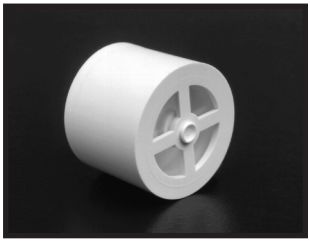
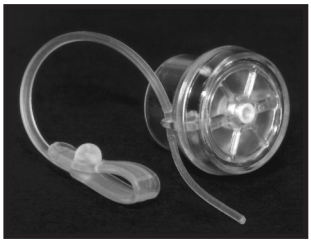
PASSY-MUIR® TRACHEOSTOMY & VENTILATOR SWALLOWING AND SPEAKING VALVES INSTRUCTION BOOKLET

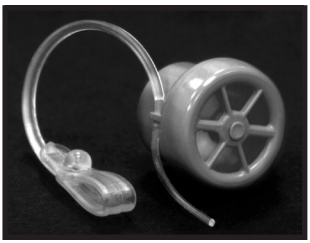


Passy-Muir® Tracheostomy & Ventilator Swallowing and Speaking Valve
PMV® 005 (white)
15mm I.D./23mm O.D.

Passy-Muir® Tracheostomy & Ventilator Swallowing and Speaking Valve
PMV® 007 (Aqua Color™)
15mm I.D./22mm O.D.
Dual Taper



Passy-Muir® Low Profile Tracheostomy & Ventilator Swallowing and Speaking Valve
PMV® 2000 (clear)
15mm I.D./23mm O.D.



Passy-Muir® Low Profile Tracheostomy & Ventilator Swallowing and Speaking Valve
PMV® 2001 (Purple Color™)
15mm I.D./23mm O.D.

For technical questions regarding utilization of the Passy-Muir Valves, please contact our respiratory and speech clinical specialists.

Touching Lives and Advancing Patient Care Through Education

CONTENTS OF PMV® PATIENT CARE KIT:

This package contains one of the following Passy-Muir® Tracheostomy & Ventilator Swallowing and Speaking Valves (PMVs): PMV 005 (white), PMV 007 (Aqua Color™), PMV 2000 (clear), or PMV 2001 (Purple Color™) and Instruction Booklet, Patient Handbook, PMV Storage Container, Patient Parameters Chart Label, and Warning Labels for use on the trach tube pilot line, chart and at bedside. A PMV Secure-It® is also included in the PMV 2000 (clear) and PMV 2001 (Purple Color) Patient Care Kit. The PMV 005 (white), PMV 007 (Aqua Color), PMV 2000 (clear) and PMV 2001 (Purple Color) **are <u>not</u> made with natural rubber latex**. Contents of PMV Patient Care Kit are non-sterile.

READ ALL WARNINGS, PRECAUTIONS AND INSTRUCTIONS CAREFULLY PRIOR TO USE:

INSTRUCTIONS FOR USE

The following instructions are applicable to the PMV 005 (white), PMV 007 (Aqua Color), PMV 2000 (clear) and PMV 2001 (Purple Color) unless otherwise indicated. See additional instructions on ventilator application of the PMVs on page 10. Please refer to the PMV 2020 Instruction Booklet for use of the PMV 2020.

INSTRUCTIONS FOR USE OF THE PASSY-MUIR TRACHEOSTOMY & VENTILATOR SWALLOWING AND SPEAKING VALVES SHOULD BE POSTED AND PROVIDED TO PATIENT AND ALL PERSONNEL INSTRUCTED IN TRACHEOSTOMY CARE.

⚠ **CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician. Store in cool, dry place.**

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

⚠ **WARNING: PATIENTS USING THE PMV MUST BE OBSERVED AND/OR MONITORED PER PHYSICIAN DIRECTION.**

⚠ **WARNING: TRACHEOSTOMY TUBE CUFF MUST BE *COMPLETELY DEFLATED* BEFORE PLACING THE PMV. PATIENT WILL BE UNABLE TO BREATHE IF CUFF IS NOT *COMPLETELY DEFLATED.* DO NOT USE WITH FOAM FILLED CUFFED TRACHEOSTOMY TUBE. OBSERVE PATIENT WITH PMV IN PLACE TO ASSURE PATIENT HAS ADEQUATE AIRWAY.**

⚠ **WARNING: DO NOT USE WITH SEVERE AIRWAY OBSTRUCTIONS SUCH AS TRACHEAL AND/OR LARYNGEAL STENOSIS. CAUTION SHOULD BE USED WITH END STAGE PULMONARY DISEASE. DO NOT USE WITH PATIENTS WHO HAVE UNMANAGEABLE PULMONARY SECRETIONS. THIS IS NOT A DEVICE FOR LARYNGECTOMIZED PATIENTS. DO NOT USE WITH ENDOTRACHEAL TUBES. DO NOT USE WHILE SLEEPING.**

⚠ **WARNING: USE CAUTION WHEN USING A PMV WITH A HEAT MOISTURE EXCHANGER (HME) DEVICE OR HYGROSCOPIC CONDENSER HUMIDIFIER (HCH). THESE DEVICES OBTAIN HUMIDITY FROM THE EXHALED BREATH OF A PATIENT. WITH THE PMV IN PLACE, AIR IS NOT EXHALED VIA THE TRACHEOSTOMY TUBE AND THIS MAY AFFECT THE PERFORMANCE OF THE HME OR HCH. ADDITIONAL HUMIDIFICATION MAY BE NEEDED.**

⚠ **CAUTION:** When using a PMV 005 (white) with a tracheostomy tube that has a disposable inner cannula with grasp ring, the inner cannula may need to be removed prior to PMV placement if the grasp ring extends beyond the 15mm hub of the tracheostomy tube. Failure to remove the inner cannula prior to use may obstruct opening movement of the PMV 005 (white) diaphragm.

⚠ **CAUTION:** Remove PMV prior to delivery of medicated nebulizer treatments. If the PMV is inadvertently used during a medicated nebulizer treatment it should be removed immediately and rinsed thoroughly to remove medication residue as some medications may adversely affect the PMV diaphragm.

