

Standard

Closed Suction System for Pediatric

General Instructions For Use

Intended Use

Sunset Standard Closed Suction System is intended for tracheostomy suction of ventilator dependent pediatric patients. It is operated by health professionals in medical institutions for single patient use.

- Recommended period of use is 24 hours or if visibly soiled or faulty. Defer to institutional policy/guidelines for changeout indications.

Product Description

Sunset Standard Closed Suction System consists of 3 essential parts: a suction catheter with a protective sleeve, a vacuum control device and a patient end adaptor with a flushing system. The device connects between the breathing circuit and the artificial airway for simultaneous suction and ventilation.

Contraindications

The device intends to suck the secretions from the patients with artificial airways. The pulmonary secretions from a patient's artificial airways should be removed to prevent its obstruction, otherwise, they cause the patient's death or to be lethal. Therefore, there is no absolute contraindication to the closed suction system.

Size

Product Code	Catheter Length	Remark	Outer Diameter	Packaging	ISO Colour
VENCSS6-305	305mm	Tracheostomy	6FR / 2.0 mm	20ea/box	
VENCSS8-203	203mm	Tracheostomy	8FR / 2.67 mm	20ea/box	
VENCSS8-355	355mm				
VENCSS10-203	203mm	Tracheostomy	10FR / 3.33 mm	20ea/box	
VENCSS10-405	405mm				

Symbol



Caution



Contains or presence of phthalate-DINP



Sterilized using ethylene oxide



Sale by or on the order of a physician



Does not contain natural rubber latex



Do not use if package is damaged



Do not reuse



Do not resterilize



Do not use in MRI



Consult instructions for use



Temperature limitation

Upper limit: 49°C

Lower limit: 5°C



Manufacturer



Date of manufacture



Catalog number



Batch code



Use by date



Keep dry



Keep away from sunlight

Warning

1. Do not use tracheostomy length catheters for endotracheal tubes. The short length will result in insufficient suctioning. Do not use endotracheal length catheter in patient with tracheostomy tube. The extra length may cause mucosal tissue injury.
2. This is single use product. Do not reuse or resterilize this device. Reuse and resterilization may lead to the device not performing as intended, malfunction or create a risk of cross infection.

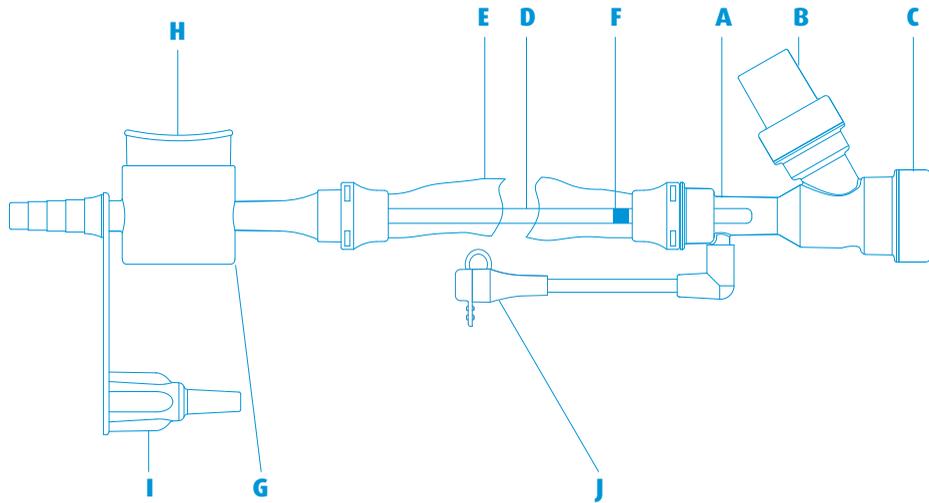
Caution

1. Check the product package before use. Do not use if product packaging has been damaged.
2. Withdraw suction catheter from the patients until the black marking can be seen on the distal side of patient-end adaptor.
3. Do not pull suction catheter out of patient-end adaptor.
4. The product should be handled by trained and qualified clinicians.
5. Rx Only – Federal law restricts this device to sale by or on the order of a physician.
6. Do not leave catheter within the airway, it will cause increased airway resistance.
7. Always place the vacuum control device in the locked position when not in use.
8. Recommended vacuum settings 80 to 120mm/Hg.
9. The entire suction procedure should last no longer than 10 to 15 seconds.
10. When used in conjunction with other manufacture' s products always refer to their instruction for use.
11. Excess fluid in heat and moisture exchangers (HMEs) or heat moisture exchanging filters (HMEFs) may increase resistance to flow. Follow manufacturer' s instructions and replace HME(F).

