



## Cadence™ Transtracheal Catheter and Mid-Section Hose (22mm OD x 11mm ID)

These instructions are intended for use of the Cadence Catheter with the Cadence System. Note the following products:

Product	Part Number
Cadence™ Self-Breathing System	1015620
11.5 cm Cadence Catheter	1025010
13.5 cm Cadence Catheter	1024999
15.5 cm Cadence Catheter	1024960
Cadence Mid-section Hose	1024904

**CAUTION:** Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

**CAUTION:** The Cadence Self-Breathing System should be used only with the following cuffed fenestrated tubes: Portex Blue Line (sizes 7, 8, & 9), Shiley DFEN (sizes 6 & 8 mm), Boston Medical Tracoe Twist (sizes 6, 7, 8, & 9), Portex D.I.C. (sizes 6, 7, 8, & 9), and Portex Ultra (sizes 6, 7, 8, & 9). These tracheostomy tubes will be referenced throughout this document as “Qualified Tracheostomy Tubes”.

Two of the Qualified Tracheostomy Tubes, Boston Medical Tracoe, and Shiley, employ separate fenestrated inner cannulas with the 15 mm connector integrated into the inner cannulas. The fenestrated inner cannula, when in place, has fenestrations that line up with the fenestrations on the tracheostomy tube shaft. The Portex DIC, Ultra, and Blue Line do not require separate inner cannulas for the fenestrations to be open with a 15 mm connection available. Removal of the non-fenestrated inner cannula on these Qualified Tracheostomy Tubes is required for use with the Cadence System.

Note:

- Read all Cadence Self-Breathing System product literature, including the complete Operator’s Manual, Quick Reference Card, and Setup Guide before initial use.
- Read individual manufacturer’s Operator’s Manuals for the Cadence Self-Breathing System components before initial use. The Cadence System is intended for use by properly trained clinicians.
- The Cadence Self-Breathing System is not intended for use with endotracheal tubes.
- The Cadence Self-Breathing System is intended for use only with the Cadence Catheter and Cadence

Mid-section Hose. The Cadence Catheter and Cadence Mid-section Hose are intended for use only with the Cadence Self-Breathing System.

- The Cadence Catheter and Cadence Mid-section Hose are sold separately.
- Medical waste: Place patient used plastic products in a plastic garbage bag and throw away with garbage. Do not recycle.

### INDICATIONS FOR USE

Cadence Self-Breathing System is indicated for the treatment of hypoxemia with delivery of transtracheal high flows of a heated and humidified air/oxygen mixture to self-breathing patients with a cuff deflated fenestrated tracheostomy tube. Cadence Self-Breathing System is indicated for hospital use in adult patients.

*Review Chapter 3, “Clinical Guide” of the Cadence Self-Breathing System Operator’s Manual for information on Potential Benefits.*

### CONTRAINDICATIONS

- Recent tracheotomy or tracheotomy revision with post procedure inflammation, edema, and/or bleeding
- Severe airway obstruction which may prevent sufficient inhalation and exhalation
- Airway abnormalities that impair proper functioning of the tracheostomy tube
- Laryngectomy patients
- Tracheostomy tube oversized for patient’s trachea
- Inflated tracheostomy tube cuff
- Use of foam filled cuffed tracheostomy tube
- Significantly impaired swallow or presence of aspiration of gastric contents
- Copious uncontrolled upper airway secretions
- Significant problems with mucus plugging
- Lack of medical readiness for self-breathing trial such as:
  - High PEEP
  - High F<sub>I</sub>O<sub>2</sub> requirements
  - Severely impaired ventilatory drive
  - Respiratory muscle fatigue or paralysis
  - Unresolved disease acute phase process (infection, sepsis, bleeding)
  - Unstable post surgical condition
  - Hemodynamic instability
  - Fever
  - Significant respiratory acidosis
  - Unstable metabolic status
  - Anemia
  - Unconsciousness or delirium
  - Severe agitation and/or significant sedation requirements
  - Absence of cough reflex

*Review Chapter 3, “Clinical Guide” of the Cadence Self-Breathing System Operator’s Manual for additional information on Contraindications.*

