PASSY-MUIR® LOW PROFILE TRACHEOSTOMY SWALLOWING AND SPEAKING VALVE PMV® 2020 (CLEAR) INSTRUCTION BOOKLET

PASSY-MUIR® LOW PROFILE TRACHEOSTOMY SWALLOWING AND SPEAKING VALVE
PMV® 2020 (clear)
15mm I.D./23mm O.D.

PMA® 2020-S ADAPTER
For use with Premier Medical or 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 Education Video, research literature packet, "Benefits" CD-ROM and Clinical Inservice DVD, please contact our respiratory and speech clinical specialists.

Touching Lives and Advancing Patient Care Through Education

CE 0050

CONTENTS OF PMV® 2020 (CLEAR) PATIENT CARE KIT

This package contains: one Passy-Muir® 2020 (clear) Low Profile Tracheostomy Swallowing and Speaking Valve (henceforth referred to as the "PMV 2020"), one PMA® 2020-S Adapter (henceforth referred to as the "PMA 2020-S"), PMV Secure-It®, Storage Container, PMV 2020 Instruction Booklet and Warning Labels for use on the tracheostomy tube pilot balloon. Not made with natural rubber latex. Contents of PMV 2020 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 and the PMA 2020-S.

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

INSTRUCTIONS FOR USE OF PMV 2020 SHOULD BE POSTED AND PROVIDED TO PATIENT AND ALL HEALTHCARE PERSONNEL.

Passy-Muir® Low Profile Tracheostomy Swallowing and Speaking Valve PMV® 2020 (clear)

PMA® 2020-S Adapter

Premier Medical or Pilling Weck metal Jackson Improved Tracheostomy Tube sizes 4-6 or equivalent with PMV® 2020 (clear) and PMA® 2020-S

⚠ **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 AND PMA 2020-S ARE NOT INTENDED FOR IN-LINE VENTILATOR USE.**

⚠ **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® 2020 MUST BE OBSERVED AND/OR MONITORED PER PHYSICIAN DIRECTION.**

⚠ **WARNING: TRACHEOSTOMY TUBE CUFF MUST BE *COMPLETELY DEFLATED* BEFORE PLACING THE PMV 2020. 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 2020 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 THE PMV 2020 WITH A HEAT MOISTURE EXCHANGER (HME) DEVICE. THIS DEVICE OBTAINS HUMIDITY FROM THE EXHALED BREATH OF A PATIENT. WITH THE PMV 2020 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 the PMV 2020 prior to delivery of medicated nebulizer treatments. If the PMV 2020 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 2020 diaphragm.

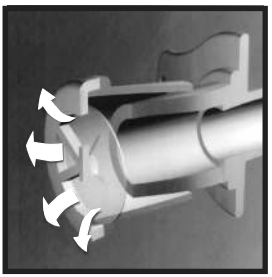
DESCRIPTION

The PMV 2020 is 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 is a lightweight one-way closed position “no leak” valve that attaches to the Premier Medical or Pilling Weck metal Jackson Improved tracheostomy tubes sizes 4 - 6 or equivalent with the use of the PMA® 2020-S. 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 maintains a bias closed position except during inspiration. When the patient inhales, the PMV 2020 opens allowing air to enter the tracheostomy tube and the lungs. At the end of inspiration the PMV 2020 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.

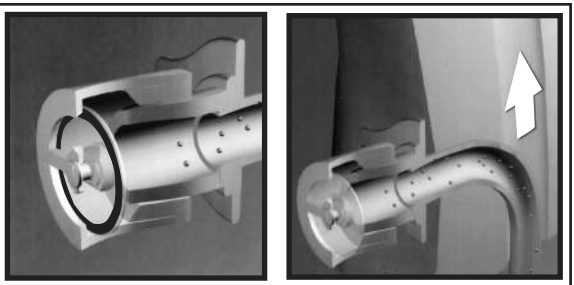
The patented closed position “no leak” design creates a column of air within the tracheostomy tube that inhibits secretions from entering the tube and occluding the PMV 2020. The bias closed position of the PMV 2020 restores the patient to a more normal closed respiratory system. This results in the 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 is intended for use by both short-term and long-term adult, pediatric and neonatal non-ventilator dependent tracheostomized 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 patients to speak more normally. However, research has validated additional significant benefits with use of the PMV® 2020:

- 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. This allows for normal development of speech and language in children.

