Parker Endo-Bronch with Standard Tip

Double-lumen Endobronchial Tube (PSTDL, PSTDR)

DESCRIPTION

The Parker Endo-Bronch with Standard Endobronchial Tube Tip, Double-lumen Endobronchial Tube (PSTDL, PSTDR) is a sterile, single-use, polyvinyl chloride (PVC), dual tube with separate, tracheal and bronchial lumens, each with own cuff, pilot balloon, self-sealing valve and connecting tube. The tracheal cuff and pilot balloon are colorless the bronchial cuff and pilot balloon are blue.

Two arms of the "Y" connector, each of which is imprinted with an arrow, are connected to shut off valves in the swivels and can be rotated to the "ON" or "OFF" position to open or close the flow of gas.

INDICATIONS

The Endo-Bronch tube is intended for use in thoracic surgery and for administering endobronchial anesthesia during pulmonary surgery and for isolation and selective inflation or deflation of either lung. The bronchial channel of the Endo-Bronch Left is indicated for intubation of the left main bronchus while the tracheal channel is situated in the trachea.

WARNINGS

Expert clinical judgment should be exercised in the selection of the appropriate size tube for each patient.

Each tube's cuffs, pilot balloons, and valves should be tested by inflation prior to use. lf disfunction is detected in any part of the inflation system, the tube should not be used.

Do not overinflate the cuffs. Ordinarily lhe cuff pressure should not exceed 25 cm H_2O. However, clinical situations may arise where a higher sealing pressure is clinically indicated. Overinflalion can result in tracheal damage, rupture of the cuff with subsequent deflation, or in cuff distortion which may lead to airway blockage.

lf the endobronchial tube is lubricated prior to intubation, it is essential to verify lhat lubricant does not enter and occlude the tube lumen.

The use of Lidocaine Topical Aerosol has been associated with the formation of pinholes in PVC cuffs. When using this substance, expert clinical judgment must be exercised to detect cuff leaks due to pinholes.

When a patient's position or the tube placement is altered after intubation, it is essential to verify that the tube position remains correct. Any tube displacement should be corrected immediately. Deflate both cuffs prior to repositioning the tube, movement with cuffs inflated could result in patient injury.

ADVERSE REACTIONS

Reported adverse reactions associated with the use of suction catheters include asphyxia, aspiration, atelectasis, bronchospasm cardiac arrest, cardiac arrhythmias, edema, hyperemia, hypoxia, laryngeal spasm, mucosal hemonhage, mucosal ulceration, respiralory tract infection, and trauma to tracheal/bronchial mucosa.

SUGGESTED DIRECTIONS FOR USE

For Left Double-lumen Endobronchial Tube

Obtain blood gases prior to commencing one-lung anesthesia and at regular intervals throughout the procedure.

1. Select the largest size Endo-Bronch tube that will fit safely in the patient's airway.

2. Remove the selected, sterile tube from its protective package. Test the cuffs, pilot balloons, and valves of each tube by inflation prior to use. lnsert a Luer tip syringe into each cuff inflation valve housing and inject enough air to fully inflale the cuffs.

3. After test inflation of the cuffs, completely evacuate all air from the cuffs and remove the syringes.

4. Examine and familiarize yourself with the Endo-Bronch "Y" airway connector assembly before the intubation procedure. After detetmining which connections are required and how the lever arms of the "Y" airway connector rotate to the "ON" and "OFF" positions to control the flow of gases, make a firm connection to the extension circuit of the anesthesia machine.

5. Verify that both shut off valve arms work properly to open and close the flow of gas.

6. If the endobronchial tube is lubricated prior to intubation, it is essential to verify that lubricant does not enter the tube lumen, thereby preventing ventilation.

7. After the patient is appropriately anesthetized, insert the tube between the cords and into the trachea, with the concave portion of the bronchial segment oriented anteriorly and the proximal ends of the tracheal tube and bronchial tube oriented toward the patient's right.

8. After inserting the distal tip of the bronchial tube past the cords, and before advancing the tube down the trachea, withdraw the stylet, if it is still present in the tube, to minimize the possibility of tracheobronchial trauma.

9. Rotate the tube 90 degrees, so that the proximal ends of the tracheal tube and the bronchial tube are pointed away from the patient's face and the bronchial portion of the tube is directed toward the left main bronchus.

10. Advance the tip and cuff of the bronchial tube past the tracheal carina into the left main bronchus, until both the bronchial tube tip and the bronchial cuff are completely contained within the left main bronchus.

11. lf the bronchial tube encounters resistance to venlilatory flow, gently adjust the position of the bronchial tube and cuff within the bronchus, according to currently accepted medical techniques, to facilitate unobtructed airflow through the bronchial tube.

12. lnflate the bronchial and tracheal cuffs, remove the syringe from the cuff inflalion valves, and promptly connect the lube to the source of ventilation.

13. Verify proper tube placement and the adequacy of ventilation, according to currenlly accepted medical techniques.

14. Both fiberoptic bronchoscopy and auscultalion of breath sounds are cunently recommended for accurate adjustment and confirmation of tube placement within the bronchus.

15. Deflate both cuffs prior to repositioning the tube. Movement of the tube with cuffs inflated could result in patient injury, requiring possible medical intervention or damage to one or both cuffs, requiring a tube change. Verify correct placement of the tube after each repositioning.

16. Check to verify that the inflation system is not leaking. lnterity of the inflation system should be monitored both initially and periodically during the intubation period. Cuff pressure should be closely monitored, and any deviation from the selected sealing pressure should be investigated and corrected immediately.

17. Suctioning and fiberoptic bronchoscopy instruments may be introduced into the tracheal and bronchial tubes through the port caps on the swivels, regardless of whether the shutoff valves are open or closed.

18. For deflation of one lung, open the corresponding tube lumen to room atmosphere prior to closing appropriate connecting tube by rotating the"Y" connector arm to the "OFF" position.

19. Prior to extubation, deflate each cuff by inserting a syringe into each valve housing and removing the gas mixture, until adefinite vacuum is noted in the syringe and the pilot balloon is collapsed.

20. Extubate the patient.

21. Discard the endobronchial tube and any accessories in accord with national regulations for discarding and disposing of biologically hazardous waste.