

Atos Design & Clinical Performance of Provox Voice Prostheses & Accessories

Ellie van Kneegsel, MSc, SLP

We are passionate about making life easier for people living with a neck stoma, by providing personalized care and innovative solutions.

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After TE puncture with the Provox Vega Puncture Set a variety of prostheses exists to fit different clinical needs

PROVOX® Vega™



Confidence to speak more naturally

PROVOX® Vega™ XtraSeal™



Confidence to eat and drink without leakage

PROVOX® ActiValve®



Longest device life

PROVOX® Vega™ Puncture Set

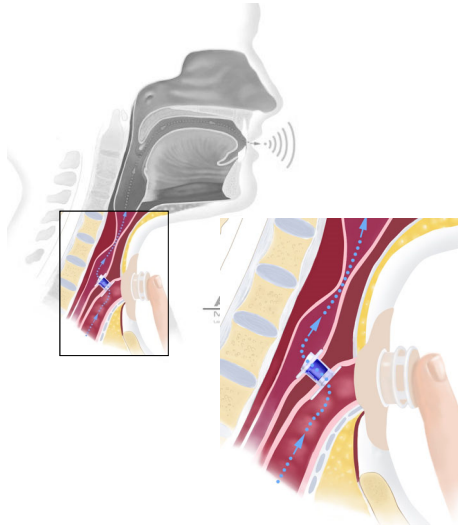


For primary puncture and VP placement during TL and for secondary puncture and placement months or years after TL

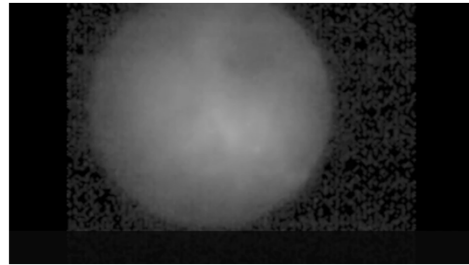
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Basic mechanism of tracheoesophageal (TE) speech



- Stoma is occluded during exhalation
- Air is diverted through the device
- New sound source – neoglottis, also called PE-segment



Courtesy of the Netherlands Cancer Institute

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Atos Provox Vega Puncture Set

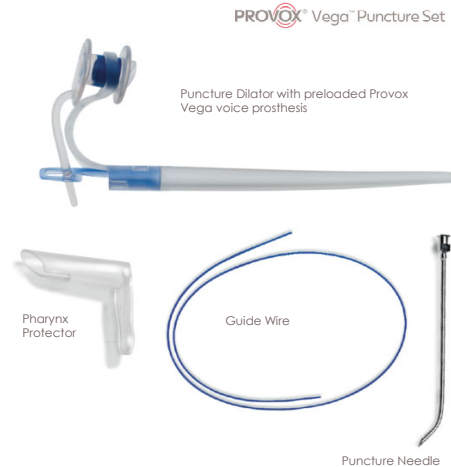
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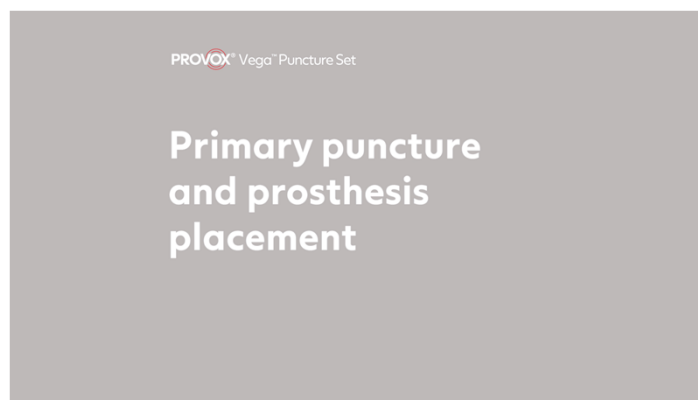
Provox Vega Puncture Set is a disposable surgical set for creating primary and secondary punctures and placement of Provox Vega VP

- **Sterile, all-in-one, disposable set** ensuring all required instruments are available, and needle is sharp every time
- **Pre-loaded voice prosthesis offering rapid procedure** with minimum preparation
 - Provox Vega for excellent voice quality, low speaking effort, ease of cleaning, and durability
- **Curved, sharp and thin puncture needle** designed for consistently round punctures and minimal tissue trauma
- **Retrograde voice prosthesis placement** to ensure esophageal flange placed correctly, and visual verification of automatic unfolding of tracheal flange



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Video animation showing Provox Vega Puncture Set used for primary puncture