### PRECAUTIONS

- Resolved significant upper airway obstruction
- Upper airway abnormalities with the absence of significant airway obstruction
- Neuromuscular weakness or neurologic disease
- Progressive neuromuscular disease
- Significant Auto-PEEP
- Mild to moderate anxiety, with or without minimal anxiolytic or sedation requirements
- Moderate secretions requiring periodic tracheal suctioning
- Adult with short stature

*Review Chapter 3, “Clinical Guide” of the Cadence Self-Breathing System Operator’s Manual for additional information on Precautions*

### PATIENT EVALUATION AND PREPARATION FOR CADENCE SELF-BREATHING TRIALS

Prior to initiation of Cadence Self-Breathing Trial, the clinician should be thoroughly familiar with delivering high flows of oxygen through a fenestrated tracheostomy tube. The clinician should also have thoroughly reviewed and understand all of the literature regarding the Cadence Self-Breathing System. The literature includes product labels, package inserts, the Cadence Self-Breathing System Operator’s Manual and related individual device manufacturer’s operator’s manuals comprising the Cadence Gas Delivery System as well as the Cadence Quick Reference Card, and Setup Guide. Furthermore, it is necessary for the clinician to have adequate management experience with patients with tracheostomy tubes, especially cuffed tubes and fenestrated tubes. The clinician must have experience in procedures related to tracheostomy use, such as tracheostomy tube care and exchange. Finally, the clinician must have adequate experience with tracheostomy related technology and procedures that are based upon similar principles to self-breathing therapy management, including speaking valves and decannulation procedures utilizing a tracheostomy cap with deflated cuff.

The ability of the patient to breathe through the upper airway must first be evaluated prior to self-breathing trial initiation. It is recommended that the “Deflated Cuff Tracheostomy Occlusion Procedure” (described below) be performed to evaluate airflow through the upper airway. During the procedure the patient should be on appropriate monitoring devices with a pulse oximetry monitor with heart rate display as the recommended minimum. A phonation and swallow evaluation by a speech therapist is recommended.

The “Deflated Cuff Tracheostomy Occlusion Procedure is as follows:

The patient should be on an appropriate monitoring device with pulse oximetry and heart rate display as the recommended

minimum. Following explanation and consent from the patient, the patient should be briefly removed from the ventilator, T-Piece or tracheostomy collar system with the tracheostomy cuff fully deflated. A gloved finger then briefly occludes the tracheostomy tube opening and the clinician carefully notes if breathing through the mouth and/or nose is present. The clinician should observe for objective signs of respiratory distress and encourage the patient to phonate. For patients that have not breathed through the upper airway without ventilator support for a number of weeks or months, it is relatively common for these individuals to have concern about a different breathing sensation. This should be clinically distinguished from distress due to significant upper airway obstruction. The presence of stridor, minimal or absent breath sounds upon auscultation over the upper neck, absence of airflow at the nose or mouth, supraclavicular or intercostal retractions, labored breathing, diaphoresis and a prolonged inspiratory phase are signs consistent with potential severe upper airway obstruction. Promptly remove the finger occlusion if there is absence of airflow through the upper airway or there are signs or symptoms of respiratory distress. Assure adequate oxygenation and ventilation.

Prior to beginning Cadence Self-Breathing Trials, a Qualified Tracheostomy Tube should be placed. The fenestrations are intended to facilitate self-breathing through the upper airway with free movement of gas around the tracheostomy tube and bulk of the deflated cuff. Only a Qualified Tracheostomy Tube should be used. The fenestrations are intended to facilitate self-breathing through the upper airway. Following placement of the tracheostomy tube, the cuff should be deflated, and the “Deflated Cuff Tracheostomy Occlusion Procedure” should be repeated to evaluate adequacy of airflow through the upper airway. Since the inner cannula of the fenestrated tube reduces the inner diameter as compared to a tube without an inner cannula, it should be confirmed that the inner cannula tube allows adequate ventilation on mechanical ventilation. An appropriately sized Qualified Tracheostomy Tube may be considered to increase breathing space around the tube as long as proper fit and adequate mechanical ventilation can be achieved with the inner cannula in place.

Once the appropriate tracheostomy tube has been placed, an AP portable chest radiograph is recommended to document proper positioning of the tracheostomy tube and to assist in selecting the initial Cadence Catheter. Endoscopic examination should be considered if there is any question about proper tracheostomy tube placement or potency of the fenestrations. Knowledge of the tracheostomy tube length and the distance between the tip of the tracheostomy tube and carina may guide initial catheter selection.

