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Blom® Tracheostomy Tube System

English

D Deutsch

DK Dansk

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I Italiano

N Norsk

NL Nederlands

P Português

PL Polski

S Svenska

T Türkçe

Caution: Federal Law (USA) restricts this device to sale by or on the order of a licensed physician.



Latex Free

Single Patient Use

STERILE EO



Pulmodyne, Inc.

2055 Executive Drive

Indianapolis, IN 46241 USA

T: 317.246.5505

F: 317.246.5501

www.Pulmodyne.com

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EC REP

QNET BV

Hommerterweg 286

6436 AM Amstelveen

The Netherlands



DEHP

Made in USA

Blom® Tracheostomy Tube System



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STERILE EO

INTENDED USE:

The Blom Tracheostomy Tube System is intended to provide tracheal access for airway management of adult tracheostomized patients >30kg.

CONTRAINDICATIONS:

Do not use this device for patients with abnormal upper airway anatomy or pathology as this may result in partial or total airway obstruction.

DESCRIPTION:

System Contents

- 1 Fenestrated Cuffed Tracheostomy Tube Kit
- 1 Non-Fenestrated Uncuffed Tracheostomy Tube Kit
- 1 Subglottic Suctioning Cannula
- 1 Speech Cannula
- 1 Exhaled Volume Reservoir™ (EVR™)
- 1 Low Profile Valve (LPV™)
- 1 SoftTouch™ Tube Holder
- 1 Training Disk

Fenestrated Cuffed Tracheostomy Tube Kit Contents

- 1 Tracheostomy Tube
- 1 Obturator
- 2 Standard Cannula
- 1 Decannulation Plug
- 1 SoftTouch Tube Holder

Non-Fenestrated Uncuffed Tracheostomy Tube Kit Contents

- 1 Tracheostomy Tube
- 1 Obturator
- 2 Standard Cannula
- 1 Decannulation Plug
- 1 SoftTouch Tube Holder

	OD (mm)	ID (mm)	CUFF RESTING DIAMETER (mm)	LENGTH (mm)
# 4	9.4	5.0	21	62
# 6	10.8	6.4	25	74
# 8	12.2	7.6	27	79
#10	13.8	8.9	32	79

WARNINGS:

- This device is only to be used by qualified healthcare practitioners and caregivers.
- This device is not designed for initial percutaneous insertion.
- Contact with electro surgery electrodes or laser surgery beams must be avoided because the materials will produce toxic fumes in the air or ignite in an enriched oxygen atmosphere.
- Patients should be adequately humidified to prevent mucosal damage and minimize encrustation of the lumen or the tracheostomy tube and/or inner cannula.
- Tracheostomy Tubes must be changed regularly according to individual patient's requirements to avoid blockage causing airway obstruction or reduction in lumen of the airway increasing the patient's effort to breathe through the tube.

- If it is not possible to remove the inner cannula from the Tracheostomy Tube, do not try to forcibly remove it. Both the inner cannula and Tracheostomy Tube should be removed together and replaced with a new Tracheostomy Tube and inner cannula.

If using a Fenestrated Cuffed Tracheostomy Tube:

- An inner cannula must be in place during deep pulmonary suctioning to prevent the suctioning catheter from protruding through the fenestration of the Tracheostomy Tube. Suctioning without an inner cannula in place could result in damage to the tracheal wall and could cause the suction catheter to become caught in the fenestration.
- Devices used during or after cuff inflation must be clean and free from foreign matter.
- Prevent cuff damage by avoiding contact with sharp edges including cartilage, instruments and other devices.
- As a further precaution for ventilator dependant patients, cuff inflation should be checked on a regular basis and replacement Tracheostomy Tubes should be kept at bedside.

ADVERSE REACTIONS:

- Reported adverse reactions associated with tracheostomy tubes are many and diverse. Consult standard textbooks and medical literature for information on specific adverse reactions.

