

**REQUEST FOR APPROVAL  
LOCAL OPTIONAL SCOPE OF PRACTICE**

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EMS MEDICAL DIRECTOR: Humberto Ochoa, M.D. DATE: February 14, 2003

LOCAL EMS AGENCY: Riverside County

NAME OF PROPOSED PROCEDURE OR MEDICATION: Trial Study on the Use of the Melker Kit  
for Needle Cricothyrotomy

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1. DESCRIPTION OF THE PROCEDURE OR MEDICATION REQUESTED:  
Use of the Melker Emergency Cricothyrotomy Catheter Kit to perform prehospital cricothyrotomy.
2. DESCRIPTION OF THE MEDICAL CONDITIONS FOR WHICH THEY WILL BE UTILIZED:  
See attached.
3. ALTERNATIVES (Please describe any alternate therapies considered for the same conditions and any advantages and disadvantages):  
See attached.
4. PATIENT POPULATION THAT WOULD BENEFIT, INCLUDING AN ESTIMATE OF FREQUENCY OF UTILIZATION:  
See attached.
5. OTHER FACTORS OR EXCEPTIONAL CIRCUMSTANCES:  
See attached.

**PLEASE ATTACH:**

6. ANY SUPPORTING DATA, INCLUDING RELEVANT STUDIES AND MEDICAL LITERATURE.
7. RECOMMENDED POLICIES/PROCEDURES TO BE INSTITUTED REGARDING USE, MEDICAL CONTROL, TREATMENT PROTOCOLS, AND QUALITY ASSURANCE OF THE PROCEDURE OR MEDICATION.
8. DESCRIPTION OF THE TRAINING AND COMPETANCY TESTING REQUIRED TO IMPLEMENT THE PROCEDURE OR MEDICATION.

Item 1 -- Description of procedure

Use of the Melker Emergency Cricothyrotomy Catheter Kit to perform prehospital Cricothyrotomy.

Item 2 -- Medical conditions for which utilized

Performing a cricothyrotomy will be the procedure of last resort in those patients with complete airway blockage in which all other means of ventilation have failed. ***This procedure will only be used on those patients who are over the age of eight (8) years. Those eight years of age and younger will have standard, age-appropriate BLS measures, and non-invasive ALS measures performed (see Item 3 below)***

Item 3 -- Alternatives

Alternative means of ventilation that would take precedence prior to attempting needle cricothyrotomy include all BLS and ALS procedures for airway manipulation, including, but not limited to:

- Heimlich maneuvers
- Insertion of OP or NP airways
- Suction
- Bleeding control
- Use of Magill forceps
- Drug therapy (albuterol HHN, ipratropium HHN, epinephrine SQ)
- Insertion of ETT
- Insertion of Combi-tube

Item 4 -- Patient population that would benefit, including an estimate of frequency

Those patients with conditions/ injuries that could produce complete airway blockage, including, but not limited to

- foreign body aspiration
- edema 2<sup>o</sup> to anaphylaxis / inflammatory response
- isolated trauma to the neck and/or face
- tumor

We anticipate use of this procedure on less than 1/100th of 1% of our patient population – not more than 3 – 4 persons per year in Riverside County.

Item 5 -- Other factors or exceptional circumstances

Needle cricothyrotomy is a procedure included in the standard scope of practice for paramedics, using a 10-gauge needle. It is our belief that a 10-gauge needle, even using translaryngeal jet ventilation (TLJV) remains an insufficient method for effective ventilation. Additionally, the manipulation of the TLJV can increase the risk of displacement. The Melker kit allows for a larger, more effective airway, yet attains placement only after proper location has been verified with a much smaller diameter device. Once placed, a simple BVM can be attached for ventilation purposes. We believe the Melker kit provides not only more effective ventilation, but is a safer, more secure method of obtaining and maintaining it as well.

