

K955781

## **Non-Confidential Safety and Effectiveness Summary**

### **Preliminary Feasibility Studies**

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An earlier design of this device was evaluated in a clinical study under IDE G900092. In that study, ten patients were studied with the device in place during emergence from a short general anesthetic. There was no difference between positive inspiratory pressure necessary to generate adequate ventilation volumes before placement of the device, (face mask only), during placement with the COPA™ cuff deflated, or during placement with the COPA™ cuff inflated. Use of the device did not affect end-tidal carbon dioxide concentrations. No patient had a complication as a result of participating in the study.

### **Design Modifications**

While the preliminary studies demonstrated the feasibility of the COPA™ device, they also implied that a change in the shape of the inflatable cuff would improve that reliability of the device. All later studies were performed on devices with a cuff design as indicated in the attached drawing.

### **Functional Testing**

Bench testing of sterile prototypes verified conformance to ISO 5364 -- Oropharyngeal airways, in its requirements for:

1. molding tolerances
2. dimensions of 15 mm connectors and airway
3. resistance to collapse of the buccal end
4. resistance to distortion

Bench testing of sterile prototypes also verified the integrity and consistency of the product in the following areas:

1. airway integrity
2. resting volumes and diameters of cuffs
3. cuff integrity
4. cuff herniation over the distal end of the airway
5. strength of the tail-airway bond
6. disconnect force of the connector from the breathing circuitry

The functionality of the COPA™ device was compared to that of predicate devices in cadaver studies. (See attachment 5) The results of these studies show that:

1. The cuff is appropriately placed in the pharynx when the device is placed as directed in the product insert. When inflated, the cuff occludes the nasopharynx and displaces the base of the tongue and epiglottis anteriorly while sealing the posterior pharynx.
2. The cuff seals the oropharynx at lower pressures than both the Sheridan Combi-Tube and the Laryngeal Mask Airway.
3. The COPA™ airway does not extend inferiorly past the vallecula or into the esophagus. Therefore, it does not raise the potential for glottic or tracheal stimulation in an anesthetized patient.

## Clinical Studies

### A. Conducted August 1995.

The current design was evaluated in a European study of twenty patients. The results of this study, as summarized in the attached abstracts, (attachment 3) show that:

1. Device placement and maintenance of a patent airway were easy.
2. Anesthetic sequelae (coughing, bucking, and sore throat) were minor and comparable to those occurring with use of tracheal tubes and laryngeal mask airways.
3. Anesthetic doses needed for device placement and maintenance are similar to those needed for the predicate devices.

### B. Conducted July 1996

A two-site Australian study was conducted on 100 patients to evaluate the COPA™ device for spontaneously breathing anesthesia. During airway maintenance with the COPA™ device, adverse events and interventions were recorded on videotape, and by verbal commentary and hand-written notes. An assessment was made of device positioning (fiberoptically, from within the device), postoperative sore throat, and skill acquisition. The COPA™ device provided a clear airway in 98% of the patients during manually assisted breathing (MAB), 100% during spontaneous breathing (SB) and emergence from anesthesia. Useful interventions were jaw lift and rotation of the head. Less useful were size changes, withdrawing the COPA™ device slightly, or changing cuff volume. Most interventions occurred during the first three minutes of each phase. Jaw lift (manual or mechanical chinlift) was required for 21.4% of the time during SB. The oxygen saturation (SpO<sub>2</sub>) briefly fell to 87-89% on six occasions. During SB the vocal cords were visible (from a vantage point of just inside the distal tip of the device) in 29% and the epiglottis in 90%. Emergence characteristics were excellent. Mild sore throat occurred in 4%. There was tentative evidence for skill acquisition. The investigators concluded that the cuffed oropharyngeal airway is suitable for spontaneous breathing anesthesia. Most patients require one or more interventions to provide a clear airway. The device has the performance characteristics of a relatively "hands-free" face mask/Guedel airway. It is well tolerated and has a low complication rate.

### C. Completed September 1996

A randomized, controlled, multi-site study was carried out under IDE G960100 to compare the safety, efficacy, and utility of the COPA™ device to that of the laryngeal mask airway (LMA) in patients undergoing spontaneously breathing general anesthesia. The results of this study indicate that the COPA™ device and the LMA are equivalent devices in terms of 1) ease of use, 2) physiological tolerance and 3) minor and major complications. Although the LMA was associated with fewer airway manipulations, both devices were equivalent in establishing a safe and effective airway for spontaneously breathing anesthetized adults. There were no reports of unanticipated adverse device effects on the health or safety of the patients, or any life threatening problems or deaths caused by or associated with either tested device in this study. The time to hands free airway (seconds) was 229 (310) for the COPA and 137 (121) for LMA. It was significantly shorter for the LMA (p=0.004.) There were significantly more patients who did not achieve a hands free airway with the COPA (29/302 = 9.6%) than the LMA (1/150 = 0.66%) (p<0.001). The time to spontaneous breathing (minutes) was similar at 7.3 (6.8) for COPA and 6.7 (6.4) for LMA (p=0.44.)

#### *Airway manipulations post-incision - propofol off. Total (%)*

Airway Manipulations	COPA	LMA
0	135/295 (45.8)	144/150 (96)
1	39/295 (13.2)	5/150 (3.3)
2	14/295 (4.8)	1/150 (0.7)
>2 or continuous support	107/295 (36.3)	0/150 (0)
Total	295 (100)	150 (100)

Major and minor problems reported are summarized in the following table:

<i>type</i>	Problems occurring during use of the device: events/patients (%)		<i>p value</i> <i>Chi Squared</i>
	<i>COPA</i>	<i>LMA</i>	
aspiration	1/302 (0.3)	0/151 (0)	0.479
regurgitation	2/302 (0.7)	1/151 (0.7)	1.000
laryngospasm	6/302 (2)	2/151 (1.3)	0.614
succinylcholine given	5/302 (1.7)	0/151 (0)	0.112
wheeze	1/302 (0.3)	0/151 (0)	0.479
hypoxia (SaO <sub>2</sub> < 92%)	30/302 (9.9)	14/151 (9.3)	0.822
failed use	14/302 (4.6)	4/151 (2.6)	0.291
bucking	2/302 (0.7)	1/151 (0.7)	1.000
hiccuping	5/302 (1.7)	8/151 (5.3)	0.029
shivering	4/302 (1.3)	0/151 (0)	0.155
gagging	4/302 (1.3)	4/151 (2.7)	0.313
coughing	28/302 (9.3)	11/151 (7.3)	0.477
stridor	9/302 (3.0)	3/151 (2.0)	0.535
nasogastric tube inserted	0/302 (0)	1/151 (0.7)	0.157
blood detected	17/294 (5.8)	23/150 (15.3)	0.001
movement	15/302 (5.0)	9/151 (6.0)	0.656
continuous chin support	90/302 (29.8)	0/151 (0)	0.001