NB. For **secondary puncture**, a rigid esophagoscope or other instrument is used for pharynx protection

<https://www.youtube.com/watch?v=IOEAiSWJxMw>

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Atos Voice prosthesis maintance by the patient

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Provox Brush, for daily care of the voice prosthesis


- Provox Brush
 - To clean the voice prosthesis, in the morning, evening and after each meal
 - Gently move the Brush back and forth while rotating
 - To insert Provox Plug into the voice prosthesis

LaryLogics

Topic:
Daily Care of your Voice
Prosthesis - Provox® Brush

Daily Care of your Voice Prosthesis

Provox® Brush



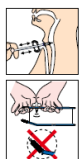
Clean the voice prosthesis in the morning and evening and after each meal using the Provox Brush and the Provox Flush.

1. Moisten the bristles of the Provox Brush and then insert all the way through the voice prosthesis. Put back on the Brush if you feel any resistance.
2. Move the Brush back and forth while rotating the brush at the same time, this will clean the whole prosthesis.
3. When you are finished:
 - a. Clean the brush with drinking water and hand washing detergents.
 - b. Rinse with tap water and store dry.
4. Replace the brush once a month or sooner if the bristles look worn and oversized.

Tip: if needed the blue shaft of the brush can be bent for better access to the voice prosthesis. Do not bend the white head of the Brush. Do not rotate the Brush during cleaning when the shaft is bent.

Tip: if your prosthesis is 12.5 mm or longer then use an XL brush. If your prosthesis is 10 mm or shorter then use a regular Brush.

5. Disinfect the Provox Brush in accordance with the Provox Brush manual.



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This leaflet does not replace nor does it add to the complete contents of the User Manual and/or Product Information for the products in this leaflet. It is a summary of the most important information. For more information, please refer to the User Manual and/or Product Information. The information in this leaflet is for informational purposes only and does not constitute a medical recommendation. Please consult your healthcare provider for more information.

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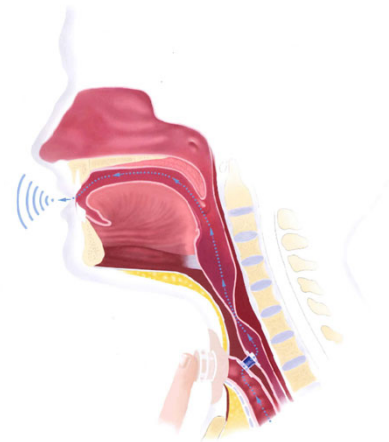
Atos Voice rehabilitation

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Voice rehabilitation: treatment scheme

- Pre-surgical counselling
 - Clinical Team & Patient advocate
 - Anatomy, consequences, speaking methods, rehabilitation, devices, etc
- First days in hospital 2 short sessions per day
 - Engage nursing staff in motivating the patient to speak
 - Primary TEP: ~10-14 days postop
 - Secondary TEP: ~as soon as patient is ready
- Discharge: education
- Follow-up
 - Continued voice and pulmonary rehabilitation
 - Advanced training



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Voice rehabilitation: First Session

- Clean voice prosthesis
- Check adhesive and HME
- Explanation to patient
- Ask patient to say /haaa/
- Therapist occludes stoma after patient has inhaled slightly

Don't explain too much about breathing the first time, see what the patient does and react on that



Courtesy of the Netherlands Cancer Institute

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LaryLogics

Topic: Occluding your stoma without an HME

Occluding your stoma without an HME

1. While wearing your stoma, if you are wearing an HME, it is still a good idea to practice occluding your stoma without your HME. There may be a time when you may not be wearing your HME and you will need to speak.
2. Use your finger or thumb to cover your stoma. If you are having trouble getting an airtight seal try using a towel but make sure it is not too tight on the stoma.
3. Say /haa/
4. Keep your arm flat in front of your chest. Keep movements small so that you do not draw attention to your stoma. Keep your head straight.
5. Take your thumb or finger off the stoma after making steps. Be careful not to take your thumb or finger off too early.
6. Work on timing. Avoid sound coming from your stoma caused by:
 - a. When you occlude the stoma too late
 - b. When you don't press firmly enough
 - c. When you take your thumb or finger away too early
7. Practice with the following utterances:

How are you?	How are you?
How are you?	How are you?
How are you?	How are you?
8. Talk to your clinician about the possibilities for a Heat and Moisture Exchanger (HME). This can make occluding your stoma much easier. Improve your voice and breath support for speaking.
9. Practice in front of a mirror if you are having a hard time occluding stoma.
10. Practice occluding the stoma with both hands so you can switch if needed. Think about which hand you prefer to use to occlude your stoma.
11. You may want to try with a stoma cover. You can put your finger on top of the cover.