Item 6 -- Supporting data

See attached -- cricothyrotomy kit comparison table  
-- research abstracts

Item 7 -- Policies, procedures and quality assurance methods

See attached policies and procedures

Quality assurance will be instituted via 100% incident audit.  
Prehospital personnel attempting this procedure will be required to complete the attached form and turn it, along with a copy of the patient care record (PCR), into their quality assurance coordinator. The quality assurance coordinator will immediately copy it and forward it to the EMS agency. The EMS Agency will conduct their investigation by:

Reviewing the attached form  
Reviewing the patient care record (PCR)  
Interviewing the prehospital crew  
Interviewing the receiving ED physician  
***Obtaining and reviewing the ED/hospital record for the patient***

Data to be collected will include:

1. Patient information – sex, age and weight
2. Pathophysiology necessitating the procedure (FBAO, anaphylaxis, etc)
3. Other airway maintenance options attempted
4. Time frames – to complete procedure, on-scene, transport
5. Success of placement
6. Patient improvement
7. Difficulties encountered
8. Complications of procedure
9. Patient outcome
10. Paramedic comfort level

***Questions to be answered include:***

1. ***What patient populations in Riverside County require use of needle cricothyrotomy?***
2. ***What pathophysiology is encountered that necessitates a needle cricothyrotomy and how does that relate to specific patient populations in Riverside County?***
3. ***Are other methods of airway maintenance being thoroughly explored?***
4. ***Are overall time frames for procedure implementation and arrival to definitive care supporting the use of needle cricothyrotomy in the field?***
5. ***What is the percentage of successful placement of the Melker airway?***
6. ***What is the percentage of patient improvement and how does that correlate with successful placement?***
7. ***What is the percentage of patient survivability to discharge (from acute care) when this procedure is performed?***

8. *What is the complication rate of this procedure, and what complications occur most frequently?*
9. *What is the level of comfort for paramedics performing this procedure, and how can this be optimized?*

*Data will be collected and reviewed on an on-going basis. At any time, should the data reveal that use of the Melker Kit creates an unacceptable risk to patients and/or prehospital personnel, the study shall be immediately suspended.*

Item 8 -- Training and competency testing  
See attached training materials

Paramedics will attend a minimum 4-hour training program where needle cricothyrotomy is but one part of an overall airway management review.

The class will consist of lecture and Power Point presentation on anatomy and physiology, pathophysiology, airway assessment measures, review of basic and advanced treatment options, and policy and procedure. It will be integrated with a skills section that will include review of basic and advanced airway maintenance practices in addition to teaching use of the Melker Kit. Both didactic and skills examinations will be given at the end.

*Instructors for this class will have completed a train-the-trainer course covering course materials, testing procedures, and data collection.*

*Every six (6) months, personnel will be required to attend a skills review/practice session that utilizes the same skills sheets as the original training. Instructors will be polled as to*

- 1) *those topics/skills steps most frequently observed to be forgotten and/or difficult for participants.*
- 2) *those teaching techniques that appear to be most helpful to the students*

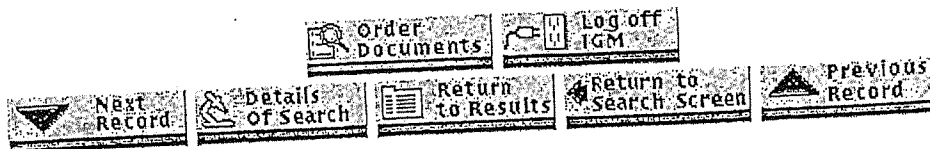
**Questions to be answered:**

1. *Is use of the Melker Kit too complex a procedure to obtain and maintain proficiency within the paramedic population?*
2. *Are every 6 month skills reviews adequate to maintain proficiency AND a minimum comfort level in the paramedic population?*
3. *Is skills maintenance for this procedure cost effective from a use vs benefit perspective?*

Item 6 -- Supporting data

## CRICOTHYROTOMY KIT COMPARISON

MODEL	SPECIAL CHARACTERISTICS	LUMEN SIZE	COST	BVM COMPATABLE?	TRNG MATERIALS AVAILABLE?
Enk Oxygen Flow Modulator	Uses regular needle/catheter only -- manual O2 flow control	2 mm inner diameter (6 Fr)	~\$50	no	
Patil	Looks like a smaller version of the Rusch --uses scalpel	2, 3 mm inner diameter (6 & 9 Fr)	~\$54	yes	
Arndt	Looks like a smaller version of the Rusch --uses a guidewire	3 mm inner diameter (9 Fr)	~\$54	yes thru flex tubing	
Melker	Used in many local EDs Uses regular needle, guidewire, scalpel, dilator	3.5, 4 mm inner diameter (9.5 Fr)	~\$87	yes	Video and printed materials, maybe slides. CD-ROM on genl airway matters
Cook Emergency Kit (AT-400)	Uses regular needle/catheter only -- uses 3-way stopcock for thumb or valve O2 control	2mm (6 Fr, 12 g)	~\$44	no	



