A Unique New Tracheostomy Tube System

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Disclosure Statement

In compliance with the American Academy of Otolaryngology-Head and Neck Surgery Foundation and with the Accreditation Council for Continuing Medical Education’s “Standards for Commercial Support of Continuing Medical Education”, Eric D. Blom, Ph.D. Discloses his commercial relationship with Pulmodyne, Indianapolis, Indiana in the form of royalties paid for patent and trademark licenses on the Blom Tracheostomy Tube System products.
Blom Tracheostomy Tube System

INTENDED USE:

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

- Airway protection
- Subglottic Suctioning
- Communication
- Cost Effective
Blom Tracheostomy Tubes

Fenestrated Cuffed Tracheostomy Tube – for ventilator dependent patients

Non Fenestrated Uncuffed Tracheostomy Tube – for spontaneously breathing patients
Concerns regarding current fenestrated tubes:

- Potential for granuloma formation
- Occlusion by anterior trachea tissue
- Sharp fenestration edges
Blom Fenestrated Cuffed Tracheostomy Tube

- Modified fenestrated outer cannula
- Fenestration location is close to the cuff

Helps prevent posterior wall contact

Helps prevent occlusions by anterior trachea tissues
Fenestration

- Rounded, smooth edges
  - Prevents tissue irritation

- Larger in diameter
  - Allows increased airflow and decreased resistance during exhalation

- Bar
  - Adds support
  - Prevents suction catheter from going through the fenestration
Neck Plate

Imprinted:
- Manufacturer or product name
- Size
- ID & OD of cannula
Concerns regarding current methods of securing inner cannula to the outer cannula

- Patient discomfort
- Difficult to connect and disconnect inner cannulas
Telephone Jack Clips

- Secures inner cannula to the outer cannula
- Distinct “click” to ensure cannula is locked in place
- Minimal effort to secure the cannula
Blom Unique Inner Cannulas

- Standard
- Subglottic Suctioning Cannula
- Speech
- LPV™ (Low Profile Valve)
Subglottic Suctioning Cannula
Fighting VAP

- **Ventilator-Associated Pneumonia**
  - A sub-type of *hospital-acquired* pneumonia which can occur in people who are on mechanical ventilation through an endotracheal or tracheostomy tube for at least 48 hours
  - Increases mortality rate and hospital stay time for patients in the ICU
Concerns regarding current subglottic suctioning tubes:

- Many tracheostomy tubes utilized do not have subglottic suctioning feature
- Traditional subglottic suctioning difficult and uncomfortable for patient
  
  Suction line is on the exterior of the outer cannula
- Blockage requires complete change of tracheostomy tube
- Flush while still in the patients airway: not approved practice by some manufacturers
Blom Subglottic Suctioning Cannula

- Provides secretion management for Trach patients
- Can assist in the fight against VAP – studies have shown proximal suctioning helps reduce VAP (see studies under tab 11)
- Small suction line on the outer surface of the inner cannula
- Suction line terminates at the lower portion of the fenestration, directly above the cuff
How it Works

• Continuous low suction at 20 mmHg (millimeters of Mercury)
• Suction on high flow applied intermittently, 100-150 mmHg using a suction regulator capable of intermittent, timed on/off cycles
Comparison

Blom Subglottic Suctioning Cannula:
- Suction line on outside of inner cannula
- Cannula is easily removed and flushed
- Or, removed and discarded
- May also be attached to an air source of 8 to 12 lpm to verify the upper airway patency of patient prior to use of the Speech Cannula

Other subglottic suctioning devices:
- Suction line on the exterior of the outer cannula
- Entire tube must be removed and replaced
- Flush while still in the patients airway: not approved practice by some manufacturers
Speech Cannula
Concerns regarding some of the current speech products available:

- Limited airflow for speech
- Inability to produce adequate subglottic pressure for speech
Blom Speech Cannula

- Used only with Blom Fenestrated Cuffed Tracheostomy Tube
- Intended for ventilator dependent patients
- Allows cognitive patients with an intact unobstructed upper airway to speak
- No cuff deflation required (diminishes risk of aspiration)
- Silicone with parylene coating
  - Smooth finish for easy insertion
  - Reduces potential areas for infection
- USE UNDER QUALIFIED SUPERVISION ONLY
Speech Cannula Features

- Bubble Valve
- Flap Valve
- Warning label
How it Works

**Inhalation**
- Bubble Valve Expands
- Flap Valve Opens
- Air delivered to lungs

**Exhalation**
- Flap Valve Closes
- Bubble Valve Collapses
- Air goes through fenestration to vocal cords allowing phonation
Patient Videos
IMPORTANT!