- **Swallowing:** Use of the PMV 2020 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 2020 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 2020 IN ADDRESSING SWALLOWING FUNCTION.**

- **Secretion Management:** The closed position "no leak" design of the PMV 2020 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 2020 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 2020 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® 2020 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 2020 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 2020 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 2020 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 Premier Medical or 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 2020 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 2020 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 and the PMA® 2020-S are not intended for in-line ventilator use.)

INSTRUCTIONS FOR TRACHEOSTOMIZED PATIENTS

PRE-PLACEMENT ASSESSMENT GUIDELINES FOR THE PMV® 2020 AND THE PMA® 2020-S

These guidelines should be used in conjunction with physician direction:

FOR TRACHEOSTOMIZED NON-VENTILATOR DEPENDENT PATIENTS, THE PMV 2020 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.

IF THE TRACHEOSTOMY TUBE HAS BEEN CHANGED, PMV 2020 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 2020 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:** Tracheostomy tubes with cuffs require mandatory deflation before PMV 2020 use 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), the patient should be reassessed for cuff deflation as changes in his/her medical condition occur.

⚠ **WARNING: IF USING A CUFFED TRACHEOSTOMY TUBE, THE CUFF MUST BE *COMPLETELY DEFLATED* BEFORE PLACING THE PMV 2020. PATIENT WILL BE UNABLE TO BREATHE IF CUFF IS NOT *COMPLETELY DEFLATED*. THE PMV 2020 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: FOAM-FILLED CUFFED TRACHEOSTOMY TUBES ARE CONTRAINDICATED WITH THE PMV 2020.**

4. **Secretion Management:** Use of the PMV 2020 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 2020 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® 2020.**

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 2020 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 2020 can improve the safety and efficiency of swallowing and may reduce aspiration. The closed position "no leak" design of the PMV 2020 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 2020 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 2020 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 2020.

   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 2020. 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 2020.

   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 2020 placement if other assessment criteria are met.

7. **Lung Compliance:** Critically ill and chronic pulmonary patients have lungs with altered compliance. Therefore, PMV 2020 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 2020 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 2020 use as it can facilitate exhaled air flow.

8. **Level of Care:** Utilization of the PMV® 2020 can occur across the continuum of healthcare settings. Evaluation for PMV 2020 placement can occur as early as 48-72 hours post tracheotomy. PMV 2020 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 2020 if the assessment criteria have been met.

PMV 2020 PLACEMENT

⚠ **WARNING: THE PMV 2020 AND THE PMA® 2020-S ARE NOT DESIGNED TO BE USED IN-LINE WITH A VENTILATOR.**

PMV 2020 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 2020, the patient, family and all personnel (all shifts) working with the patient should be instructed in the directions for use of the PMV 2020 including contraindications, cautions and warnings. Review all package inserts and labeling with patient, family and staff. Free patient information and clinical inservice videos, CD's, and DVD's 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 2020 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 2020 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 2020.

⚠ **WARNING: TRACHEOSTOMY TUBE CUFF MUST BE *COMPLETELY DEFLATED* BEFORE PLACING THE PMV 2020. PATIENT WILL BE UNABLE TO BREATHE IF CUFF IS NOT *COMPLETELY DEFLATED*. THE PMV 2020 CANNOT BE USED WITH FOAM FILLED CUFFED TRACHEOSTOMY TUBES. THE PMV 2020 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 2020.

