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Introduction to Tracheoesophageal Voice

Presenter: Julie Bishop-Leone, M.A., CCC-SLP

Moderated by:

Amy Natho, M.S., CCC-SLP, CEU Administrator, SpeechPathology.com

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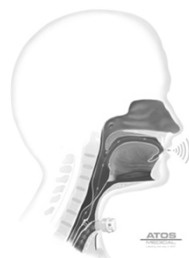
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Introduction to Tracheoesophageal Voice Restoration



Julie K. Bishop-Leone, M.A., CCC-SLP
Co-Director & Senior Clinical Education Specialist
Atos Medical, Inc.

Disclosure Statements

- Julie Bishop-Leone, MA, CCC-SLP is the Co-Director and Senior Clinical Education Specialist in the Educational Division of Atos Medical. She has the following financial relationship or relationship affiliations to disclose: She is employed by the Educational Division of Atos Medical. She does not have any relevant nonfinancial relationships to disclose.

Purpose of the Course

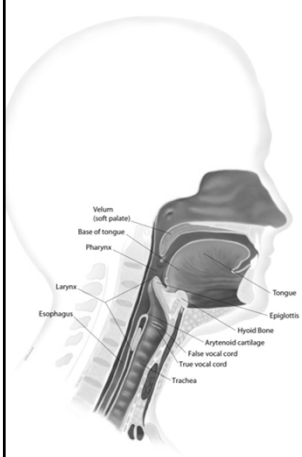
- Describe what tracheoesophageal (TE) speech is and how it works
- Determine who is an appropriate candidate for a tracheoesophageal puncture
- How to size the tracheoesophageal puncture
- Identify the various types of voice prostheses and how they are placed
- Describe strategies of how to initiate TE voice

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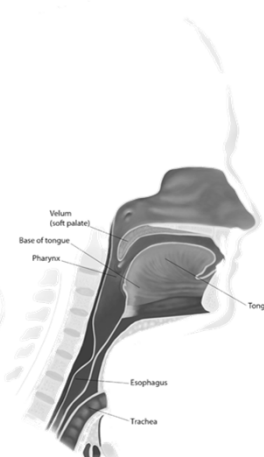
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Anatomy Review



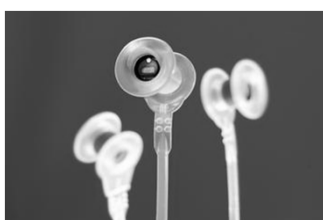
- Separate aerodigestive tract
- Stoma
- No aspiration
- Olfactory changes
- Loss of laryngeal communication (verbal, psychological and emotional)
- Articulation unaffected
- Affects vocal intensity,, pitch and duration



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Tracheoesophageal (TE) Voice Restoration

- **Tracheoesophageal speech**
 - Sound source is pharyngoesophageal (PE) segment or neoglottis, **NOT** the voice prosthesis
 - Pulmonary air
 - One-way valve TE Voice Prosthesis (VP)
 - Pts without VP tend to have fewer social contacts (Brook et al, 2013)
 - Considered the “Gold Standard”



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TE Speech Success Factors

- Candidate selection
- Patient education
- Knowledge, skill and experience level of the head & neck surgeon and speech pathologist



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Candidacy for TE Voice Restoration: Surgical/Non-Surgical Factors

- Will the patient be overwhelmed?
- Cognitive & psychological status?
- Manual dexterity?
- Visual acuity?
- Support system?
- Financial status?
- Proximity to SLP familiar with TE voice?
- Type of reconstruction?
- Can patient tolerate a second surgery for secondary puncture?
- If secondary, is their PE segment capable of vibration?
- GOOD CANDIDATE ≠ GOOD VOICE

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Timing of the Tracheoesophageal Puncture (TEP)

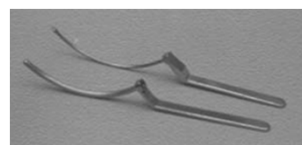
▪ Primary TEP

- TEP tract created at the time of the total laryngectomy (TL)



▪ Secondary TEP

- TEP created as a separate procedure after the TL (second surgery)



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Primary vs. Secondary TEP Considerations

