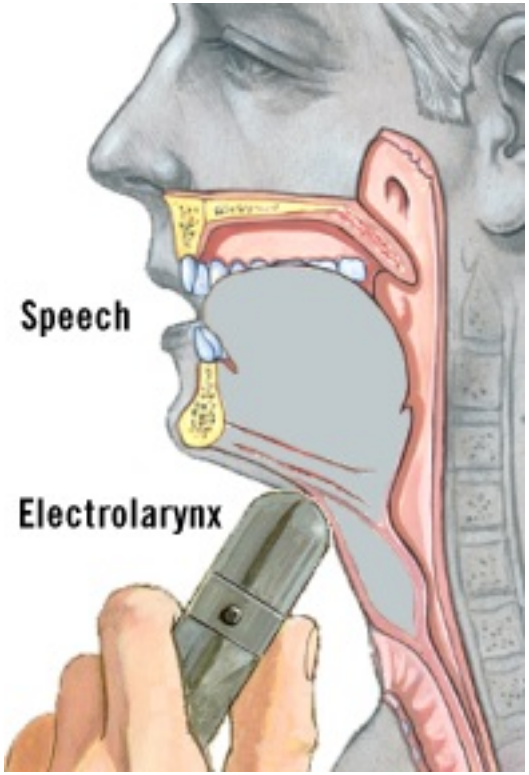
Low-Cost Electrolarynx



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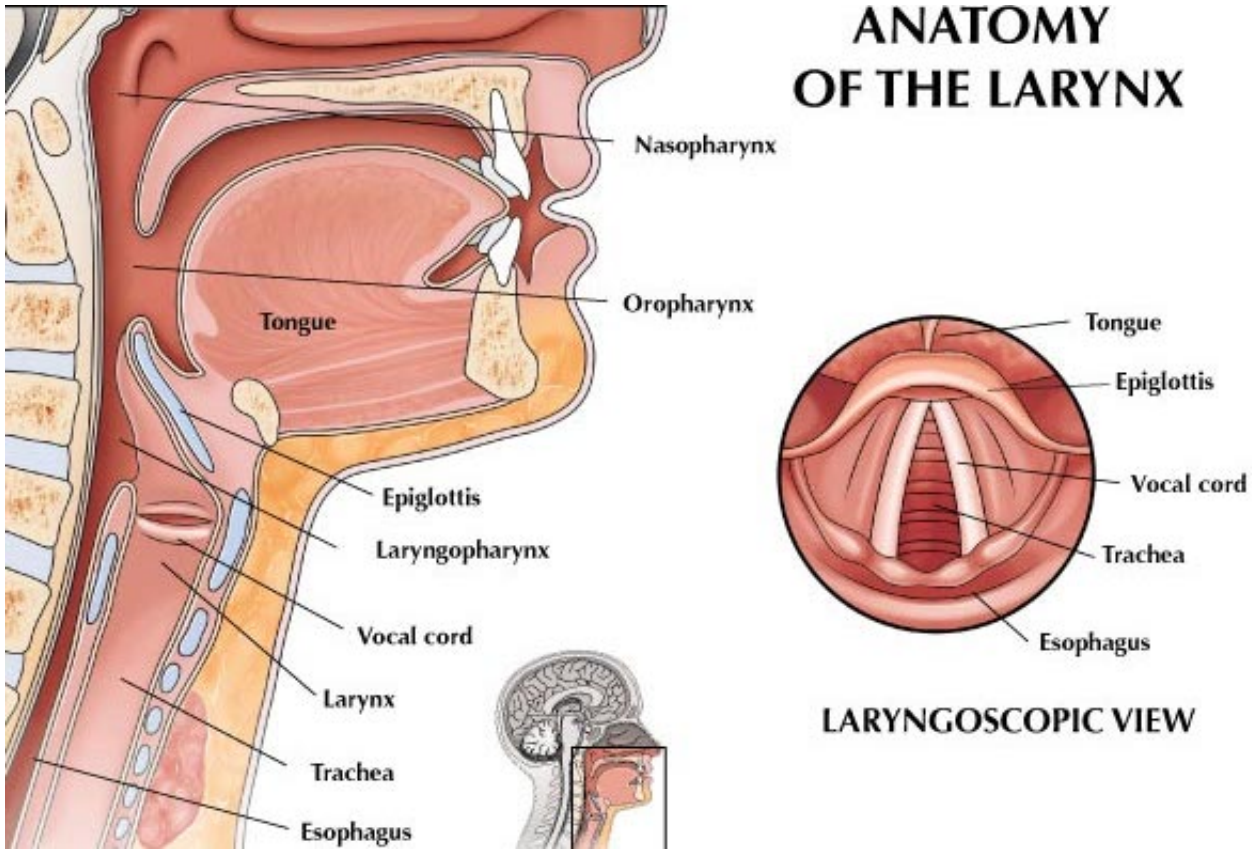
Need Statement

