

## **PASSY-MUIR TRACHEOSTOMY SPEAKING VALVE PMV 2020 INSTRUCTION BOOKLET**



**PASSY-MUIR TRACHEOSTOMY  
SPEAKING VALVE**  
PMV 2020 (Clear) Valve  
15mm I.D./23mm O.D.



**PMA 2020-S (JIT 4-6) ADAPTER**  
For use with Pilling Weck Metal  
Jackson Improved Tracheostomy  
Tubes - Sizes 4, 5 & 6 or Equivalent

For technical questions regarding utilization of the Passy-Muir Valves or to receive our free clinical video and research literature, please contact our respiratory and speech clinical specialists.

*Touching Lives and Advancing Patient Care Through Education*

*Passy-Muir Inc.*

## PMV 2020 INSTRUCTION BOOKLET

### CONTENTS OF PMV 2020 (CLEAR) PATIENT CARE KIT

This package contains: one Passy-Muir 2020 (Clear) Tracheostomy Speaking Valve (PMV), one PMA 2020-S (JIT 4-6) Adapter (henceforth referred to as the "PMA 2020-S Adapter"), PMV Secure-It™, Storage Container, PMV 2020 Instruction Booklet and Warning Labels for use on the tracheostomy tube pilot balloon. Contains no latex. Contents of PMV 2020 (Clear) Patient Care Kit are nonsterile.

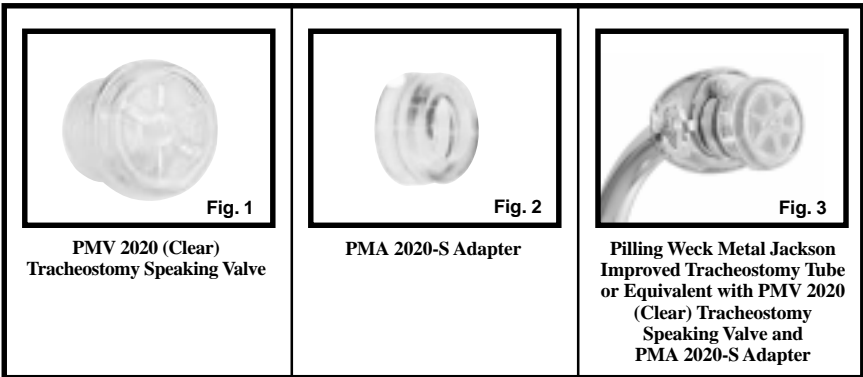
**⚠ READ ALL WARNINGS, PRECAUTIONS AND INSTRUCTIONS CAREFULLY PRIOR TO USE:**

### INSTRUCTIONS FOR USE

The following instructions are applicable to the PMV 2020 (Clear) Tracheostomy Speaking Valve and the PMA 2020-S Adapter. These directions are intended for use by qualified Healthcare Personnel

The PMV 2020 (Clear) Speaking Valve (Fig. 1) and PMA 2020-S Adapter (Fig. 2) are designed for use with the Pilling Weck metal Jackson Improved tracheostomy tubes sizes 4 - 6 or equivalent (Fig. 3). The PMV 2020 (Clear) Speaking Valve can also be used, without an adapter, on Bivona non-foam filled cuffed tracheostomy tubes currently on the market. See Tracheostomy Tube Table on page 12.

**INSTRUCTIONS FOR USE OF THE PASSY-MUIR SPEAKING VALVE 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:** THE PMV 2020 (CLEAR) SPEAKING VALVE AND PMA 2020-S ADAPTER ARE NOT INTENDED FOR IN-LINE VENTILATOR USE.

ALL OTHER PASSY-MUIR VALVES CAN BE USED ON OR OFF THE VENTILATOR.

**WARNING:** NOT INTENDED FOR USE ON 15MM HUBS EXCEPT BIVONA NON-FOAM FILLED CUFFED TRACHEOSTOMY TUBES.

**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. 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:** 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.