Primary TEP

- No need for additional surgery
- Immediate, more “normal” voice rehabilitation
- May be overwhelming
- Unable to predict fluency
- Can place prosthesis at the time of surgery
- If postop XRT, may interfere with TE voice
- May have means of feeding if use RR catheter

Secondary TEP

- Need additional surgery/procedure
- Delayed voicing
- Patient may be better prepared
- Able to determine if PE segment capable of vibration pre-op
- Can place prosthesis at the time of surgery/procedure
- Pt. may be voicing in recovery
- Able to complete botox or myotomy, if indicated

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Primary TEP with Provox Vega Puncture Set

- Video 1

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How to Create Secondary TEP: New Provox Vega Puncture Set

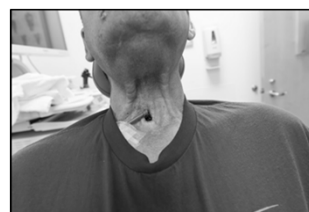
- Video 2

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Timing of Voice Prosthesis (VP) Placement

- **Primary VP Placement**
 - Placement of the voice prosthesis into the puncture at the time it is created
- **Delayed VP Placement**
 - TEP maintained with catheter or feeding tube
 - VP fitting completed approximately 5-10 days post op in the clinic



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Primary Placement vs. Delayed Placement of VP

Delayed Placement of VP

- Requires RR catheter to stent
- Discomfort at puncture site
- Delayed voicing
- Frequent Replacements due to size fluctuations
- RR catheter can easily dislodge
- If primary TEP, can feed through RR catheter

Primary Placement of VP

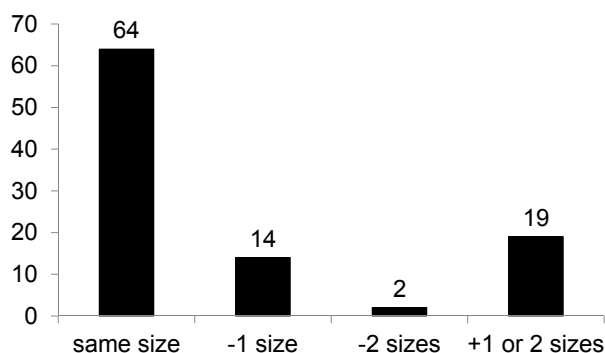
- Eliminate “initial fitting” trauma & concentrate on voicing, not fitting
- Less pain at stomal site (Burkey, 2011)
- Earlier & more optimal voicing (Gultekin et al, 2010; Deschler et al, 2011; Burkey et al, 2011)
- Eliminate need for frequent resizing = ↓ cost (OpdeCoul B et al, 2000)
- Less likely to dislodge (Gultekin *et al.*, 2010 ; Burkey et al, 2011)
- **Potential for more efficient rehabilitation & decreased cost**

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Results of 318 Pts with Primary Placement

Two-thirds of replaced indwelling Provox prostheses had the same size (N=2396)*



* OpdeCoul B, Hilgers FJM, Balm AJM, Tan IB, van Tinteren H, van den Hoogen FJA. A decade of postlaryngectomy vocal rehabilitation in 318 patients: a single institution's experience with consistent application of indwelling voice prostheses (Provox). Arch Otolaryngol Head Neck Surg 2000; 126: 1320-1328.

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Tracheoesophageal Puncture (TEP) Fitting: A Comparison of Voice Restoration and Complications

April 2011-August 2013; Joann Kmiecik-Brian Burkey

Information presented at the 2013 Medical College of Wisconsin Head & Neck Symposium for the Advanced Practitioner updating the Cleveland Clinic's Head & Neck Institute 2011 Outcomes Speech Pathology by Joann Kmiecik, SLP and Brian Burkey, MD. Used by permission.