CAUTIONS:

- For Single Patient Use only
- Product Reuse will cause failure
- Contents sterile unless package is damaged or opened
- Read all provided information before using this product
- Patency of the Tracheostomy Tubes and inner cannulas must be checked prior to insertion and be assured during use by regular suctioning. Inner cannulas must be checked regularly and replaced regularly to maintain a patent airway. The maximum recommended period of use for the Tracheostomy Tube is 30 days. The maximum recommended period of use for the Standard Cannula, Subglottic Suctioning Cannula and Decannulation Plug is 24 hours or according to local established protocols. The maximum recommended period of use for the Speech Cannula and the LPV is 60 days.
- Use universal precautions when in contact with a tracheostomized patient's tube and/or inner cannulas
- Proper sizing, insertion, and withdrawal of the Tracheostomy Tube should be in accordance with accepted medical techniques and expert clinical judgment.
- If abnormal anatomy is encountered or unusual positioning of the head and neck is required, care should be taken to avoid kinking of the Tracheostomy Tube. The use of a reinforced tube should also be considered.
- When selecting an inner cannula, ensure that the size corresponds with the Tracheostomy Tube. Size markings are provided on the tube, flange, and package label to help identify the correct inner cannula size to use.
- Ventilator circuits should be well supported to reduce stress on the tracheostomy hub and the patient's stoma site. A swivel adapter may be used to reduce torque and motion at the 15 mm hub of the Tracheostomy Tube.
- Make sure all ventilator circuit connections are snug and that the inner cannula clips are fastened securely
- Only sterile saline should be used to clean accessible parts. If the tube is removed it should be discarded. No reusable device is included.
- Dispose of the product in a safe manner according to local established protocols

If using the Fenestrated Cuffed Tracheostomy Tube:

- Cuff pressure or volume should be monitored and recorded to avoid over inflation and any associated damage
- The inflation line valve may interfere with MRI clarity. Ensure that the valve is positioned away from the area being scanned.

USE OF THE BLOM TRACHEOSTOMY TUBE AND BLOM STANDARD CANNULA

Preparation

1. Selection of the appropriate device size is left to the discretion of the physician.
Note: With morbidly obese patients or patients with neck edema, the skin to trachea distance may render the Tracheostomy Tube too short, preventing ventilation of the patient
2. Remove the contents from the package
3. Verify the Tracheostomy Tube function and integrity. Check that the Standard Cannula can be inserted and removed and is not damaged. Check that the Obturator can be inserted and removed and is not damaged.

If using the Fenestrated Cuffed Tracheostomy Tube:

4. Check the integrity of the cuff by inflating and deflating it prior to insertion
5. Lubricate with a water soluble lubricant, by applying it to the Tracheostomy Tube and Obturator. Ensure that the lubricant does not occlude the lumen or fenestration of the tube and prevent patient ventilation.

Insertion

1. Suction the patient before insertion
2. With the Obturator, in place, insert the Tracheostomy Tube through the stoma in accordance with currently accepted medical techniques
3. Verify tube position by bronchoscopic view or chest X-ray to ensure correct placement. Incorrect placement could result in trauma to the trachea or respiratory obstruction.

If using the Fenestrated Cuffed Tracheostomy Tube:

4. Using a syringe inflate the cuff
Warning:
 - Cuff pressure should be monitored
 - If used during anesthesia, nitrous oxide may change the cuff inflation. Verify cuff volume periodically.
 - Cuff should not be inflated with a measured volume of air
 - Avoid repositioning of the tube with the cuff inflated
 - Prior to removal, deflate the cuff fully

5. Secure the Tracheostomy Tube with SoftTouch Tube Holder, Twill Tube Holder or other Tracheostomy Tube securing device. Ensure the tube is properly positioned.
6. Insert the Standard Cannula. Verify that the Standard Cannula has been securely fastened.
Warning:
 - The Standard Cannula is designed to be used only in conjunction with the Blom Tracheostomy Tube
 - The Standard Cannula is available in four sizes: #4, 6, 8, 10 and should only be used with the equivalent size Blom Tracheostomy Tube
 - Make sure the correct size has been selected. If the Standard Cannula

is too long, it may protrude from the Tracheostomy Tube causing tracheal damage or occlusion. If it is too short, it may lead to a buildup of secretions that can cause infection and/or airway obstruction. Additionally, insertion of an incorrect size inner cannula can result in inadequate ventilation due to leakage.

- Inner cannulas should be routinely checked or replaced at regular intervals to avoid blockage causing reduced lumen diameter and increased respiratory effort
 - Do not lubricate the inner cannula as lubricant may occlude the inner lumen causing airway obstruction. This may also prevent the inner cannula from being retained in the Tracheostomy Tube.
 - The Tracheostomy Tube should always be used with an inner cannula in place unless the Decannulation Plug is being used.
7. If the patient requires ventilator support, a swivel adapter may be utilized to reduce stress on the tube. Reconnect all adapters and the ventilator circuit.

