ADULT PERTRACH® DIRECTIONS FOR USE
Directions for Pertrach Disposable Emergency Cricothyrotomy or Emergency / Elective Tracheostomy Device

1. Remove dilator from the package and protective sheath and advance it into tracheostomy tube.

   Landmark cricothyroid membrane.

   Either make an incision in the skin or simply insert Splitting Needle through skin directly over cricothyroid membrane, depending on local medical protocol. While advancing Splitting Needle perpendicular to the skin, lightly pull back on the plunger of syringe. When air bubbles occur or you feel a break in resistance, cease advancement of Splitting Needle.

   Incline needle more than 45 degrees toward carina and complete insertion. Always maintain the tip of the needle in the midline of the airway. Remove syringe.

2. Insert tip of dilator into the hub of Splitting Needle. Squeeze wings of needle together, then open them out completely to split the needle. Remove needle, continuing to pull it apart in opposite directions, while leaving dilator in trachea.

   Place thumb on dilator knob while first and second fingers are curved under flange of trachea tube. By exerting pressure, advance dilator and tracheostomy tube into position until flange is against skin.

3. Remove dilator. Inflate cuff until you have control of the airway. Attach resuscitator or ventilator to tracheostomy tube. Secure tracheostomy tube around patient’s neck with twill tape.

RECOMMENDATIONS:
1. Included in the kit is an optional 5” extension tube that may be placed between resuscitation device and tracheostomy tube.

2. Gauze pads may be placed around the tracheostomy tube, between skin and the 15mm adaptor, thus varying the length of the tube in the trachea, as needed.

3. Test position of tracheostomy tube in airway after its insertion by suctioning trachea through it. Also, listen for breathing sounds. If you are not sure you are in the airway, use the second needle and repeat the procedure.

4. Procedure is best done with the patient’s head extended (if cervical spine is intact). If this is not advisable, and if two people are available, one should place both thumbs on patient’s maxillae (cheekbones) and your index and middle fingers on both sides of the mandible (lower jaw) where it angles toward the ear. Apply upward pressure with your fingers without tilting the head.

5. It is helpful if an assistant holds the tracheostomy tube in place while the operator uses both hands.

6. Local anesthetic can be used in tissues and also to numb tracheal mucosa for elective tracheotomy.

WARNINGS:
1. Store in clean, dry conditions away from heat and light.

2. If the Splitting Needle is inserted too deep, perpendicular to the skin, it could puncture posterior wall of trachea.

3. Insertion of device through thyroid cartilage can injure vocal cords.

4. Retraction of the dilator back through unsplit needle could result in damage to dilator.

CAUTIONS:
1. Federal Law (USA) restricts this device to sale by or on the order of a physician.

2. This product must only be used by personnel thoroughly trained in the techniques of Percutaneous Tracheostomy and/or Cricothyrotomy.

3. Overinflation of cuff may cause cuff to burst.

4. Reuse or reprocessing of this device may compromise material and design characteristics leading to device failure. Reuse may also create a risk of contamination leading to patient infection or cross-infection.

5. DEHP is a commonly used plasticizer. The potential effects of DEHP on nursing/pregnant women and children have not been fully characterized and there may be concern for reproductive and development effects.
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