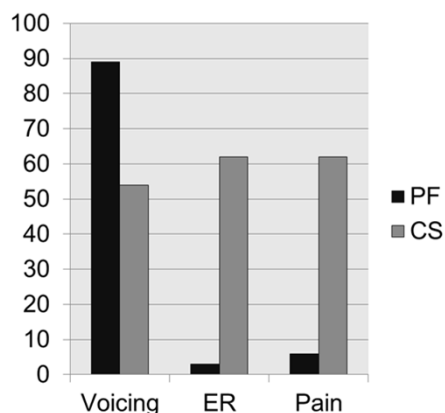


The Cleveland Clinic Experience - UPDATE

Years	Primary Fit (PF)	Catheter Stent (CS)
2011	9	11
2012	17	2
2013	10	0
N	36	13

Parameters

- Voicing at first SLP visit
- ER visits (catheter reinsertion)
- Pain/discomfort at stoma site



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Tracheoesophageal Voice Prostheses

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Types of Voice Prostheses

- **Indwelling:** Placed by a professional only
- **Non-indwelling:** Patient and/or professionally managed



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Voice Prosthesis Sizes

Diameter:

Measured in French = 1 Fr = 1/3 mm

- Standard diameter options:
 - 16 Fr = 5.3 mm
 - 17 Fr = 5.6 mm
 - 20 Fr = 6.6 mm
 - 22.5 Fr = 7.4 mm
- Standard industry length options:
 - 4-28 mm

diameter



length



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Non-indwelling Voice Prostheses

- **Provox® NiD™**: 17, 20 Fr
 - Non-sterile



- **Blom-Singer® Low Pressure**: 16, 20 Fr
 - Increased resistance, standard
 - Non-sterile



- **Blom-Singer® Duckbill**: 16 Fr
 - Non-Sterile



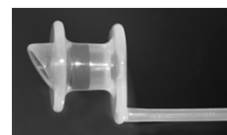
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Provox® Indwelling Voice Prostheses

- **Provox®(1)**
 - Original Provox voice prosthesis
 - Retrograde insertion/removal
 - Used in OR as well as in the clinic
 - Sterile



- **Provox®2**
 - Second generation Provox
 - Bi-directional (anterograde or retrograde) insertion
 - Used in OR and in clinic
 - Sterile



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Provox® Indwelling Voice Prostheses (continued)

▪ Provox® ActiValve®

- Designed for pts. with short device lifetime
- Short device lifetime = 5 consecutive changes where device life is ≤ 6 wks
- Bi-directional insertion
- Non-sterile



▪ Provox® Vega™

- Third generation Provox product
- Bi-directional insertion
- Sterile



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InHealth Indwelling Voice Prostheses

▪ Blom-Singer Classic™ Indwelling

- Anterograde insertion only
- Comes in std & increased resistance
- Non-sterile



▪ Blom-Singer Classic™ Indwelling Sterile

- Bi-directional insertion
- Sterile

▪ Blom-Singer Advantage®

- Anterograde insertion only
- Soft & hard valve assembly
- Non-sterile



▪ Dual Valve

- Anterograde insertion
- Designed for pts. with short device life
- Non-sterile

▪ Rapid Response Indwelling

- Non-sterile
- Large Tracheal and/or Esophageal Flange
- Increased resistance or special length



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Sizing & Dilation Of The TE Tract

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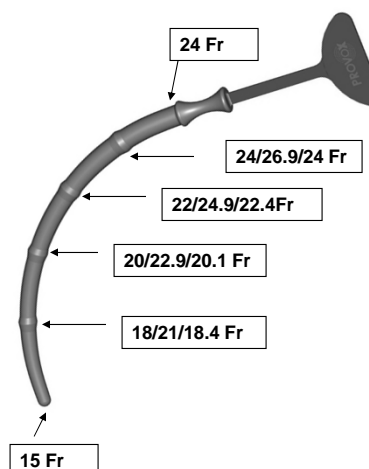
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Tract Dilation

■ Provox® Dilator

- Maintains puncture size during placement
- Orients one to tract direction
- Upsizing of punctures
- 15 Fr at the tip increases to 24 Fr
- Retention collars at the end of each section
- Steps 18, 20, 22, 24 Fr
- Silicone, autoclavable



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Tract Dilation

- **InHealth® Dilator**

- Maintains puncture size during placement
- Acquaints clinician to puncture tract
- Upsizing of puncture
- 14 Fr at the tip increases to 18fr or 22 Fr
- Must advance fully to obtain the 18 and 22 diameter
- Silicone, autoclavable



- **Blom-Singer® Dilator-Sizer**

- Maintains puncture size during placement
- Dilates and sizes with one instrument
- Upsizing of puncture
- 18 or 22 Fr sizes
- Must fully advance to obtain the 18 or 22 diameter
- Silicone, autoclavable



