STERILE: Unless package has been opened or damaged

Discard after single use, do not re-use

ethylene oxide gas sterilization

Exposure to elevated temperatures and ultraviolet light should be avoided during storage.

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

This device cannot be adequately cleaned and/or sterilized by the user in order to facilitate safe reuse, and is therefore intended for single use. Attempts to clean or sterilize these devices may result in a biocompatibility, infection or product failure risks to the patient.

This product contains DEHP. When used as indicated, very limited exposure to trace amounts of DEHP may occur. The DEHP concentration is clear that chronic exposure increases clinical risk. However, in order to minimize risk of DEHP exposure in children and nursing or pregnant women, this product should only be used as directed.

DESCRIPTION:

The Laser Oral Tracheal Tube Dual Cuffed is a sterile, single-use device supplied with a permanently attached 15mm connector. The tube body consists of a flexible stainless steel hose with a soft plastic segment at the distal end. The Tracheal Tube has two cuffs, each with an associated self-sealing valve and pilot balloon. The sealing diameters of the proximal end of the Laser Tracheal Tube are equivalent to 8.0mm I/D tracheal tubes with high volume, low pressure cuffs. The tube design also includes a Magill Curve and a smooth molded distal tip with Murphy eye.

INDICATIONS:

The Laser Oral Tracheal Tube Dual Cuffed is intended for airway management during surgical procedures involving the use of only CO2 or KTP lasers in surgery of the larynx or other areas in close proximity to the tracheal tube. The stainless steel shaft of the tube is such that accidental momentary contact with a laser beam will not cause tube perforation, but will result in the reflection of a defocused beam. The secondary shield the distal cuff from unintentional laser beam contact, thereby helping to provide protection of the cuff intended for a tracheal seal. To provide a better surgical visibility, the Tracheal Tube is offered with a reduced shaft size. As such, the tube is useful in circumstances where the airway has been narrowed by a tumor or other abnormality to such an extent that normal size tracheal tubes cannot be inserted.

The Laser Oral Tracheal Tube Dual Cuffed is intended for oral intubation only.

CONTRAINDICATIONS:

The Laser Oral Tracheal Tube Dual Cuffed is contraindicated in surgical procedures requiring the use of Nd:YAG laser and other high power laser instruments which may damage the tracheal tube and cause injury to the patient.

WARNINGS / PRECAUTIONS (CUFF-RELATED):

Avoid contact of the laser beam with the unprotected plastic segment and cuffs at the end of the tube. Such contact, especially in the presence of oxygen-enriched or nitrous oxide mixtures could result in rapid combustion of the plastic segments of the tube with harmful thermal effects and with the emission of corrosive and toxic combustion products, including hydrochloric acid (HCl). It has been reported by Hirshman and Smith that mixtures of nitrous oxide and oxygen support combustion about the same as pure oxygen and that in addition to ignition by direct contact with the beam, the interior of the tube can also be ignited by contact with flaming tissue in close proximity to the tip of the tracheal tube.

Contact of the cuffs with a laser beam should be avoided to protect against the loss of a tracheal seal. If either cuff is damaged, the surgical procedure should be stopped immediately. The tube should be removed immediately because:

• Perforation of the stainless steel shaft could expose the internal inflation lines to laser contact which could result in melting, occlusion, or perforation. Refer to chart provided in this insert for Laser Resistance Test.

• For added protection during laser surgery, sterile isotonic saline must be used to completely fill (with no air bubbles) both cuffs at appropriate times..

• The protective function of the upper (secondary) cuff might be lost if the cuff is not completely filled with isotonic saline. If unfilled areas (air pockets) are detected the procedure should be stopped immediately.

• Saline presents a greater resistance to withdrawal from the cuffs than air. When deflating, the user should continue efforts until no more saline is returned.

• The cuffs should be lubricated completely with a sterile water-soluble lubricant to reduce ignition of the cuff tissue if they are struck with a laser beam.

After lubrication of the cuffs, it is essential to verify that lubricant does not enter and obstruct the tube lumen thereby impairing patient ventilation. When the tube is in place, the following should not be used:

• As these devices may have been subjected to handling, storage conditions or preparations which compromised functional integrity; each tube’s cuffs, pilot balloons and valves should be tested by inflation prior to use, and any tube that fails the test should not be used.

• Initiating treatment using a tube already shown to have a dysfunction in the inflation system could unnecessarily subject the patient to the untoward effects of extubation, re-intubation, or loss of respiratory support. Since at least one cuff must remain inflated throughout the intubation period.

• 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

the-wall 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 cuffs by ‘feel’ alone or by using a measured amount of sterile isotonic saline is not recommended since the thin-walled cuffs are under pressure and may not be felt. It should be noted that the recommended inflation procedure involves the use of sterile isotonic saline, a non-compressible fluid. Deflated cuffs are tighter against the wall of the trachea and result in patient injury, requiring possible medical intervention or damage to a cuff. Verifying correct placement of the tube after each repositioning.