A **low-cost, easy to use, and reliable** device to produce vibration and allow speech for patients undergoing laryngectomy

Voice Production Anatomy



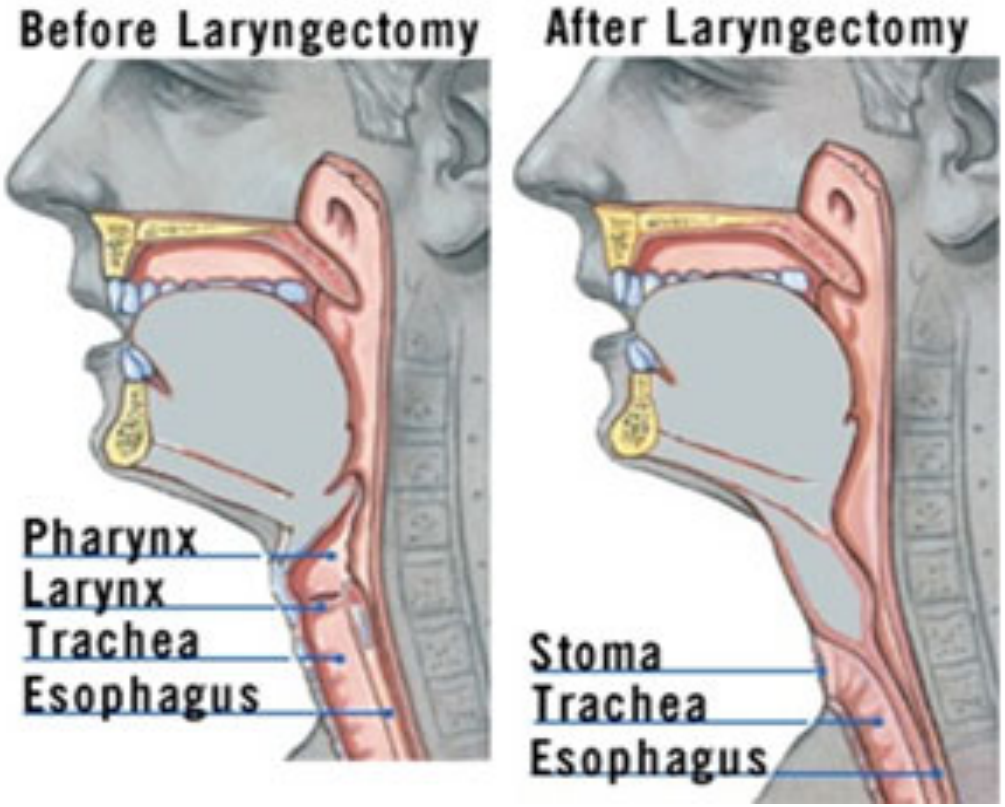
Voice Production Anatomy

- Vibration of vocal cords produces sound
- Range of frequency in human:
  - Adult male 125 Hz,
  - adult female 210 Hz,
  - Children over 300 Hz.