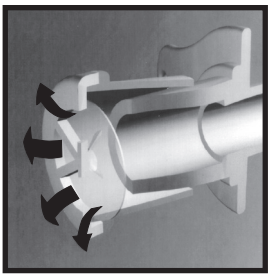
DESCRIPTION

The Passy-Muir® Tracheostomy & Ventilator Swallowing and Speaking Valves (PMVs) are designed to eliminate the necessity of finger occlusion for the patient with a tracheostomy tube while allowing the patient full-power, uninterrupted speech.

The PMVs are light weight one-way closed position "no leak" valves that attach to the universal 15mm hub of adult, pediatric and neonatal tracheostomy tubes including the following: fenestrated, non-fenestrated, cuffless, metal, and air-filled cuffed with cuff completely deflated. Unlike open position one-way speaking valves, the closed position "no leak" PMVs maintain a bias closed position except during inspiration. When the patient inhales, the PMV® opens allowing air to enter the tracheostomy tube and the lungs. At the end of inspiration the PMV closes automatically and remains closed throughout exhalation, without leakage. During exhalation, air is redirected around the tracheostomy tube and up through the larynx and pharynx enabling speech as the air passes through the vocal cords and through the oral and nasal cavities.

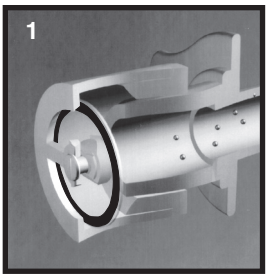
The patented closed position "no leak" design creates a column of air within the tracheostomy tube that inhibits secretions from entering the tube and occluding the PMV. The bias closed position of the PMV restores the patient to a more normal closed respiratory system. This results in the restoration of positive subglottic pressure that facilitates a better swallow, may reduce aspiration and facilitates a stronger, more effective cough that allows the patient to expectorate secretions orally.

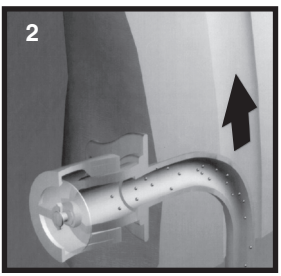
The PMVs are intended for use by both short-term and long-term adult, pediatric and neonatal tracheostomized and/or ventilator dependent patients.



All Other Speaking Valves

Open Position Speaking Valves have Air Leak During Exhalation and Do Not Provide a Closed Respiratory System.





PMV® Closed Position "No Leak" Design

(1) PMVs Close Completely at End of Inhalation with No Air Leak, thereby Providing a Closed Respiratory System and More Normal Breathing Pattern. (2) Closed Position "No Leak" Design Maintains a Column of Air in Tracheostomy Tube Redirecting Airflow and Secretions Up the Trachea (Airway) and Out of the Mouth and/or Nose.

BENEFITS

The PMVs were developed to allow tracheostomized and ventilator dependent patients to speak more normally. However, research has validated additional significant benefits with use of the PMV:

- Closed Position "No Leak" Design Restores a Closed Respiratory System
- Improves Speech Production
- Improves Swallowing and May Reduce Aspiration
- Facilitates Secretion Management
- Facilitates Weaning
- Expedites Decannulation
- Improves Olfaction
- Promotes Better Hygiene
- Ventilator Application

- **Closed Position "No Leak" Design:** Restores a more normal closed respiratory system which allows the patient to create positive airway pressure without the need for manual occlusion of the tracheostomy tube.

- **Speech:** Tracheostomized and ventilator dependent patients can produce clearer speech with more normal phrasing, better vocal quality and increased volume. This allows for normal development of speech and language in children.
- **Swallowing:** Use of the PMV® can improve the safety and efficiency of swallowing and may reduce aspiration. A closed position valve restores the patient to a more normal closed system which facilitates increased pharyngeal/laryngeal sensation and restores positive subglottic air pressure.

⚠ **WARNING: ALTHOUGH PMV USE CAN IMPROVE SWALLOWING AND MAY REDUCE ASPIRATION IN SOME PATIENTS, THE PRESENCE AND/OR RISK OF ASPIRATION SHOULD BE EVALUATED CAREFULLY WITH EACH PATIENT TO DETERMINE APPROPRIATE USAGE OF THE PMV IN ADDRESSING SWALLOWING FUNCTION.**

- **Secretion Management:** The closed position "no leak" design of the PMV facilitates secretion management as it re-establishes a "closed system" that enables the patient to produce a stronger, more effective cough and improves swallowing due to restored positive subglottic pressure. It also facilitates evaporation of secretions due to redirection of air through the upper airway during exhalation. As a result, suctioning needs may be reduced.
- **Weaning:** The PMV can be used as an augmentative tool for weaning patients from mechanical ventilation. The closed position "no leak" design re-establishes a more normal closed respiratory system which restores physiologic PEEP, which can improve oxygenation. As the patient becomes accustomed to exhaling through the upper airway, patient confidence is improved and respiratory muscle retraining is facilitated.
- **Decannulation:** The PMV can be used as an alternative to tracheal tube plugging for patients who cannot tolerate plugging due to physiologic or emotional reasons. If a patient is tolerating plugging for only short periods of time, the PMV can be used in the interim (between plugging trials) as a step to assist the patient's transition from an open tracheostomy tube to tracheal plugging. The PMV assists in the tracheostomy decannulation process by allowing the patient to begin to adjust to a more normal breathing pattern through the upper airway on exhalation. This allows the patient to gain confidence and the physician to assess for airway patency.
- **Olfaction:** The PMV can improve the sense of smell by re-establishing airflow through the oral/nasal cavities during exhalation. This improved sense of smell may lead to an increase in sense of taste, appetite and caloric intake.
- **Hygiene:** The PMV facilitates improved tracheal hygiene. This is due to the elimination of the need for manual/finger occlusion of the tracheostomy tube which can lead to infections. The PMV also acts as a filter to prevent particulates from entering the trachea. Secretions are redirected through the upper airway allowing oral expectoration and reducing contamination of the environment.
- **Ventilator Use:** The PMV 005 (white), PMV 007 (Aqua Color™), PMV 2000 (clear) and PMV 2001 (Purple Color™) can be used interchangeably on or off the ventilator with adult, pediatric and neonatal patients.

