Airtraq sp

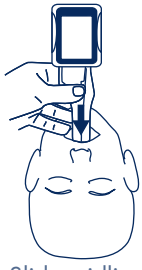
VIDEO LARYNGOSCOPE FOR DOUBLE LUMEN ENDOTRACHEAL TUBES

US Patent No 6,843,769

INSTRUCTIONS FOR USE

ENGLISH

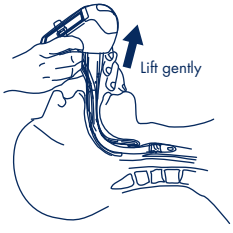
1



Slide midline

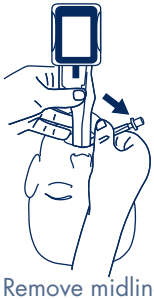
- Do not insert too deep
- Lift gently
- Twist Airtraq to center vocal cords
- Corkscrew ETT

2



Center glottis
Advance ETT

3



Remove midline

DESCRIPTION AND INDICATIONS

The Airtraq SP DL is a SINGLE USE video laryngoscope designed to facilitate insertion of double lumen endobronchial tubes (DLT). It allows full visualization of the airway, during 100% of the intubation. It does not require hyper extension of the neck and permits intubating patients in virtually any position. It is provided clean, ready to use. Visualization can be performed directly through the eyecup or connecting it to any Endo Cam or to the accessories offered by the manufacturer.

SIZES

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.

TECNIQUE 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 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.

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.

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.

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 -5ºC/23ºF or over 55ºC/131ºF. 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 W applicable only if the device is purchased from an authorized distributor.

The Airtraq SP DL is designed for SINGLE-PATIENT-USE.

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

disclaims all other warranties, whether expressed or implied, including, without limitation, the warranties of merchantability or fitness for a particular use.

MD

Rx Only

Manufactured by:
PRODOL MEDITEC LIMITED
1/F, 4/F, Block C
No. 18, 7th Science Ave.,
Zhuhai, Guangdong. 519085 China.

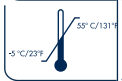
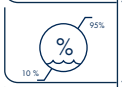
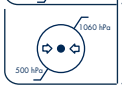
USA Representative: **AIRTRAQ LLC**
2414 Lawton Ln.
Rowlett, TX, 75089, USA

EU Representative:
PRODOL MEDITEC, S.A.
Muelle Tomás Olavarri 5, 3°
48930 Las Arenas SPAIN

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

For further advice on using the Airtraq SP please visit: www.airtraq.com or contact: info@airtraq.com or info.usa@airtraq.com

SYMBOL GLOSSARY DEFINITIONS (MULTI LANGUAGE)

