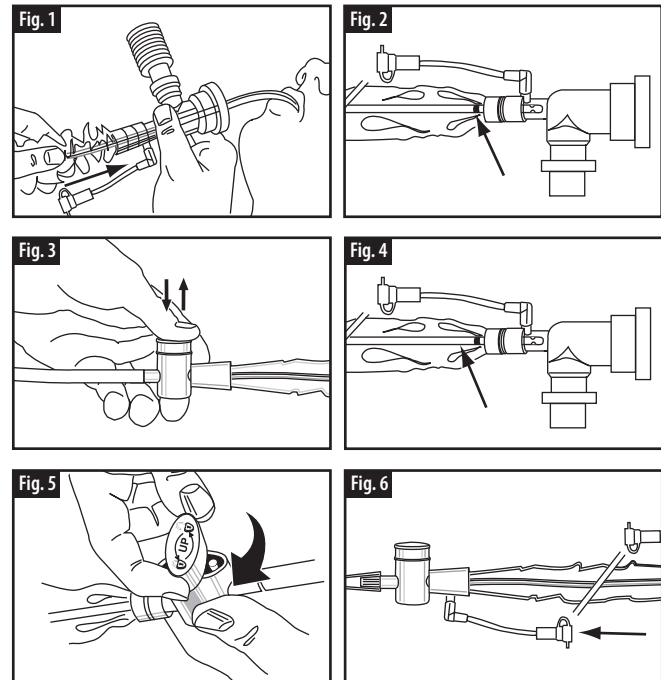


BALLARD® TURBO-CLEANING CLOSED SUCTION SYSTEM FOR ADULTS



Instructions for Use

Rx Only: Federal (USA) law restricts this device to sale by or on the order of a physician.

These instructions apply to the following families of BALLARD® products:

- Double Swivel Elbow
- T-Piece
- BALLARD® Turbo-Cleaning
- Regular Elbow
- WET PAK®

These instructions also apply to the following configurations of the above families of products:

- Dual Lumen
- Tracheostomy Length
- Metered Dose Inhaler Adapter
- Directional Tip

⚠ Warning:

- Cap on BALLARD® T-Piece prevents continuous flow therapy. Remove cap before starting continuous flow therapy. Failure to remove cap prior to continuous flow therapy may result in serious injury or death.**
- Do not trim or cut the endotracheal tube (not supplied) while the BALLARD® Turbo-Cleaning Closed Suction System is attached, otherwise the BALLARD® catheter may also be cut and that portion of the catheter may be aspirated into the lower respiratory tract of the patient and may cause death or serious injury.**
- Do not reuse, reprocess, or resterilize this medical device. Reuse, reprocessing, or resterilization may 1) adversely affect the known biocompatibility characteristics of the device, 2) compromise the structural integrity of the device, 3) lead to the device not performing as intended, or 4) create a risk of contamination and cause the transmission of infectious diseases resulting in patient injury, illness, or death.**

⚠ Cautions:

The following cautions apply to all BALLARD® products, as indicated:

- Inspect BALLARD® catheter package before opening. Do not use product if packaging has been

- compromised. Non-sterile contents may cause infection.
- Excess fluid in heat and moisture exchanger (HME) may increase gas flow resistance. When introducing fluid into T-Piece, ensure that fluid does not enter HME.
- Always place the thumb valve in the locked position when not in use to prevent inadvertent activation.
- Single patient use only.
- BALLARD® Turbo-Cleaning catheters are intended to be used for 72 hours before changing. Change more frequently if catheter becomes heavily soiled during use.
- Remove red wedge plug from BALLARD® Turbo-Cleaning prior to use.
- Inspect sodium chloride vial prior to opening. Do not use product if vial has been compromised. Compromised contents may cause infection.
- Do not use 54 cm (21.3 inch) catheters on tracheostomy patients. Mucosal damage may result.
- Select the appropriate size BALLARD® catheter. Most experts suggest that the catheter selected should occupy no more than one half of the internal diameter of the artificial airway.
- Do not leave the catheter within the airway. Always pull back until the black stripe is visible within the sleeve. Any catheter left extended into the airway will cause increased airway resistance.
- Use appropriate regulated vacuum levels. Most experts suggest -80 to -120 mm/Hg (-10.7 to -15.9 kPa).
- Use appropriate suction technique. Most experts suggest that the entire suction procedure should last no longer than 10 to 15 seconds and that actual duration of negative pressure should be no longer than 5 to 8 seconds per episode.
- Always use caution and good clinical judgement no matter what ventilator mode is in use. If the clinician notes any signs of suction intolerance such as oxygen desaturation, negative ventilator system pressures, patient stress or excessive discomfort, adjustments to the ventilator settings may need to be made. These

adjustments (please refer to the ventilator's instructions for use) may include manipulation of the inspiratory trigger sensitivity, inspiratory volume or flowrate, and selection of a different ventilator mode; or may require the use of an alternate suction technique. Failure to follow the above precautions may increase the risk of positive and negative barotrauma.

