

# 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 within 24 hours.

- Maximum period of use is 24 hours and it is indicated 24 hrs on the pack.

#### 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<br>2.0 / 2.5 mm       | 5FR / 1.67 mm  | 20ea/box  |  |
| VEN26000600 / VEN26000600M | 305mm           | Y-Adaptor<br>2.5 / 3.0 / 3.5 mm | 6FR / 2.0 mm   | 20ea/box  |  |
| VEN26000700 / VEN26000700M | 305mm           | Y-Adaptor<br>3.0 / 3.5 / 4.0 mm | 7FR / 2.33 mm  | 20ea/box  |  |
| VEN26000800 / VEN26000800M | 305mm           | Y-Adaptor<br>3.5 / 4.0 / 4.5 mm | 8FR / 2.67 mm  | 20ea/box  |  |
| VEN26001000 / VEN26001000M | 405mm           | Y-Adaptor<br>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.

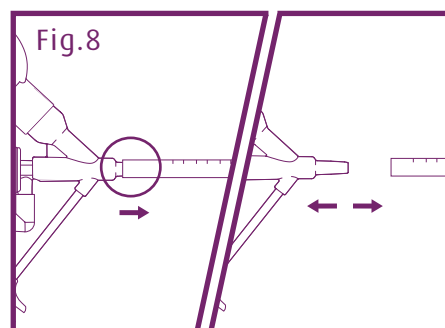
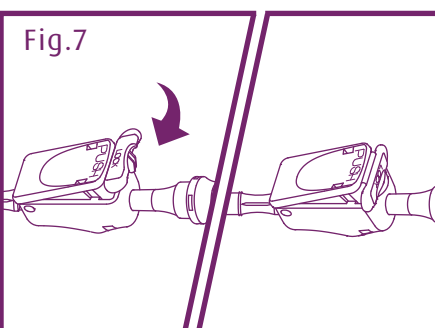
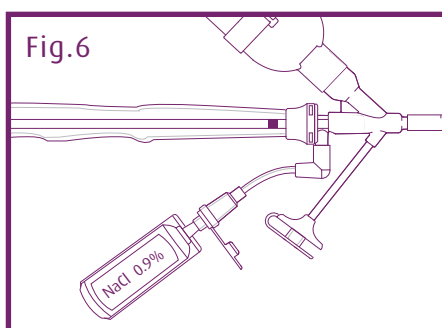
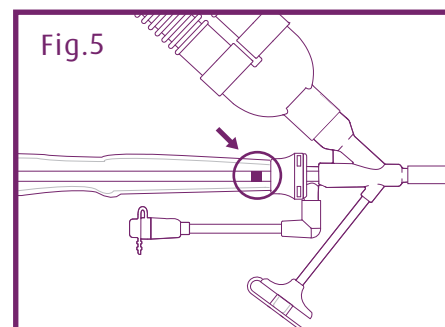
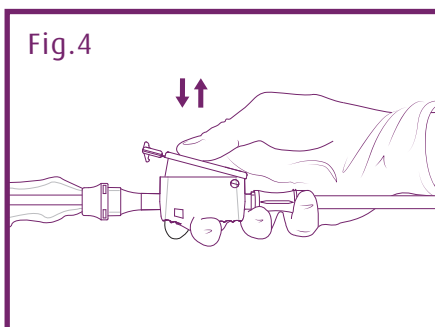
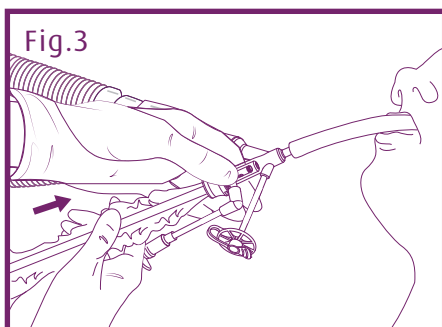
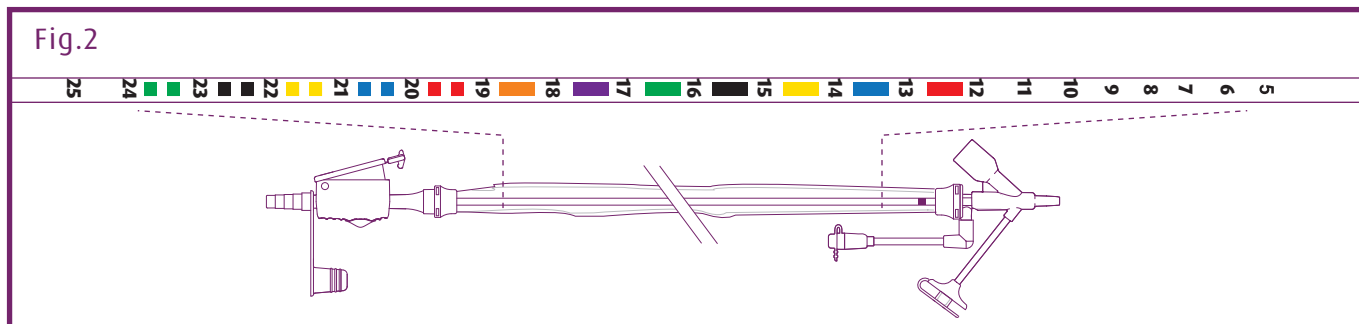
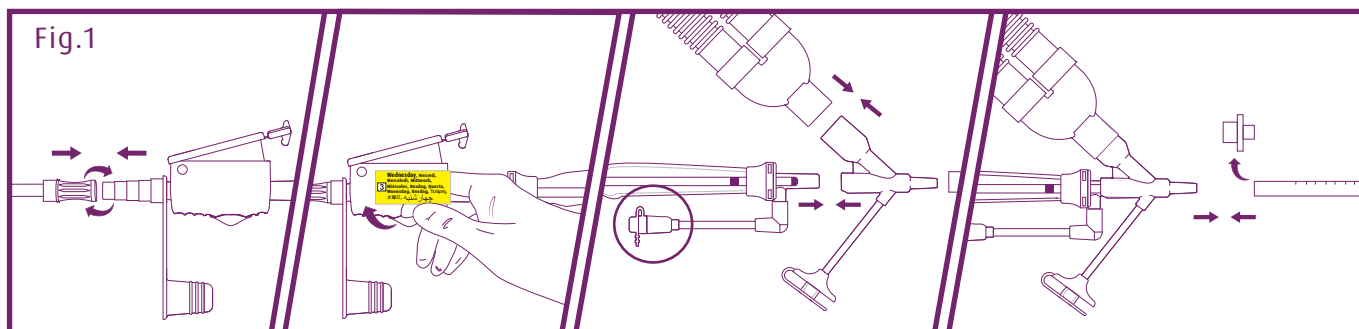
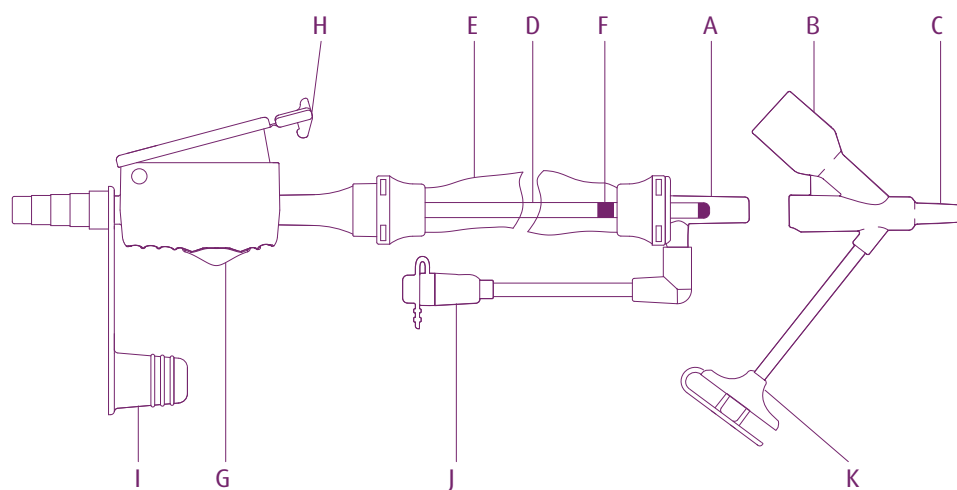
## Caution

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



## 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.