

Passy Muir® Low-Profile **DB15™ Adapter** PM-DB15 (15mm I.D.)



For use with duckbill style tracheostomy tubes

INSTRUCTIONS FOR USE











Passy-Muir, Inc.

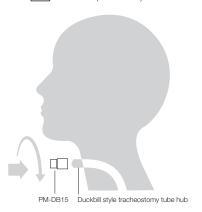
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Made in USA

Passy Muir[®] Low-Profile **DB15**[™] **Adapter**REF PM-DB15 (15mm I.D.)



INSTRUCTIONS FOR USE

Intended Use:

The PM-DB15 Adapter is a non-sterile, lightweight, single patient use, low-profile adapter for placement on the 15mm hub of a tracheostomy tube with a duckbill designed inner cannula to allow finger occlusion or placement of a Passy Muir Valve, models PMV® 2000 or PMV 2001.

Indications for Use:

For non-mechanically ventilated tracheostomy patients who have a tracheostomy tube with a duckbill designed inner cannula, where finger occlusion or placement of a Passy Muir Valve, models PMV 2000 or PMV 2001, is desired.

Environment of Use:

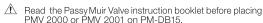
Clinical settings that include hospital, sub-acute, rehabilitation, outpatient, skilled nursing, long-term care, and in the home setting.

Professional use only. Not intended for use by neonatal or infant patients. Non-sterile. Not made with natural rubber latex.

WARNINGS

- SINGLE PATIENT USE ONLY. USE ON MORE THAN ONE PATIENT COULD CAUSE CROSS-CONTAMINATION AND LEAD TO INFECTION.
- ATTIENTS USING THE PM-DB15 MUST BE ABLE TO REMOVE THE DEVICE THEMSELVES AS NEEDED OR SHOULD BE MONITORED BY A TRAINED HEALTHCARE PROVIDER OR CAREGIVER.
- NOT FOR USE IN A VENTILATOR CIRCUIT AS THE VENTILATOR MAY DISCONNECT.
- NOT FOR USE AS A CONNECTOR FOR STANDARD 15MM TUBING, ADAPTERS, ACCESSORIES, OR OTHER CONNECTIONS TO THE HUB OF THE TRACHEOSTOMY TUBE, AS THE CONNECTION MAY NOT BE SECURE.
- ⚠ DO NOT USE IF THE PM-DB15 IS DIRTY OR OBSTRUCT-ED WITH MUCUS OR OTHER PARTICULATES. CLEAN PRIOR TO USE, OR INFECTION MAY OCCUR.
- FINGER OCCLUSION OR USE OF A PASSY MUIR VALVE REQUIRES THAT A PATIENT'S TRACHEOSTOMY TUBE CUFF IS COMPLETELY DEFLATED, AS THE PATIENT WILL NOT BE ABLE TO BREATHE.
 - NOT FOR USE TO CONNECT DEVICES OTHER THAN THE PMV 2000 OR THE PMV 2001 TO A TRACHEOSTOMY TUBE HUB.

CAUTIONS



riangle Discard when worn or damaged.

DO NOT use hot water, peroxide, bleach, vinegar, alcohol, brushes, cotton swabs, or chemicals to clean the PM-DB15. Do not autoclave or sterilize.

Care must be taken so that the PM-DB15 is only used with finger occlusion or a Passy Muir Valve.

Finger occlusion is a potential source of bacterial or viral pathogens. It is recommended to follow universal precautions, including use of a gloved hand or appropriate hand sanitizer and washing procedures.

⚠ Do not force the PM-DB15 onto the tracheostomy tube hub.

⚠ You should not force the Passy Muir Valve onto the PM-DB15.

♠ DO NOT use with a suction catheter, as the catheter may not connect appropriately.

CONTRAINDICATIONS

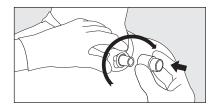
- **Do not use** on patients who are on any form of mechanical ventilation.
- Do not use while a patient is receiving medicated aerosol treatment.

PLACEMENT

The following instructions are for the placement of the PM-DB15.