### SELECTION OF CADENCE CATHETER SIZE

Cadence Catheters are available with internal catheter lengths of 11.5 cm (p/n 1025010), 13.5 cm (p/n 1024999), and 15.5 cm (p/n 1024960). It is recommended that an AP portable chest radiograph with the appropriate Qualified Tracheostomy Tube in place is obtained to estimate catheter size for initial use. The radiograph should be reviewed to measure the distance from the tip of the tracheostomy tube to the carina. The optimal

placement of the tip of the Cadence Catheter is 2 to 3 cm above the carina. Utilization of radiograph measurements in estimating the initial catheter selection is discussed in *Chapter 3, “Clinical Guide” of the Cadence Self-Breathing System Operator’s Manual.* Once the initial catheter has been selected, it is also recommended that an AP chest radiograph is obtained during the initial self-breathing trial to guide selection of catheter length for subsequent use.

**WARNING:** DO NOT INITIATE CADENCE SELF-BREATHING THERAPY IF THERE IS ABSENCE OF AIR MOVEMENT AT THE MOUTH OR NOSE OR THERE IS RESPIRATORY DISTRESS WITH THE CUFF DEFLATED AND THE TRACHEOSTOMY OPENING OCCLUDED. THIS CLINICAL PRESENTATION SUGGESTS UPPER AIRWAY OBSTRUCTION. ADEQUATE VENTILATION SHOULD BE IMMEDIATELY ASSURED.

### DEVICE MONITORING DURING CADENCE SELF-BREATHING TRIALS

Though some clinical information related to the patient-device interface is presented here, this document is only a supplement to device set up and operations instructions and clinical management and monitoring recommendations found in other Cadence Self-Breathing System labeling, operations and clinical guidance product information.

The level of device monitoring and the frequency of bedside clinical assessment should be adjusted according to the specific patient needs during a particular weaning trial.

**Continuous pulse oximetry with heart rate monitoring and airway pressure monitoring are recommended as a minimum for all Cadence Self-Breathing Trials in all patients.**

Trained clinicians should be able to recognize alarms from monitoring devices and promptly present themselves to the bedside for appropriate evaluation and intervention. Patients with identified clinical precautions may require use of additional monitoring devices as well as more frequent clinical assessment. Clinical precautions, monitoring and management are discussed in Chapter 3, “Clinical Guide” of the Cadence Self-Breathing System Operator’s Manual.

**CAUTION:** When using Cadence, patients should be titrated to the lowest F<sub>I</sub>O<sub>2</sub> setting that achieves adequate oxygenation to reduce the risk of oxygen toxicity.

## Cadence™ Transtracheal Catheter and Mid-Section Hose (22mm OD x 11mm ID)

### INSTRUCTIONS FOR USE

The Cadence Self-Breathing System should be fully assembled and operational according to Cadence Self-Breathing System Operator's Manual and related individual device manufacturer's operator's manuals comprising the Cadence Gas Delivery System as well as the Quick Reference Card, and Setup Guide. The Cadence Self-Breathing System should be at the patient's bedside, along with the appropriate supplies and the selected Cadence Catheter size. Endotracheal suctioning should be available as needed. The preferred position for weaning the patient is with the head of the bed elevated. This enhances respiratory mechanics and places the patient in an appropriate position for the portable chest radiograph (previously recommended). The humidifier chamber should be adjusted on the pole so that it is below the level of the patient's bed. This will reduce the potential for inadvertent gravitational drainage of water or water condensate into the patient's airway.

Prior to initiating Cadence Self-Breathing System, note warnings and cautions and notes attached to the products and accompanying product literature.

**WARNING** labels are attached to the Cadence Mid-section Hose and the Cadence Catheter pouch stating that the tracheostomy cuff must be deflated prior to Cadence Self-Breathing Trial initiation and stating that the Cadence Catheter must be fully removed prior to inflating the tracheostomy tube cuff at the termination of the Cadence Self-Breathing Trial.

A **CAUTION** label is affixed to the blender knob alerting the clinician to keep the Cadence Self-Breathing System below the 77% setting to reduce the risk of oxygen toxicity.