Loosen cords, lower pitch

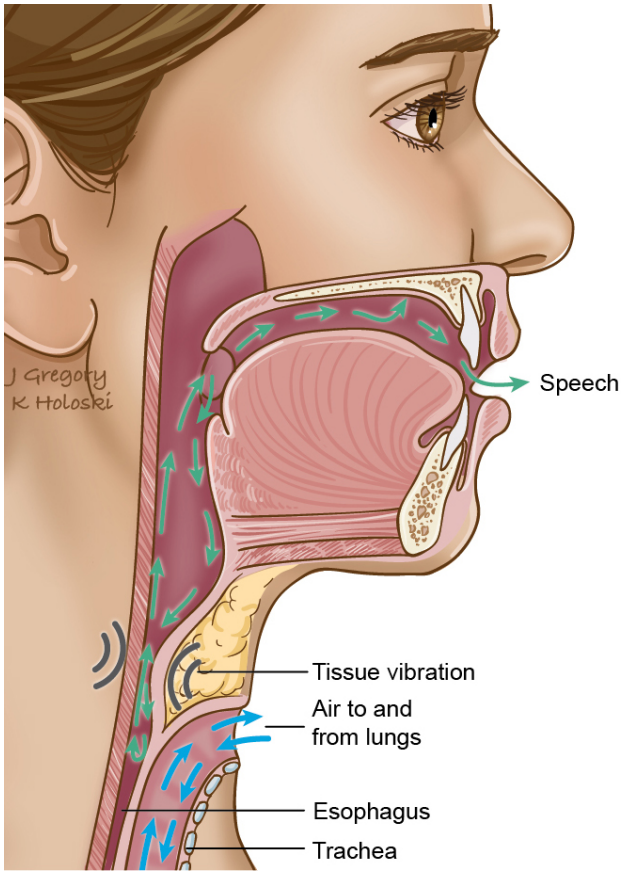
Stretch cords, Increase pitch

Disease State Fundamentals



Treatment Options/Gaps

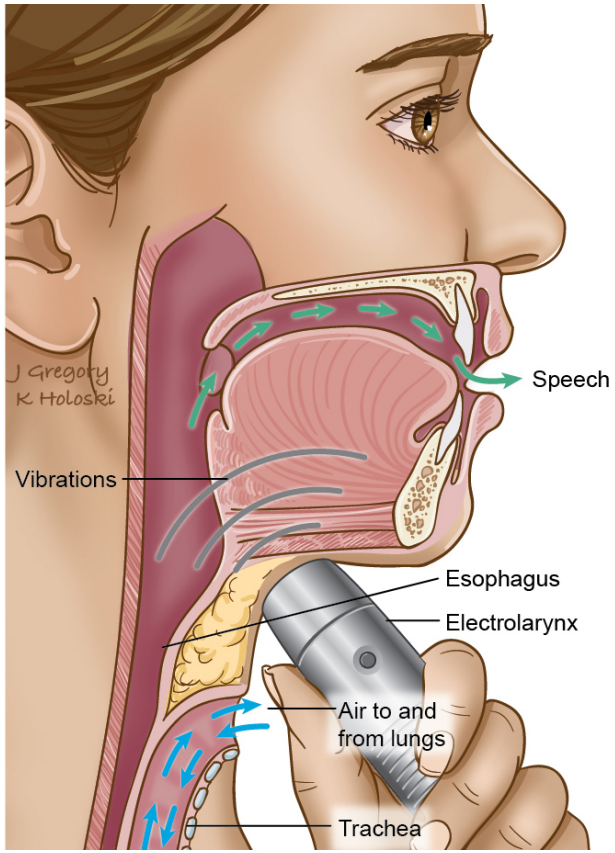
I) Esophageal Speech



	Esophageal Speech
Mechanism	Air injected into esaphagus and then propelled into PE segment.
Advantages	Hands free; natural voice; patient independent of devices
Disadvantages	Low fundamental frequency (~65 Hz); short duration; low acquisition rate; extended learning period.
Success Rate	5-30%