INDICATIONS FOR USE

Awake and alert tracheostomized (ventilator or non-ventilator dependent) adult, pediatric and neonatal patients should be considered candidates for PMV use if they meet the assessment guidelines. During exhalation, air passage must be sufficient around the tracheostomy tube and through the upper airway. The PMV is intended only for single patient use.

INDICATIONS FOR USE CAN INCLUDE BUT ARE NOT LIMITED TO THE FOLLOWING:

- Ventilator Dependency
- Neuromuscular Disease
- Quadriplegia
- Head Trauma
- Chronic Obstructive Pulmonary Disease
- Tracheomalacia
- Mild Tracheal and/or Laryngeal Stenosis
- Bilateral Vocal Cord Paralysis without significant airway obstruction
- Non-Obstructive Laryngeal Tumors (can include patients who have vocal cord function following surgical resection of the tumor)
- Sleep Apnea patients who are tracheostomized as an alternative to plugging when awake
- Patients who emotionally or physically are unable to tolerate tracheal plugging

CONTRAINDICATIONS

- Unconscious and/or Comatose Patients
- Inflated Tracheostomy Tube Cuff
- Foam Filled Cuffed Tracheostomy Tube
- Severe Airway Obstruction Which May Prevent Sufficient Exhalation
- Thick and Copious Secretions
- Severely Reduced Lung Elasticity That May Cause Air Trapping
- This Device Is Not intended For Use With Endotracheal Tubes

INSTRUCTIONS FOR TRACHEOSTOMIZED PATIENTS

PRE-PLACEMENT ASSESSMENT GUIDELINES FOR PASSY-MUIR® TRACHEOSTOMY & VENTILATOR SWALLOWING AND SPEAKING VALVES

These guidelines should be used in conjunction with physician direction:

FOR TRACHEOSTOMIZED NON-VENTILATOR DEPENDENT PATIENTS, THE PMV® MAY BE PLACED 48 TO 72 HOURS AFTER THE TRACHEOTOMY IS PERFORMED IF THE PATIENT'S TRACHEAL EDEMA AND/OR SECRETIONS FROM THE SURGICAL PROCEDURE HAVE DECREASED.

FOR VENTILATOR DEPENDENT PATIENTS SEE VENTILATOR APPLICATION INSTRUCTIONS.

IF THE TRACHEOSTOMY TUBE HAS BEEN CHANGED, PMV PLACEMENT MAY NEED TO BE DELAYED 48-72 HOURS AS THIS PROCEDURE MAY HAVE INDUCED TRACHEAL SWELLING AND/OR BRONCHOSPASM.

IT IS RECOMMENDED THAT UNIVERSAL PRECAUTIONS BE FOLLOWED.

1. **Cognitive Status:** Patient must be awake, responsive and attempting to communicate. The PMV should not be used while the patient is sleeping.

2. **Medical/Pulmonary Status:** Patient must have the appropriate lung mechanics necessary to exhale around the tracheostomy tube and out of the nasal and oral cavities. Patient assessment should include but is not limited to:

    - vital signs
    - oxygen saturation
    - patient reaction
    - work of breathing
    - airway patency
    - breath sounds
    - proper positioning of patient and tracheostomy tube
    - patient psychological and motivational issues

3. **Ability to Tolerate Cuff Deflation:** Cuff deflation is mandatory with the PMV® to allow exhaled air to pass around the tracheostomy tube and through the oronasopharynx. If it is determined that the patient cannot tolerate cuff deflation initially (i.e., due to risk of gross aspiration or need for intensive critical control of mechanical ventilation), the patient should be reassessed for cuff deflation as changes in his/her medical condition occur.

4. **Secretion Management:** Use of the PMV can facilitate movement and oral expectoration of secretions by the patient. Overabundance, viscosity and/or on-going infection affect secretion manageability. Ability to manage increased and/or different viscosities of secretions will vary with each patient. PMV use may need to be limited or deferred temporarily until secretions become manageable.

⚠ **WARNING: PATIENTS WITH THICK UNMANAGEABLE SECRETIONS THAT MAY CAUSE AIRWAY OBSTRUCTION SHOULD BE CAREFULLY EVALUATED FOR USE OF THE PMV.**

5. **Swallowing:** The patient's risk for aspiration should be evaluated as this can influence the amount, thickness and manageability of secretions. Presence of gross aspiration can play an important role in determining a patient's appropriateness for cuff deflation and PMV use. The safety and efficiency of the swallowing process can be negatively affected by the presence of a tracheostomy tube. While some tracheostomized individuals exhibit no swallowing difficulties, many will experience dysphagia and aspiration even though their primary diagnosis would not typically indicate swallowing problems. Use of the PMV can improve the safety and efficiency of swallowing and may reduce aspiration. The closed position "no leak" design of the PMV restores the patient to a more normal closed system which improves swallowing as it facilitates increased pharyngeal/laryngeal sensation and restores positive subglottic air pressure.

⚠ **WARNING: ALTHOUGH PMV USE CAN IMPROVE SWALLOWING AND MAY REDUCE ASPIRATION IN SOME PATIENTS, THE PRESENCE AND/OR RISK OF ASPIRATION SHOULD BE EVALUATED CAREFULLY WITH EACH PATIENT TO DETERMINE APPROPRIATE USE OF THE PMV IN ADDRESSING SWALLOWING FUNCTION.**

6. **Airway Patency:** The patient must be able to exhale efficiently around the tracheostomy tube, up through the larynx and pharynx and out the nasal and oral cavities in order to wear the PMV.

   a. Check diagnosis to ensure that there are no known airway obstructions (e.g., tumors, stenosis, granulation tissue).

   b. Tracheostomy tube size plays an important role in the patient's ability to exhale efficiently. The tracheostomy tube should be sized to allow for sufficient airflow around the tracheostomy tube to facilitate speech and use of the PMV. The cuff on a tracheostomy tube can also create an obstruction even when deflated and should be taken into consideration during airway patency assessment. The patient with a cuffed tracheostomy tube should be evaluated for a cuffless tracheostomy tube if medically appropriate to eliminate the need for cuff deflation with use of the PMV.

   c. Bedside assessment of airway patency.