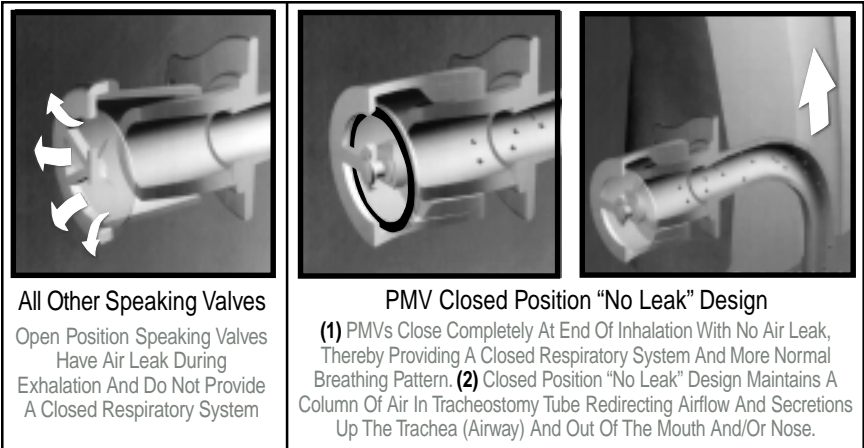
## **DESCRIPTION**

The Passy-Muir Tracheostomy 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 PMV 2020 (Clear) is a light weight one-way closed position “no leak” valve that attaches to the Pilling Weck metal Jackson Improved tracheostomy tubes sizes 4 - 6 or equivalent with the use of the PMA 2020-S Adapter. (See Tracheostomy Tube Table on page 12.) It can also be used on the adult, pediatric and neonatal Bivona non-foam filled cuffed tracheostomy tubes currently on the market. Unlike *open position* one-way speaking valves, the *closed position* “no leak” PMV 2020 (Clear) maintains a bias closed position except during inspiration. When the patient inhales, the PMV 2020 (Clear) opens allowing air to enter the tracheostomy tube and the lungs. At the end of inspiration the PMV 2020 (Clear) closes 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 out 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 2020 (Clear). The bias closed position of the PMV 2020 (Clear) 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 (see diagram on page 3).

The PMV 2020 (Clear) is intended for use by both short-term and long-term adult, pediatric and neonatal non-ventilator dependent tracheostomized patients.



**BENEFITS**

The PMVs were developed to allow tracheostomized 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
  - Expedites Decannulation
  - Improves Olfaction
  - Promotes Better Hygiene
- **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 patients can produce clearer speech with more normal phrasing, better vocal quality and increased volume.
  - **Swallowing:** Use of the PMV can improve the safety and efficiency of swallowing and may reduce aspiration. Positive closure 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 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 oral secretions due to redirection of air through the upper airway during exhalation. As a result, suctioning needs may be reduced.
- **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.

## **INDICATIONS FOR USE**

**Awake and alert tracheostomized non-ventilator dependent patients utilizing either the Pilling Weck metal Jackson Improved tracheostomy tubes sizes 4 - 6 or equivalent or the Bivona non-foam filled cuffed tracheostomy tubes currently on the market 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:**

- Neuromuscular Disease
- Non-Ventilator Dependent Quadriplegia\*
- Brain Injury
- 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**

- Ventilator Dependent Patients\*
- 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
- Severe Aspiration
- This device is not intended for use with endotracheal tubes

\*(The PMV 2020 (Clear) Valve and the PMA 2020-S Adapter are not intended for in-line ventilator use. All other Passy-Muir Valves can be used on or off the ventilator.)

**INSTRUCTIONS FOR TRACHEOSTOMIZED PATIENTS****PRE-PLACEMENT ASSESSMENT GUIDELINES  
FOR PASSY-MUIR 2020 (CLEAR) TRACHEOSTOMY  
SPEAKING VALVE AND PMA 2020-S ADAPTER**

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 TRACHEOSTOMY IS PERFORMED IF THE PATIENT'S TRACHEAL EDEMA AND/OR SECRETIONS FROM THE SURGICAL PROCEDURE HAVE DECREASED.**

**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
  - bedside oximetry and/or spirometry
  - 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:** Tracheostomy tubes with cuffs require mandatory deflation before PMV use to allow exhaled air to pass around the tracheostomy tube and through the oronasopharynx.