Symptoms three-way stopcocks or other devices should not be left inserted in either inflation valve for extended periods of time.

• The use of LiquefacT Topical Aerosol has been associated with the formation of pinholes in PVC cuffs. (U.S. Food and Drug Administration. U.S. Food and Drug Administration. Airway Device -- Endotracheal Tube Base Aerosol, Br. J. Anaesth. 53:1138, 1981.)

• Clinical expert judgement must be used when prescribing treatment involving the use of this substance to help prevent situations of cuffed leaks due to pinhole formation. The same authors report that LiquefacT hydrochloride solution is not a substitute for saline.

WARNINGS / PRECAUTIONS (GENERAL):

• Predilection of exposure of the stainless steel hose to the laser beam should be avoided due to the potential for inadvertent tissue damage. Laser power delivered beyond the tube could damage the laser ports of the tracheal tube with serious consequences for the surgical procedure.

• Do not use the reinforced tubes with magnetic resonance imaging (MRI) or similar instruments, due to the potential for inadvertent tissue damage. Laser power delivered beyond the tube could damage the laser ports of the tracheal tube with serious consequences for the surgical procedure.

• Precautions should be taken when discarding the device and disposal of the device shall be made in accordance with applicable legal requirements for hazardous waste.

• Do not use the reinforced tubes with magnetic resonance imaging (MRI) or similar instruments, due to the potential for inadvertent tissue damage. Laser power delivered beyond the tube could damage the laser ports of the tracheal tube with serious consequences for the surgical procedure.

SUGGESTED DIRECTIONS FOR USE:

Do not use package if has been opened or damaged

1. Assemble and connect the Tracheal Tube to your protective package.

2. Test the cuffs, pilot balloons, and valves of each tube by inflation prior to use. Insert a Luer tip syringe into the cuff inflation valve housing and inject enough air to fully inflate the cuff. Repeat test with all three cuffs to assess any tube for leaks.

3. After test inflation, completely evacuate the air.

4. Lubricate cuffs completely with a sterile water-soluble lubricant.

5. Intubate the patient orally following currently accepted medical techniques with consideration being given to the specific WARNINGS / PRECAUTIONS (CUFF RELATED) stated in the instruction insert.

6. Once the patient is intubated, inflate the distal cuff only with enough sterile isotonic saline to provide an effective seal at the desired lung inflation pressure.

7. Fill the proximal and second cuff with sterile isotonic saline in a similar manner, ensuring that there are no air pockets (see WARNINGS / PRECAUTIONS (CUFF RELATED)). It should be noted that the primary function of this secondary cuff is to seal the distal sealing cuff, and as such, it need not be deflated if the cuff is not completely filled.

8. Remove syringe from the valve housing after cuff inflation. Leave the syringe attached will keep the valve intact, in the event the cuff is deflated.

9. Firmly seat the 15mm connector into the breathing circuit, to help prevent disconnection during use.

10. The small bore of the tube requires careful monitoring and expert clinical judgement to ensure that adequate ventilation is occurring and that no build-up of secretions that could affect patient ventilation by compromising the airway lumen thereby preventing ventilation.

11. Check to verify inflation system is not leaking. Integrity of the system should be verified periodically during the intubation period. Uncorrected failure of the inflation system could result in death. Cuff pressure should be closely monitored and any deviation from the seal pressure should be investigated and corrected immediately.

12. Corrective placement by hearing or feeling air escape at the tube orifice and auscultation of both lungs.

13. If patient position is altered while intubated, verify that tube placement remains correct.

14. To prevent extubation, deflate both cuffs by inserting a syringe into each valve housing and remove saline from both cuffs. If there is no air in the cuff valves, re-inflate cuffs using a measured amount of saline. The presence of metal parts within the airway.

15. Exhale patient following currently accepted medical techniques.

16. Discard the Tracheal Tube. Consideration should be given to the specific WARNINGS / PRECAUTIONS (CUFF RELATED) stated in the instruction insert.
1. The test method used to obtain these data addresses the laser resistance of the stainless steel shaft of the tracheal tube. Other components of the tracheal tube, such as the inflation system and cuff, are outside the scope of this test method.

2. These data were derived with a 0.5mm spot size laser beam continuously applied perpendicular to the shaft of a 6.0mm ID tracheal tube in a 98% oxygen atmosphere. Refer to ASTM F1497-99a for further information.

3. Each data point is the average of 5 tubes tested.

4. The test method data measures and describes the properties of materials, products, or assemblies in response to heat and flame under controlled laboratory conditions and does not describe or appraise the fire hazard or fire risk of materials, products, or assemblies under actual fire conditions. However, results of this test may be used as elements of a fire risk assessment which takes into account all of the factors which are pertinent to an assessment of the fire hazard of a particular end use.

5. Caution should be observed since the direct applicability of the results of the test method to the clinical situation has not been fully established.

REFERENCES: