Laser Resistant Endotracheal Tube

Product Information and Instructions for Use

℞ Only

DESCRIPTION

The Tenax® Laser Resistant Endotracheal Tube is a silicone endotracheal tube with a laser resistant overwrap of aluminum and a silicone outer sheath. The visible aluminum wrap is laser resistant per the values in the sections below titled *Performance Testing* and *Power Recommendations*.

The proximal and distal end of the silicone endotracheal tube shaft are not covered by aluminum wrap and are not laser resistant.

The smooth, low traumatizing, endotracheal tube is fitted with two fluid filled cuffs designed to provide an effective tracheal seal. The pilot balloons of the endotracheal tube have been filled with FD&C #1 blue dye to enable the detection of cuff ruptures.

The tube and cuff are non-wetting, which reduces secretion accumulation during intubation and allows for easy insertion and removal. The flexible tube easily adapts to changes in airway positioning. The tubes are provided sterile and are intended for single use.

EXTREME CARE MUST BE TAKEN IN MAINTAINING THE APPROPRIATE POWER DENSITY OF THE LASER AND OXYGEN GAS MIXTURE CONCENTRATIONS FOR LASER APPLICATIONS.

Failure to comply with these Instructions for Use, the Contraindications and Warnings below, and the Product Usage Recommendations and Laser Power Recommendations will cause unnecessary risk to the health and safety of the patient.

INDICATIONS FOR USE

The Tenax® Laser Resistant Endotracheal Tube is intended for endotracheal intubation. It is indicated for use for all types of surgical procedures involving carbon dioxide (10.60 microns) or KTP (532 nm) laser use (normal pulsed or continuous beam delivery in the non-contact mode), when endotracheal intubation is required to administer anesthetic gases or to overcome emergency obstruction of an airway.

CONTRAINDICATIONS

- The Tenax® Laser Resistant Endotracheal Tube should not be used in patients with narrow airways, which could restrict ventilation, resulting in excessive elevation of intratracheal pressure.
- Do not use in any patient suffering from conditions that may preclude endotracheal intubation. Do not use this device for any purpose other than its intended use.
- To avoid device damage, do not exceed a power density of 10,394 W/cm^2 when used with a CO_2 laser.
- To avoid device damage, d not exceed a power density of 5,305 W/cm^2 when used with a KTP laser.
- Do not use with continuous irradiation lasting longer than 30 seconds.

Read and follow all warnings and instructions.

Failure to read and follow warnings may result in patient injury or death.

WARNINGS

- This device is not made with natural rubber latex. There are no analytical methods currently* available that can identify all proteins and components in natural rubber latex that may lead to allergic reactions in medical products. Any claim of "latex-free" is not scientifically supportable.
  **as of FDA Guidance dated December 2, 2014*
- For intubation during laser surgery use < 24 hours only.
- Not tested for radiopacity or for use with radiographic imaging. Intubate under direct visualization or video laryngoscopy.
- The Tenax Laser Resistant Endotracheal Tube has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Tenax Laser Resistant Endotracheal Tube in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.
- Do not use with any ND:YAG Laser or Argon laser, or any laser type other than CO2 or KTP.
- Do not use any contact tip style laser delivery instrument with this product.
- Do not contact the laser resistant endotracheal tube with a laser beam. If the reflective aluminum wrapping is exposed, the energy of the laser beam may be reflected onto the patient's tissue, causing injury.
- Do not contact the cuff or distal end of the shaft with a laser beam or electrosurgical instruments. The cuffs, the distal end of the tube, and the proximal end of the tube are not laser resistant. Laser contact may cause deflation of the cuff and result in combustion and fire.
- Do not use surgical lasers or electro- or thermal-cautery power sources in the presence of elevated oxygen levels or other flammable gases – damage to the tube may result in ignition and serious patient injury.
- Do not use nitrous oxide for dilution of oxygen. Nitrous oxide is a flammable gas and may result in ignition and serious patient injury.
- Do not over-inflate either cuff. Over-inflation may result in tracheal damage, cuff rupture with subsequent deflation or cuff distortion leading to herniation and airway blockage. Use only a disposable slip-tip 10 mL syringe for inflation of cuffs.
- Do not modify the Tenax® Laser Resistant Endotracheal Tube by trimming, removing or adding additional foil wrapping – patient injury may occur as a result.
- Avoid damage to the tube. Do not use sharp instruments in close proximity to the tube – damage to the tube may compromise patient ventilation.
- In the event of an airway fire*, IMMEDIATELY:*
  - *TURN OFF THE OXYGEN FLOW,*
  - *OCCLUDE THE CIRCUIT TUBING WITH A CLAMP,*
  - *DISCONNECT THE BREATHING CIRCUIT,*
  - *EXTINGUISH THE FIRE WITH STERILE WATER OR SALINE,*
  - *REMOVE THE TUBE FROM THE PATIENT,*
  - *PROVIDE IMMEDIATE CARE TO THE PATIENT.*

INSTRUCTIONS FOR USE

The surgeon must exercise best medical judgment in selecting patients as candidates for the use of this device. Proper patient selection, proper tube placement and proper connection of the endotracheal tube are essential for the safe and effective ventilation of the patient.

