purple Color™) Low Profile Tracheostomy & Ventilator Swallowing and Speaking Valve. The curvatures of the two parts should fit tightly to one another, with no gaps or interference from the small Secure-It[®] ring that is molded into the side of the Passy-Muir[®] Valve. When properly attached, the cowling (see Fig.1B) of the PMA 2000 Adapter should overhang the front edge of the Passy-Muir Valve in order to deliver oxygen directly in front of the diaphragm of the valve.
- After the PMA 2000 Adapter (with oxygen tubing attached) has been snapped onto the Passy-Muir Valve, the PMV can then be placed on the hub of the tracheostomy tube in the conventional manner (see *Passy-Muir Valve Instruction Booklet*).



WARNING: AS COMPARED TO DELIVERY OF OXYGEN VIA A TRACH COLLAR, THE PMA 2000 ADAPTER IS AN OPEN OXYGEN DELIVERY SYSTEM. THEREFORE, DELIVERY OF F_IO₂ VIA THE PMA 2000 ADAPTER MAY BE DIFFERENT THAN WITH THE USE OF A TRACH COLLAR. THE CLINICIAN SHOULD USE METHODS SUCH AS PULSE OXIMETRY TO ENSURE PROPER TITRATION OF O₂ WHILE USING THE PMA 2000 ADAPTER.

REMOVAL:

- Remove the PMV from the hub of the tracheostomy tube (as per *Passy-Muir Valve Instruction Booklet*).
- Remove the PMA 2000 Adapter from the Passy-Muir Valve with a gentle pulling motion.
- Remove the oxygen tubing from the PMA 2000 Adapter.

CARE AND CLEANING:

- The PMA 2000 Adapter should be cleaned daily to prevent debris from accumulating within the oxygen port and chamber. Before cleaning, remove the adapter from the Passy-Muir Valve and remove the oxygen tubing from the PMA 2000 Adapter. Wash the PMA 2000 Adapter and Passy-Muir Valve as separate units (see separate cleaning instructions for the Passy-Muir Valve, provided in the *Passy-Muir Valve Instruction Booklet*).
- Swish the PMA 2000 Adapter in soapy, warm water.
- Rinse the PMA 2000 Adapter thoroughly with warm water.
- Allow the PMA 2000 Adapter to air dry thoroughly before placing it in the storage container that is packaged with the Passy-Muir Valve.
- Do not apply heat to dry PMA 2000 Adapter. Do not use hot water, peroxide, bleach, vinegar, or alcohol to clean PMA 2000 Adapter. Do not autoclave.