

Deluxe

Closed Suction System for Neonatal/Pediatric Endotracheal

with “Y” Endotracheal tube adaptors

General Instructions for Use

Intended Use

Sunset Deluxe Neo/ Ped Plus Closed Suction System is intended for endotracheal suction of ventilator dependent neonate/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 Deluxe Neo/ Ped Plus 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. It features for a Y-adaptor for size adoption. It can be with or without a MDI port.

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 Color
VEN26000500 / VEN26000500M	305mm	Y-Adaptor 2.0 / 2.5 mm	5FR / 1.67 mm	20ea/box	
VEN26000600 / VEN26000600M	305mm	Y-Adaptor 2.5 / 3.0 / 3.5 mm	6FR / 2.0 mm	20ea/box	
VEN26000700 / VEN26000700M	305mm	Y-Adaptor 3.0 / 3.5 / 4.0 mm	7FR / 2.33 mm	20ea/box	
VEN26000800 / VEN26000800M	305mm	Y-Adaptor 3.5 / 4.0 / 4.5 mm	8FR / 2.67 mm	20ea/box	
VEN26001000 / VEN26001000M	405mm	Y-Adaptor 4.5 / 5.0 / 5.5 mm	10FR / 3.33 mm	20ea/box	

- M = with MDI port

Symbol



EN / Caution



EN / Sterilized using ethylene oxide



EN / Contains or presence of phthalate-DINP



EN / Sale by or on the order of a physician



EN / Does not contain natural rubber latex



EN / Do not use if package is damaged



EN / Do not reuse



EN / Do not resterilise



EN / Do not use in MRI



EN / Consult instructions for use



EN / Temperature limitation
Upper limit: 49°C
Lower limit: 5°C



EN / Manufacturer



EN / Date of manufacture



EN / Catalog number



EN / Batch code



EN / Use by date



EN / Keep dry



EN / Keep away from sunlight

Warning

1. Sunset Deluxe Neo/ Ped Plus Closed Suction System 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.
2. Do not CUT endotracheal tube while Closed Suction System is attached. Otherwise, the suction catheter may be cut and the portion of catheter may be aspirated into lower respiratory tract.

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. Recommended vacuum settings 80-100mm/Hg
8. The entire suction procedure should last no longer than 5 to 10 seconds.
9. Always place the switch of vacuum control device in locked position when not in use.
10. Excess fluid in heat and moisture exchangers (HMEs) or heat and moisture exchanging filters (HMEFs) may increase resistance to flow. Follow manufacturer's instructions and replace HME(F).
11. When used in conjunction with other manufacture's products always refer to their instruction for use.