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LaryLogics

Topic: Occluding your stoma with your HME

Occluding your stoma with your Heat and Moisture Exchanger (HME)

1. Press on the HME with a finger to occlude the stoma. Practice in front of a mirror if you are having a hard time getting a good occlusion.
2. Say /haa/
3. Take your finger off the HME after you have spoken. Be careful not to remove your finger too early.
4. Keep your arm flat in front of your chest. Keep movements small so that you do not draw attention to your stoma. Keep your head in a straight position.
5. Work on timing.
 - a. Avoid sound coming from your stoma caused by air escaping:
 - i. When you occlude too late
 - ii. When you don't press firmly enough
 - iii. When you take your finger off the stoma too early
6. Practice occluding with both hands so you can switch hands if needed.
7. You may want to try with a stoma cover. You can close your cover on top of the cover.
8. Vary the finger pressure you use to occlude your stoma and listen to the effect of air escaping underneath the top of the cover. Your finger pressure should be just firm enough to avoid the air escaping. Using too much finger pressure might hurt your stoma and might be tiring.

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Voice rehabilitation: following steps

- Occlude the stoma together with the patient to teach the right timing of the stoma occlusion
- Let patient occlude the stoma
- First focus on basic aspects
 - Stoma occlusion
 - Posture
 - Pulmonary support
- Defining speech by focusing on specific aspects
 - Intelligibility
 - Voice quality
 - Fluency
 - Intonation and inflection
- Advises for stoma care (together with HN nurse)
- Voice prosthesis change



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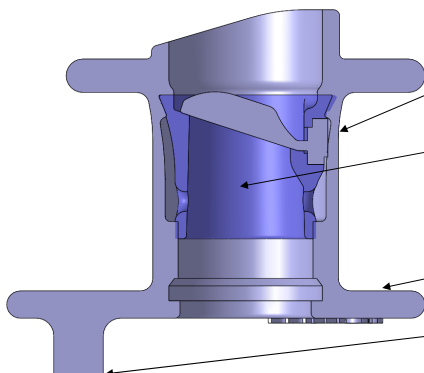
Atos Provox Vega & Insertion System

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Key features Provox Vega

- Sterile voice prosthesis
- Diameters 17, 20, and 22.5 Fr
- Lengths 4, 6, 8, 10, 12.5, 15 mm



Angled flap increases the valve opening area for less speaking effort

Larger inner diameter: Optimized inner and outer dimensions to facilitate speaking

Oval shaped flange fits the curvature of the trachea

Safety strap placement to minimize the risk to harm tissue



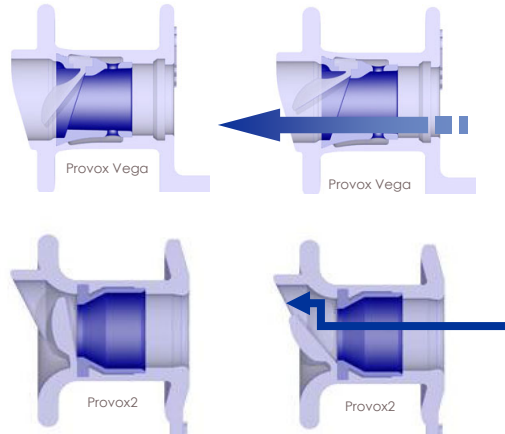
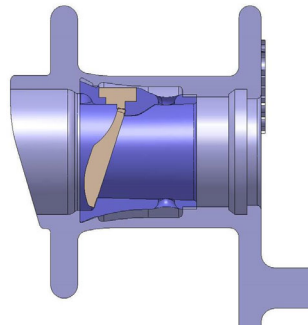
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Provox Vega is designed for good voice quality

- Optimized airflow to reduce airflow resistance, less effort needed to maintain speech
 - Larger inner diameter
 - 18° angled flap
 - Improved flap and hinge design



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Provox Vega voice prosthesis comes with an Insertion System that gives more control and greater flexibility

Key benefits

- Adapts to patient anatomy
- Creates a perfect fold of the voice prosthesis esophageal flange
- Intuitive and easy to use



