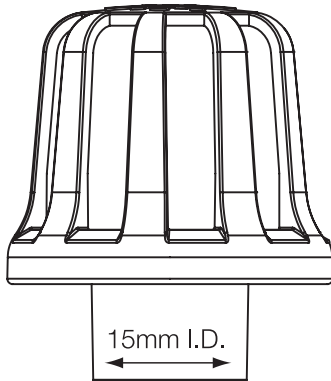


Passy Muir®

Passy Muir Tracheostomy Viral & Bacterial
Airway Protection Filter (PM-APF15)



PM-APF15 Attaches to a Tracheostomy Tube

INSTRUCTIONS FOR USE

CAUTION:

Federal law restricts this filter to
sale by or on the order of a physician.

Rx only



Single
use
only



Non
sterile



Do not use
if package
is damaged



Keep
dry



Keep away
from direct
sunlight

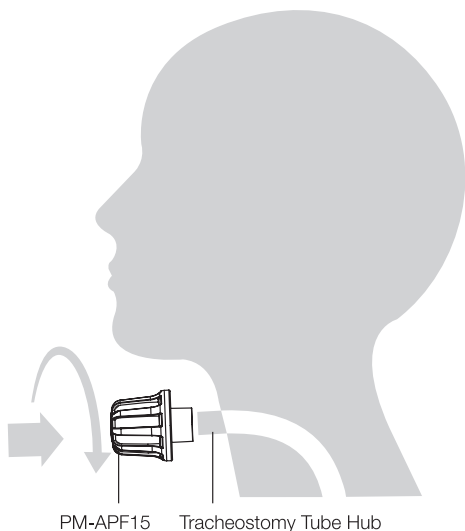


Medical
device



Instructions
for use

Passy Muir Tracheostomy Viral & Bacterial Airway Protection Filter (PM-APF15)



INSTRUCTIONS FOR USE

DEVICE DESCRIPTION

The Passy Muir Tracheostomy Viral & Bacterial Airway Protection Filter (PM-APF15) is a non-sterile, lightweight, single-patient use device for ***non-mechanically ventilated tracheostomy patients*** to filter viral, bacterial, and other particulate matter. The filter is intended to fit onto the 15mm hub of a tracheostomy tube. The filter is easy to apply and remove with a gentle twist motion.

INDICATIONS FOR USE

For non-mechanically ventilated tracheostomy patients who are awake and alert or monitored by a trained healthcare provider or caregiver, where filtration of inspired and/or expired gases is desired. Use up to 24 hours.

Environment of use – clinical settings including hospital, sub-acute, pre-hospital, and home. For adults with Tidal Volumes >300ml and pediatrics with Tidal Volumes >80ml. Do not use on neonate or infant patients.










PATIENT POPULATION


The device may be used by non-mechanically ventilated tracheostomy pediatric and adult patients. The device should NOT be used by infants, neonates, and patients who require humidification.


CONTRAINDICATIONS

- **Do not use** on patients who are unable to remove the PM-APF15 themselves as needed **OR** who are not monitored by a trained healthcare provider or caregiver.
- **Do not use** on patients with thick, copious secretions or fluid accumulation in the lungs.
- **Do not use** on patients who are on any form of mechanical ventilation.
- **Do not use** on patients who are not awake and alert, or who are not monitored by a trained healthcare provider or caregiver.
- **Do not use** on patients with significant exsiccosis (dehydration).
- **Do not use** on patients with significant air leakage at the stoma site which could result in air not flowing through the filter.
- **Do not use** while a patient is receiving high-flow O₂ therapy, heated or cold humidification, or medicated aerosol treatment.
- **Do not use** on neonate or infant patients.

WARNINGS

-  **CAUTION:** Federal law restricts this filter to sale by or on the order of a physician.
-  **WARNING:** Visually inspect the filter and **DO NOT USE** if the filter is wet, dirty, or obstructed with mucus or other particulates. If the filter is obstructed, ***the patient may not be able to breathe***, and the filter may be ineffective, unable to filter viral, bacterial, and other particulate matter, and it must immediately be removed and discarded.
-  **WARNING:** Filter must not be used for more than 24 hours as the filter will be ineffective and will not filter viral, bacterial, and other particulate matter.
-  **WARNING:** Single-patient use only. Use on more than one patient could cause cross-contamination and lead to infection.
-  **WARNING:** Do not clean. The filter must not be cleaned, sterilized, or disinfected, as use of cleaning agents will render the filter ineffective and unable to filter viral, bacterial, and other particulate matter.
-  **WARNING:** Patients using the filter must be able to remove the filter themselves as needed **OR** should be monitored by a trained healthcare provider or caregiver.
-  **WARNING:** This filter is not designed, sold, or intended for uses except as indicated. Misuse may result in sickness or death.
-  **WARNING:** Not intended for use during mechanical ventilation.
-  **WARNING:** Not intended for use during treatment that will moisten or clog the filter, including high-flow O₂, heated or cold humidification, and medicated aerosol treatment.

