Parker Endo-Bronch™ Left with Standard Tip Double-lumen Endobronchial Tube (PSTDL)

DESCRIPTION

The Parker Endo-Bronch with Standard Endobronchial Tube Tip, Double-lumen Endobronchial Tube (PSTDL) is a sterile, single-use, left style, polyvinyl chloride (PVC), dual tube with separate, tracheal and bronchial lumens, each with its 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. The distal end of the bronchial lumen terminates in a standard endobronchial tube tip. The tracheal connecting tube is labeled "TRACHEAL," and the bronchial connecting tube is labeled "BRONCHIAL." A radiopaque, blue stripe extends along the entire length of the bronchial lumen to assist in radiographic visualization. A black ring mark encircling the bronchial tube at the distal end of the tracheal lumen is provided to facilitate fiberoptic placement of the bronchial tube. Printed depth marks indicate their distance from the tip of the bronchial tube. Also included as sterile items with the Endo-Bronch tube are one stylet in the bronchial tube, two low-friction suction catheters, and a "Y" connector with two right angle swivels that connect the proximal ends of the bronchial and tracheal tube extensions to the extension circuit of the anesthesia machine. Port caps on the right angle swivels allow introduction of suctioning and fiberoptic bronchoscopy instruments into the proximal ends of the tracheal and bronchial tubes through a large port or a smaller, flexible membrane in the port caps connected to those swivels. Two arms of the "Y" connector, each of which is imprinted with an arrow, are connected to shutoff valves in the swivels and can be rotated to the "ON" or "OFF" position, instead of clamping and unclamping the tracheal and bronchial connecting tubes, to open or close the flow of gas.

INDICATIONS

The Endo-Bronch Left 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.

CONTRAINDICATIONS

- The Endo-Bronch Left is contraindicated in patients with stenosis or obstruction of the left main bronchus.
- Use of the Endo-Bronch is also contraindicated in procedures which involve the use of a laser or an electrosurgical active electrode in the immediate area of the device. Contact of the endotracheal tube with a laser beam or electrosurgical active electrode, especially in the presence of oxygen-enriched mixtures, could result in rapid combustion of the endotracheal tube with harmful thermal effects and with emission of corrosive and toxic products, including hydrochloric acid (HCl).

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. If dysfunction is detected in any part of the inflation system, the tube should not be used.
- Do not overinflate the cuffs. Ordinarily the cuff pressure should not exceed 25 cm H2O. However, clinical situations may arise where a higher sealing pressure is clinically indicated. Overinflation can result in tracheal damage, rupture of the cuff with subsequent deflation, or in cuff distortion which may lead to airway blockage.
- If the endobronchial tube is lubricated prior to intubation, it is essential to verify that 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.
- Patients who are difficult to intubate may occasionally require the use of a stylet to pass the tip of the tube between the cords.
- Syringes, three-way stopcocks, or other Luer-tip devices should not be left inserted in the inflation valves for extended periods of time.
- Use only with equipment having standard 15 mm connectors.
- The integrity of the inflation system should be monitored both initially and periodically during the intubation period. Uncorrected failure of the inflation system could result in death.
- Check to be sure that both port caps are securely closed when ports are not in use.
- Nitrous oxide is known to diffuse through tracheal and bronchial tube cuffs causing a potentially hazardous increase in cuff volume and pressure. If left unchecked, the overinflation of the tracheal or bronchial cuff could cause tracheal or bronchial damage, or extension of the cuff over the tracheal or bronchial opening of the tube, with partial or complete occlusion of the lumen. Therefore, when using nitrous oxide mixtures, the user should monitor cuff volume and pressure and make inflation adjustments as required. Additionally, inflating the cuff with the gas mixture which will contact its external surface is recommended as a means to reduce the extent of such diffusion.
- Various bony anatomical structures (e.g., teeth) within the intubation route, or any intubation tools with sharp surfaces, present a threat to maintaining cuff integrity. Care must be taken to avoid damaging the thin-walled cuffs during insertion, which would create the need to subject the patient to the trauma of extubation and re-intubation. If either cuff is damaged, the tube should not be used.
- Inflation of the cuff by "feel" alone or by using a measured amount of air is not recommended, since resistance is an unreliable guide during inflation. Intracuff pressure should be closely monitored with a pressure measuring device.
- After inflation of the cuffs, cuff pressure should continue to be monitored, and any deviation from the selected seal pressure should be investigated and corrected immediately.
- Seat connectors firmly in both the Endo-Bronch and the adaptor on the ventilator equipment to prevent disconnection during use. The security of the connection is usually increased by twisting the two elements together.
- Perform intubation and extubation following currently accepted medical technique.
- Tracheo-bronchial suctioning of mechanically ventilated patients without disconnection of the mechanical ventilator may result in a negative patient airway pressure excursion. Selection of appropriate ventilator settings may limit negative patient airway pressure excursions.
- Exposure to elevated temperatures and ultraviolet light should be avoided during storage, as they can degrade the integrity of the device.
- Suction catheter insertion and use in a particular patient must be governed by clinical judgment.