**WARNING: IF USING A CUFFED TRACHEOSTOMY TUBE, THE 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.**

**WARNING: DO NOT USE THE PMV WITH FOAM-FILLED CUFFED TRACHEOSTOMY TUBES.**

If it is determined that the patient cannot tolerate cuff deflation initially (i.e., due to risk of gross aspiration), 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 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 nonelastic 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 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 has been met.



### **PASSY-MUIR TRACHEOSTOMY SPEAKING VALVE PLACEMENT**

The following instructions are for the assembly and placement of the PMV 2020 (Clear) Speaking Valve and the PMA 2020-S Adapter only.

**WARNING: THE PMV 2020 (CLEAR) SPEAKING VALVE AND THE PMA 2020-S ADAPTER ARE NOT DESIGNED TO BE USED IN-LINE WITH A VENTILATOR.**

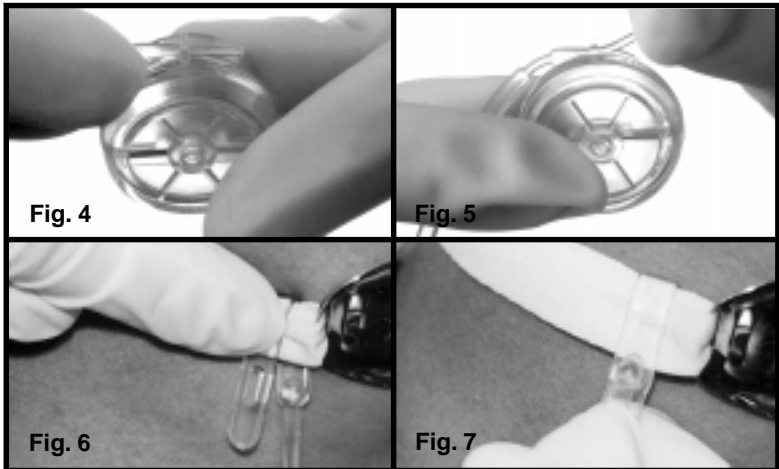
PMV placement should occur in conjunction with physician order using (but not limited to) the following guidelines:

- 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. to assist you with your educational efforts.
- 2. Patient Assessment:** The patient should be assessed before, during and after PMV placement for 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, during and after tracheostomy tube cuff deflation (if present). Coughing is common with tracheal suctioning. Therefore, it is important to allow patients a rest period before continuing with PMV placement. This allows time for the coughing to subside and for patients to catch their breath. As patients recover from suctioning, their respiratory status and saturation will stabilize and they will return to their respiratory baseline.
- 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.**

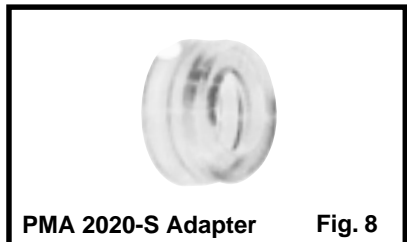
- 5. Tracheostomy Tube Size:** Per physician direction, changing to a smaller tracheostomy tube or cuffless tube may be needed to provide sufficient exhaled airflow to allow use of the PMV.

6. **Use of Warning Labels:** If using the Bivona air filled (non-foam filled) cuffed tracheostomy tube, attach warning labels provided with PMV to the pilot balloon and post at the patient’s bedside to facilitate staff awareness of proper PMV use.
7. **PMV Secure-It™ Attachment:** 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 tube 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 2020 (Clear) (Fig. 4) and pulling it through until it rests between the two notches (Fig. 5).
  - B. Place the other end of the PMV Secure-It™ around the patient’s tracheostomy tie/collar near to the hub of the tracheostomy tube (Fig. 6) and fasten it like a button in a button hole (Fig. 7).
  - C. After removing the PMV from the tracheostomy tube hub as described in sections 9 & 10 below, the PMV Secure-It™ 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.