 **WARNING:** The filter is not intended for use when thick, copious secretions are present.

 **WARNING:** Not intended to replace personal protective equipment (PPE), universal precautions, or requirements from facility policy for use of PPE.

PRECAUTIONS

- Care must be taken to ensure that the filter opening is not blocked by clothing or other material as this may impede breathing (risk of respiratory distress).
- Care must be taken to ensure there is not an air leak around the tracheostomy tube and out of the stoma site. If there is a leak, properly cover or seal the exposed open area on the neck around the tracheostomy tube to prevent air leakage during inspiration and expiration.
- When a filter is in place, standard precautions related to face coverings and other PPE should be followed.

TECHNICAL SPECIFICATIONS

Dead Space	6 ml
Flow Resistance	<0.8 cmH ₂ O @ 28.3 LPM
Filtration Efficiency*	
Particles @ 0.1µm (PFE)	> 99.0%
Bacterial (BFE)	> 99.9%
Viral (VFE)	> 99.9%
* ASTM F2100. Bacterial and Viral Filtration Efficiency test method adapted from ASTM F2101	



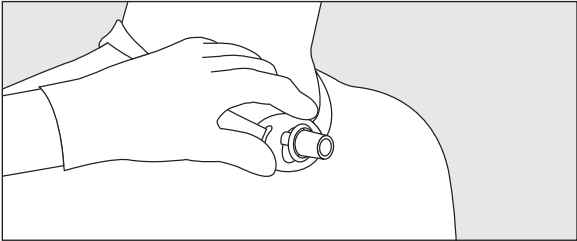
Passy-Muir, Inc.
Irvine, CA 92614-6813 USA
Tel: 949.833.8255 • 800.634.5397
Fax: 949.833.8299
website: www.passymuir.com
email: info@passymuir.com

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Patented

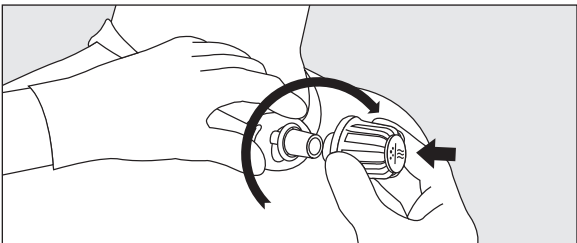
IB/APF15/R1024

PLACEMENT

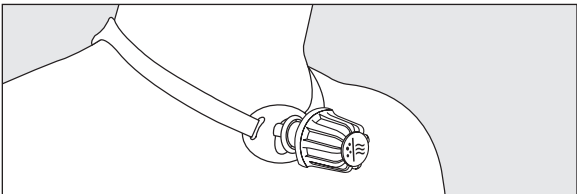
The following instructions are for the placement of the Passy Muir Tracheostomy Viral & Bacterial Airway Protection Filter (PM-APF15).



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



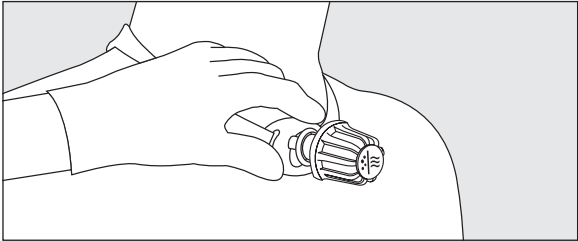
Step 2: Place the PM-APF15 gently onto the 15mm hub of the tracheostomy tube with a gentle quarter turn clockwise (to the right) while placing it onto the hub. Do not PUSH the PM-APF15 onto the tracheostomy tube hub.



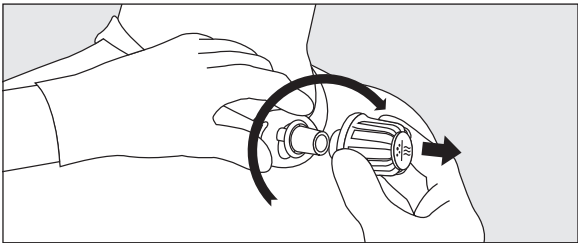
Step 3: Monitor the patient's respiratory status and assess for changes from baseline parameters.

REMOVAL

The following instructions are for the removal of the Passy Muir Tracheostomy Viral & Bacterial Airway Protection Filter (PM-APF15).



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



Step 2: Remove the PM-APF15 with a gentle quarter turn clockwise (to the right) while gently removing the PM-APF15 from the 15mm hub.

STORAGE AND DISPOSAL

- Dispose of the PM-APF15 as medical waste per CDC recommendation and facility policy.
- Store away from direct sunlight.