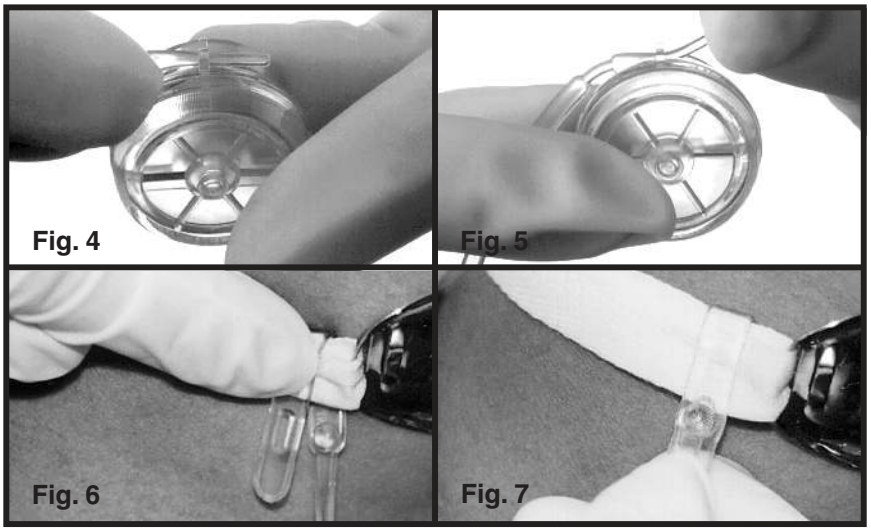
6. **Use of Warning Labels:** If using Bivona (non-foam filled) cuffed tracheostomy tubes, attach warning labels provided with the PMV® 2020 to the pilot balloon and post at the patient's bedside to facilitate staff awareness of proper PMV 2020 use.

7. **PMV Secure-It® Attachment:** Attach the PMV Secure-It to the PMV 2020 prior to placing the PMV 2020 on the tracheostomy tube. Use of the PMV Secure-It which attaches to the tracheostomy tube tie/collar will help to prevent the loss of the PMV 2020 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 (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 the neckplate of the tracheostomy tube (Fig. 6) and fasten it like a button in a button hole (Fig. 7).

   C. After removing the PMV 2020 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/collar prior to removal of the PMV Secure-It from the PMV 2020. The PMV Secure-It can then be removed by gently pulling it out of the small hole in the side of the PMV 2020.



Placement of the PMV® Secure-It®

8. **Assembly and Placement of the PMV 2020 using the PMA® 2020-S**

   A. The PMA 2020-S (Fig. 8) is designed for use on the single ridged and double ridged style Premier Medical or 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**


Fig. 9


Fig. 10

B. Stabilize the tracheostomy tube with one hand. With the other hand, firmly press the PMA® 2020-S 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).

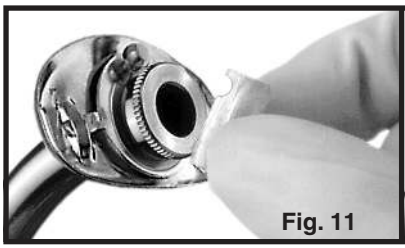


Fig. 11

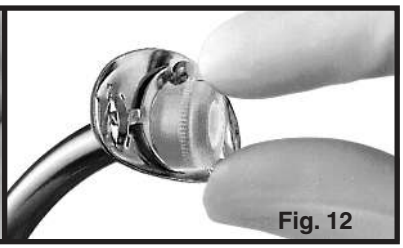


Fig. 12

C. Once the PMA 2020-S is secure on the hub, firmly push the PMV® 2020 on to the PMA 2020-S (Fig. 13 and Fig. 14).

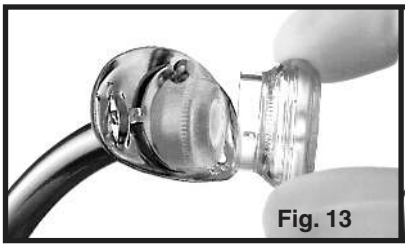


Fig. 13

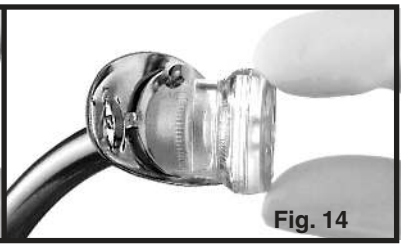


Fig. 14

9. Patient Monitoring and PMV 2020 and PMA 2020-S Removal

Observe patient to ensure that the diaphragm of the PMV 2020 opens during patient's inspiration and remains closed during exhalation. Observe the patient with the PMV 2020 in place to ensure the patient has adequate airflow around the tracheostomy tube. If patient exhibits signs of respiratory distress, remove the PMV 2020 immediately and reassess for airway patency.