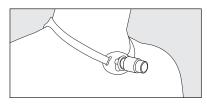


Step 1: Using universal precautions and appropriate PPE, stabilize the patient's tracheostomy tube.

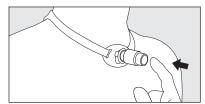


Step 2: Place the PM-DB15 gently onto the 15mm hub of the tracheostomy tube with a gentle quarter turn clockwise (to the right) while placing it onto the hub.

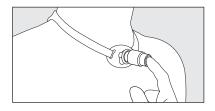
CAUTION: Do not force the PM-DB15 onto the tracheostomy tube hub.



Step 3: Monitor the patient's respiratory status and assess for changes from baseline parameters.



Step 4: To use for finger occlusion, monitor the patient's respiration. Either have the patient take a breath in or observe an inspiratory breath. Gently place the tip of a gloved finger over the opening immediately following inspiration.

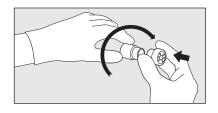


Step 5: To check for airflow out the mouth and nose, have the patient say "ah" or count to five.

⚠ WARNING:

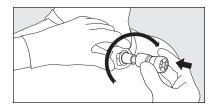
FINGER OCCLUSION OR USE OF A PASSY MUIR VALVE REQUIRES THAT A PATIENT'S TRACHEOSTOMY TUBE CUFF IS COMPLETELY DEFLATED, AS THE PATIENT WILL NOT BE ABLE TO BREATHE.

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Step 6: If using a Passy Muir Valve, first place the Valve onto the PM-DB15 with a gentle quarter twist to the right prior to placement on the tracheostomy tube hub.

↑ CAUTION: You should not force the Passy Muir Valve onto the PM-DB15.



Step 7: While stabilizing the patient's tracheostomy tube, and after deflating the patient's cuff (if present), place the combined PM-DB15 and PassyMuir Valve unit gently onto the 15mm hub of the tracheostomy tube with a gentle quarter turn clockwise (to the right).

A CAUTION: Do not force the PM-DB15 onto the tracheostomy tube hub.

WARNING:

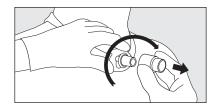
USE OF A PASSY MUIR VALVE REQUIRES THAT A PATIENT'S TRACHEOSTOMY TUBE CUFF IS COMPLETELY DEFLATED, AS THE PATIENT WILL NOT BE ABLE TO BREATHE.

REMOVAL

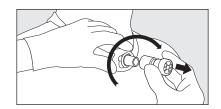
The following instructions are for the removal of the PM-DB15.



Step 1: Using universal precautions and appropriate PPE, stabilize the patient's tracheostomy tube.

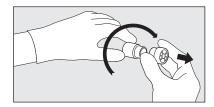


Step 2: Remove the PM-DB15 with a quarter turn clockwise (to the right) while gently removing the PM-DB15 from the tracheostomy tube hub.



Step 3: If using a Passy Muir Valve with the PM-DB15, remove the combined PM-DB15 and Passy Muir Valve unit by grasping the PM-DB15 and using a gentle quarter turn clockwise (to the right) to remove both.

If the patient has a cuffed tracheostomy tube, have a respiratory therapist or other healthcare provider check the cuff status following use of the PM-DB15.



Step 4: Remove the Passy Muir Valve from the PM-DB15 with a gentle quarter turn clockwise (to the right) while gently pulling apart.

CLEANING AND STORAGE



The PM-DB15 should be cleaned daily after use and as needed.

Swish the PM-DB15 in soapy, warm water (not hot water). Rinse thoroughly with warm water. Allow the PM-DB15 to air dry thoroughly. Do not apply heat to dry.

⚠ CAUTION: DO NOT use hot water, peroxide, bleach, vinegar, alcohol, brushes, cotton swabs, or chemicals to clean the PM-DB15. Do not autoclave or sterilize.

Store at room temperature and away from direct sunlight.

Recommended use is up to one month.

Dispose of the PM-DB15 following facility policy and procedure.

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SYMBOLS



Single patient multiple use



Non-sterile



Medical device



Product reference number



Caution



Instructions for use



Manufacturer