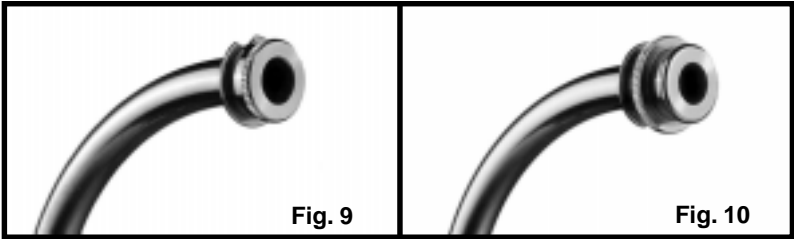


Placement of the PMV Secure-It™

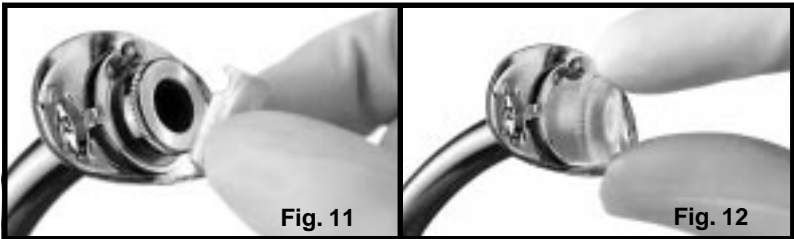
8. **Assembly and Placement of the PMV 2020 (Clear) Speaking Valve using the PMA 2020-S Adapter (see Tracheostomy Tube Table on page 12.)**
  - A. The PMA 2020-S Adapter (Fig. 8) is designed for use on the single ridged and double ridged style Pilling Weck metal Jackson Improved tracheostomy tubes sizes 4 - 6 or equivalent (Fig. 9 & Fig. 10 on next page ).



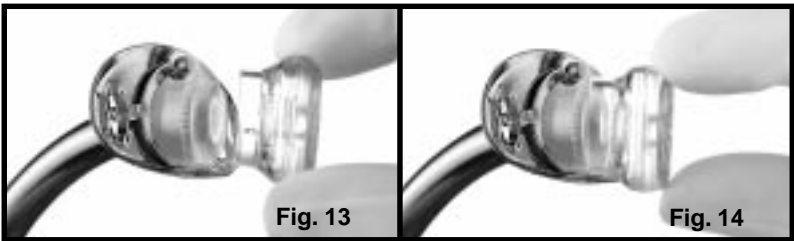
PMA 2020-S Adapter Fig. 8



- B.** Stabilize the tracheostomy tube with one hand. With the other hand, firmly press the PMA 2020-S Adapter onto the hub of the tube. Note: the notch of the adapter should be lined up with the ball lock of the tracheostomy tube (Fig. 11 and Fig. 12).



- C.** Once the PMA 2020-S Adapter is secure on the hub, firmly push the PMV 2020 (Clear) Speaking Valve on to the PMA 2020-S Adapter (Fig. 13 and Fig. 14).



**9. Patient Monitoring and PMV 2020 (Clear) Speaking Valve and PMA 2020-S Adapter Removal**

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.

There are two ways to remove the PMV 2020 (Clear) Speaking Valve and PMA 2020-S Adapter assembly:

**A. Removal of PMV 2020 (Clear) Speaking Valve only:**

1. If the PMV Secure-It™ is being used, unbutton the fastener of the PMV Secure-It™ from the tracheostomy tie prior to removal of the PMV.

2. Stabilize the tracheostomy tube with one hand and gently pull or rock the PMV 2020 (Clear) Speaking Valve off with the other hand.

**B. Removal of PMV (Clear) Speaking Valve and the PMA 2020-S Adapter:**

1. If the PMV Secure-It™ is being used, unbutton the fastener of the PMV Secure-It™ from the tracheostomy tie prior to removal of the PMV.
2. Stabilize the tracheostomy tube with one hand and gently pull or rock the PMV 2020 (Clear) Speaking Valve off with the other hand.
3. Remove the PMA 2020-S Adapter from the hub of the inner cannula by grasping the adapter from the center opening and gently pulling it off of the hub.

