5. Warnings

a. This CPAP/BiLevel mask should be used only with CPAP/BiLevel systems recommended by your physician or respiratory therapist. This mask should not be used unless the CPAP/BiLevel system is turned on and operating properly. The vent holes in the mask should never be blocked.

b. These masks are intended to be used only with CPAP/BiLevel systems which require vent holes in the mask to allow continuous air flow out of the mask. When the CPAP/BiLevel machine is turned on and functioning properly, the air from the CPAP/BiLevel machine flushes the exhaled air out through the mask vent holes. However, when the CPAP/BiLevel machine is not operating properly, enough fresh air will not be provided through the mask, and exhaled air may be rebreathed. Rebreathing of exhaled air for longer than several minutes in some cases lead to suffocation.

c. This mask is shipped cleaned but nonsterile. If disinfection or sterilization procedures described in this document prior to use of the mask. Discontinue use of the mask if patient skin or mucous membrane irritation or allergic reaction develops due to the mask.

d. If a fixed flow rate of supplemental oxygen is used, the exhaled percent oxygen will vary depending upon the pressure setting, patient breathing pattern, mask size and leak rate. Oxygen flow must be turned off when the CPAP/BiLevel system is not operating.

6. Contraindications

a. a minimum pressure less than 3 cm H2O at mask
b. open wounds that are prone to infection

c. hyperemic or hyperaemic instability

7. Complications

a. infection due to improper use over open wounds
b. skin irritation after prolonged use caused by rubbing of the mask

c. eye irritation or conjunctivitis

d. gastric distention and abdominal pain or flatulence from re-breathing of exhaled air for longer than several minutes

8. Mask Components and Material Descriptions (fig 1)

9. Applying and Fitting Mask

a. a. Anti-Asphyxia Valve (AAV): (fig 4) The AAV allows room air through the mask when the CPAP/BiLevel machine is not operating or turned off. The AAV also allows room air to escape from the mask when the CPAP/BiLevel machine is turned on and functioning properly, or the AAV is disconnected from the mask. The AAV is located on the mask adapter face piece.

b. Headgear is a breathable, stretchable polyurethane foam that is used to connect the mask to the ventilator device. The headgear is designed to fit the patient's head comfortably and securely.

c. AVALON™ Mask Adapter Face Piece: (fig 1) The Mask Adapter Face Piece is attached to the mask to connect it to the ventilator device.

d. QUICK-RELEASE HEADGEAR: (fig 5) The Quick-Release Headgear is used to connect the mask to the ventilator device. The Quick-Release Headgear is designed to allow quick and easy removal of the mask assembly from the patient.

10. Verification of Safety Features

a. Anti-Asphyxia Valve (AAV): (fig 4) The AAV allows room air through the mask when the CPAP/BiLevel machine is not operating or turned off. The AAV also allows room air to escape from the mask when the CPAP/BiLevel machine is turned on and functioning properly, or the AAV is disconnected from the mask. The AAV is located on the mask adapter face piece.

b. Quick-Release Headgear: (fig 5) Unsnipping one of the lower headgear strap clips allows quick removal of the mask assembly from the patient.

11. Removing the Mask: To remove the mask, slide one of the lower strap clips slightly forward towards the front of the mask and it will disengage from the mask and headgear to the opposite side or up over the patient's head.

12. Disassembly for Cleaning, Disinfection or Sterilization

a. Detach mask from the ventilator
b. Separate the headgear from the mask

c. Separate the swivel port assembly from the mask, AAV from the swivel port (squeeze two locking tabs and pull AAV off) and the rubber cap plug from the sampling port of the mask adapter

13. Cleaning Mask face piece, swivel port components and headgear

a. Mask and swivel port assembly: Soak all the components for 5 minutes in warm water with a mild detergent (neutral pH)

b. Hand wash the components with a sponge or soft brush

c. Rinse with warm tap water. Place the components in a bath of warm water and agitate for two minutes.

d. Rinse in clean tap water for at least 1 minute

e. Allow the components to air dry or dry them with a clean, lint-free cloth
Headgear
a. Submerge the headgear in warm soapy tap water and gently rub all the areas.
b. Rinse in clean tap water for 1 minute or until all signs of the soap are removed.
c. Air dry.
d. Caution: Fabric dye on the headgear material may run the first couple times during cleaning. We recommend washing the headgear before first time use.
e. Precuation: Do not use bleach, chlorine or alcohol based solutions to clean any of the mask and headgear components. These solutions can damage this product. Direct sunlight exposure with the mask and headgear components can cause deterioration and reduce product life.

2. Dry the device with a clean, preferably sterile lint free cloth.
3. Inspect all Components for Cleanliness, Function and Defects
   a. If there are any signs of residues, stains or organic debris then repeat the previous steps. If these signs remain following further cleaning and disinfection then replace with new components.
   b. Visually inspect all components for defects. Check rubber parts for nicks, tears, deformation or distortion. Check plastic parts for crazing and cracking.
   c. Dispose of and replace all defective parts.

4. Reassembly
   a. Check AAV diaphragm function: with the mask installed the diaphragm should flex instantly to close the room air breathing port with a minimum CPAP/BiLevel of 3 cm H2O mask pressure. When there is no CPAP/BiLevel pressure in the mask the diaphragm will OPEN and allow room air breathing directly through the room air port opening.
   b. Snap the AAV into the elbow of the suction port assuring the elbow locking tabs are fully engaged with the slots of the AAV.
   c. Press the rubber cap plug on to the sampling port of the mask adapter.
   d. Install the swivel port assembly into the grooved opening of the face mask. Orient the sampling port on either side of the nose portion of the mask face. The flame of the swivel port mask adapter mates with the groove of the mask. Start with placing one portion of the adapter into the mask groove then continue completely around stretching it and working it into the mask groove until completely installed.

