

CLOSED SUCTION SYSTEM FOR NEONATES/PEDIATRICS

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:

- Neonates / Pediatrics Y
- Neonates / Elbow and Manifold

Warnings:

1. **Do not trim or cut the endotracheal tube (not supplied) while the BALLARD® 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.**
2. **Always test the catheter for occlusion prior to setting it up in the ventilatory system for use on any patient, while maintaining the catheter's sterility. If the catheter appears occluded, do not use and immediately replace the product. Testing for occlusion can be conducted by connecting the catheter's suction adapter to a suction unit and suctioning sterile water or saline, or by covering the distal tip openings with a sterile glove resulting in an increase in the suctioning pressures.**
3. **Do not reuse, reprocess, or sterilize this medical device. Reuse, reprocessing, or sterilization 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:

1. Inspect BALLARD® catheter package before opening. Do not use product if packaging has been compromised. Non-sterile contents may cause infection.
2. Excess fluid in heat and moisture exchanger (HME) may increase gas flow resistance. When introducing fluid into airway connection, ensure that fluid does not enter HME.
3. Stop withdrawal when black mark on the tip of the catheter is visible within the dome (Fig. 2). Withdrawal of the black mark past the dome, may inflate the protective sleeve of the suction catheter and

4. Always place the thumb valve in the locked position when not in use to prevent inadvertent activation.
5. Single patient use only.
6. BALLARD® systems are intended to be used for 24 hours before changing. Change more frequently if catheter becomes heavily soiled during use.
7. Inspect Sodium Chloride vial prior to opening. Do not use product if vial has been compromised. Compromised contents may cause infection.
8. 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.
9. Do not leave the catheter within the airway. Always withdraw until black mark on the tip of the catheter is visible within the dome. Any catheter left extended into the airway will cause increased airway resistance.
10. Use appropriate regulated vacuum levels. Though experts in the neonatal community cannot agree on a set regulated level of suction, some experts recommend you should use no more than -100 mm Hg.
11. Use appropriate suction technique. Though experts in the neonatal community cannot agree on duration of the suction procedure, some experts recommend the entire suction procedure should last no longer than 5 to 10 seconds. Actual duration of negative pressure should be no more than 5 seconds per episode.
12. 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.
13. Avoid instillation of normal saline or fluids into the lungs via the catheter unless clinically required.

Setup for Manifold or Elbow Product:

1. Select appropriate size BALLARD® catheter.
2. Test the catheter for occlusion prior to setting it up in the ventilatory system. If the catheter appears occluded, do not use and immediately replace the

- product.
3. Remove original endotracheal tube (ET) adapter and replace it with same size (mm) BALLARD® low deadspace ET adapter.
4. Reconnect the ventilator circuit.
5. Depress and hold thumb control valve and simultaneously adjust vacuum regulator to the desired level.
6. Release thumb control valve, attach the manifold or elbow between ventilator circuit and ET adapter.

Setup for Neonates / Pediatrics Y Products:

1. Select appropriate size Neonatal / Pediatric Y (same size as the endotracheal tube).
2. Select appropriate size BALLARD® Catheter.
3. Test the catheter for occlusion prior to setting it up in the ventilatory system. If the catheter appears occluded, do not use and immediately replace the product.
4. Attach BALLARD® catheter to Y.
5. Attach thumb control valve to suction tubing.
6. Hold thumb control valve depressed and simultaneously adjust the vacuum regulator to the desired level; release the thumb control valve.
7. Remove the original ET adapter, and attach Y to endotracheal tube and ventilator circuit.

Suggested Suction Procedure:

1. Stabilize BALLARD® catheter and ET adapter with one hand then advance the catheter into the endotracheal tube with the thumb and forefinger of the opposite hand (Fig. 1).
2. Release catheter and repeat until desired depth is reached.
3. Depress thumb control valve and hold; withdraw catheter gently. Stop withdrawal when black mark on the tip of the catheter is visible within the dome (Fig. 2).
4. Repeat steps 1-3 as necessary.

Patient Lavage Procedure:

1. Test the catheter for occlusion prior to setting it up in the ventilatory system. If the catheter appears occluded, do not use and immediately replace the product.
2. Advance the catheter 5-8 cm (2-3 inches) into the airway.
3. Instill desired amount of fluid through the lavage port.
4. Advance catheter to desired depth and perform suggested suction procedure as above.