**Related Articles**

**TITLE:** Cricothyrotomy performed by prehospital personnel: a comparison of two techniques in a human cadaver model.

**AUTHORS:** Johnson DR; Dunlap A; McFeeley P; Gaffney J; Busick B

**AUTHOR AFFILIATION:** Department of Emergency Medicine, New Mexico Emergency Medical Services Academy, University of New Mexico, Albuquerque 87131.

**SOURCE:** Am J Emerg Med 1993 May;11(3):207-9.

**CITATION IDS:** PMID: 8489658 UI: 93256999

**COMMENT IN:** Am J Emerg Med. 1993 May;11(3):310  
Am J Emerg Med. 1994 Jan;12(1):124-5

**ABSTRACT:** Little is known about the proficiency of prehospital personnel when performing cricothyrotomies. The authors compared two techniques for establishing an airway through the cricothyroid membrane used by paramedic students. One technique used a prepackaged kit that consisted of a dilator that is passed percutaneously through a breakaway needle. This percutaneous device (PD) was compared with a standard surgical approach (SA) using a scalpel and endotracheal tube. Data was collected on a total of 44 paramedic students who were allowed to attempt each of the procedures. No significant difference in the success rate on the first attempt was found between the two procedures (86% for the SA and 73% for the PD;  $P = .186$ ). The surgical approach was significantly faster (46 +/- 17 seconds v 103 +/- 62 seconds;  $P < .01$ ). It was also judged to be significantly easier to perform when evaluated on a linear analog scale (SA, 2.6 +/- 2.0 v PD, 5.1 +/- 2.8;  $P < .001$ ). Because some procedures were performed on cadavers whose cricothyroid membranes had already been violated, the procedures performed on intact membranes only were also analyzed. Similar, statistically significant differences for insertion time and ease of insertion were again found. Prehospital personnel can be trained to perform cricothyrotomies with a reasonable degree of proficiency. A traditional surgical approach, however, may be faster and less difficult to perform than a comparable procedure using a commercially available percutaneous device.

**MAIN MESH HEADINGS:** Cricoid Cartilage/\*surgery  
\*Emergency Medical Technicians  
Thyroid Cartilage/\*surgery  
Tracheotomy/\*methods

**ADDITIONAL MESH HEADINGS:** Airway Obstruction/surgery  
Cadaver  
Comparative Study  
Human  
Tracheotomy/instrumentation  
1993/05  
1993/01

**PUBLICATION TYPES:** Journal Article

**LANGUAGES:** eng

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**TITLE:** Emergency cricothyroidotomy in trauma victims.  
**AUTHORS:** Salvino CK; Dries D; Gamelli R; Murphy-Macabobby M; Marshall W  
**AUTHOR AFFILIATION:** Loyola University Medical Center, Maywood, IL 60153.  
**SOURCE:** J Trauma 1993 Apr;34(4):503-5.  
**CITATION IDS:** PMID: 8487335 UI: 93253821

**ABSTRACT:** The first dictum of trauma care is to establish an airway. Infrequently endotracheal intubation is unsuccessful or contraindicated, and a surgical airway is required. We reviewed 30 emergency cricothyroidotomies among 8320 admissions over a 36-month period at a level I trauma center. Twenty cricothyroidotomies were performed in the emergency room by Trauma Service personnel and 10 during prehospital care by flight nurses. Cricothyroidotomy was the first airway control maneuver performed in 7 patients and 23 cricothyroidotomies were performed after attempts at oral intubation failed. No major complications were identified. Minor complications identified in the hospital included minimal subglottic stenosis (2), local wound infection (1), and nonthreatening hemorrhage (1). Fifteen patients were long-term survivors. We conclude that emergency cricothyroidotomy is a safe and rapid means of obtaining an airway when endotracheal intubation fails or is contraindicated.