      1. Deflate tracheostomy tube cuff completely, if present. **2.** Instruct the patient to inhale through the tracheostomy tube. **3.** Manually occlude the tracheostomy tube with a gloved finger as you instruct the patient to exhale through the mouth and nose to ensure adequate exhalation. This may be observed by having the patient blow on a tissue, mirror, feather, etc. Encourage the patient to vocalize (e.g., say "Ah", count, etc.) to determine presence and quality of voicing. Although some patients may be able to exhale adequately, they may not be able to vocalize initially and may require voice assessment and/or retraining. **4.** Some patients may require repeated attempts of steps

1-3 to become accustomed to exhaling through the upper airway. Upon determination that the patient is able to exhale and/or voice adequately, you may consider PMV® placement if other assessment criteria are met.

7. **Lung Compliance:** Critically ill and chronic pulmonary patients have lungs with altered compliance. Therefore, PMV usage may be limited to short periods of time during the day with close monitoring. Severe lung disease causes a loss of lung elasticity and poor natural recoil. Exhalation is thus prolonged. Careful assessment for PMV use is needed to avoid potential complications associated with air trapping that can occur with non-elastic lungs. An appropriately sized tracheostomy tube is especially crucial for these patients when considering PMV use as it can facilitate exhaled air flow.

8. **Level of Care:** Utilization of the PMV can occur across the continuum of healthcare settings. Evaluation for PMV placement can occur as early as 48-72 hours post tracheotomy. PMV placement can occur with physician order as soon as the patient has stabilized and is attempting to communicate, depending upon the degree of tracheal edema and secretions present. Infants as young as a week old can utilize the PMV if the assessment criteria have been met.

PASSY-MUIR® TRACHEOSTOMY & VENTILATOR SWALLOWING AND SPEAKING VALVE PLACEMENT

Non-Ventilator Dependent Application

After pre-assessment criteria have been met, PMV placement should occur in conjunction with a physician order using, but not limited to, the following guidelines:

1. **Education:** To reduce anxiety and ensure successful transition to the PMV, the patient, family and all personnel (all shifts) working with the patient should be instructed in the directions for use of the PMV including contraindications, cautions and warnings. Review all package inserts and labeling with patient, family and staff. Free patient information and clinical inservice videos are available from Passy-Muir Inc. at ***www.passymuir.com***.

2. **Patient Assessment:** The patient should be assessed before, during and after PMV placement for, but not limited to, the following:

   - Vital signs (e.g., heart rate, respiratory rate, oxygen saturation)
   - Breath sounds
   - Change in patient's color and responsiveness
   - Work of breathing
   - Tracheal and oral secretion status

3. **Suctioning:** It is recommended that both tracheal and oral suctioning be performed as needed. This includes before and after deflating the tracheostomy tube cuff (if present).

4. **Cuff Deflation:** Slowly deflate the cuff of the tracheostomy tube (if present). The patient may need to be suctioned again following cuff deflation to remove secretions that were present on and/or above the cuff. The patient with a cuffed tracheostomy tube should be evaluated for a cuffless tracheostomy tube if medically appropriate to eliminate the need for cuff deflation with use of the PMV.

⚠ **WARNING: TRACHEOSTOMY TUBE CUFF MUST BE *COMPLETELY DEFLATED* BEFORE PLACING THE PMV. PATIENT WILL BE UNABLE TO BREATHE IF CUFF IS NOT *COMPLETELY DEFLATED.* PMV CANNOT BE USED WITH FOAM FILLED CUFFED TRACHEOSTOMY TUBES. THE PMV CAN BE USED WITH A CUFFED TRACHEOSTOMY TUBE IF THE CUFF IS *COMPLETELY DEFLATED* AND THE PATIENT HAS SUFFICIENT AIRFLOW AROUND THE TRACHEOSTOMY TUBE AND BULK OF THE DEFLATED CUFF.**

5. **Tracheostomy Tube Size:** Per physician direction, changing to a smaller tracheostomy tube or cuffless tube may be needed to provide sufficient exhaled airflow to allow use of the PMV.®

6. **Use of Warning Labels:** Attach warning labels provided with PMV to the pilot line of the patient's cuffed tracheostomy tube and post at the patient's bedside and in the patient's chart to facilitate staff awareness of proper PMV use.

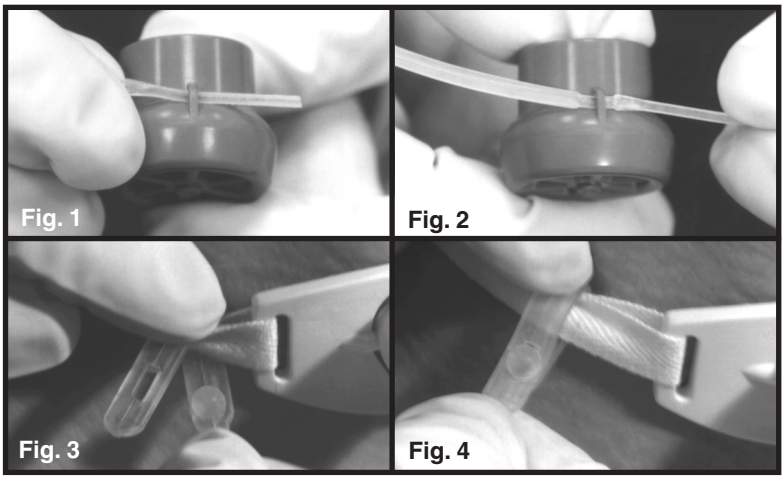
7. **PMV Secure-It® Attachment:** (Applies to PMV 2000 (clear) and PMV 2001 (Purple Color™) only). If using the PMV 2000 (clear) or PMV 2001 (Purple Color) and not using them in-line with the ventilator, attach the PMV Secure-It to the PMV prior to placing the PMV on the tracheostomy tube. Use of the PMV Secure-It which attaches to the tracheostomy tie will help to prevent the loss of the PMV if it should inadvertently come off the tracheostomy tube (e.g., during cough). Use of the PMV Secure-It is optional.

   a. The PMV Secure-It can be attached by threading the long tapered end of the PMV Secure-It through the small hole provided in the side of the PMV 2000 (clear) and PMV 2001 (Purple Color) (Fig.1) and pulling it through until it rests between the two notches (Fig. 2).

   b. Place the other end of the PMV Secure-It around the patient's tracheostomy tie near the neckplate of the tracheostomy tube (Fig. 3) and fasten it like a button in a button hole (Fig. 4).