The surgeon must be trained in laser surgery techniques and the anesthesiologist must be trained in laser safety protocols. Equipment used must be capable of providing diluted gas mixture concentrations for the safe use of this endotracheal tube in laser surgery.

Prior to Intubation

1. The risk of damaging an endotracheal tube is greater under extreme operating conditions, such as very long procedures and/or repeated manipulations and movements of the endotracheal tube. A

spare Tenax® Laser Resistant Endotracheal Tube of the correct size and type should be readily available.

2. Cuffs should be tested before use with 5 to 10cc of air. Replace the tube with a spare if any leaks or cuff damage are observed. Thoroughly evacuate all test air before intubation.

Intubation

3. The cuff should be slowly inflated with a minimum volume of sterile, normal saline necessary to provide an effective seal. The saline will act as a heat sink. Use only
4. To obtain maximum coloration of FD&C #1 blue dye, add approximately 3cc of sterile, normal saline to the cuff. Slowly aspirate and reinject the normal saline. Repeat to further enhance coloration.
5. Place a wet cotton gauze around the cuffs and keep moist during the entire procedure as an added heat sink. If either of the cuffs are penetrated or ruptured, blue solution will stain the wet cotton gauze. Wet cotton gauze will not withstand the laser power levels described in the *Power Recommendations* and must not be relied upon for cuff protection.
6. Monitor the cuffs' volume and pressure during surgery for changes.
7. Immediately discontinue use of the laser if cuff deflation occurs or is suspected. Remove the damaged tube and replace with a new tube.

During Procedure

8. Dilute oxygen or other flammable gases with helium, nitrogen or room air as needed. Dilute oxygen to the minimal inspired concentration compatible with satisfactory oxygen saturation.
9. RECOMMENDATION: Use 30% oxygen/70% helium, or 30% oxygen/70% room air. Closely monitor the patient for any signs of hypoxemia. Immediately reposition the tube, adjust the oxygen/gas mixture or rate of delivery, or intubate the patient with a conventional tracheal tube if hypoxemia occurs.

Extubation

10. Fully deflate the cuffs prior to extubation. Exercise caution while extubating the patient.

Performance Testing

The Tenax® Laser Resistant Endotracheal Tube was tested to ISO 11990:2018 *Lasers and laser related equipment – Determination of laser resistance of tracheal tube shaft and tracheal tube cuffs*.

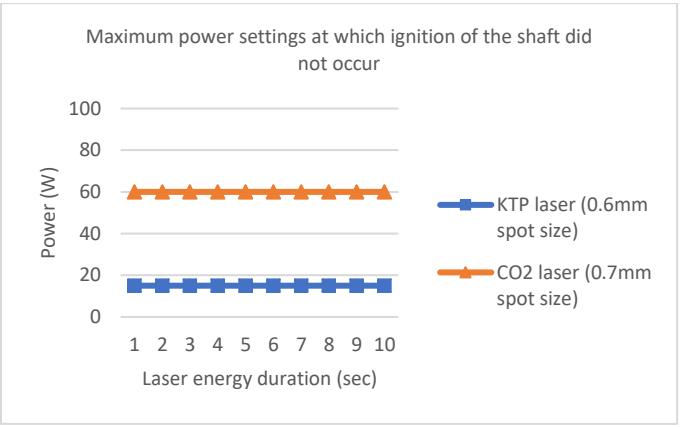

Chart 1. Maximum power settings at which ignition of the shaft did not occur.
When set to the maximum power setting for each laser (15W for KTP; 60W for CO_2) and set to continuous mode, ignition did not occur at any time point. (Testing performed by the Department of Otolaryngology, Cincinnati Children's Medical Center.)

Power Recommendations

	Power	Spot Size	Power Density
CO^2 Laser, Continuous Mode	60W	0.7mm	Maximum 10,394 W/cm^2
KTP Laser	15W	0.6mm	Maximum 5,305 W/cm^2

Symbol Key

℞ **ONLY**	Caution: Federal law restricts this device to sale by or on the order of a physician.		Do not use if package is damaged
	Consult instructions for use		Keep dry
	Caution, see instructions for use		Keep away from sunlight
	Do not resterilize		Do not reuse
	Sterilized using ethylene oxide		Catalogue number
	Batch code		MR unsafe
	Use-by date		Manufacturer

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