Treatment Options/Gaps

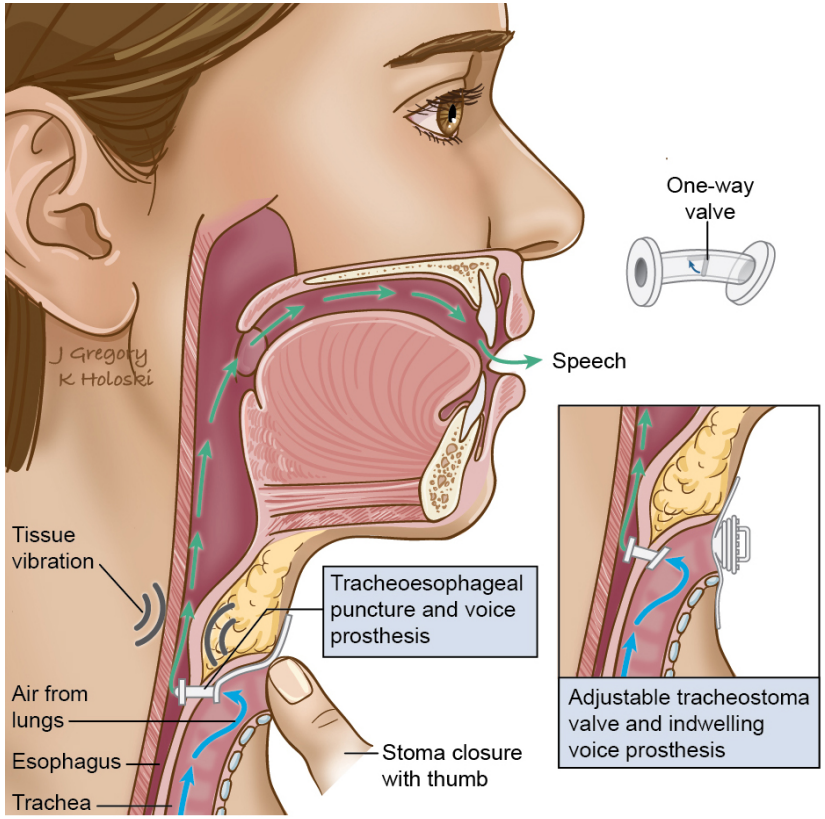
II) Artificial Larynx



	Artificial Larynx
Mechanism	Mechanical sound introduced into vocal tract.
Advantages	Rapid learning; does not interfere with acquisition of other forms of speech; loud
Disadvantages	Dependence on batteries; mechanical voice; device needs to be held in position using hands. Not affordable for every patient ($500-800)
Success Rate	~100%

Treatment Options/Gaps

III) Tracheoesophageal Puncture (TEP)



	TEP
Mechanism	Tracheal air exhaled into pharynx through fistulous tract
Advantages	Natural phrasing of voice; more acoustically normal speech
Disadvantages	Tract can be difficult to maintain; salivary reflux into trachea; expensive (~$4000)
Success Rate	40-90%

Market Analysis

Criteria	Attribute
Market Size	Life Time Incidence of Larynx Cancer in Canada: Females: 1 in 959 | Males: 1 in 173 New Cases in Canada (2015 Est.): 1050 Total Annual Laryngectomies in the US (2008): 3414
Market Dynamics	Relatively small market, decreasing in size due to a decrease in the incidence of larynx cancer. Highly affordable devices not available in the market. Low profitability. Potentially high impact on patients' quality of life. Regulatory requirements.
Market Needs	Highly affordable (<$100) battery powered artificial larynx.
Willingness to Pay	Current price range: ~$500-$800. Larynx cancer most strongly associated with smoking and alcohol. Most patients from lower socioeconomic standings. High rate of adoption expected only if the device is highly affordable.

Canadian Cancer Statistics 2015, Statistics Canada
Maddox, Patrick Tate, and Louise Davies. "Trends in Total Laryngectomy in the Era of Organ Preservation A Population-Based Study." *Otolaryngology--Head and Neck Surgery* 147.1 (2012): 85-90.

Preliminary Stakeholder Analysis

Stakeholder	Primary Benefits	Primary Costs	Net Impact
Patients	Improved communication. Enables them to speak.	Device cost (Presumably low).	**Positive**
Families and Friends of Patients	Improved access, comfort and handling of the tissue during procedure makes to procedure significantly easier to perform.	none.	**Positive:** Improved access and handling of the tissue during procedure.
Health Care Professionals	Improved care for an more patients, specially those those from a lower socioeconomic status.	none.	**Positive**
Healthcare System	Improved care for a larger number of population. Decreased per patient cost.	Device cost, in public health systems.	**Positive:** If the device is low cost. Potential to save $400 to $700 per patient.
Manufacturer	Increased profit. Larger share of the market. Increased sales in developing countries.	Manufacturing cost.	**Positive:** If instrument is low cost

Regulatory Requirements

FDA Class I Device, Subject to FDA General Controls:

- Establishment Registration
- Quality Control and GMP
- Product Listing
- Adulteration and Misbranding
- etc.

Device	Larynx, Artificial (Battery-Powered)
Regulation Description	Battery-powered artificial larynx.
Regulation Medical Specialty	Ear Nose & Throat
Review Panel	Ear Nose & Throat
Product Code	ESE
Premarket Review	Office of Device Evaluation (ODE) Division of Ophthalmic and Ear, Nose and Throat Devices (DOED) Ear, Nose, and Throat Devices Branch (ENTB)
Submission Type	510(K) Exempt
Regulation Number	874.3375
Device Class	1
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No

Note: FDA has exempted almost all class I devices (with the exception of reserved devices) from the premarket notification requirement, including those devices that were exempted by final regulation published in the *Federal Registers* of December 7, 1994, and January 16, 1996. It is important to confirm the exempt status and any limitations that apply with 21 CFR Parts 862-892. Limitations of device exemptions are covered under 21 CFR XXX.9, where XXX refers to Parts 862-892.

If a manufacturer's device falls into a generic category of exempted class I devices as defined in 21 CFR Parts 862-892, a premarket notification application and fda clearance is not required before marketing the device in the U.S. however, these manufacturers are required to register their establishment. Please see the Device Registration and Listing website for additional information.

Implanted Device?	No
Life-Sustain/Support Device?	No
Third Party Review	Not Third Party Eligible

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm?ID=1371
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm

a place of mind

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