System Insertion

For straightforward, easily accessible punctures



Tube Insertion

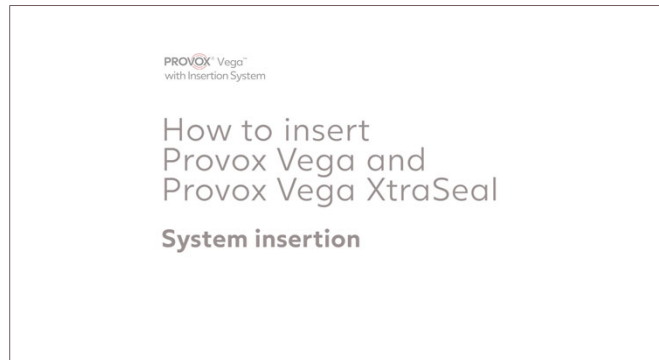
For more difficult-to-reach or angled punctures

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Video animations showing insertion of Provox Vega

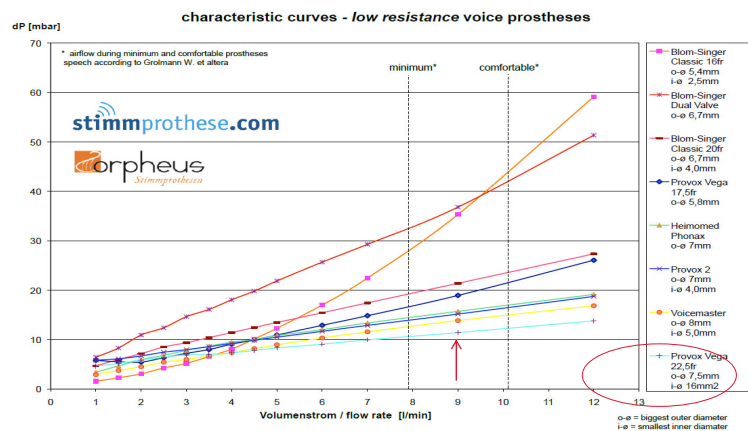


<https://www.youtube.com/watch?v=0AlgRpYpFVs>

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Provox Vega has optimal airflow characteristics during voice prosthesis speech



With permission of Prof. Kress; source: Stimmprothese.com

- X-axis: airflow in liter per minute; airflow for comfortable speaking is 10 liter per minute
- Y-axis: pressure drop dP (resistance)
- Lower dP = lower resistance = less effort to maintain valve opening = less effort to speak

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Provox Vega is reported to provide significantly better voice quality and less effort to speak

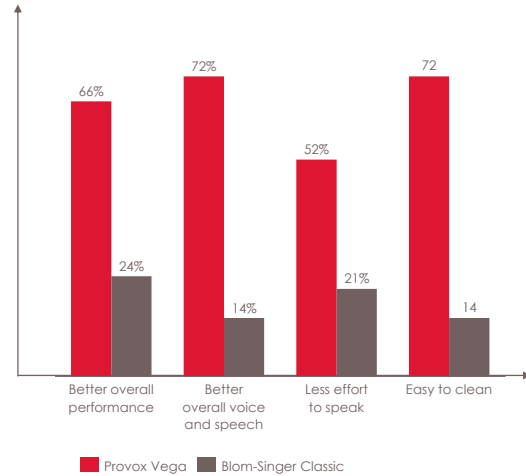
Study method

- 29 patients using voice prosthesis
- Randomized crossover study design. All participants used both Provox Vega and Blom-Singer Classic for 3-weeks each
- At the end, overall preference and factors influencing device preference were examined.
- Provox Vega patients had a better voice quality (59% vs 27%; $p=0.028$) and less effort to speak (69% vs 24%; $p=0.006$) when compared to Blom-Singer Classic

Ward EC, Hancock K, Lawson N, van As-Brooks CJ. Perceptual characteristics of tracheoesophageal speech production using the new indwelling Provox Vega voice prosthesis: a randomized controlled crossover trial. *Head Neck*. 2011;33(1):13-9.

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Study results



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Patients felt overall voicing, speaking effort and ease of cleaning were superior for Provox Vega

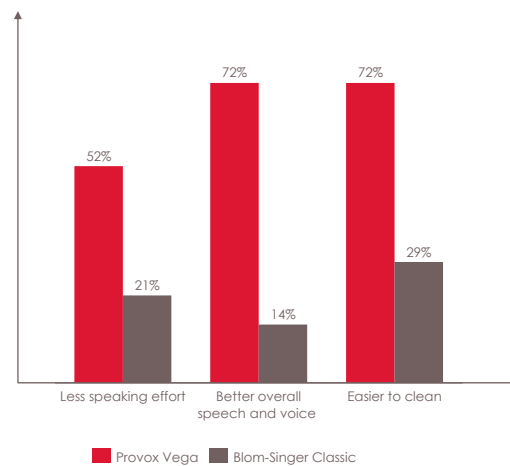
Study method

- 31 patients using voice prosthesis
- Randomized crossover study design. All participants used both Provox Vega and Blom-Singer Classic for 3-weeks each
- At the end, overall preference and factors influencing device preference were examined.
- Significantly higher proportion of patients felt voice effort (52% vs 21%; $p=0.05$), overall voicing (72% vs 14%; $p=0.001$), and ease and effectiveness of cleaning (72% vs 29%; $p=0.001$) were superior for the Provox Vega

