Airtraq sp

VIDEO LARYNGOSCOPE FOR DOUBLE LUMEN ENDOTRACHEAL TUBES

US Patent No 6,843,769

INSTRUCTIONS FOR USE

REF: A071; A871

INTENDED USE AND DESCRIPTION

Airtraq SP DL is a video laryngoscope to facilitate intubation when using double lumen endobronchial tubes (DLT). It allows visualization of the airway during intubation. It minimizes hyper extension of the neck and permits intubating from virtually any position. ET Tube is loaded into the lateral channel of the device and when advanced it is guided towards the glottis of the patient.

It is a SINGLE USE medical device provided clean and ready to use.

To perform its purpose Airtraq SP must have attached to its proximal end, either

- its eyecup or
- the WiFi Camera (Ref A-390) offered by the manufacturer, attached after removing its eyecup, or
- an Endoscopic camera attached to the eyecup.

SIZES AND SPECIFICATIONS

Double Lumen Tubes: A-071

For use with double lumen tubes sizes 28-41 Fr.

Any style of DLT (right-sided or left-sided, Carina hooked or not hooked) can be used.

Minimum patient mouth opening: 18 mm

Maximum insertion portion width: 33.8 mm.

Working Length: 117.3 mm.

Field of View: Vertical 28 degrees; Horizontal 32 degrees

Direction of View: Vertical 112 degrees; Horizontal 12 degrees

USE INSIDE OF THE MRI ENVIRONMENT

This medical device was determined to be MR conditional according to the terminology specified by ASTM Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.

The device can be used in the MRI environment according to the following conditions:

- Static magnetic field of 3-Tesla or less
- Spatial gradient magnetic field of 720-Gauss/cm or less

IMPORTANT NOTE: The device is intended for use inside of the MRI environment (e.g., in the MR system room). It will not be utilized directly inside of the MR system (e.g., inside of the bore of the scanner), during its operation (i.e., scanning). As such, the assessment of magnetic field interactions for the device specifically involved evaluations of translational attraction in relation to exposure to a 3-Tesla MR system, only.

TECHNIQUE FOR USING THE AIRTRAQ SP DL

I. PREPARATION & TEST

- Press orange switch located below the battery cover to Turn On the light.
- After 30 seconds check that the light is steady. If so, anti-fog system is fully activated.
  NOTE: If light automatically turns off, the unit has become defective and must not be used.
- Remove the stylet from inside DTL.
- Check DLT cuffs and fully deflate both.
- Lubricate (preferably using water soluble lubricant, not spray) the lower 1/3 of the DLT and place it into the lateral channel of the Airtraq SP DL.

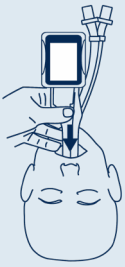
ORIENTATION OF THE DLT IN THE AIRTRAQ SP DL GUIDE CHANNEL.

- Load the DLT and orient the deviated tip of the DLT so it points towards the light of the Airtraq SP DL. If the DLT tube is a right side style, then rotate the DLT 180 degrees until the deviated tip of the of the right DL tube is pointing towards the light of the Airtraq SP DL.
- If the DLT has a carina hook, the hook should point toward the open side of the Airtraq SP DL guiding channel.
- Lubricate the DLT and place it into the lateral channel of the Airtraq SP DL without contacting the lens.
- Align the tip of the DLT with the end of the guide channel.

II. AIRTRAQ SP DL PLACEMENT (Fig. 1)

- Insert the Airtraq SP DL along midline of the patient's mouth. Take care to avoid pushing the tongue inside the oropharynx.
- Advance the Airtraq SP DL through the oropharynx keeping it in the midline.
- Before it reaches the vertical plane, begin looking to identify airway structures.
- Continue insertion until the epiglottis is identified. Place the tip of the Airtraq SP DL in the vallecula. Alternatively, the tip can be placed under the epiglottis, lifting it out of the way.
- Gently lift up the Airtraq SP DL to expose the vocal cords.

1



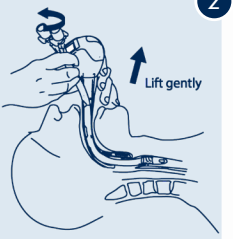
Slide midline

✔ Do not insert too deep

III. DLT INSERTION (Fig. 2)

- **Align the vocal cords in the center of the visual field** by gently moving the tip of the Airtraq SP DL as needed.
- Gently advance the DLT while in the guiding channel. STOP advancing when the DLT proximal cuff has just passed through the vocal cords. Do not insert further. This places the DLT at approximately the midpoint of the trachea. Check insertion depth.
- Inflate the DLT cuff as normal and check for proper positioning.

2



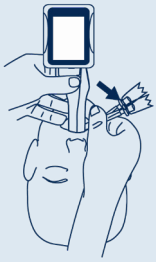
Center glottis
Advance DLT

✔ Lift gently
✔ Twist Airtraq to center vocal cords
✔ Corkscrew ETT

IV. AIRTRAQ SP DL REMOVAL (Fig. 3)

- Separate the DLT from the Airtraq SP DL by pulling it laterally from the guiding channel, while holding the DLT in position.
- Check final insertion depth and location in the bronchi pursuant to hospital standard protocol, e.g. stethoscope or fiberoptic bronchoscope).
- Remove the Airtraq SP DL from the patient´s airway following the midline.

