

Guidelines for Use

Portex® Bivona® Fome-Cuf® Tracheostomy Tubes

IMPORTANT: Please refer to the *Instructions for Use* supplied with the product for detailed instructions, warnings, and cautions.

Novation

Agreement MS30042

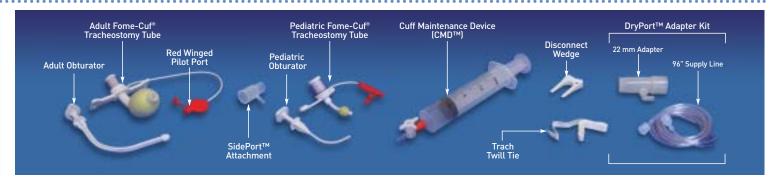
Fome-Cuf® tracheostomy tubes incorporate an auto-expanding foam cuff which conforms to the unique contours of each patient's tracheal anatomy, providing a low cuff-to-tracheal wall sealing pressure throughout the ventilatory cycle.

The cuff volume and pressure are inversely related. As the cuff expands, the volume of air inside the cuff increases while the pressure exerted by the foam decreases.

(Fome-Cuf® also available in endotracheal tube configurations.)

Components:

Use only the supplied 60 cc CMD™ device with attached 3-way stopcock.



Insertion:



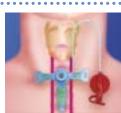
Push the plunger of the Cuff Maintenance Device (CMD™) all the way in and align the stopcock to the "9 o'clock" position.



Attach the CMD™ device to the red winged pilot port and evacuate the contents of the cuff. Note the "dimple."



3 Pinch the pilot port with your fi remove the CMD™ device, and plug the port with the stopper cap. The cuff should remain deflated for insertion



Insert the Fome-Cuf® tracheostomy tube into the patient's trachea.

DO NOT inject air or liquids into the cuff.



Open the stopper cap of the red winged pilot port. NEVER plug or clamp the red pilot

port when the tube

is in the patient.

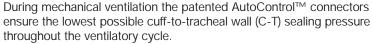


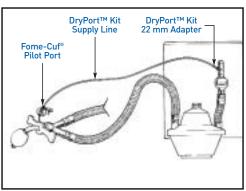
passively expand. Leave port open or refer to AutoControl™ Set-Up. NEVER occlude Fome-Cuf® tube with

a one-way valve.

AutoControl™ Set-Up **Options:**

For high frequency jet or oscillation ventilation, leave pilot port open to atmosphere.



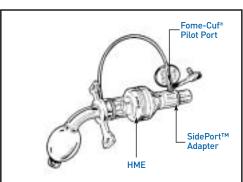


DryPort™ Configuration

1. Connect one end of the oxygen supply tubing provided with the DryPort™ Kit to the pilot port of the Fome-Cuf® trach tube

2. Connect the other end of the tubing to the port on the multiaccess adapter.

3. Connect the multiaccess adapter to the ventilator outlet in front of the humidifier.



DryPort™ with HME Configuration

1. Connect the Fome-Cuf® pilot port to the SidePort™ adapter. 2. Connect the SidePort™

adapter in-line between the HME and the patient wye of the ventilator circuit.

Cuff Maintenance:

Recommended to be

done once per 8 hour shift, or as needed.

Purpose of Fome-Cuf® Maintenance:

· Verify cuff integrity

Align the $\mathsf{CMD}^{\mathsf{TM}}$

the "9 o'clock"

starting position.

device stopcock to

- · Remove excess condensate from the cuff
- Measure cuff volume to alert caregiver of changes in tracheal dimensions

2 Insert the CMD™ device ***

device tip into the

Fome-Cuf® tube.

red pilot port of the



3 At the onset of ventilator and ventilator cycle, evacuate the contents of the cuff by pulling back on the plunger of the

CMD™ device until "dimple" forms.



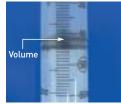
should be removed.

4 Turn stopcock to the 12 o'clock position, then remove the $\mathsf{CMD}^{\scriptscriptstyle\mathsf{TM}}$ device from the red pilot port.



NOTE: Prior to cuff maintenance, pooled secretions above the cuff

Push the plunger in to apply pressure to the trapped contents of the CMD™ device, then release.



Record the volume of 6 air remaining in the CMD™ device.

Removal:

- 1. Use the CMD™ device to evacuate the contents of the cuff. Note the "dimple" on the red pilot port.
- 2. Plug the pilot port and remove the tube.