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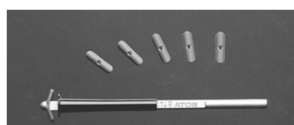
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Sizing the TEP

Measure devices

- **Provox® Measure**
20 Fr and 22.5 Fr



- **Blom-Singer Voice Prosthesis Sizers:**
16 Fr and 20 Fr



- **Blom-Singer Dilator-Sizers:**
18 Fr and 22 Fr



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Sizing Tips

- **Prior to sizing:**
 - Use the proper sizer:
 - 16 or 17Fr, use the 16Fr sizer
 - 20 or 22.5Fr, use the 20Fr sizer
 - Obtain adequate TE tract patency
 - Dilate the TE tract as needed (general rule)
 - 16 or 17Fr, dilate to 18Fr
 - 20Fr, dilate to 22Fr
 - 22.5Fr, dilate to 24Fr
 - Orient yourself to TE tract direction w/ tip of dilator or RR catheter!
- **Sizing steps:**
 - Insert tip of the sizer & position in direction of TEP;
 - Push until feel it “pop;”
 - Once you feel a “pop”, make sure to push the **sizer flush against the tracheal side** of the puncture before pulling back and reading the size.
 - If you are in between sizes, **ALWAYS PLACE A LONGER PROSTHESIS!**

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Inserting the Sizing Device

Video 3 & 4



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Checking the Fit of the Current Prosthesis:

Using actual sizing device provides optimal results

The novice clinician should always resize and not guess



Video 5

Courtesy of Saint Louis University Cancer Center – Dennis Fuller

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Non-Indwelling Voice Prostheses



Pros

- User independence
- Ideal for patients living far from care facilities
- Cleaned in situ or externally
- Smaller flange diameter and thickness relative to indwelling

Cons

- Less consistent follow-up with SLP
- Requires retention strap to be taped to the neck
- May have shorter durability than indwelling
- High risk of dislodgement (Hancock et al., 2005)
- Frequent changes over time may result in increased risk of party wall separation and granulation

Hancock, K, Houghton, B. & VanAs-Brooks, C.J (2005). First Clinical Experience with a New Non-Indwelling Voice Prosthesis. *Acta Oto-Laryngologica*, 125: 981-990.

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InHealth® Non-Indwelling Voice Prosthesis

- Sizes: 16 or 20 Fr diameter
- 4-28mm lengths
- Low Pressure
(std or increased resistance)
- Duckbill
- Accessories:
 - Dilator 18 or 20
 - Flushing Device
 - Gel Cap



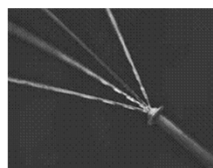
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Provox® NiD™ Voice Prosthesis

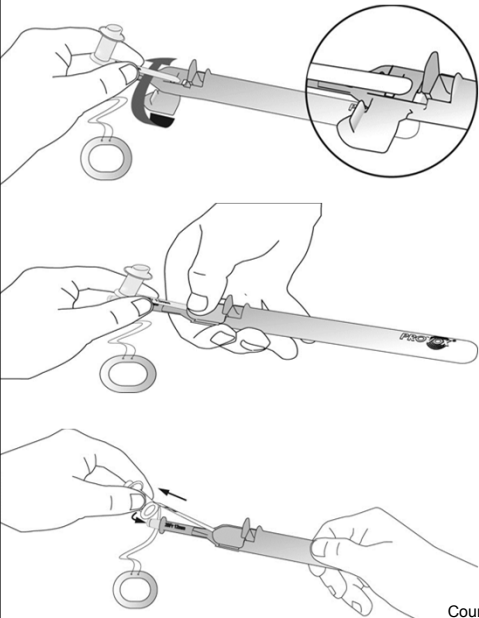
- Sizes: 17 or 20 Fr diameter
- 6, 8, 10, 12, 14, 18 mm lengths
- Accessories:
 - Provox® Dilator 17 or 20
 - Provox® Flush
 - Provox® Brush