- In a respiratory distress/arrest situation:
  - Immediately remove the Speech Cannula and replace with a Standard or Subglottic Suctioning Cannula
    - Fenestration could be occluded
    - Could be a valve malfunction
Speech Cannula Recap

Benefits

- Allows patients who cannot tolerate cuff deflation the ability to vocalize
- Decreased risk of aspiration since cuff remains inflated
- More natural speech. Vocalization takes place during exhalation.
- Positive subglottic pressure may assist in swallowing and secretion management
Exhaled Volume Reservoir (EVR™)
EVR

- Prevents the occurrence of “false” low expiratory minute volume alarms which occur when the Blom Speech Cannula is in use and air is redirected through the upper airway during exhalation (instead of back to the ventilator)
- Compatible with most positive pressure ventilators
EVR

- Composed of a small silicone bellows system which attaches to a tee piece with a standard 22mm ID connection on one end, and a 15/22mm ID connector on the other
Placement

Machines that measure exhaled volume at the machine – install at the end of the expiratory limb of the circuit prior to the exhalation inlet port of the ventilator

Machines that measure exhaled volume via a proximal flow sensor – install between the flow sensor and the patient
EVR

Upon placement:
   The low exhaled tidal/minute volume alarm must be set to the lowest possible active position when using the EVR

After use of the Speech Cannula:
   The EVR should be removed from the circuit and ventilator alarms returned to original settings
LPV
Concerns regarding current speaking valves available:

- Typically used with deflated cuff
- High profile
- Risk of cardio pulmonary complications if used inappropriately
Blom Low Profile Valve (LPV™)

- Use with Blom Non-Fenestrated Uncuffed or Fenestrated Cuffed Tracheostomy Tube for spontaneously breathing patients
- One-way Valve
  - Fits in outer cannula
  - For non-ventilator dependent patients
  - Cuff may be inflated, partially deflated or fully deflated
LPV

- Should not be used with mechanical ventilation
- Patients can not have upper airway obstruction
- Patient must be fully awake, remove during sleep
- Unlike other speaking valves, **does not** require cuff deflation
- Does not increase the risk of cardio pulmonary complications if caregiver fails to deflate the trach cuff
IMPORTANT!

- The LPV does not have a standard 15mm hub connector and 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.
LPV Recap

LPV
- Fits in the outer cannula
- Low profile
- Works regardless of cuff inflation level

Other speaking valves
- Sits on the 15mm hub of the inner cannula
- High profile
- Typically, cuff must be fully deflated
Other Components

- Obturator
- Standard Cannula
- Decannulation Plug
- SoftTouch™ Tube Holder
Periods of Use

Tracheostomy Tubes – *up to 30 days*

Standard Cannula, Subglottic Suctioning Cannula and Decannulation Plug – 24 hours or according to local established protocol

Speech Cannula and LPV – *up to 60 days*
Available in 4 adult sizes:

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Available as:

- Blom Tracheostomy Tube Kits

  - Fenestrated Cuffed Tube
  - Non-Fenestrated Uncuffed Tube
  - Obturator
  - Standard Cannula
  - Decannulation Plug
  - Twill Tie
Available as:

- **Individual Components**
  - Standard Cannula
  - Subglottic Suctioning Cannula
  - Speech Cannula
  - LPV
  - EVR
  - Decannulation Plug
  - SoftTouch Tube Holder
XLT Tracheostomy Tube With...

- Standard Inner Cannula
- Suction Inner Cannula
- Speech Inner Cannula
- Low Profile Speaking Valve
Two Series of Blom Tracheostomy Tubes

1.) Rigid type material (like Shiley)

2.) Soft type material (like Portex)
Company – Specific Ventilator
Settings when using the Speech Cannula

(see Pulmodyne website)

- Drager Evita
- LTV 100
- PB 760 and 840
- Trilogy 100 and 200
- Servo I and 300A
- Respironics Espirit
- Maqet