Catheter Irrigation Instructions:

1. Neonatal / Pediatric Y Family
Use port for catheter irrigation (Fig. 3).
2. Manifold and Elbow Families

1. The distal (furthest from patient) irrigation port should be used for catheter irrigation (Fig. 4).
1. Withdraw the catheter completely. The black marking on the tip of the catheter should be completely visible within the dome (Fig. 2).
2. Introduce fluid slowly into the irrigation port, simultaneously depress the thumb control valve.
3. Continue irrigation until secretion viewing window is clear (Fig. 5).
4. Close irrigation port. Lift and turn thumb control valve 180 degrees to lock position (Fig. 6).

Controlled Depth Suction:

⚠️ **Caution:** Tip placement methods listed below are not precise. Placement may vary. Centimeter markings on endotracheal tubes should be verified.

Method 1

1. Align any printed depth number on the catheter with the same number printed on the endotracheal tube.
2. Catheter tip will be within 0.5 cm to 1 cm of the end of the endotracheal tube.

Method 2

1. Observe the printed depth number on the endotracheal tube closest to the end of the endotracheal tube adapter.
2. Add 5 to this number.
3. Advance catheter until the cm (depth number plus 5) appears in the area directly across from irrigation port connector. Note the nearest color band.
4. Catheter tip will be within 0.5 cm to 1 cm of the end of the endotracheal tube.
5. Color bands allow easier visualization on subsequent suction procedures.

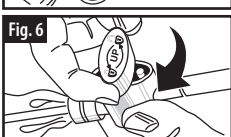
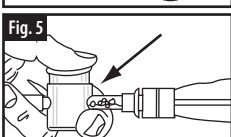
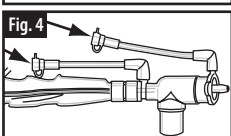
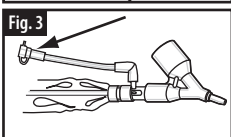
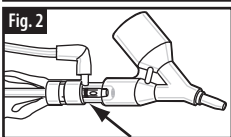
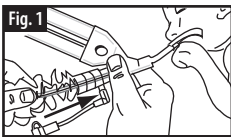
Thumb Control Valve Operation:

1. 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. 6).

Day Sticker Usage

1. Apply the appropriate day sticker to the thumb valve. Example: If BALLARD® product is opened on Monday, place the Tuesday sticker on thumb valve.

Manufactured by Avanos Medical, Inc.,
5405 Windward Parkway, Alpharetta, GA 30004 USA.
Distributed in the USA by Avanos Medical Sales, LLC,
5405 Windward Parkway, Alpharetta, GA 30004 USA.
In USA, 1-844-428-2667. www.avanos.com
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Interval Volume	Diameter	Length	Single use only	STERILE	Do not use if package is damaged	Do not re sterilize	Not made with natural rubber latex	Product is NOT made with DEHP	Rx Only	Caution	Consult instructions for use	Endotracheal Length	Tracheostomy Length
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Table 1: Internal Manifold Volume

Patient End Adaptor Manifold	Internal Volume (mL)
BALLARD® Neonate Manifold	4
BALLARD® Neonate Y-Adaptor (2.0 mm – 4.5 mm)	3
BALLARD® Pediatric Y-Adaptor (5.0 mm – 6.5 mm)	4
BALLARD® Closed Suction Elbow	7

Table 2: Resistance to Flow for Y-Adaptor

Y-Adaptor Resistance to Flow			
Y-Adaptor size (mm)	Resistance to Flow hpa/l/min for Neonatal Flow Rate at 2.5 l/min	Resistance to Flow hpa/l/min for Pediatric Flow Rate at 15 l/min	Compatible French Sizes (F)
2.0	0.866**	3.926**	5
2.5	0.326	1.461**	5 and 6
3.0	0.192	0.836**	6, 7 and 8
3.5	0.097	0.383**	6, 7 and 8
4.0	0.043	0.240**	7 and 8
4.5	0.040	0.17**	10
5.0	0.008	0.1**	10
5.5	0.020	0.07**	10 and 12
6.0	0	0.05	12
6.5	0	0.04	12

Per ISO 8836:2019, Table 2 outlines the intended delivered volumes that can be achieved at the flow rates listed for product french sizes.

**Use clinical judgement when utilizing smaller neonatal Y configurations with pediatric patient populations as this may increase resistance within the circuit.