Pre-Use Check

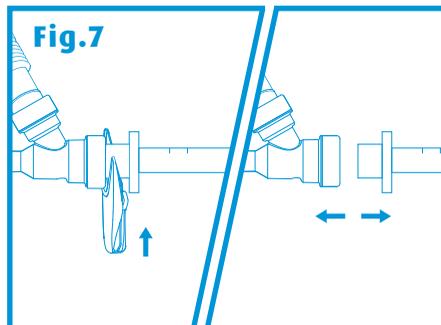
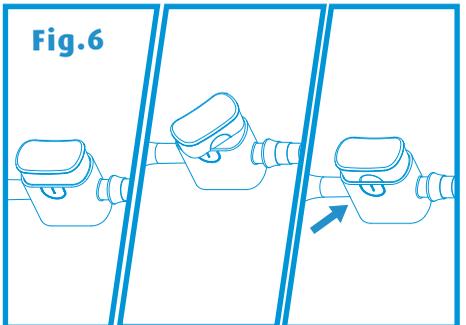
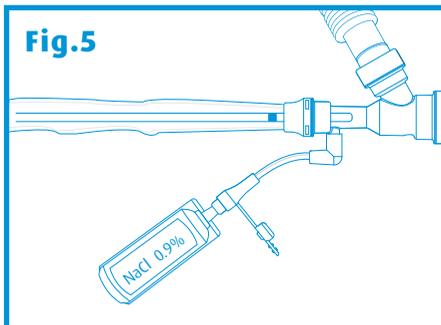
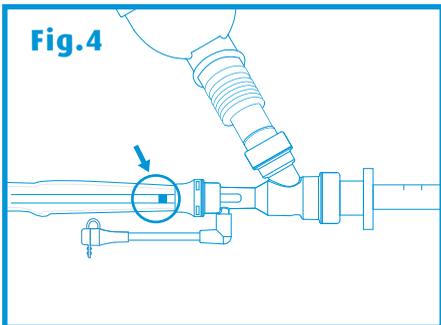
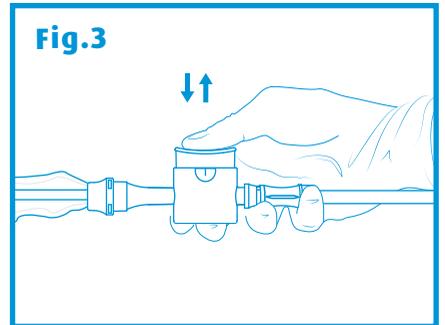
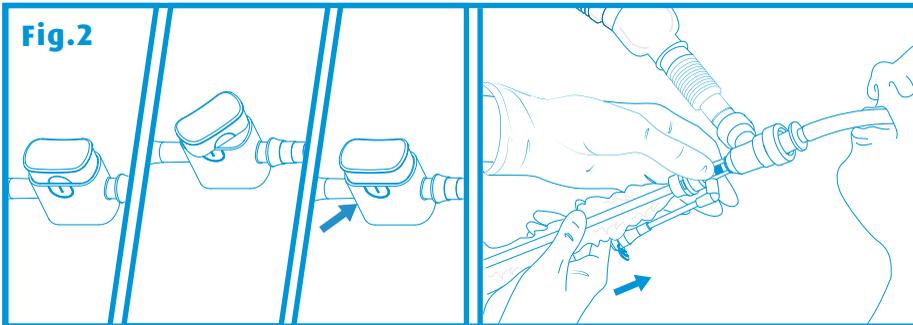
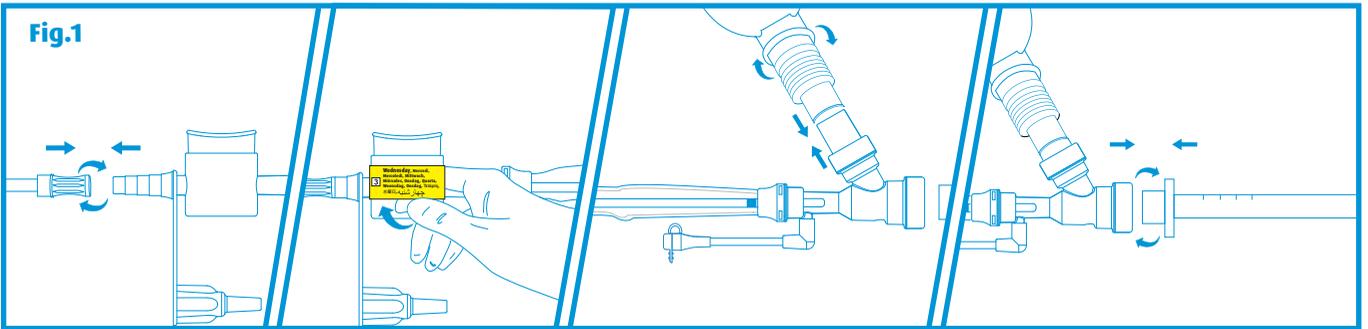
- There are no standard connections for suction tubing, hospitals should qualify the tubing fits the series of Sunset Standard Closed Suction Systems.
- Inspect the package before opening. Ensure the product has not been compromised.
- Select the appropriate catheter length and size following clinical guideline. It is recommended that the catheter size is no more than half the size of patient' s artificial airway.