**MAIN MESH HEADINGS:** Airway Obstruction/\*surgery  
 Cricoid Cartilage/\*surgery  
 Thyroid Cartilage/\*surgery  
 Wounds and Injuries/\*surgery

**ADDITIONAL MESH HEADINGS:** Emergencies  
 Human  
 Retrospective Studies  
 Tracheotomy  
 1993/04  
 1993/01

**PUBLICATION TYPES:** Journal Article

**LANGUAGES:** eng

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**TITLE:** Acute airway management. Role of cricothyroidotomy.  
**AUTHORS:** DeLaurier GA; Hawkins ML; Treat RC; Mansberger AR  
**AUTHOR AFFILIATION:** Department of Surgery, Medical College of Georgia, Augusta 30912.  
**SOURCE:** Am Surg 1990 Jan;56(1):12-5.  
**CITATION IDS:** PMID: 2294806 UI: 90103287

**ABSTRACT:** Thirty-four cases of emergency cricothyroidotomy performed from September 1984 through January 1988 are reviewed. Thirty-one of the cases were required out of 2,200 acute-trauma patients. The indication for cricothyroidotomy was inability to establish an airway by intubation usually in a situation of possible neck injury or severe facial trauma. Fourteen of the patients died as a result of their injuries, 13 of these in the first several hours after injury. The 20 surviving patients are studied in two groups: eleven patients whose cricothyroidotomy remained in place until decannulation (group I) and nine patients who underwent tracheostomy subsequent to cricothyroidotomy (group II). Clinical follow-up included physical examination in all survivors and endoscopic evaluation in twelve patients. Three minor complications were discovered in each of the two groups and two major complications were noted in group II. The major complications included a case of tracheal stomal stenosis requiring tracheal resection and a case of partially obstructing tracheal granulation tissue requiring endoscopic resection. This study supports the use of emergency cricothyroidotomy in situations in which intubation is not successful or thought to be safe. Data is also presented that suggests that tracheostomy subsequent to emergency cricothyroidotomy does not necessarily reduce airway-related morbidity in these patients.

**MAIN MESH HEADINGS:** Cricoid Cartilage/\*surgery  
 Laryngeal Cartilages/\*surgery  
 \*Respiration, Artificial  
 Thyroid Cartilage/\*surgery  
 \*Tracheotomy

**ADDITIONAL MESH HEADINGS:** Airway Obstruction/therapy  
 Craniocerebral Trauma/therapy  
 Emergencies  
 Human  
 Neck/injuries  
 Neck Injuries  
 Postoperative Complications  
 Tracheal Stenosis/etiology  
 Wounds and Injuries/therapy  
 1990/01  
 1990/01

**PUBLICATION TYPES:** Journal Article  
**LANGUAGES:** eng



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**TITLE:** Prehospital cricothyrotomy: an investigation of indications, technique, complications, and patient outcome.

**AUTHORS:** Spaite DW; Joseph M

**AUTHOR AFFILIATION:** Section of Emergency Medicine, University of Arizona College of Medicine, Tucson.

**SOURCE:** Ann Emerg Med 1990 Mar;19(3):279-85.

**CITATION IDS:** PMID: 2310067 UI: 90178771

**ABSTRACT:** The records of all patients who presented to a Level 1 trauma center during a two-year period for whom a prehospital cricothyrotomy was attempted or ordered were reviewed. Twenty patients met the study criteria. The average age was 37 years (range, 11 to 65 years). Indications for prehospital cricothyrotomy were massive facial trauma (eight), failed oral intubation (seven), and suspected cervical-spine injury (one). Cricothyrotomy was attempted in 16 patients (80%), with the remaining four having the procedure ordered but not attempted. A successful airway was achieved in 14 patients (88%). Horizontal incisions were used in all cases and were anatomically correct in 15 of 16 attempts (94%). The overall immediate complication rate was 31%. Two patients (12%) sustained major complications (failure to obtain an airway). No hemorrhagic complications occurred, but 16 of the 20 were in cardiac arrest in the field. Long-term complications were not evaluated. All patients sustained major injuries (mean Injury Severity Score, 53.7), except one patient who suffered airway obstruction from food. Three patients (15%) survived; two of the three suffered permanent, severe brain dysfunction. These preliminary findings demonstrate that prehospital cricothyrotomy is being used chiefly in massively injured patients who are already beyond recovery. It is thus difficult to assess whether the procedure is either safe or effective. There is a need for further investigation to determine whether prehospital cricothyrotomy has any beneficial effect on outcome and, if so, in what setting. (ABSTRACT TRUNCATED AT 250 WORDS)