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Loading the Provox NiD

Video 6

Courtesy of Saint Louis University Cancer Center – Dennis Fuller

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Provox NiD™ Insertion

Video 7

Courtesy of Saint Louis University Cancer Center – Dennis Fuller

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Indwelling Voice Prosthesis

PROS

- Less demands on user
- Long term cost may be same as non-indwelling over time
 - May require reduced therapy time
 - May have longer durability than non-indwelling
- More regular f/u
- Insertion at time of TEP is possible
- Cleaned in situ
- Good for pts. with poor visual acuity and/or manual dexterity
- Eliminate need for a strap

CONS

- Dependent on clinician
- Higher initial cost

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Provox®2

- Hinged pre-tensioned valve
- Low resistance
- Blue fluoroplastic ring
 - Radiopaque
- Esophageal flange stronger than tracheal flange
- 22.5 Fr diameter

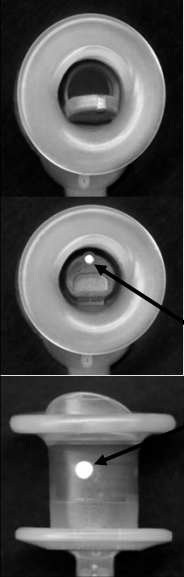


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Provox ActiValve®* Features

- Valve and valve seat made of fluoroplastic
- Nonsterile
- Magnets counteract increased esophageal pressure and provide 'active' valve closure
- Magnet strengths: Light, Strong & Extra Strong

* A problem-solving indwelling voice prosthesis, eliminating frequent candida and 'under-pressure'- related replacements: Provox ActiValve.
Hilgers FJM, Ackerstaff AH, Balm AJM, van den Brekel MWM, Tan IB, Persson JO. Acta Otolaryngol (Stockh) 2003; 123: 972-9

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Loading the Provox®2 & ActiValve® VPs

- Use Provox Insertion Tool - no gel cap
- Insert & secure prosthesis tail in insertion tool
- Set tracheal end of prosthesis on end of inserter
- Pinch esophageal flange forward
- Introduce into insertion tube
- Depress top flange portion down and forward while inserting prosthesis into tube
- Advance prosthesis until #1 on stick is even with rim of loading tube.

Video 8

Provided by the Netherlands Cancer Institute

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Inserting the Provox2 & ActiValve VPs

Video 9

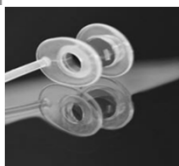
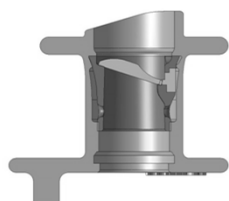
Courtesy of Saint Louis University Cancer Center – Dennis Fuller

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Provox® Vega™



- Preloaded and sterile
- Automatic folding of flanges
- Prevents unintentional overshooting
- Easier and more hygienic handling
- SmartInserter is replacement device only (not to be used in a fresh non-healed TEP)
- 3 Diameters: 17, 20, 22.5* Fr
- Lengths: 4,6,8,10, 12.5, 15 mm
- Accessories:
 - Provox Brush
 - Provox Flush
 - Provox Vega Plug
 - Provox Dilators



*Same Outer Diameter as Provox2

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Provox® Smartinserter™

Video 10

- **Key Points for insertion:**

- Always preload and ensure correct position of voice prosthesis in loading tube prior to actual insertion
- Use a two handed approach
- Maintain a steady position during insertion to avoid undershoot
- Dilate the puncture prior to insertion if the puncture is tight, angled, or 'difficult' for any reason

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Provox Vega Placement

Video 11

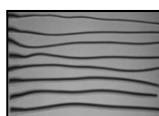
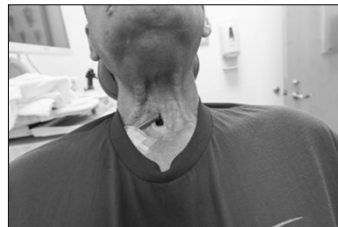
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Accidental Dislodgement

- Don't panic!
- Pt. should lean forward and cough to make sure that prosthesis is not lodged in airway
- Once Pt. is breathing easily, insert catheter or dilator in puncture
- Tie exposed end off so that gastric juices do not leak out
- Tape to neck
- If prosthesis wasn't located, go to hospital for chest xray to ensure that prosthesis is not in the lung
- **If there is not anything stenting TEP, can close up in minutes to hours and patient can aspirate!**



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Voice Prosthesis Care/Cleaning “Brush and Flush”



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Step One: Clean with Provox® Brush

- Designed for use with Provox VPs only!
- Two sizes for all Provox® VPs:
 - Standard (lengths 4-10mm)
 - XL (lengths 12-18mm)
- Discard every 30
- VP should be cleaned with brush at least twice a day and after meals
- VP should also be brushed if leaking or malfunctioning
- Brush is designed for safety & to not:
 - harm the esophagus
 - inadvertently remove VP
 - damage the Provox VP valve
- Avoid vigorous brushing!