These instructions apply to the following families of BALLARD® products:

- Double Swivel Elbow
- T-Piece
- BALLARD® Turbo-Cleaning
- Regular Elbow
- WET PAK®

Setup:

- Select appropriate size BALLARD® Turbo-Cleaning catheter.
- Attach thumb control valve to suction tubing.
- Depress and hold thumb valve and simultaneously adjust vacuum regulator to desired level.
- Release thumb control valve and attach BALLARD® catheter between patient and the ventilator circuit.

Suggested Suction Procedure:

- Stabilize BALLARD® catheter and endotracheal (ET) adapter with one hand then push the catheter into the endotracheal tube with the thumb and forefinger of the opposite hand (Fig. 1).
- Advance catheter to desired depth.
- Depress and hold thumb control valve, then gently withdraw catheter. Stop withdrawal when black marking ring is visible inside sleeve (Fig. 2).
- Release thumb control valve.
- Repeat steps 1 through 4 above as necessary.

Patient Lavage Instructions:

- For intubated patient, advance catheter 10-13 cm (4-5 inches) into the endotracheal tube. For tracheostomy patient, advance the catheter 3-4 cm (1.5-2 inches) into the tracheostomy tube.
- Instill desired amount of fluid into the lavage port.
- Advance catheter to desired depth and follow the above suggested suction procedure.

Catheter Irrigation Instructions:

- Be sure that the black ring is visible inside the sleeve (Fig. 2). Open cap on the irrigation port.
- Insert saline vial (REF 116) into irrigation port.
- Intermittently depress and release thumb valve (Fig. 3) until the catheter and chamber are clear (Fig. 4), or until the vial is empty.
- Lift and turn the thumb valve lock.

Control Depth Suction

(Catheters printed with numerical markings only):

- Align any printed depth number on the catheter with the similar number printed on the endotracheal tube, or observe the printed number on the endotracheal tube closest to the endotracheal tube adapter.
- Add 8 cm to this number.
- Advance catheter until the sum (depth plus 8) appears in the window directly across from irrigation port connector.
- Catheter tip will be within 1 cm of the end of the artificial airway.

Thumb Control Valve Operation:

- The thumb control valve can be locked to prevent inadvertent or accidental suction. To lock, lift white part of thumb control valve and rotate 180 degrees. To unlock, repeat this action (Fig. 5).

Day Sticker Usage:

- Apply the appropriate day sticker to the thumb control valve. Example: If BALLARD® Turbo-Cleaning catheter is opened on Monday, place the Thursday sticker on the thumb control valve.

WET PAK® Saline Vial Instructions for Use:

- Twist top to remove.
- Insert vial into irrigation valve port.
- Intermittently depress and release thumb valve (Fig. 3) until the catheter and chamber are clear (Fig. 4) or until vial is empty.
- Discard properly after use.

These instructions also apply to the following configurations of the above families of products:

- Dual Lumen
- Directional Tip
- Tracheostomy Length

Metered Dose Inhaler Adapter

Dual Lumen:

- For lavage, advance the catheter to desired depth and instill fluid at the lavage port located nearest the thumb control valve (Fig. 6).
- Perform the suction procedure as previously indicated.
- Rinse the catheter according to the previously mentioned catheter instructions. Use the port located nearest the patient.

Directional Tip Procedure:

- For optimal catheter directional control, tracheostomy or endotracheal tube should be positioned 4-5 cm above carina.
- Radiopaque green line indicates the direction the catheter tip will follow.
- Direct the catheter into the desired side by keeping the green line oriented toward the desired side.

Tracheostomy Patients:

- Use tracheostomy 30 cm (12 inch) catheters for patients with tracheostomy artificial airway only. If 30 cm catheter is used on endotracheal artificial airway, ineffective suction may result.
- Do not use 54 cm (21.3 inch) catheters on tracheostomy patients. Mucosal damage may result.

Metered Dose Inhaler (Adapter Only):

- Remove cap on port and attach canister. Use care to avoid discharge of canister when connecting.
- Hold canister in vertical position. Depress canister during, or just prior to inspiration cycle. Repeat as prescribed by physician or protocol.
- Remove canister and replace cap on port.

End Tidal CO₂ Monitor Connection:

- Predetermine appropriate tubing for attachment to luer fitting.
- Remove luer cap and attach tubing from CO₂ analyzer tubing to begin sampling.

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Interval volume	Diameter	Length	Single use only	STERILE R	Do not use if package is damaged	Do not resterilize	Not made with natural rubber latex	Product is NOT made with DEHP	Rx Only	Caution	Consult instructions for use	Endotracheal Length	Tracheostomy Length	Metered dose inhaler (not included)
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Table 1: Internal Manifold Volume

Patient End Adaptor Manifold	Internal Volume (mL)
BALLARD* Turbo Double Swivel Elbow	12
BALLARD* Turbo T-Piece	19
BALLARD* Turbo Qwik Clip*	3