⚠ **WARNING: DO NOT ATTACH THE PMV SECURE-IT WHEN USING THE PMV 2000 (CLEAR) OR PMV 2001 (PURPLE COLOR) IN-LINE WITH THE VENTILATOR AS THIS MAY INTERFERE WITH DISCONNECT ALARM.**

   c. After removing the PMV from the tracheostomy tube hub as in number 9, the PMV Secure-It (with PMV 2000 (clear) or PMV 2001 (Purple Color) only) can be removed by unbuttoning the fastener that is attached to the tracheostomy tie prior to removal of the PMV Secure-It from the PMV. PMV Secure-It can then be removed from the PMV by gently pulling it out of the small hole in the side of the PMV.



Placement of the PMV® Secure-It®

8. **PMV Attachment:** Stabilize the tracheostomy tube with one hand while attaching the PMV to the 15mm hub of the tracheostomy tube with the other hand using an approximate 1/4 twist. The PMV has a friction fit for secure placement.

⚠ **CAUTION:** Excessive force should not be used when placing the PMV 005 (white) on the tracheostomy tube as it may obstruct movement of the PMV diaphragm.

9. **Patient Monitoring and Removal of PMV®:** Observe patient to ensure that the diaphragm of the PMV opens during patient's inspiration and remains closed during exhalation. Observe the patient with the PMV in place to ensure the patient has adequate airflow around the tracheostomy tube. If patient exhibits signs of respiratory distress, remove PMV immediately and reassess for airway patency.

   To remove PMV, stabilize the tracheostomy tube with one hand and twist PMV off gently with the other hand. If using a tracheostomy tube that has a hub that rotates, it may be necessary to use a rocking rather than twisting motion to remove the PMV. At this time the Patient Parameters Chart Label should be completed and placed in the patient's chart.

⚠ **WARNING: IF THE PATIENT EXPERIENCES DIFFICULTY UTILIZING THE PMV, THE PATIENT MAY HAVE AIRWAY OBSTRUCTION DUE TO STENOSIS, TISSUE MASS, TRACHEOMALACIA, GRANULATION, VOCAL CORD PARALYSIS IN THE MIDLINE POSITION, SECRETIONS, OR A TRACHEOSTOMY TUBE THAT IS OVERSIZED FOR THE PATIENT'S TRACHEA. WITH CORRECTION OF THE OBSTRUCTION, THE PATIENT SHOULD BE RE-EVALUATED FOR PMV USE.**

10. **Patient Transitioning:** Many patients adjust immediately and easily to the PMV. However, some patients may require a gradual transition to wearing the PMV. Some patients can tolerate the PMV during all waking hours (e.g., 16-18 hours per day). Re-education of breathing pattern and voice/speech production may be needed if the patient has not vocalized for a prolonged period of time. A Speech-Language Pathologist can assist in retraining. Patients will experience more normal respiratory sensations such as airflow in the oral/nasal chambers, and the effects of increased respiratory muscle activity. Patients may initially experience increased coughing due to restoration of a closed respiratory system, which re-establishes subglottic pressure and normal exhaled airflow in the oral/nasal chambers. Therefore, secretion management is facilitated creating movement and clearing of tracheal secretions, which aids in pulmonary hygiene. If patient exhibits prolonged excessive coughing, PMV should be removed and airway patency should be reassessed.

TROUBLESHOOTING

If patient is unable to exhale adequately through the upper airway, the following may need to be considered for reassessment:

- **Cuff Assessment:** Check to ensure that the tracheostomy tube cuff is completely deflated. Although not required, a cuffless tracheostomy tube may provide optimal airway patency for use with the PMV and should be considered if the patient is an appropriate candidate.
- **Tracheostomy Tube Assessment:** Evaluate tracheostomy tube size to determine whether downsizing the tube is necessary due to the size of the tracheostomy tube or bulk of the deflated cuff to enable adequate exhalation.
- **Airway Obstruction:** Physician assessment (e.g., bronchoscopy) for presence of unknown airway obstruction (e.g., stenosis, granulation, mass, vocal cord paralysis, etc.) should be considered.
- **Positioning:** Reassess to ensure optimal patient and tracheostomy tube positioning.
- **Patient Anxiety:** Tracheostomized patients may experience anxiety with initial PMV placement. Patient education prior to placement of PMV with explanation that the patient will experience sensation of airflow through the upper airway upon exhalation, and may initially experience movement of secretions through the airway and out the mouth, may help reduce some anxiety. In addition, distraction techniques (e.g., telephone calls, family and physician visits) may

be used to facilitate exhalation and/or voice, as well as visual techniques such as: simple spirometry or use of mirrors, cotton, feathers, whistles or bubbles. A patient information video featuring successful PMV® users is available free of charge from Passy-Muir Inc., which may assist in patient education and motivation.

PMV CONNECTIONS

Fenestrated Tracheostomy Tubes: The PMV can be used with fenestrated tracheostomy tubes although a fenestrated tube is NOT required. If using an inner cannula to connect the PMV, it is necessary that both the inner and outer cannula be fenestrated to take advantage of the fenestration. If the fenestrated tube is cuffed, the cuff must be c*ompletely deflated*. Using the PMV with a fenestrated tube may offer the advantage of further improvement in speech volume along with the other benefits of the PMV.

Inner Cannula: The PMV fits on the universal 15mm hub of adult, pediatric and neonatal tracheostomy tubes with a friction fit. Some tracheostomy tube designs may provide the 15mm hub as part of the inner cannula or the outer cannula. When using the PMV 005 (white) on tracheostomy tubes that have a disposable inner cannula with grasp ring, it is necessary to ensure that the grasp ring does not extend beyond the 15 mm hub of the tracheostomy tube. If it does extend beyond the 15mm hub, the inner cannula should be removed prior to PMV 005 (white) use.