**WARNING: IF THE PATIENT EXPERIENCES DIFFICULTY UTILIZING THE PMV, REMOVE THE VALVE IMMEDIATELY. 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. Bivona Tracheostomy Tubes**

- A. PMV Attachment:** Stabilize the Bivona tracheostomy tube with one hand while attaching the PMV 2020 (Clear) 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. Do not use the PMA 2020-S Adapter when connecting the PMV 2020 Speaking Valve to Bivona tracheostomy tubes.

**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.**

- B. Patient Monitoring and Removal of PMV:** Observe the 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 the patient exhibits signs of respiratory distress, remove the PMV immediately and reassess for airway patency.

To remove the PMV 2020 (Clear), stabilize the Bivona tracheostomy tube with one hand and twist the PMV off gently with the other hand. Due to the tracheostomy tube having a rotating hub, it may be necessary to use a rocking motion rather than a twisting motion to remove the PMV.

**WARNING: IF THE PATIENT EXPERIENCES DIFFICULTY UTILIZING THE PMV, REMOVE THE VALVE IMMEDIATELY. 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.**

## **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 if present 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 completely 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.

**Oxygen:** Oxygen can be administered while the PMV is in place at the tracheostomy tube site via trach collar.

**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 or T-piece.

**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.

 **TRACHEOSTOMY TUBE TABLE**

The following table lists the specific Pilling Weck metal Jackson Improved tracheostomy tubes sizes 4-6 and Bivona tracheostomy tube product identifiers that are compatible with the PMV 2020 (Clear) Valve.

Pilling Weck Metal Jackson Improved Tracheostomy Tubes (All require use of the PMA 2020-S Adapter)			
Product #	Size	Product #	Size
<b>Regular Length (Stainless Steel)</b>		<b>Sterling Silver</b>	
51-8025	4	51-1125	4
51-8029*	4	51-1130	5
51-8030	5	51-1135	6
51-8034*	5		
51-8035	6	<b>Extra Long with Rotating Lock (Stainless Steel)</b>	
51-8039*	6	51-8900	5
51-8025A	4	51-8902	6
51-8029A*	4		
51-8030A	5	<b>Short Length (Stainless Steel)</b>	
51-8034A*	5	51-8220	4
51-8035A	6	51-8225	5
51-8039A*	6	51-8230	6
<b>Bivona (non-foam filled cuffed) tracheostomy tubes currently on the market (Does not require use of an adapter)</b>			
<b>Acronyms:</b> JIT = Jackson Improved Tracheostomy Tube PMV = Passy-Muir Valve PMA = Passy-Muir Adapter		<b>PMV 2020 (Clear) Patient Care Kit</b> consists of the following: <ul style="list-style-type: none"> <li>• PMV 2020 (Clear) Valve</li> <li>• PMA 2020-S Adapter</li> <li>• PMV Secure-It™</li> <li>• Storage Container</li> <li>• Instruction Booklet</li> <li>• Warning Labels</li> </ul>	

\*Fenestrated metal Jackson Improved tracheostomy tubes

**CARE INSTRUCTIONS FOR THE PMV 2020 (CLEAR) SPEAKING VALVE,  
PMA 2020-S ADAPTER AND PMV SECURE-IT™**

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. Clean the PMV 2020 (Clear) Speaking Valve, PMA 2020-S Adapter and the PMV Secure-It™ daily (or more frequently as needed) to prevent debris from accumulating under and/or around the adapter and the speaking valve.

- 1. Cleaning Instructions for the PMV 2020 (Clear) Speaking Valve, PMA 2020-S Adapter and the PMV Secure-It™:**
  - A.** Before cleaning, separate the PMV 2020 (Clear) Speaking Valve from the PMA 2020-S Adapter and remove the PMV Secure-It™.
  - B.** Swish the PMV 2020 (Clear) Speaking Valve, PMA 2020-S Adapter and PMV Secure-It™ in soapy, warm water (not hot water).
  - C.** Rinse thoroughly with warm water.
  - D.** Allow PMV 2020 (Clear) Speaking Valve, PMA 2020-S Adapter and PMV Secure-It™ to air dry thoroughly. Do not apply heat to dry the PMV 2020 (Clear) Speaking Valve, PMA 2020-S Adapter or PMV Secure-It™.
  - E.** DO NOT use hot water, peroxide, bleach, vinegar, alcohol, brushes or Q-tips to clean the PMV 2020 (Clear) Speaking Valve, PMA 2020-S Adapter or PMV Secure-It™. Do not autoclave.