USE OF THE BLOM SUBGLOTTIC SUCTIONING CANNULA

Intended Use

The Subglottic Suctioning Cannula is designed to be used only in conjunction with the Blom Fenestrated Cuffed Tracheostomy Tube. Located on the exterior surface of the cannula is a separate lumen which can be connected to intermittent or continuous suction. The Subglottic Suctioning Cannula is intended for the evacuation of secretions situated above the Tracheostomy Tube cuff.

Blom Subglottic Suctioning Cannula Directions for Use

1. The Subglottic Suctioning Cannula is available in four sizes: #4, 6, 8, 10 and should only be used with the equivalent size Blom Fenestrated Cuffed Tracheostomy Tube
2. Select the appropriate size Subglottic Suctioning Cannula
3. Suction the patient (if required) prior to removing the existing inner cannula and inserting the Subglottic Suctioning Cannula
4. Disconnect any device tubing and adapters connected to the hub of the existing inner cannula and slowly remove the cannula from the Tracheostomy Tube
5. Insert the Subglottic Suctioning Cannula into the Tracheostomy Tube. Verify that it has been securely fastened.
6. Reconnect any device tubing and adapters and insure proper functionality
7. Connect the subglottic suction line to suction tubing and regulator. Insure the thumb port valve is closed. Select intermittent or continuous suction and set the vacuum level appropriately -- continuous low pressure suction should not exceed 20 mmHg. Intermittent suction should be 100-150 mmHg.
8. Routinely monitor the suction lumen by visual inspection. Absence of secretions may indicate that no subglottic secretions are present or that the suction port has become occluded. If a blockage is suspected, a bolus of air may be injected into the suction lumen to clear the line, or the Subglottic Suctioning Cannula can be removed and replaced with a new Subglottic Suctioning Cannula. Alternately, the removed occluded cannula can be flushed with sterile water or saline and then re-inserted.
9. All inner cannulas should be routinely checked or replaced at regular intervals to avoid blockage causing reduced lumen diameter and increased respiratory effort
Warning: Never place saline or other liquids directly into the suction lumen while the Subglottic Suctioning Cannula is in the patient

USE OF THE BLOM SPEECH CANNULA

Intended Use

The Speech Cannula is designed to be used only in conjunction with the Blom Fenestrated Cuffed Tracheostomy Tube. The Speech Cannula is intended to allow ventilator dependent adults, >30kg, with a functional larynx and unobstructed upper airway, to vocalize/phonate while full cuff inflation is maintained.

Patient Requirements:

- The patient must be ventilator dependent on a standard or portable ventilator
- The patient must have a Fenestrated Cuffed Blom Tracheostomy Tube
- The patient must be arousable and have the potential to communicate
- The patient may be in volume or pressure ventilation in any ventilatory mode
- The patient does not need to be breathing spontaneously
- The patient does not need to be able to tolerate cuff deflation
- FIO₂ should not exceed 60%
- PEEP should not exceed 10
 - Warning: Patients who require PEEP should be placed on ventilators with Flow Trigger or supplemental bleed in oxygen.*
- The patient should not have copious, thick secretions requiring suctioning more than five times per hour
- The patient should have a patent, unobstructed upper airway
 - Warning: A partially or completely obstructed upper airway will result in increased airflow resistance and work of breathing for the patient, which may cause further medical complications*
- The patient must first be evaluated and monitored by a qualified healthcare professional when trying the Speech Cannula for the first time to ensure patient safety and proper use of this device. Each person involved with the care and use of this device requires appropriate training to ensure patient safety. These Directions for Use along with hands-on training should be completed.
- The recommended duration of use for the Speech Cannula is as tolerated by the patient
- Use under qualified supervision only. If the Speech Cannula were to become occluded the intrathoracic pressure will rise to a degree governed by the pressure-limiting features of the ventilator.
- The Speech Cannula has a series of valves which if obstructed could prevent phonation or be occluded like an inner Standard Cannula with secretion blockage. If the ventilator's high pressure limit alarm continuously sounds, remove the Speech Cannula.