3



Remove midline

WARNINGS AND PRECAUTIONS

- This product should only be used by personnel trained in insertion of Double Lumen Endobronchial tubes (DLT).
- Do not sterilize.
- Do not incinerate unless batteries have been removed.
- Do not submerge in liquids.
- Use only with non-flammable anesthetics.
- Do not put pressure on the teeth with this device.
- Do not force the Airtraq SP DL into the upper airway.

USAGE TIPS

1. Initial experience should be gained in non-difficult airways.
2. Lubricate DLT generously (preferably using water soluble lubricants, not spray) and check that cuffs are fully deflated).
3. Insert the Airtraq SP DL, avoiding the tongue, and slide it softly and slowly.
4. Keep the Airtraq SP DL in the mouth's midline.
5. Look before the Airtraq SP DL gets to the vertical plane.
6. Do not insert too deep. If structures (arytenoids, epiglottis, etc.) are not clearly recognized or tube cannot be inserted, withdraw the Airtraq SP DL slightly.
7. Once the tip is located at the epiglottis, either at the vallecula (Macintosh style), or under the epiglottis (Miller style), gently lift up the Airtraq SP DL (do not tilt or use a lever action).
8. Advance the DLT slowly. If needed rotate DLT inside the channel.

BATTERY CHARACTERISTICS

Each Airtraq SP DL is equipped with two AAA batteries in serial connection that provide a voltage of 3 volts. The batteries provide power to the LED light and to the anti-fog system when the switch is turned on. They should not be replaced.

STORAGE, TRANSPORT, SHELF LIFE AND SERVICE LIFE

The Airtraq SP DL should not be used, stored or transported at temperatures below -5°C/23°F or over 55°C/131°F. The relative humidity must not exceed 95 %. The air pressure must not exceed 500 to 1060 hPa.

Airtraq SP DL shelf life is limited to the expiration date.

Airtraq SP DL service life is limited to 40 accumulative minutes, 5 minutes before its end; the Airtraq SP DL will start blinking for 2 seconds every 20 seconds. Once maximum operating time is reached the Airtraq SP DL will blink continuously until battery is depleted.

DISPOSAL

To dispose the Airtraq SP DL once it has been used:

- Separate the eyecup from the main body by pulling it up.
- Remove the battery cover by pulling it away from the main body (pull away from the small notches).
- Remove the batteries from the Airtraq SP DL and place them in an appropriate battery recycling container (dispose of them according to established recycling policies). The batteries are classified as non hazardous waste material and comply with European Directive WEEE. However, the manufacturer recommends separating them from standard trash.
- Discard the Airtraq SP DL as any other potentially contaminated waste.

MANUFACTURER´S WARRANTY

The manufacturer warrants the Airtraq SP DL against faulty materials or manufacturing defects for only one use or until the expiration date, whichever comes first, provided that the Airtraq SP DL is used in accordance with the procedures set forth in these instructions. This Warranty is applicable only if the device is purchased from an authorized distributor.

This device has not been designed to be cleaned or sterilized. Use beyond this recommendation may generate serious consequences in the product's performance and will void the Airtraq SP's warranty. The manufacturer disclaims all other warranties, whether expressed or implied, including, without limitation, the warranties of merchantability or fitness for a particular use.

USER ASSISTANCE INFORMATION

Instructions for use are available online at https://www.airtraq.com/IFU

Visit **www.airtraq.com** for further advice on using this device

Any serious incident that occurs in relation to this device should be reported to the manufacturer and the competent Health Authority in which the user and/or patient is established. For communication with manufacturer, please email **user.assistance@airtraq.com**, or:

1. Contact directly with Manufacturer at its address or by phone:
   USA & Canada: +1877-624-7929
   EU & Other: +34944804690
2. Contact Manufacturer´s Representative for your area (details below) or
3. Contact your Local Distributor

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GLOSSARY OF SYMBOLS

SYMBOL	SYMBOL MEANING	SYMBOL	SYMBOL MEANING	SYMBOL	SYMBOL MEANING
REF	Reference Number	QTY	Number of Units		Legal Manufacturer
LOT	Batch code		Manufacturing Date		Use-By date
EC REP	Authorized representative in the European Community		Importer	MD	Medical device
	Fragile, handle with care		Consult instructions for use		Do not re-use
	Temperature limit.		Humidity limitation		Atmospheric Pressure Limitation
LATEX	Not Made with Natural Rubber Latex		Keep Dry / Protect from moisture	Rx Only	Federal (USA) law restricts the use of this device to sale by or on the order of a physician
CE	CE Mark, European Conformity	EAC	EAC Mark, Eurasian Conformity	UK CA	UKCA Mark, UK Conformity Assessment
	This side up		Do not use if package is damaged		Distributor
	Separate collection for waste of electrical and electronic equipment		Type BF applied part	Australian Sponsor	Australian sponsor
MR	Magnetic resonance conditional		Box/packaging recyclable		