SYMBOL	EN DEFINITION	ES DEFINICIÓN	DE DEFINITION	FR DÉFINITION	IT DEFINIZIONE	PT DEFINIÇÃO	NL DEFINITIE	CS DEFINICE	JP 意味	RU ОПРЕДЕЛЕНИЕ
	Legal Manufacturer	Fabricante	Hersteller	Fabricant	Produttore legale	Fabricante Legal	Wettelijke fabrikant	Výrobce	法的メーカー	Официальный производитель
	Authorized representative in the European Community	Representante autorizado en la Comunidad Europea	Bevollmäch tigter in der Europäischen Gemeinschaft	Mandataire dans la Communauté européenne	Rappresentante autorizzato nella Comunità Europea	Representante Autorizado na Comunidade Europeia	Gemachtigde vertegenwoordiger in de Europese Gemeenschap	Zplnomocněný zástupce pro Evropské společenství	欧州共同体認定代表事務所	Уполномоченный представитель в Европейском сообществе
	Date of Manufacturer	Fecha de fabricación	Herstellungs datum	Date de fabrication	Data di produzione	Data de fabrico	Productiedatum	Datum výroby	メーカーの日付	Дата производства
	Do not re-use	No reutilizar	Nur zum einmaligen Gebrauch	Ne pas réutiliser	Non riutilizzare	Não reutilize	Niet nogmaals gebruiken	Nepoužívejte opakovaně	再使用しないでください	Не использовать повторно
	Medical device	Producto sanitario	Medizinprodukt	Dispositif médical	Dispositivo medico	Aparelho médico	Medisch apparaat	Zdravotnický prostředek	医療機器	Медицинское изделие
	Batch code	Número de lote	Losnummer	Code de lot / Numéro de lot	Numero Lotto	Número do lote	Lot nummber	číslo šarže	ロット番号	Номер партии
	Reference Number	Número de catálogo	Bestellnummer	Numéro de catalogue	Numero di catalogo	Número de catálogo	Catalogusnummer	Katalogové číslo	リファレンス/ カタログ番号	Справочный номер / Номер по каталогу
	Type BF applied part	Pieza aplicada tipo BF	Anwendungsteil vom Typ BF	Partie appliquée de type BF	Parte applicata di tipo BF	Peça aplicada tipo BF	Type BF toegepast onderdeel	Příložná část typu BF	タイプBF装着部	Рабочая часть типа BF
	Box/packaging recyclable	Embalaje reciclable	Verpackung recycelbar	Emballage recyclable	Imballaggio riciclabile	Embalagens recicláveis	Verpakking recyclebaar	Obal je recyklovatelný	リサイクル可能な包装	Упаковка пригодна для вторичной переработки
	Fragile, handle with care	Frágil, manipular con cuidado	Zerbrechlich - Vorsichtig behandeln	Fragile manipuler avec soin	Fragile, maneggiare con cura	Frágil, manuseie com cuidado	Breekbaar - voorzichtig behandelen	Křehké, zacházejte opatrně	壊れやすい、慎重に扱う	Хрупкий, обращайтесь с заботой
	Keep Dry/Protect from moisture	Mantener seco / Protéjalo de la humedad	Trocken lagern / Vor Feuchtigkeit schützen	Garder sec / Protection contre la moisissure	Mantenere asciutto / Proteggere dall'umidità	Manter seco / Proteger da humidade	Droog houden / Beschermen tegen vocht	Uchovávejte v suchu. / Chraňte před vlhkem	乾燥した状態に保ってください / 湿気から保護してください。	Хранить в сухом месте / Беречь от влаги
	Importer	Importador	Importeur	Importateur	Importatore	Importador	Importeur	Dovozce	輸入業者	импортер
	Temperature limit.	Límites de temperatura	Temperatur grenze	Limite de température	Limiti temperatura	Limitação de temperatura	Beperking temperatuur	Teplotní omezení	保管温度制限	Допустимая температура хранения
	Humidity limitation	Límites de humedad	Feuchtigkeits limiti erung	Limite d'humidité	Limiti umidità	Limitação de humidade	Beperking luchtvochtigheid	Limity vlhkosti vzduchu	湿度制限	Ограничение по влажности
	Atmospheric Pressure Limitation	Límites de presión atmosférica	Luftdruck limitierung	Limite de pression atmosphérique	Limitazione della pressione atmosferica	Limitação da Pressão Atmosférica	Atmosferische drukbeperking	Omezení atmosférického tlaku	大気圧制限	Ограничение атмосферного давления

SYMBOL GLOSSARY DEFINITIONS (MULTI LANGUAGE)