⚠ **CAUTION:** If the grasp ring on the inner cannula is sprung outward beyond the 15mm hub it may obstruct movement of the PMV 005 (white) diaphragm.

Premier Medical or Pilling Weck Metal Jackson Improved Tubes:

Note: This instruction book is not to be used with the PMV 2020 (clear).

The PMV 2020 (clear) (15mm I.D./23mm O.D.) is the *only* light weight one-way closed position "no leak" valve designed to attach to the Premier Medical or Pilling Weck metal Jackson Improved tracheostomy tubes (sizes 4 - 6 or equivalent) with use of the PMA® 2020-S Adapter (Fig. 5a). Please contact Passy-Muir Inc. for additional information.

Fig. 5a

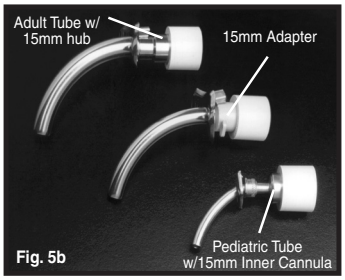
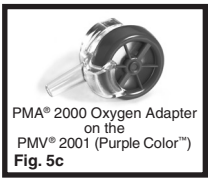


Fig. 5b

Other Metal Tracheostomy Tubes: Some manufacturers of metal tracheostomy tubes (pediatric and adult sizes) offer an optional inner cannula with a 15mm hub which will allow for connection of the PMVs, as well as other respiratory equipment. The inner cannula with a 15mm hub may be ordered from the manufacturer or its distributor. A plastic endotracheal tube adapter may be sized to a low-profile metal tracheostomy tube to create a 15mm hub that will allow for placement of the PMV (Fig. 5b).

Oxygen: Oxygen can be administered while the PMV is in place at the tracheostomy tube site via trach collar or the Passy-Muir® PMA 2000 Oxygen Adapter (Fig. 5c). Please contact Passy-Muir Inc. for additional information about the PMA 2000.


PMA® 2000 Oxygen Adapter on the PMV® 2001 (Purple Color™)
Fig. 5c

Humidity: Humidity (non-medicated heated aerosol) can be applied at the tracheostomy tube site with the PMV in place via the use of a trach collar.

⚠ **WARNING: USE CAUTION WHEN USING A PMV WITH A HEAT MOISTURE EXCHANGER (HME) DEVICE OR HYGROSCOPIC CONDENSER HUMIDIFIER (HCH). THIS DEVICE OBTAINS HUMIDITY FROM THE EXHALED BREATH OF A PATIENT. WITH THE PMV IN PLACE, AIR IS NOT EXHALED VIA THE TRACHEOSTOMY TUBE AND THIS MAY AFFECT THE PERFORMANCE OF THE HME. ADDITIONAL HUMIDIFICATION MAY BE NEEDED.**

⚠ **CAUTION:** Remove PMV prior to delivery of medicated nebulizer treatments. If the PMV is inadvertently used during a medicated nebulizer treatment it should be removed immediately and rinsed thoroughly to remove medication residue as some medications may adversely affect the PMV diaphragm.

INSTRUCTIONS FOR VENTILATOR APPLICATION

When using PMVs with ventilator dependent patients all previous instructions, warnings and cautions should be carefully reviewed and incorporated with the following ventilator application guidelines:

The PMV® 005 (white), PMV 007 (Aqua Color™), PMV 2000 (clear) and the PMV 2001 (Purple Color™) can be used with acute care and portable ventilators and in conjunction with most conventional modes of ventilation.

The PMV 005 (white), PMV 007 (Aqua Color), PMV 2000 (clear) and PMV 2001 (Purple Color) can be used interchangeably on or off the ventilator depending upon the type of ventilator tubing. The PMV 005 (white), PMV 2000 (clear) and the PMV 2001 (Purple Color) have a 23mm outer diameter (O.D.) and must be used with short, wide mouth, flexible, non-disposable (rubber) ventilator tubing. The PMV 007 (Aqua Color), which has a 22mm O.D., is designed to fit directly into disposable ventilator tubing and can also be used with wide mouth flexible non-disposable (rubber) tubing.

⚠ **WARNING: DO NOT USE PMV 005 (WHITE), PMV 2000 (CLEAR) OR PMV 2001 (PURPLE COLOR) WITH DISPOSABLE VENTILATOR TUBING AS THERE IS A POTENTIAL FOR DISCONNECT. USE WITH WIDE-MOUTH FLEXIBLE NON-DISPOSABLE(RUBBER) TUBING.**

1. **Review the previous section marked "Passy-Muir® Tracheostomy & Ventilator Swallowing and Speaking Valve Placement: Non-Ventilator Dependent Application" (page 6) for the following information.**

   • Education • Patient Assessment • Suctioning

2. **Ventilator Assessment:** Assessment of ventilator settings before, during and after PMV placement include but are not limited to the following:

   - Mode
   - Tidal Volume (V_T)
   - Rate
   - Fraction of Inspired Oxygen Content ($FI0_2$)
   - Positive End Expiratory Pressure (PEEP)
   - Peak Inspiratory Pressure (PIP)
   - Sensitivity
   - Alarm Settings

Note: All ventilator adjustments require a physician's order.

3. **Cuff Deflation:** If the patient has a cuffed tracheostomy tube, ventilator adjustments may be required to compensate for leakage around the tracheostomy tube after cuff deflation in order to meet the patient's comfort and ventilatory requirements. The cuff should be deflated slowly over a 2 - 5 minute period of time. This allows the patient's oropharyngeal muscles to adjust to the sensation of airflow. As these muscles adjust they begin to tone creating resistance to air leakage through the upper airway during inspiration.