Suggested Suction Procedure



Optional accessory :

- Disconnect wedge
- Corrugated connector



Suggested Suction Procedure

1. **(Fig. 1)** Attach suction tubing to the connector on the vacuum control device (G) . Connect suction tubing to the hospital vacuum system.
2. **(Fig. 1)** Attach a day label to the vacuum control device indicating the date of use.
3. **(Fig. 1)** Attach the 15 mm male connector (B) of the patient end adaptor to the breathing system (machine-end); the 15 mm female connector (C) to the patient' s artificial airway (patient-end) .
Note: A corrugated connector (optional accessory) can be attached between the 15 mm male connector (B)and the breathing system if needed.
4. **(Fig. 2)** Unlock the switch of the vacuum control device(H) .
5. **(Fig. 2)** Hold the patient end adaptor with one hand. Carefully advance the catheter down the airway with the other hand.
6. Advance catheter(D)to desired depth. For endotracheal tube type, line up the marking numbers. There are no markings on tracheostomy tubes. Follow hospital procedures when advancing the catheter.
7. **(Fig. 3)** Hold the vacuum control device(G) and depress switch of vacuum control device (H) .
8. **(Fig. 4)** Then gently withdraw catheter (D) until the black ring (F)is visible on the distal side of the patient-end adaptor.
9. Repeat steps 5-7 above if necessary.

Catheter Irrigation

1. **(Fig. 5)** Open cap on irrigation port (J) . A prefilled saline vial or a 15ml syringe filled with saline is prepared to be used.
2. **(Fig. 5)** Attach saline vial/syringe to the irrigation port.
3. Depress the switch of vacuum control device (H) for saline to enter the irrigation chamber (A) . Ensure the non-return valve is closed and continue to irrigate until the catheter is clear of secretion.
4. Close the cap of irrigation port(J) .
5. **(Fig. 6)** Lock the switch of vacuum control device(H)when not in use to prevent accidental depression.
6. Turn off the vacuum after use. If the suction catheter is disconnected in-line use, put the protective cap (I) on the end of vacuum control device(G) .

Disconnection (optional accessory)

1. A disconnect wedge (optional accessory) can be used for easier disconnection with Sunset Standard Closed Suction System from the patient' s airway by steps below **(Fig. 7)**.
2. Press upwards against the thumb to disconnet the system.
3. After use, the product must be disposed in conformance with the local hygiene and waste disposal protocols and regulation.