ADVERSE REACTIONS

The following adverse reactions have been reported to be associated with the use of cuffed endotracheal tubes during the intubation procedure, or during the intubation period or subsequent extubation. These adverse reactions may also be associated with the use of an endobronchial tube. The order of listing does not indicate frequency or severity.

Reported adverse reactions include: abrasion of the arytenoid cartilage vocal process; cartilage necrosis; cicatrix formation; consequences of failure to ventilate, including death; damage to the perichondrium; development of dense or diffuse fibrosis invading the entire glottic area; emphysema; endobronchial aspiration; endobronchial intubation (hypoxemia); tracheobronchial aspiration; epistaxis; esophageal intubation (stomach distension); excoriated membranes of the pharynx; eye trauma; fibrin deposition; formation of subglottic web; fracture-luxation of cervical column (spinal injury); fragmentation of cartilage; glottic edema (supraglottic, subglottic, retroarytenoidal); granuloma of the inner arytenoid area; infections (laryngitis, sinusitis, abscess, respiratory tract infection); inflammation; intermittent aphonia and recurrent sore throat; laryngeal fibrosis; laryngeal granulomas and polyps; laryngeal obstruction; laryngeal stenosis; laryngeal ulcers; laryngotracheal membranes and webs; membranous glottic congestion; membraneous tracheobronchitis; mild edema of the epiglottis; mucosal sloughing; paresis of the hyoglossal and/or lingual nerves; perforation of esophagus; perforation of the trachea; pneumothorax; replacement of the tracheal wall with scar tissue; respiratory obstruction; retrobulbar hemorrhage; retropharyngeal abscess; retropharyngeal dissection; rupture of the trachea; sore throat; dysphagia; stricture of nostril; stridor; subglottic annular cicatricial stenosis; submucosal hemorrhage; submucosal puncture of the larynx; superficial epithelial abrasion; swallowed tube; synechia of the vocal cords; teeth trauma; tissue burns; tracheal bleeding; tracheal stenosis; trauma to lips, tongue, pharynx, nose, trachea, glottis, palate, tonsil, etc.; traumatic lesions of the larynx and trachea; ulcerations exposing cartilaginous rings and minor erosions at cuff site; ulceration of the lips, mouth, pharynx; ulcers of the arytenoids; vocal cord congestion; vocal cord paralysis; and vocal cord ulcerations.

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 hemorrhage, mucosal ulceration, respiratory tract infection, and trauma to tracheal/bronchial mucosa.

SUGGESTED DIRECTIONS FOR USE

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

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. Insert a Luer tip syringe into each cuff inflation valve housing and inject enough air to fully inflate the cuffs.
3. After test inflation of the cuffs, completely evacuate all air from the cuffs and remove the syringes.
4. Examine and familarize yourself with the Endo-Bronch "Y" airway connector assembly before the intubation procedure. After determining 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 shutoff 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. If the bronchial tube encounters resistance to ventilatory flow, gently adjust the position of the bronchial tube and cuff within the bronchus, according to currently accepted medical techniques, to facilitate unobstructed airflow through the bronchial tube.
12. Inflate the bronchial and tracheal cuffs, remove the syringe from the cuff inflation valves, and promptly connect the tube to the source of ventilation.
13. Verify proper tube placement and the adequacy of ventilation, according to currently accepted medical techniques.
14. Both fiberoptic bronchoscopy and auscultation of breath sounds are currently 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. Integrity 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 the 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 a definite 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.

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