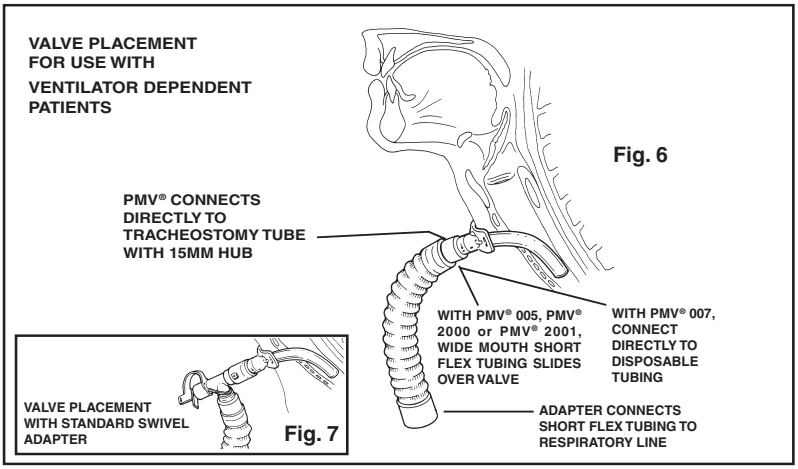
   If the PIP decreases significantly following cuff deflation, inspired air may be escaping through the upper airway and not entering the lungs. To compensate, adjustments to V_T may be necessary. When an increase in V_T is necessary, it should be made in small increments to avoid overcompensation. When adjusting V_T for cuff deflation, V_T increases may result in an increase in PIP.

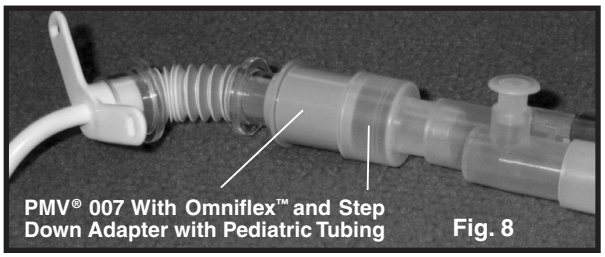
⚠ **WARNING: DO NOT EXCEED PRE-CUFF DEFLATION PEAK INSPIRATORY PRESSURES.**

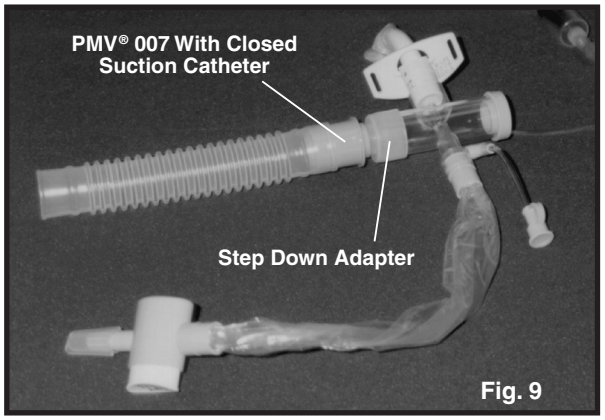
⚠ **WARNING: TRACHEOSTOMY TUBE CUFF MUST BE *COMPLETELY DEFLATED* BEFORE PLACING THE PMV. PATIENT WILL BE UNABLE TO BREATHE IF CUFF IS NOT *COMPLETELY DEFLATED.* PMV CANNOT BE USED WITH FOAM FILLED CUFFED TRACHEOSTOMY TUBES. THE PMV CAN BE USED WITH A CUFFED TRACHEOSTOMY TUBE IF THE CUFF IS *COMPLETELY DEFLATED* AND THE PATIENT HAS SUFFICIENT AIRFLOW AROUND THE TRACHEOSTOMY TUBE AND BULK OF THE DEFLATED CUFF.**

4. **PMV® Attachment:** Apply connector side of the PMV directly to patient's tracheostomy tube (Fig. 6) by stabilizing the tracheostomy tube with one hand and attaching the PMV to the 15mm hub of the tracheostomy tube with the other hand using an approximate 1/4 twist. The PMV has a friction fit to ensure secure placement. The PMV can also be attached using a swivel adapter (Fig. 7), Omniflex™ (Fig. 8) or closed suction catheter (Fig. 9). The PMV 007 (Aqua Color™) can be used in-line with pediatric ventilator circuitry by using adapters that provide for a 22mm I.D. and 15mm O.D. connection (step down adapter).

⚠ **WARNING: DO NOT ATTACH THE PMV SECURE-IT® WHEN USING THE PMV 2000 (CLEAR) OR PMV 2001 (PURPLE COLOR™) IN-LINE WITH THE VENTILATOR.**







⚠ **CAUTION:** Excessive force should not be used when placing the PMV® 005 (white) on the tracheostomy tube, swivel adapter or in-line suctioning system, as it may obstruct movement of the PMV diaphragm.

5. **Monitoring and Removal of PMV:** Observe the patient with the PMV in place to ensure the patient has adequate airflow around the tracheostomy tube. If patient exhibits signs of respiratory distress, remove PMV immediately and reassess for airway patency. To remove PMV, stabilize the tracheostomy tube and twist off gently. If using a tracheostomy tube that has a hub that rotates, it may be necessary to use a rocking rather than twisting motion to remove the PMV.

⚠ **WARNING: IF THE PATIENT EXPERIENCES DIFFICULTY UTILIZING THE PMV, THE PATIENT MAY HAVE AIRWAY OBSTRUCTION DUE TO STENOSIS, MASS, TRACHEOMALACIA, GRANULATION, VOCAL CORD PARALYSIS IN THE MIDLINE POSITION, SECRETIONS, OR A TRACHEOSTOMY TUBE THAT IS OVERSIZED FOR THE PATIENT'S TRACHEA. WITH CORRECTION OF THE OBSTRUCTION, THE PATIENT SHOULD BE RE-EVALUATED FOR PMV USE.**

⚠ **CAUTION:** The PMV should be attached as close to the tracheostomy tube as possible and not further down in-line to prevent an increase in dead space and obstruction of the PMV from water condensation in the ventilator tubing.