SYMBOL	EN DEFINITION	ES DEFINICIÓN	DE DEFINITION	FR DÉFINITION	IT DEFINIZIONE	PT DEFINIÇÃO	NL DEFINITIE	CS DEFINICE	JP 意味	RU ОПРЕДЕЛЕНИЕ
	Not Made with Natural Rubber Latex	Fabricado sin látex de caucho natural	Nicht mit Naturlatex hergestellt	Non fabriqué à partir de latex de caoutchouc naturel	Non composto da lattice di gomma naturale	Não fabricado com Látex de Borracha Natural	Niet gemaakt met natuurlijk rubberlatex	Při výrobě nebyl použit přírodní kaučuk	天然ゴムラテックス不使用	Изготовлено без использования натурального каучукового латекса
	Consult instructions for use	Consultar las instrucciones de uso electrónicas	Elektronische Anleitung zum Gebrauch konsultieren	Consulter le mode d'emploi. Disponible sur le site Internet à l'adresse	Consultare le istruzioni elettroniche per l'uso	Consulte as instruções eletrônicas de uso	Raadpleeg de elektronische gebruiksaanwijzing	Prostudujte elektronický návod k použití	使用説明書を参照してください	См. инструкции по применению
Rx Only	Federal (USA) law restricts the use of this device to sale by or on the order of a physician	Las leyes federales estadounidenses restringen la venta de este dispositivo a médicos o por prescripción facultativa	Laut US-Gesetzgebung darf dieses Produkt nur von einem Arzt oder im Auftrag eines Arztes gekauft werden	Les lois fédérales (USA) limitent la vente de ce dispositif aux seuls médecins ou sur prescription médicale	La legge federale (USA) limita la vendita di questo dispositivo a opera o per conto di un medico	A lei federal (dos Estados Unidos da América) restringe a utilização deste dispositivo a médicos ou mediante prescrição médica	De Amerikaanse federale wet beperkt de verkoop van dit apparaat aan of in opdracht van een arts	Podle federálních zákon ů USA je prodej tohoto za řízení povolen pouze léka řům nebo na léka řský předpis	米国連邦法は、本装置の販売を医師または 医師の指示によるものに限定しています。	Согласно федеральному законодательству США продажа этого устройства разрешена только врачам или по их заказу
	CE Mark, European Conformity	Marcado CE, conformidad técnica europea	CE-Kennzeich nung, kennzeichnet technische Konformität mit europäischen Richtlinien	Marquage CE, conformité européenne	Marchio CE, Conformità Europea	Marca CE, Conformidade Europeia	CE-markering, Europese conformiteit	Označení CE, Označuje shodu s evropskými technickými požadavky	CE マーク、欧州適合性	Знак CE, Европейское соответствие
	EAC Mark, Eurasian Conformity	Marca EAC, conformidad euroasiática	EAC-Zeichen, eurasische Konformität	Marque EAC, conformité eurasienne	Marchio EAC, Conformità eurasiatica	Marca EAC, Conformidade Eurasiana	EAC-keurmerk, Euraziatische conformiteit	Značka EAC, Euroasijská shoda	EAC マーク、ユーラシア適合性	Евразийское соответствие
	UKCA Mark, UK Conformity Assessment	Marcado UKCA, conformidad técnica de Gran Bretaña	UKCA Kennzeichnung, Kennzeichnet die technische Konformität gemäß der britischen Verordnung	Marque UKCA, évaluation de la conformité au Royaume-Uni	Marchio UKCA, Valutazione di conformità del Regno Unito	Marca UKCA, Avaliação de Conformidade do Reino Unido	UKCA Mark, UK Conformiteitsbeoordeling	Ozna čení UKCA, znamená technickou shodu ve Velké Británii	UKCA マーク、英国適合性評価	UkCA Mark, Великобритания Оценка соответствия
	This side up	Este lado hacia arriba	Diese Seite nach oben	Ce côté vers le haut	Questo lato in su	Este lado para cima	Deze kant naar boven	Touto stranou nahoru	こちら側を上に	Не кантовать
	Do not use if package is damaged	No utilice el producto si el envoltorio está dañado	Nicht verwenden, wenn die Verpackung beschädigt ist	Ne pas utiliser si l'emballage est endommagé	Non utilizzare se la confezione è danneggiata	Não utilize se a embalagem estiver danificad	Niet gebruiken indien de verpakking is beschadigd	Nepoužívejte, pokud je obal poškozený, a prostudujte si návod k použití	パッケージが開封または破損している場合は使用しな	Не использовать, если упаковка вскрыта или повреждена
	Distributor	Distribuidor	Verteiler	Distributeur	Distributore	Distribuidor	Distributeur	Distributor	ディストリビューター	распределитель
	Separate collection for waste of electrical and electronic equipment	Reciclaje: Equipos electrónicos	Recycling: Elektronische Geräte	Équipement électronique: Éliminer de manière appropriée	Raccolta separata per rifiuti di apparecchiature ettriche ed elettroniche	Separe para a recolha de resíduos de equipamento elétrico e eletrónico	Aparte inzameling van afval van elektrische en elektronische apparatuur	Recyklace: elektronická za řízení	電子機器廃棄物分別回収	Утилизация электроотходов
	Use-By date	Fecha de caducidad	Verfallsdatum	Utiliser avant	Usare entro / Data di scadenza	Use por Data / Expiração	Gebruik door / Vervaldatum	Datum použitelnosti	有効期限まで使用	Использовать до / Дата истечения срока годности
	Australian sponsor	Patrocinador Australiano	Australischer Sponsor	Sponsor Australien	Sponsor Australiano	Patrocinador Australiano	Australische sponsor	Australský zadavatel	オーストラリアのスポンサー	Австралийский спонсор
	Magnetic resonance conditional	Compatible con resonancia magnética bajo ciertas condiciones	Bedingt MR-sicher	Compatibilité RM conditionnelle	A compatibilità condizionata con risonanza magnetica	Condicional para ressonância magnética	MR-conditioneel	MR podmíněné	MR に条件付きで対応	Условно совместимо с МРТ
	Number of Units	Número de unidades	Nombre d'unités	Nombre d'unités	Numero di unità	Número de unidades	Aantal eenheden	Počet jednotek	ユニット数	Количество единиц