Each PMV 2020 (Clear) Speaking Valve is guaranteed 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.

**Disclaimer of Warranties:** Passy-Muir, Inc. warrants that reasonable care has been used in the manufacture of this device. This warranty is exclusive and in lieu of all other warranties, whether expressed, implied, written or oral, including, but not limited to, any implied warranties of merchantability or fitness. As a result of the biological differences of individuals, no product is 100% effective under all circumstances. Because of this fact and since we have no control over the conditions under which the device is used, diagnosis of the patient, methods of administration or its handling after the device leaves our possession, Passy-Muir, Inc. does not warrant either a good effect or against an ill effect following its use. Passy-Muir, Inc. shall not be liable for any incidental or consequential loss, damage or expense arising directly or indirectly from the use of the device. Passy-Muir, Inc. will replace any device that we feel was defective at the time of shipment. No representative of Passy-Muir, Inc. may change any of the foregoing or assume any additional liability or responsibility in connection with this device.

## **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:

Within CA (949) 833-8255 or Outside CA (800) 634-5397.

### **Free Clinical Video and Literature**

The Clinical Video contains information appropriate for patient and family education as well as practical clinical information for healthcare professionals working with tracheostomized and ventilator dependent adult and pediatric patients. Comprehensive literature including many recent research articles validating the benefits of the PMVs is also available upon request.

### **Tracheostomy T.O.M.™ Anatomical Teaching Model for Instructors and Clinicians**

A portable, durable polyurethane anatomical model ideal to use for hands on demonstration and training of tracheostomy care related issues.

### **Passy-Muir Seminar Manual and Video Tape Set**

A comprehensive 200-page manual and video compilation of the popular national series of Passy-Muir One Day Continuing Education Seminars entitled “Application of the Passy-Muir Speaking Valves with Tracheostomized and Ventilator Dependent Patients: A Team Approach.”

#### **Topics Include:**

- Psychosocial Issues
- Communication Options
- PMV Benefits
- Patient Assessment
- PMV Placement
- Pediatric Application
- Ventilator Application
- Dysphagia Issues
- Case Study & Troubleshooting

### **Educational Textbooks**

- Speech Pathology for Tracheostomized and Ventilator Dependent Patients  
*by Mary F. Mason, M.S., CCC-SLP*
- Speech Evaluation of the Patient With a Tracheostomy Tube  
*by Nancy Conway, M.S., CCC-SLP*
- Communication and Swallowing Management of Tracheostomized and Ventilator Dependent Adults  
*by Karen Dikeman, M.A., CCC-SLP & Marta Kazandjian, M.A., CCC-SLP*
- Clinical Practitioners Guide to Respiratory Care and Neonatal/Pediatric Respiratory Care  
*by Dana Oakes, B.A., RRT*
- Tracheotomy - Airway Management, Communication and Swallowing  
*by Eugene N. Myers, M.D., Jonas T. Johnson, M.D. and Thomas Murry, PhD.*
- Additional titles are available upon request

### **Pediatric Therapy and Educational Materials**

Toby Tracheasaurus™ Stuffed Animal or Puppet comes complete with tracheostomy tube and PMV. Toby Tote Exhalation Kits and Toby Coloring Books help clinicians educate children and their families about having a tracheostomy. Friendly Toby dinosaur character helps to make therapy fun.

For further information and placement of orders for these and other educational materials, please contact Passy-Muir, Inc. at (800) 634-5397.

**Visit our website at: [www.passy-muir.com](http://www.passy-muir.com)**



***David A. Muir  
Inventor of the PMV***

*“We at Passy-Muir 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  
President  
Passy-Muir, Inc.***

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Patent # 4,759,356  
IB2020/R:0202