Video 12

Courtesy of Saint Louis University Cancer Center –
Dennis Fuller, PhD

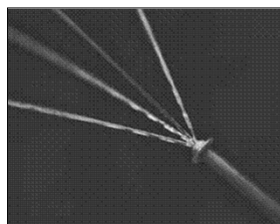
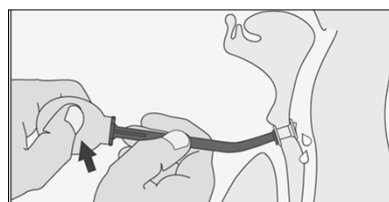
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Step 2: Use the Provox® Flush

- For cleaning of the inner lumen of the VP
- Removes debris which loosens after brushing
- Four jets for optimal cleaning – air or water
- Universal for all Provox® VP
- Free et al. (2003) found in vitro that daily airflow through VP with the Provox® Flush reduces biofilm formation & may increase VP device lifetime



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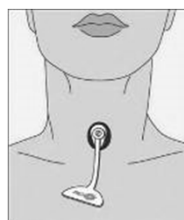
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Using the Provox® Plug



- Every patient should have the appropriate plug to temporarily stop the leakage.
- All Provox® VP have plugs except NiD



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Prosthesis Selection: Considerations

- Diameter of the TEP
- Clinical indicators
- Patient independence
- Quality of voicing
- Ease of use and cleaning
- Prosthetic design to accommodate pt's anatomic configurations
- Cost-effective prosthesis
 - Cheaper upfront cost \neq cost effective
- Mean device lifetime

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VP Device Lifetime

- Patient Dependent
- Presence of GERD/GPR
- Biofilm formation
- Oral flora
- XRT vs. no XRT
- Care and maintenance of device
- Diet
- Pressure in pharynx
- Valve opening during inhalation

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Quality of Life with Hands-Free Speech

Benefits:

- Patient free to use hands while speaking
 - Can work more safely
 - Talk and hold telephone while writing a message
- Improved social acceptance
- More hygienic

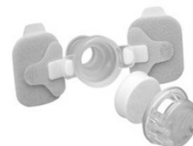


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Principle of Automatic Valves for Laryngectomees

- **Not everyone is a candidate!**
- **Two-way valve = bias open valve**
 - Inhalation & exhalation through the stoma
- **Pressure sensitive valve**
 - Open while breathing
 - Closed when talking due to increased pressure
 - Application of “forced exhalation” closes the valve and allows for airflow through the voice prosthesis



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Therapy

- Instruction on daily care and maintenance
- Ongoing troubleshooting
- Re-assessing factors affecting TE voice
- Pulmonary Rehabilitation with Heat Moisture Exchange (HME) system
- Free-Hands Communication
- Laryngectomy supplies
- Insurance coverage



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Initial Outpatient Session

- Measure TE Tract Length (if indicated)
- Check VP length and cleanliness (if primary placement done)
- Teach what to do in case of prosthetic dislodgement
- Instruct on care/use/maintenance of TE voice prosthesis
- Focus on appropriate digital occlusion
- Re-assess heat & moisture exchange (HME) use
- Set up f/u visit in 7-10 days

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Subsequent Outpatient Tx Sessions

- Resize TE tract if indicated
- Work on obtaining fluent TE voice, good digital occlusion, adequate care and HME use
- Re-instruct on proper care/use/maintenance of TE prosthesis
- Reassess HME attachment use and function
- Continuous follow up until patient is independent
- Fit with FreeHands valve if appropriate
- Total rehabilitation of these patients goes beyond just providing products and changing prostheses.

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Final Outcomes

- Video 13

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Conclusions

- Ultimately, functional success rests on the expertise and familiarity of the speech pathologist with head and neck cancer patients.
- Not every patient does it the same way!

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