5. Mount the headgear to the face piece. Snap the strap quick release clips into the appropriate plastic slots on the mask.
6. Functional Check
   a. All swivel port joints should swivel freely.
   b. AAV is installed completely in the port, locking tabs fully engaged and the diaphragm flexes freely without any obstruction.
   c. Swivel port assembly is completely engaged in the mask face piece.

7. Storage
   a. All components should be completely dry before storage.
   b. Place completely assembled in clear plastic bag and seal the bag.
   c. Label the bag with disinfection/clean status, mask description, date and initials.
8. E. Hot Water Pasteurization
   a. Completely immerse the device components in a hot water bath. All surfaces should be in direct contact with the hot water for 30 minutes at temperatures set between 71.1 C and 76.6 C.
9. f. Hot Water Pasteurization
   a. Submerge and soak the device components in the hot water pasteurization method.
   b. Remove the device from the colution and submerge in 1500 ml of sterile water for at least 1 minute.
   c. Repeat the previous step a second time.
   d. Dry the device with a clean (preferably sterile) lint free cloth.

10. g. Hot Water Pasteurization
    a. Completely immerse the device components in a hot water bath. All surfaces should be in direct contact with the hot water for 30 minutes at temperatures set between 71.1 C and 76.6 C.
    b. Submerge and soak the device components in the hot water pasteurization method.
    c. Remove the device from the solution and submerge in 1500 ml of sterile water for at least 1 minute.
    d. Repeat the previous step a second time.
    e. Dry the device with a clean (preferably sterile) lint free cloth.

11. 1. Completely immerse the device components in a hot water bath. All surfaces should be in direct contact with the hot water for 30 minutes at temperatures set between 71.1 C and 76.6 C.
     2. Remove the device from the solution and submerge in 1500 ml of sterile water for at least 1 minute.
     3. Repeat the previous step a second time.
     4. Dry the device with a clean, preferably sterile lint free cloth.

12. 14. High Level Disinfection (Mask and Swivel port components only)
    a. The mask assembly should be disinfected or sterilized between multiple patient uses.
    b. The mask must be thoroughly cleaned in accordance with the cleaning instructions prior to disinfection or sterilization.
    c. Disinfection/sterilization should be performed in accordance with the manufacturer’s recommendations.
    d. Liquid Chemical Disinfection
     1. Submerge and soak the device components in the liquid solution according to manufacturer’s instructions.
     2. Remove the device from the solution and submerge in 1500 ml of sterile water for at least 1 minute.
     3. Repeat the previous step a second time.
     4. Dry the device with a clean (preferably sterile) lint free cloth.

13. 15. Steam Sterilization (Face Mask assembly less Headgear)
    a. Mask must be cleaned and dry in accordance with instructions prior to sterilization.
    b. The mask should be completely assembled (less headgear)
    c. It is the user’s responsibility to validate any deviations from these methods.
    d. Steam Sterilization cycles
     1. Temperature: 132.2 +3/-1 C
     2. Sterilization time: 30 minutes
     3. Dry time: 10 minutes
     4. Packaging: Double pouched or wrapped in CSR
     5. Gravity Displacement cycle
      1. Temperature: 132.2 +3/-1 C
      2. Sterilization time: 30 minutes
      3. Dry time: 10 minutes
      4. Packaging: Tyvek® sterilization pouch

14. 16. Mask Vent Pressure Flow Curve
    a. This graph illustrates the air flow leak rate through the mask vent holes at a full range of mask pressures with Vents & AAV.
    b. Values measured using a facial profile include the face mask and swivel port components.
    c. Air dry
     1. If there are any signs of residues, stains or organic debris then repeat the previous steps. If these signs remain following further cleaning and disinfection then replace with new components.
     2. Visually inspect all components for defects. Check rubber parts for nicks, tears, deformation or distortion. Check plastic parts for crazing and cracking.
     3. Dispose of and replace all defective parts.

15. 21. Recommendations for Mask Disposal
    a. All components of this product can be treated as conventional solid waste and disposed of in accordance with your local and Federal regulations.
    b. It is the user’s responsibility to validate any deviations from these methods.
    c. Steam Sterilization cycles
     1. Temperature: 132.2 +3/-1 C
     2. Sterilization time: 30 minutes
     3. Dry time: 10 minutes
     4. Packaging: Tyvek® sterilization pouch

22. 22. Ordering Information
    7600 Series Reusable V2 Oro-Nasal Mask with Elbow Swivel Port 22mm OD with AAV, Vents & Headgear (HG)
    a. Description: 7600 EXTRA SMALL
    b. P/N: 113488
    c. Description: 7600 SMALL
    d. P/N: 113487
    e. Description: 7600 MEDIUM
    f. P/N: 113486
    g. Description: 7600 LARGE
    h. P/N: 113485
    i. Description: AAV PORT ASSEMBLY
    j. P/N: 201523
    k. Description: HEADGEAR STRAP CLIPS (package of four)
    l. P/N: 201525
    m. Description: AV PORT ASSEMBLY
    n. P/N: 201521
    o. Description: CUFF PLUGS FOR SAMPLING PORT PACKAGE OF TWO
    p. P/N: 201520

23. 23. Safety Information
    a. Safety or technical information regarding this product can be obtained from Hans Rudolph inc.
    Phone: 913-422-7788 Fax: 913-422-3337 hr@rudolphkc.com
    b. Distributed non-exclusively by DeVilbiss Healthcare LLC
    Phone: (800) 338-1988 Fax: (815) 398-9672 sales@devilbisshealthcare.com
    ENGLISH