Pre-Use Check

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

Suggested Suction Procedure

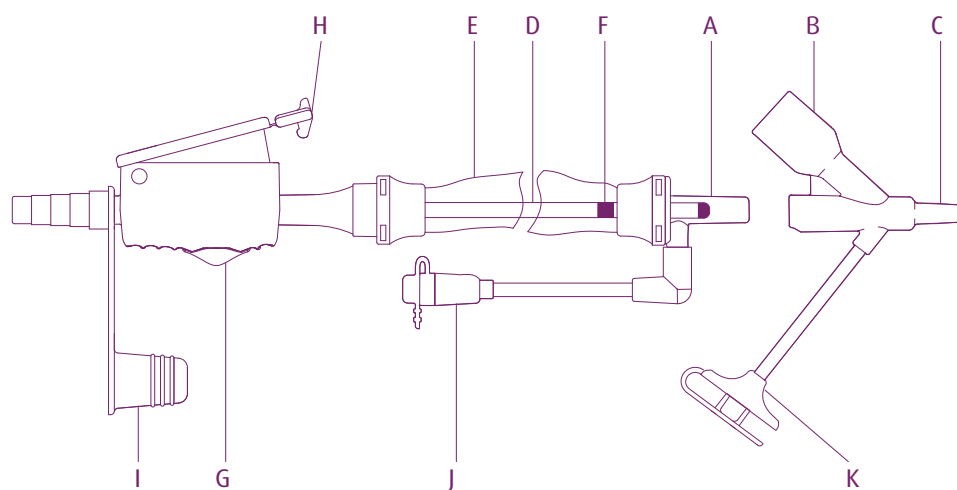


Fig.1

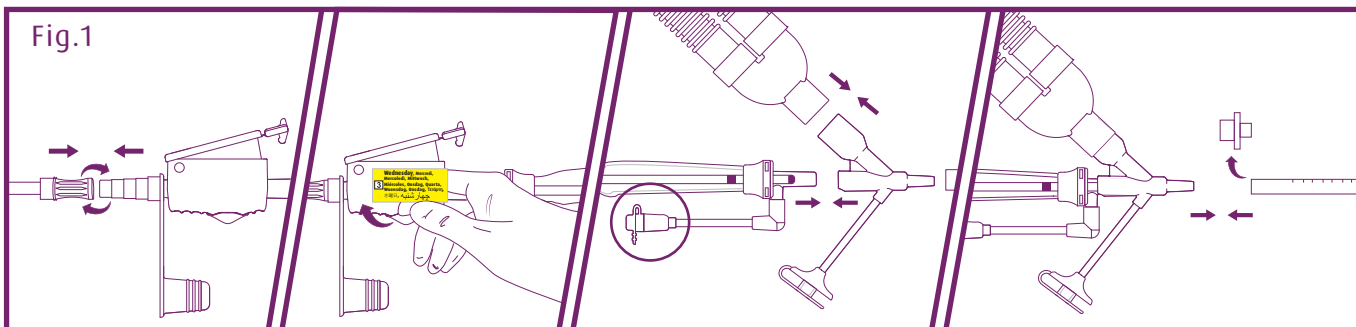


Fig.2

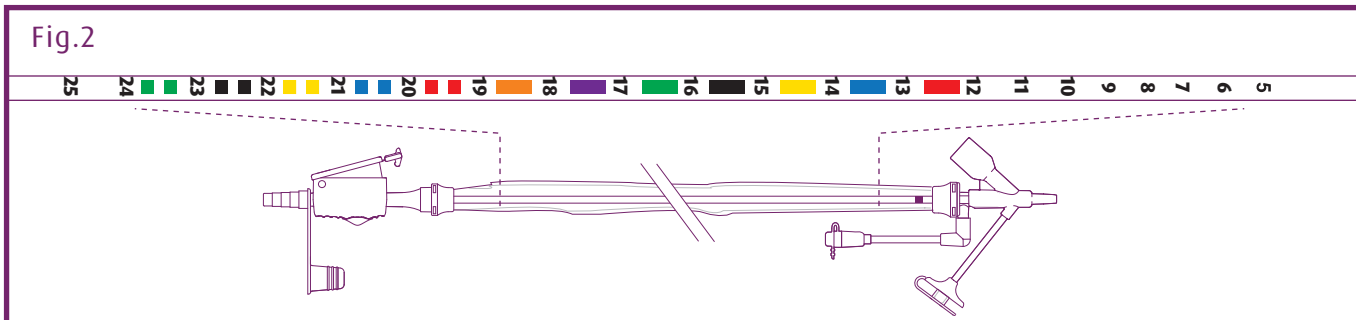


Fig.3

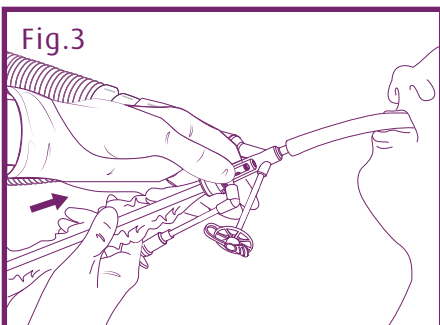


Fig.4

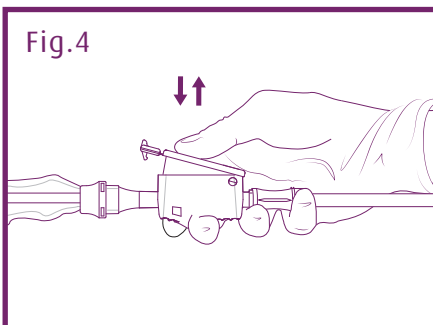


Fig.5

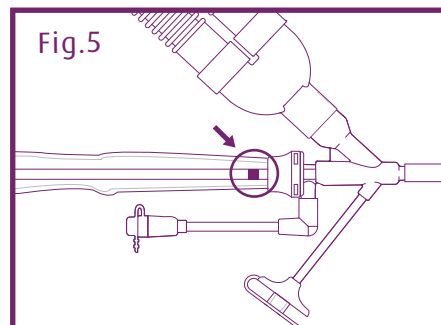


Fig.6

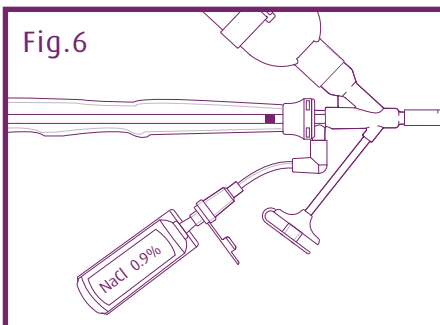


Fig.7

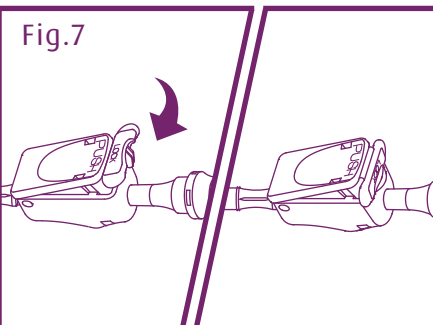
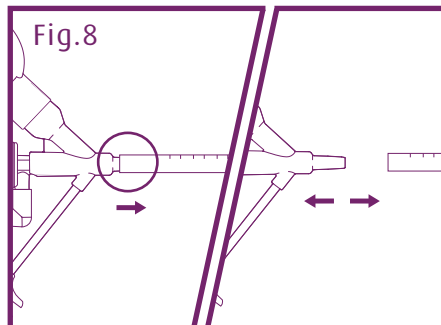


Fig.8



Suggested Suction Procedure

1. **(Fig. 1)** Select appropriate size of Neo/Ped Y-Adaptor (C) . (Same size as the endotracheal tube). Attach Y-Adaptor to patient-end adaptor (A) .
2. **(Fig. 1)** Attach vacuum control device (G) to suction tubing.
3. **(Fig. 1)** Remove original endotracheal tube adaptor, and attach machine-end connector (B) to breathing system.
4. **(Fig. 1)** Attach a day label to the vacuum control device indicating the date of use.
5. **(Fig. 3)** Unlock the switch of the vacuum control device (H) .
6. **(Fig. 3)** Stabilize Sunset Deluxe catheter (D) and airway adaptor with one hand. Carefully advance the catheter down the airway with the other hand.
7. Advance catheter (D) to desired depth. For endotracheal tube, line up the marking numbers and advance a further two centimeter.
8. **(Fig. 2)** Color bands allow easier visualization on subsequent suction.
9. **(Fig. 4)** Hold the vacuum control device (G) and depress switch of vacuum control device (H) .