**MAIN MESH HEADINGS:** Cricoid Cartilage/\*surgery  
Emergency Medical Services/\*standards  
Laryngeal Cartilages/\*surgery  
\*Outcome and Process Assessment (Health Care)  
Thyroid Cartilage/\*surgery  
Tracheotomy/\*methods

**ADDITIONAL MESH HEADINGS:** Adolescence  
Adult  
Aged  
Airway Obstruction/surgery  
Arizona  
Child  
Facial Injuries/complications  
Female  
Human  
Injury Severity Score  
Intubation, Intratracheal  
Male

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**TITLE:** Surgical cricothyroidotomy in trauma patients: analysis of its use by paramedics in the field.

**AUTHORS:** Jacobson LE; Gomez GA; Sobieray RJ; Rodman GH; Solotkin KC; Misinski ME

**AUTHOR AFFILIATION:** Indiana University School of Medicine, Indianapolis, USA.

**SOURCE:** J Trauma 1996 Jul;41(1):15-20.

**CITATION IDS:** PMID: 8676411 UI: 96291307

**ABSTRACT:** **OBJECTIVE:** To analyze the indications for and the success rate, complications, and neurologic outcomes of surgical cricothyroidotomy when performed in the field by ambulance paramedics. **METHODS:** The ambulance and hospital records of all trauma patients on whom a surgical cricothyroidotomy was attempted in the field by ambulance paramedics over a 5-year period were reviewed. A telephone survey of survivors was used to assess long-term complications and neurologic outcome. **RESULTS:** Surgical cricothyroidotomy was attempted on 50 patients, or 9.8% of those requiring definitive airway control. The most common indications were clenched teeth, blood or vomit obscuring visualization of the upper airway, severe maxillofacial injuries, and inaccessibility because the patient was trapped. Airway establishment was successful in 47 patients (94%). Major complications occurred in 2 patients (4%), where inadvertent dislodgement of the tube developed, requiring replacement. No patient developed significant subglottic stenosis. Nineteen patients (38%) survived and no patient died because of an inadequate airway. Evaluation of neurologic outcome revealed 12 patients (63%) with no significant deficits, 3 (16%) with moderate disability, 2 (10%) with severe disability, and only 2 in a persistent vegetative state. **CONCLUSIONS:** Surgical cricothyroidotomy can be performed on the critically injured patient in the field by ambulance paramedics with a high success rate and a low complication rate. The use of surgical cricothyroidotomy should be included in airway protocols for well-trained, ambulance Advanced Life Support paramedics.

**MAIN MESH HEADINGS:** Cricoid Cartilage/\*surgery  
Resuscitation/\*methods  
Wounds and Injuries/\*surgery

**ADDITIONAL MESH HEADINGS:** Adolescence  
Adult  
Aged  
Emergencies  
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Treatment Outcome  
1996/07  
1996/01

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**TITLE:** Comparison of conventional surgical versus Seldinger technique emergency cricothyrotomy performed by inexperienced clinicians.

**AUTHORS:** Eisenburger P; Laczika K; List M; Wilfing A; Losert H; Hofbauer R; Burgmann H; Bankl H; Pikula B; Benumof JL; Frass M

**AUTHOR AFFILIATION:** Department of Internal Medicine I, University of Vienna, Austria.

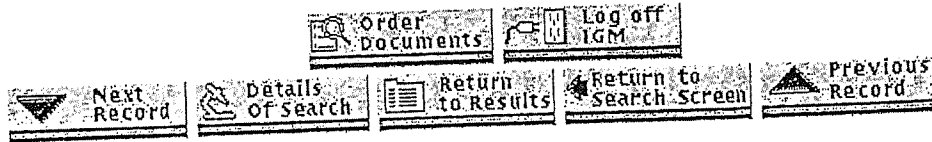
**SOURCE:** Anesthesiology 2000 Mar;92(3):687-90.