The following are recommended steps in the initiation of the Cadence Self-Breathing Trial:

1. Universal Precautions should be employed when using the Cadence Self-Breathing System.
2. Properly power up the Cadence Gas Delivery System. Position the Cadence Gas Delivery System so that all sides are a minimum of 12 inches away from a wall or any obstruction. Do not place the device in a confined area.
3. Position the Cadence Catheter on the bedside stand and partially open the package so easy access to the Catheter can be obtained.
4. The blender F<sub>I</sub>O<sub>2</sub> may be analyzed with a calibrated oxygen analyzer to ensure proper delivered F<sub>I</sub>O<sub>2</sub>.
5. Using the clip on the Cadence Mid-section Hose, secure the Hose to the patient gown.

6. Perform tracheal suctioning, as necessary, then FULLY DEFLATE TRACHEOSTOMY TUBE CUFF.
7. Need for additional suctioning should be addressed once the tracheostomy tube cuff is fully deflated. The 15 mm ventilator circuit connector can then be quickly removed from the tracheostomy tube. The non-fenestrated inner cannula of the fenestrated tube should be promptly removed and managed as per manufacturer recommendations. Where appropriate for the Qualified Tracheostomy Tube design, insert a fenestrated inner cannula.

**WARNING:** THE TRACHEOSTOMY TUBE CUFF MUST BE COMPLETELY DEFLATED BEFORE INSERTION OF THE CADENCE CATHETER. THE PATIENT WILL BE UNABLE TO BREATHE IF CUFF IS NOT COMPLETELY DEFLATED.

**CAUTION:** The non-fenestrated inner cannula of the fenestrated tracheostomy tube must be COMPLETELY REMOVED before inserting the Cadence Catheter. The fenestrations are occluded when the non-fenestrated inner cannula is in place. Where appropriate for the Qualified Tracheostomy Tube design, insert a fenestrated inner cannula.

10. Fully open the Cadence Catheter pouch, removing the catheter. The Cadence Catheter can then be inserted with a gloved hand through the tracheostomy tube and into the trachea. Gently twirling in a circular fashion may facilitate insertion. If the catheter can not be easily passed, apply a small amount of water soluble jelly and try again. If the catheter still does not easily pass, reinsert the non-fenestrated inner cannula, place the patient back on mechanical ventilation, properly inflate the cuff and monitor the patient's status. Evaluate for possible causes for difficulty in catheter insertion and consider another trial if cause or causes are identified and resolved. **DO NOT FORCE** the Cadence Catheter into position.

**CAUTION:** DO NOT INSERT the Cadence Catheter into the tracheostomy tube with the catheter connected to the Cadence Mid-section Hose and Cadence Self-Breathing System. No flow should be going through the catheter while inserting the Cadence Catheter into the tracheostomy tube.

11. Once the Cadence Catheter is properly inserted, the Cadence Catheter connector should be promptly attached to the 15 mm tracheostomy tube connector. The 11 mm connector of the Cadence Mid-section Hose is then attached to the 11 mm connector on the Cadence Catheter. Previously set flow, oxygen concentration and heat and humidity should now be flowing into the patient's trachea.

Adjustments in flow may be required for patient comfort and tolerance. For example, patients experiencing excessive cough or discomfort on initiation of Cadence flow may benefit from initial reduction in flow (and appropriate adjustments in F<sub>I</sub>O<sub>2</sub>). Additional clinical management of cough or discomfort associated with initiation of Cadence is discussed in Chapter 3, "Clinical Guide" of the Cadence Self-Breathing System Operator's Manual.

12. Once the Cadence Catheter is properly inserted and flow is initiated, remove the luer cap from the Cadence Catheter sideport. Promptly attach the patient end of the airway pressure monitor tubing to the female luer sideport on the Cadence Catheter. The alarm pressure limit should be adjusted to alarm at a peak pressure value selected by the clinician. Refer to the Patient Monitoring Section of the Clinical Guide for recommendations on device monitoring and clinical assessment at the bedside.
13. Ensure that the airway pressure monitor tubing is attached to the back of the airway pressure monitor in the appropriate port. Ensure that the remote monitoring alarm is functional.

Note the following regarding airway pressure monitoring:

- The airway pressure monitor measures pressure within the tracheostomy tube lumen, and does not directly measure pressure within the trachea.
- The airway pressure monitor does not measure pressure within the Cadence Gas Delivery System.
- The airway pressure monitor is intended to alarm when a peak pressure within the tracheostomy tube lumen is exceeded. The peak pressure threshold is set by the clinician and the monitor does not limit the pressure delivered to the patient airway.