10. **(Fig. 5)** Then gently withdraw catheter until the back ring(F)is visible on the distal side of the patient-end adaptor(A).
11. Repeat steps 6-10 above if necessary.

Catheter Irrigation

1. Open cap on irrigation port (J) .
2. **(Fig. 6)** A prefilled saline vial or a 5ml syringe filled with saline is prepared to be used.
3. **(Fig. 6)** Attach saline vial/syringe to the irrigation port.
4. Depress the switch of vacuum control device (H) for saline to enter the irrigation chamber (A) . Keep the switch of vacuum control device depressed until saline vial/syringe is empty. Be attention that saline is not entering the patient's airway.
5. Close cap on irrigation port (J) .
6. **(Fig. 7)** Lock the switch of vacuum control device (H) when not in use to prevent accidental depression.
7. Turn off the vacuum after use. If the suction tubing is disconnected in-line use, put the cap (I) on the end of vacuum control device (G) .

Metered Dose Inhaler (MDI)

1. Remove the cap on MDI port (K) , and attach canister. Avoid discharge of canister when connecting.
2. Hold canister in vertical position. Depress canister during inspiration cycle. Repeat as prescribed by physician or protocol.
3. Remove canister and put the cap on MDI port (K) .

Disconnection

1. Disconnect the Sunset Deluxe Neo/ Ped Plus Closed Suction System from the patient's airway .
2. Press upwards against the thumb to disconnet the system.
3. After use, the product must be disposed of in line with the local hygiene and waste disposal protocols and regulation.