Blom Speech Cannula Directions for Use

1. The Speech Cannula is available in four sizes: #4, 6, 8, 10 and should only be used with the equivalent size Blom Fenestrated Cuffed Tracheostomy Tube
2. Ensure that an Exhaled Volume Reservoir (EVR) is in the appropriate location in the circuit. For proper locations, see Directions for Use provided for the EVR.
3. Baseline heart rate, respiratory rate, oxygen saturation and ventilator parameters should be noted prior to use and during use of the Speech Cannula
 - Suggestion: Prior to inserting the Speech Cannula, use the Subglottic Suctioning Cannula to confirm NO upper airway obstruction by blowing air into the suction port to provide air to the mouth for verification.*
4. Select the appropriate size Speech Cannula

5. Suction the patient (if required) prior to removing the existing inner cannula and inserting the Speech Cannula
6. Disconnect any device tubing and adapters connected to the hub of the existing inner cannula and slowly remove the cannula from the Tracheostomy Tube

Warning: The Speech Cannula should be used under qualified supervision only

Note: With the Speech Cannula, during the inhalation cycle the Peak Pressures as measured at the ventilator show a higher value; but the actual delivered, intra-pulmonary peak pressures are at the clinically expected values

7. Insert the Speech Cannula and ensure that it is securely fastened
8. Reconnect any device tubing and adapters to the hub of the Speech Cannula
9. Confirm proper function by observing airflow exiting the patient's mouth and nose on EACH expiration and/or requesting the patient to phonate
 - Warning: If the Speech Cannula is obstructed, it may be occluded with secretions. If the ventilator alarms, investigate the alarm, assess the problem, and if necessary, remove the Speech Cannula.*
10. After use of the Speech Cannula, remove it and remove the EVR from the ventilator circuit
11. Insert a new Standard Cannula or Subglottic Suctioning Cannula and ensure that it is securely fastened
12. Reconnect any device tubing and adapters to the hub of the inner cannula
13. After use, the Speech Cannula should be cleaned, air dried and stored in the supplied container. The maximum recommended period of use for the Speech Cannula is 60 days. See Cleaning Instructions.

USE OF THE EXHALED VOLUME RESERVOIR (EVR)

Intended Use:

The EVR is designed to be used only in conjunction with the Blom Fenestrated Cuffed Tracheostomy Tube and Speech Cannula. The EVR is to be inserted into the ventilator circuitry to impede the function of the low exhaled tidal/minute volume alarm during the use of the Speech Cannula. The EVR is intended to deliver a reduced volume of air to the ventilator monitoring apparatus to fulfill the requirements of the low exhaled tidal/minute volume alarm setting when this parameter is synchronized at the minimum level.

EVR Position in the Circuit:

For Ventilators which measure exhaled volumes at the machine:

Install the EVR at the end of the expiratory limb of the circuit just prior to the exhalation inlet port

For volumes which are measured via a proximal flow sensor:

Install the EVR between the flow sensor and the patient

EVR Directions for Use:

1. The low exhaled tidal/minute volume alarm must be set to the lowest possible active position when using the EVR
2. During the inspiratory phase of the ventilator, a small portion of gas fills and expands the bellows of the EVR (approximately 30-50ml)
3. When the ventilator cycles to the expiratory phase, the bellows contracts and the volume of gas is then returned to the ventilator for measurement. This will diminish

the amount of “nuisance” alarms that may occur during the use of the Speech Cannula thus allowing the practitioner to reduce the low exhaled tidal/minute volume alarm threshold instead of completely disabling it and the ability of the ventilator to warn of disconnects.

4. In the event of a disconnection in the circuit, the EVR will not prevent the low exhaled tidal/minute volume alarm from sounding
5. The EVR should be removed from the circuit after use of the Speech Cannula.
Warning: It is recommended that the EVR is removed from the patient circuit during use of a Standard Cannula as it may add deadspace depending on its location in the circuit. It can be left in place if approved by a healthcare professional and can be tolerated by the patient
6. After removing the EVR from the circuit, return the low exhaled tidal/minute volume setting to the appropriate level.

USE OF THE BLOM LOW PROFILE VALVE (LPV)

Intended Use

The LPV is designed to be used only in conjunction with the Blom Fenestrated Cuffed or the Blom Non-Fenestrated Uncuffed Tracheostomy Tube. The LPV is a normally closed one-way valve that is placed inside the Blom Tracheostomy Tube and is intended to allow the tracheostomized, non-ventilator dependent patient, the ability to speak. During inspiration, the valve opens allowing air to flow into the lungs. During exhalation, the valve is closed and the airflow is redirected to the upper airways enabling speech. The LPV should not be used in conjunction with mechanical ventilation, or with patients whom have upper airway obstructions.