6. **Airway Pressures:** Airway pressures may rise when patients use the PMV due to exhalation through the oronasopharynx which creates (natural) physiologic PEEP. This is part of the natural physiology restored with a closed respiratory system created by the closed position "no leak" design of the PMV. Consequently, mechanical PEEP requirements may be reduced. In addition, normal turbulent airflow through the tubing is increased, creating higher pressures. Although airway pressures may rise slightly, they should be within allowable limits for a patient.

   When peak pressures are above the allowable limits, the PMV needs to be removed immediately and assessment for upper airway patency performed. In addition, due to a slight increase in airway pressure experienced by some patients with PMV use, it is necessary as with any modification to the ventilator circuit to re-evaluate low pressure settings for disconnect to ensure that settings are appropriate.

7. **Ventilator Alarm Settings:** All alarms on ventilators need to be re-evaluated for appropriate adjustments before, during and after use of the PMV.

⚠ **WARNING: FAILURE TO RE-EVALUATE AND ADJUST VENTILATOR ALARMS MAY COMPROMISE PATIENT SAFETY.**

   When the PMV is placed in-line with the ventilator, the patient will no longer be exhaling into the ventilator circuit. Therefore, on most acute care ventilators the high and low tidal volume, the high and low minute volume and the apnea alarms must be reassessed. **High and Low pressure alarm settings on the ventilator must be reassessed at this time to ensure patient safety. Follow manufacturer's recommendations for ventilator self testing (e.g., a short EST should be performed with circuit changes on some acute care ventilators). Some manufacturers provide a speaking valve mode that should be utilized with the PMV.**

8. The patient's ventilator settings should be returned to previous levels after PMV is removed.

⚠ **WARNING: REMOVE PMV AND RETURN VENTILATOR SETTINGS TO PREVIOUS LEVELS PRIOR TO REINFLATING TRACHEOSTOMY TUBE CUFF.**

9. **Patient Transitioning:** Review the "Patient Transitioning" section of Passy-Muir® Tracheostomy & Ventilator Swallowing and Speaking Valve Placement: Non-Ventilator Dependent Application (page 8).

ADDITIONAL TRANSITIONING ISSUES:
Excessive air loss through mouth and nose: If the patient reports discomfort due to feeling a continuous rush of air through the mouth and nose, the following suggestions should be considered:

a. Vocal cord and/or breathing retraining may be indicated due to reduced glottal control.

b. Ventilator compensation may be useful in this situation to help control the rushing of air through the upper airway. Adjustments made in flow rate, tidal volume and/or mode may help to reduce the discomfort the patient is feeling.

c. Gradual cuff deflation prior to PMV® use over a few days (as tolerated) may help your patient to adjust more comfortably to the sensation of airflow through the upper airway.

CARE AND LIFETIME OF THE PMV

The PMVs are packaged in single units. Ideally, the patient should have an additional PMV to serve as a back-up so that one can be cleaned while the other is being used. The PMV and PMV Secure-It® should be cleaned daily after wearing.

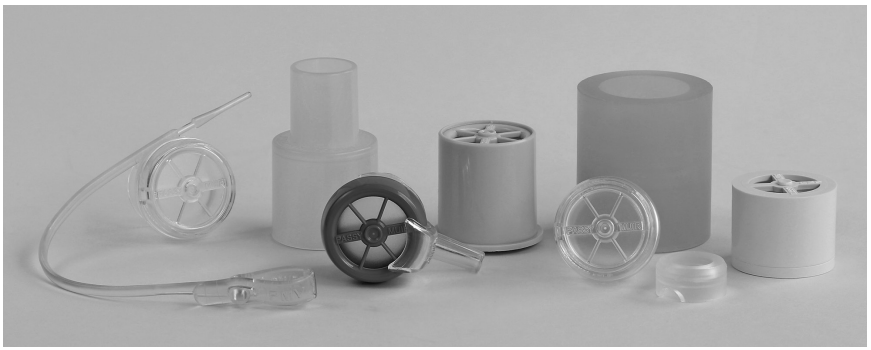
1. Cleaning Procedure

The following cleaning instructions also apply to the PMV Secure-It:

- Swish PMV in soapy, warm water (not hot water.) Rinse thoroughly with warm water. Allow PMV to air dry thoroughly before placing in storage container. Do not apply heat to dry PMV.
- DO NOT use hot water, peroxide, bleach, vinegar, alcohol, brushes or cotton swabs to clean PMV. Do not autoclave.

2. Lifetime of the PMV

Each PMV is designed to last for a minimum of two months. Lifetime cannot be guaranteed if cleaned or used improperly. Due to conditions of use and maintenance beyond the control of the manufacturer, if PMV should become sticky, noisy or vibrate prior to or after two months, the PMV should be replaced. The PMV can continue to be used as long as it does not exhibit stickiness, noise, vibration, increased resistance on inspiration or any other difficulties.



ADDITIONAL EDUCATIONAL MATERIALS AND SUPPORT AVAILABLE FROM PASSY-MUIR INC.

Clinical Specialist Support
Respiratory and Speech Clinical Specialists are available to answer technical questions regarding assessment and placement of the PMVs at:

949.833.8255 or 800.634.5397

Passy Muir is committed to improving the quality of life for tracheostomized and ventilator dependent patients. Visit our website at www.passymuir.com for a variety of helpful resources for healthcare professionals, caregivers and patients.

Anatomical Teaching Models for Instructors and Clinicians

Passy Muir offers a complete line of anatomical teaching models for hands-on demonstration and tracheostomy education. For more information, visit our website at www.passymuir.com.

For further information and placement of orders for these and other educational materials, please contact Passy-Muir Inc. at 949.833.8255 or 800.634.5397.

Visit our website at: www.passymuir.com

David A. Muir
Inventor of the PMV®

"We at Passy-Muir, Inc. believe that communication is the essence of the human spirit; it is essential to individual rights and dignity. We are committed in our efforts to offer tracheostomized and ventilator dependent patients a step toward independence and dignity through speech."

Patricia E. Passy

EC REP

EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands

Passy-Muir, Inc.
Irvine, CA 92614-6813 USA
Phone 949.833.8255 • 800.634.5397
FAX 949.833.8299
website: www.passymuir.com
e-mail: info@passymuir.com

CE 0050

IB/R0120