**CAUTION:** An airway pressure monitor alarm requires immediate attention for clinical assessment and appropriate intervention.

14. Delivered F<sub>I</sub>O<sub>2</sub> should be adjusted as required by pulse oximetry and analyzed as needed to the lowest setting that achieves adequate oxygenation and reducing the risk of oxygen toxicity. During Cadence Self-Breathing Trials a portion of the patient's minute volume is composed of room air which is breathed through the upper airway. Consequently, the blender oxygen concentration setting may be higher than the F<sub>I</sub>O<sub>2</sub> of the total minute alveolar volume that the patient inspires.

Adjustments in delivered flow may require adjustments in delivered oxygen concentration (F<sub>I</sub>O<sub>2</sub>) to meet oxygen saturation requirement.

**CAUTION:** There is potential for acute lung injury from oxygen toxicity to occur. The total inspired oxygen concentration should be evaluated. Total inspired oxygen concentrations of an F<sub>I</sub>O<sub>2</sub> greater than 0.50 (50%) are considered to subject a patient to risk of oxygen toxicity.

15. Observe the patient for any signs or symptoms of distress and observe monitors for values such as oxygen saturation (S<sub>p</sub>O<sub>2</sub>), heart rate and peak airway pressures (See Chapter 3, "Clinical Guide" of the Cadence Self-Breathing System Operator's Manual for information on monitoring and management).

### ADDITIONAL PATIENT-DEVICE CONSIDERATIONS

Airway pressure, oximetry, and heart rate alarms warrant immediate clinical assessment and patient intervention. Similarly, activation of the pressure relief valve requires immediate clinical assessment and intervention. Refer to the Cadence Self-Breathing System Operator's Manual for further information on measures to assess and resolve issues related to Cadence System components.

Note:

- The pressure relief valve reflects pressure within the Cadence Self-Breathing System. It is not intended to directly respond to patient airway pressures.
- The pressure relief valve does not have an audible alarm. The airway pressure monitor is designed to alarm in the presence of an excessive peak airway pressure.

**CAUTION:** Upon activation of pressure relief valve or airway pressure monitor alarm, immediately assess the patient for adequacy of self-breathing. If unable to resolve the cause of pressure buildup in the patient or the Cadence Self-Breathing System promptly discontinue Cadence and assure adequate ventilation.

**CAUTION:** If inadequate oxygen saturation is present or there are signs or symptoms of respiratory compromise, promptly discontinue therapy and assure adequate ventilation and oxygen administration.

### DISCONTINUING THE CADENCE SELF-BREATHING TRIAL

1. Ensure that mechanical ventilator is operational and adjusted to proper settings at the patient bedside.
2. Disconnect the patient from the Cadence Self-Breathing System and flow by removing the Cadence Mid-section Hose from the Cadence Catheter.
3. Fully detach the Cadence Catheter from the tracheostomy tube connector and discard the Cadence Catheter in the appropriate biohazard waste container.

4. Where appropriate for the Qualified Tracheostomy Tube design, remove the fenestrated inner cannula. Promptly reinsert the appropriate non-fenestrated inner cannula, place the patient back on mechanical ventilation and appropriately inflate the tracheostomy tube cuff.
5. Monitor and manage the patient as prescribed.

**WARNING:** WHEN DISCONTINUING THE CADENCE SELF-BREATHING TRIAL FOR ANY REASON, DO NOT INFLATE THE TRACHEOSTOMY TUBE CUFF UNTIL THE CADENCE CATHETER IS COMPLETELY REMOVED.

The disposable components of the Cadence Self-Breathing System should be discarded and disposed of according to the following schedule:

Disposable Component	Scheduled Change
Cadence Mid-section Hose	7 days
Cadence Catheter	24 hours or after each self-breathing trial that is less than 24 hours in length
2' Oxygen tubing	7 days
Pressure Relief Valve with nipple adaptor	7 days
Pressure Monitor Pressure tubing	7 days
Humidification Chamber	30 days
6' 15mm heated circuit	30 days
Qualified Tracheostomy Tubes (See front page for list)	According to manufacturer's recommended guidelines

Manufactured For:  
Respironics California, Inc.  
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