Blom LPV Directions for Use:

1. The LPV is available in four sizes: #4, 6, 8, 10 and should only be used with the equivalent size Blom Tracheostomy Tube
2. Assess the patient prior to insertion. Assessment should include - respiratory rate, oxygenation, heart rate, breath sounds, work of breathing, airway patency, secretion status, and patient’s mental condition.
3. Select the appropriate size LPV
4. Perform tracheal and oral suctioning (as required) prior to insertion of the LPV

If using a Blom Fenestrated Cuffed Tracheostomy Tube:

5. Deflate the Tracheostomy Tube cuff and repeat suctioning as required
Note: Since the Blom Tracheostomy Tube is a fenestrated tube the need for cuff deflation is not required; however the patient’s work of breathing may be increased if the cuff is left inflated.
6. Remove the inner cannula (if present) and insert the LPV into the Tracheostomy Tube. Insure that the LPV is securely connected to the Tracheostomy Tube.
7. Observe and monitor the patient for adequate airflow and any change in vital signs. If the patient develops respiratory distress, immediately remove the LPV and reassess the patient for airway obstruction/patency.
8. Oxygen and/or humidity may be added via a mask or trach collar. Medication aerosols may also be delivered without removing the LPV.
9. It is not necessary to remove the LPV for suctioning. An appropriately sized suction catheter may be easily passed bi-directionally through the valve.
10. The LPV does not have a standard 15mm hub connector and therefore will not attach to a ventilator circuit or manual resuscitator. A Standard or Subglottic Suctioning Cannula of the correct size should be readily available in case the

use of a 15mm connector is needed.

11. After use, the LPV should be cleaned, air dried and stored in the supplied container. The maximum recommended period of use for the LPV is 60 days. See Cleaning Instructions.

USE OF THE BLOM DECANNULATION PLUG

Intended Use:

The red Decannulation Plug is designed to be used only in conjunction with the Blom Fenestrated Cuffed Tracheostomy Tube and the Blom Non-Fenestrated Uncuffed Tracheostomy Tube. The Decannulation Plug occludes the proximal end of the Blom Tracheostomy Tube, requiring the patient to breathe through the fenestration (if present), around the outer diameter of the tracheostomy tube through the upper respiratory tract. The Decannulation Plug is intended to assist in the weaning process of ventilator dependent tracheostomized patients and to determine eligibility of a patient for tracheostomy tube removal.

If using a Blom Fenestrated Cuffed Tracheostomy Tube:

Warning: Prior to inserting the Decannulation Plug make sure the fenestration is not occluded, that the cuff is completely deflated and that there is a sufficient airway for adequate air movement. If the patient has difficulty breathing, immediately remove the Decannulation Plug, insert a Standard Cannula or Subglottic Suctioning Cannula and verify airway patency.

Blom Decannulation Plug Directions for Use:

1. Establish the patency of the patient’s upper airway tract. The patient’s airway should be cleared by coughing and/or suctioning before using the Decannulation Plug.

If using a Blom Fenestrated Cuffed Tracheostomy Tube:

2. Completely deflate the cuff of the Tracheostomy Tube
3. Remove the inner cannula
4. Attach the Decannulation Plug to the Tracheostomy Tube. Verify that it has been securely fastened.
5. The maximum recommended period of use for the Decannulation Plug is 24 hours or according to local established protocols.

CLEANING INSTRUCTIONS

These cleaning instructions only apply to the Blom Speech Cannula and the Blom LPV.

Daily, intermittent use:

1. During daily intermittent use, the Blom Speech Cannula and the Blom LPV should be rinsed with warm water or saline solution immediately after removal from the Tracheostomy Tube and allowed to thoroughly air dry before using again. *Do not apply heat to dry*

Overnight or prolonged storage:

1. When removing for overnight or prolonged (more than 8 hours) storage, swish the Speech Cannula or the LPV in pure, fragrance-free soap and warm (not hot) water
2. Rinse the Speech Cannula or LPV thoroughly in warm running water
3. Allow to air dry thoroughly before placing in the storage container. *Do not apply heat to dry.*
4. **DO NOT USE HOT WATER, PEROXIDE, BLEACH, VINEGAR, ALCOHOL, BRUSHES OR COTTON SWABS TO CLEAN THE SPEECH CANNULA OR THE LPV**