Laryngeal lesions and tracheal procedures

Using COBLATION[⋄] technology

A laryngeal technique guide





Introduction

The PROCISE⁶ MLW laryngeal Wand provides 'pinpoint' ablation and coagulation capabilities

Surgical technique

COBLATOR[⋄] II surgery system setup

1. Set up the Coblator II system and the PROCISE MLW laryngeal Wand according to the Controller User's Manual and Wand Instructions for Use (IFU).

NOTE: This guide is not intended to replace the Coblator II User's Manual or Wand IFU. Thoroughly review the User's Manual and Wand IFU before installing or operating this system.

- 2. Default settings: Coblate 7, Coag 3. Adjust as needed and per surgeon preference.
- 3. Connect the Wand's suction tubing to an OR suction source separate from any other suction instrumentation. Suction should be set to approximately 250mmHg.
- 4. Connect the Wand's saline tubing to bag of normal saline and adjust saline flow to a minimum intermittent drip.

Patient/other preparation

1. To ensure optimal visualization throughout the procedure, the Wand can be used with standard laryngoscopes and microscopes. Use the largest laryngoscope that can be accommodated. Those with proximally and distally adjustable blades are particularly useful.

2. Standard cuffed microlaryngeal tubes are adequate for protection of the lower airways from any excess saline. This can be aided by gentle packing above the balloon with wet cottonoids. Chance contact of the COBLATION® Wand with the tube will not cause damage to the airway tube.

Note: Recent studies about airway fires suggest that using COBLATION technology in place of traditional electrosurgical or laser devices during oropharyngeal surgery substantially reduces the risk of igniting an airway fire due to the low heat generated and the lack of spark or ignition medium under normal operating circumstances. ^{1,2,3} Special endotracheal tubes used with lasers are not necessary.

Venturi ventilation has also been used successfully in conjuntion with COBLATION technology. A 'head down' (Trendelenberg) position should be utilized to ensure any excess saline flows into the pharynx and not in the trachea.



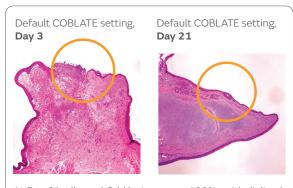




Figure 1. Before COBLATION[⋄] technology treatment



Figure 2. After COBLATION technology treatment



At Day 21, all vocal-fold lesions were 100% epithelialized in canine model. Gross appearance of vocal-fold lesions was fully healed with no exudates present.

Figure 3. Histology (animal model)⁵

Procedure

1. To ablate tissue, position Wand tip in close proximity to target tissue.

CAUTION: Care should be taken in monitoring the targeted tissue during ablation to ensure consistent and controlled tissue removal is achieved. Care should also be taken to ensure surrounding tissue is properly monitored. Due to the smaller anatomies of certain patients, carefully monitor the surrounding tissues to ensure tissue ablation is localized to the targeted tissue.

2. Press the ablation pedal (yellow) of the Foot Control to activate the Wand. Make brief contact (1-2 seconds) with target tissue through the use of a dabbing motion. Continue ablation briefly after removing the tip from target tissue to allow "digestion" of any tissue on the electrode surface. Deactivate the Wand by taking your foot off the foot pedal.

CAUTION: Keep the active electrode directly facing target tissue. User should always pay close attention to the position of the PROCISE[®] MLW Wand, and to its proximity to surrounding untargeted tissue. Ensure non-targeted tissue does not contact the exposed metal of active or return electrodes. Do not bend the Wand shaft or rub the Wand tip against target tissue during ablation as this could result in clogging of the suction line. Do not use the Wand suction line as a standard surgical suction device to clear debris from the surgical field as this could result in clogging of the suction line.

3. To coagulate tissue, position Wand tip directly over the source of bleeding and depress the Coagulation pedal (blue).

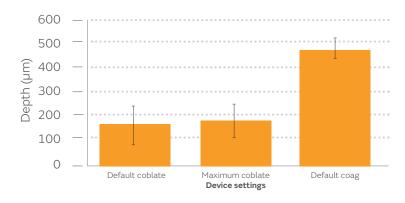


Figure 4. Thermal effect^{4*} (the error bars represent standard deviation)



The ultra-slim, extended Wand shaft of the PROcise MLW Wand provides access to the trachea, making it well-suited for operating on small anatomy. $\frac{1}{2} \left(\frac{1}{2} \right) = \frac{1}{2} \left(\frac{1}{2} \right) \left(\frac$

Ordering information

COBLATION® PROCISE® MLW Laryngeal Wand	
Reference #	Description
EIC7071-01	PROCISE MLW COBLATOR [◊] II
13546-01	COBLATOR II CONTROLLER 120V
EICA7071-01	PROCISE MLW COBLATOR II
13546-02	COBLATOR II CONTROLLER 240V

Additional instruction

To order the instruments used in this technique, call +1 800 343 5717 in the U.S. or contact an authorized Smith+Nephew representative. Prior to performing this technique, consult the Instructions for Use documentation provided with individual components - including indications, contraindications, warnings, cautions and instructions.

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

Learn more at smith-nephew.com



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US Customer Service: +1 800 343 5717

Distributred by: Sports Medicine Smith & Nephew, Inc. 150 Minuteman Road Andover, MA 01810

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References

1. Smith LP, Roy S. Operating room fires in otolaryngology: risk factors and prevention. Am J Otolaryngol. Article in press (Epub 2010 Apr 14). 2. Roy S, Smith LP. Device-related risk of fire in oropharyngeal surgery: a mechanical model. Am J Otolaryngol. 2010 Sept; 31(5):356-359. This article references preclinical non-human data. As such, results may not necessarily be the same in human procedures. 3. Matt BH, Cottee LA. Reducing risk of fire in the operating room using COBLATION® technology. Otolaryngol Head Neck Surg. 2010 Sept;143(3):454-5. **4.** Data on file – report # 35764-01. **5.** Data on file – report # 35766-01.