There are two ways to remove the PMV 2020 and PMA 2020-S assembly:

A. Removal of the PMV 2020 only:

1. If the PMV Secure-It® is being used, unbutton the fastener of the PMV Secure-It from the tracheostomy tie/collar prior to removal of the PMV 2020.

2. Stabilize the tracheostomy tube with one hand and gently pull or rock the PMV® 2020 off with the other hand.

B. Removal of PMV 2020 and the PMA® 2020-S

1. If the PMV Secure-It® is being used, unbutton the fastener of the PMV Secure-It from the tracheostomy tie/collar prior to removal of the PMV 2020.

2. Stabilize the tracheostomy tube with one hand and gently pull or rock the PMV 2020 off with the other hand.

3. Remove the PMA 2020-S 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 2020, 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 2020 USE.**

10. Bivona Tracheostomy Tubes

A. PMV Attachment: Stabilize the Bivona tracheostomy tube with one hand while attaching the PMV 2020 to the 15mm hub of the tracheostomy tube with the other hand using an approximate 1/4 twist. The PMV 2020 has a friction fit for secure placement. Do not use the PMA 2020-S when connecting the PMV 2020 to Bivona tracheostomy tubes.

⚠ **WARNING: TRACHEOSTOMY TUBE CUFF MUST BE *COMPLETELY DEFLATED* BEFORE PLACING THE PMV 2020. PATIENT WILL BE UNABLE TO BREATHE IF CUFF IS NOT *COMPLETELY DEFLATED*. THE PMV 2020 CANNOT BE USED WITH FOAM FILLED CUFFED TRACHEOSTOMY TUBES. THE PMV 2020 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 2020 opens during patient's inspiration and remains closed during exhalation. Observe the patient with the PMV 2020 in place to ensure the patient has adequate airflow around the tracheostomy tube. If the patient exhibits signs of respiratory distress, remove the PMV 2020 immediately and reassess for airway patency.

To remove the PMV 2020, stabilize the Bivona tracheostomy tube with one hand and twist the PMV 2020 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 2020.

⚠ **WARNING: IF THE PATIENT EXPERIENCES DIFFICULTY UTILIZING THE PMV 2020, 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 2020 USE.**

PATIENT TRANSITIONING

Many patients adjust immediately and easily to the PMV®2020. However, some patients may require a gradual transition to wearing the PMV 2020. Some patients can tolerate the PMV 2020 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, the PMV 2020 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 2020 and should be considered if the patient is an appropriate candidate.
- **Tracheostomy Tube Assessment:** To enable adequate exhalation, 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.
- **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 2020 placement. Patient education prior to placement of PMV 2020 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 Clinical Education DVD or 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 2020 can be used with fenestrated tracheostomy tubes although a fenestrated tube is NOT required. If using an inner cannula to connect the PMV 2020, 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 2020 with a fenestrated tube may offer the advantage of further improvement in speech volume along with the other benefits of the PMV 2020.

Oxygen: Oxygen can be administered while the PMV 2020 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 2020 in place via the use of a trach collar or T-piece.

⚠ **WARNING: USE CAUTION WHEN USING THE PMV® 2020 WITH A HEAT MOISTURE EXCHANGER (HME) DEVICE. THIS DEVICE OBTAINS HUMIDITY FROM THE EXHALED BREATH OF A PATIENT. WITH THE PMV 2020 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 2020 prior to delivery of medicated nebulizer treatments. If the PMV 2020 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 2020 diaphragm.

CARE INSTRUCTIONS FOR THE PMV 2020, PMA® 2020-S AND THE PMV SECURE-IT®

The PMV 2020 is packaged as a single unit. Ideally, the patient should have an additional PMV 2020 to serve as a back-up so that one can be cleaned while the other is being used. Clean the PMV 2020, PMA 2020-S and the PMV Secure-It daily (or more frequently as needed) to prevent debris from accumulating under and/or around the adapter and the valve.

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

Each PMV 2020 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 the PMV 2020 should become sticky, noisy or vibrate prior to or after two months, the PMV 2020 should be replaced. The PMV 2020 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 PMV® 2020 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® 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

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