**CITATION IDS:** PMID: 10719947 UI: 20182866

**ABSTRACT:** **BACKGROUND:** Cricothyrotomy is the ultimate option for a patient with a life-threatening airway problem. **METHODS:** The authors compared the first-time performance of surgical (group 1) versus Seldinger technique (group 2) cricothyrotomy in cadavers. Intensive care unit physicians (n = 20) performed each procedure on two adult human cadavers. Methods were compared with regard to ease of use and anatomy of the neck of the cadaver. Times to location of the cricothyroid membrane, to tracheal puncture, and to the first ventilation were recorded. Each participant was allowed only one attempt per procedure. A pathologist dissected the neck of each patient and assessed correctness of position of the tube and any injury inflicted. Subjective assessment of technique and cadaver on a visual analog scale from 1 (easiest) to 5 (worst) was conducted by the performer. **RESULTS:** Age, height, and weight of the cadavers were not different. Subjective assessment of both methods (2.2 in group 1 vs. 2.4 in group 2) and anatomy of the cadavers (2.2 in group 1 vs. 2.4 in group 2) showed no statistically significant difference between both groups. Tracheal placement of the tube was achieved in 70% (n = 14) in group 1 versus 60% (n = 12) in group 2 (P value not significant). Five attempts in group 2 had to be aborted because of kinking of the guide wire. Time intervals (mean +/- SD) were from start to location of the cricothyroid membrane 7 +/- 9 s (group 1) versus 8 +/- 7s (group 2), to tracheal puncture 46 +/- 37s (group 1) versus 30 +/- 28s (group 2), and to first ventilation 102 +/- 42s (group 1) versus 100 +/- 46s (group 2) (P value not significant). **CONCLUSIONS:** The two methods showed equally poor performance.

**MAIN MESH HEADINGS:** \*Emergency Medical Services  
Larynx/\*surgery  
Respiratory Muscles/\*surgery  
Respiratory System/\*surgery  
\*Surgical Procedures, Operative  
Thyroid Cartilage/\*surgery

**ADDITIONAL MESH HEADINGS:** Aged  
Cadaver  
Comparative Study  
Female  
Human  
Intensive Care Units  
Larynx/anatomy & histology  
Male  
Middle Age  
Neck/anatomy & histology  
Respiratory Muscles/anatomy & histology

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**TITLE:** Extra inspiratory work of breathing imposed by cricothyrotomy devices.  
**AUTHORS:** Ooi R; Fawcett WJ; Soni N; Riley B  
**AUTHOR AFFILIATION:** Magill Department of Anaesthesia, Westminster Hospital, London.  
**SOURCE:** Br J Anaesth 1993 Jan;70(1):17-21.  
**CITATION IDS:** PMID: 8431326 UI: 93159924  
**ERRATUM IN:** Br J Anaesth 1993 Apr;70(4):494  
**ABSTRACT:** Using a lung model for spontaneous ventilation, we have assessed the additional work of inspiration imposed by a variety of cannulae ranging from the 12- and 14-gauge intravascular cannulae to the 8.0-mm i.d. adult tracheostomy tube. Work (W) ranged between 9 and 2262 mJ litre<sup>-1</sup> and power (P) between 0.2 and 37.7 mW litre<sup>-1</sup> min; the smallest values were obtained with the 8.0-mm i.d. adult tracheostomy tube and the 12- and 14-gauge intravascular cannulae gave the largest values. With any given cannula, W and P were influenced by ventilation (tidal volume and frequency) and ventilatory wave pattern of the analogue lung. The results obtained from the 12- and 14-gauge cannulae represent what is probably an excessive inspiratory workload, whereas the other four devices (Portex MiniTrach, 4.0, 6.0 and 8.0 tracheostomy tubes) may be suitable in the short term for relieving airway obstruction and compatible with spontaneous ventilation.

**MAIN MESH HEADINGS:**

\*Models, Biological  
 Tracheostomy/\*instrumentation  
 Work of Breathing/\*physiology

**ADDITIONAL MESH HEADINGS:**

Comparative Study  
 Cricoid Cartilage/surgery  
 Human  
 Pulmonary Ventilation/physiology  
 Support, Non-U.S. Gov't  
 Tidal Volume/physiology  
 Time Factors  
 1993/01  
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**PUBLICATION TYPES:** Journal Article**LANGUAGES:** eng