Hancock K, Ward E, Lawson N, van As-Brooks CJ. A prospective, randomized comparative study of patient perceptions and preferences of two types of indwelling voice prostheses. *Int J Lang Commun Disord*. 2012 May-Jun;47(3):300-9.

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Study results



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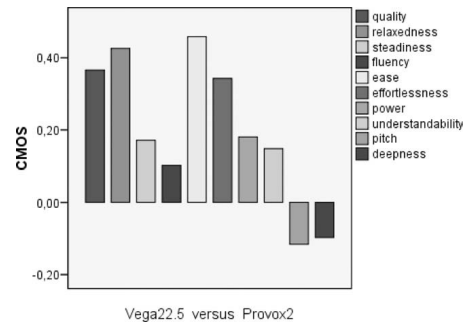
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Better voice quality with Provox Vega 22.5Fr compared to Provox2 and Vega 20Fr

Study method

- 33 patients evaluating Provox Vega 22.5Fr; 26 patients Provox Vega 20Fr
- Prospective study to evaluate device life, airflow characteristics and voice characteristics of Provox Vega 22.5 and 20 Fr, compared to Provox2
- The optimized airflow characteristics of Provox Vega with the wider inner diameter (22.5 Fr) resulted in **significantly patient preference** and **better voice characteristics** compared to Provox 2 (22.5 Fr)
- Provox Vega 20 Fr resulted in comparable voicing to Provox 2 (22.5 Fr)
- Device life of Vega 22.5 and 20Fr was as good as that of Provox 2

Study results



Hilgers FJ, Ackerstaff AH, Jacobi I, et al. Prospective clinical phase II study of two new indwelling voice prostheses (Provox Vega 22.5 and 20 Fr) and a novel anterograde insertion device (Provox Smart Insertor). Laryngoscope 2010;120(6):1135-43.

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Provox solutions for leakage around the voice prosthesis

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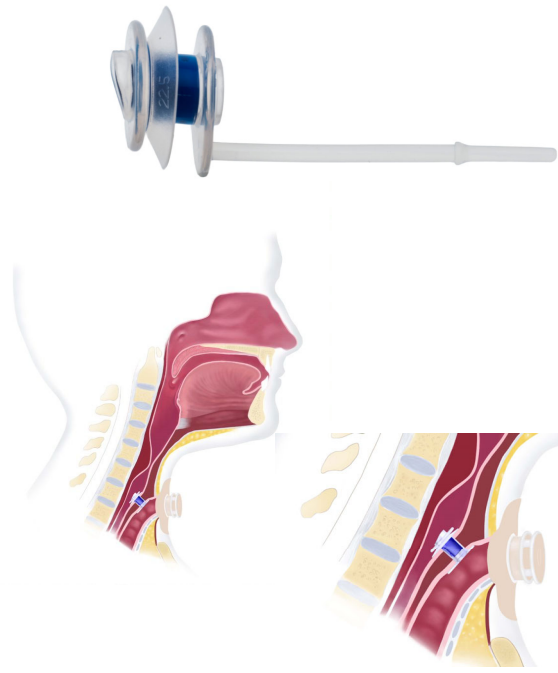
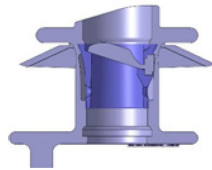
Provox Vega XtraSeal Confidence to eat and drink without leakage

Key benefits

- Manages leakage around
- Conforms to the tissue around the TE puncture
- Can be combined with Provox XtraFlange if severe leakage

Key features

1. Large esophageal flange that is thin, concave and flexible
2. Esophageal flange designed to provide step-less sizes between 3-15 mm



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Animation showing insertion of Provox Vega XtraSeal

PROVOX[®] Vega[™]
with Insertion System

How to overshoot
Provox Vega and
Provox Vega XtraSeal
System insertion

<https://www.youtube.com/watch?v=jogn0ZT0REA>

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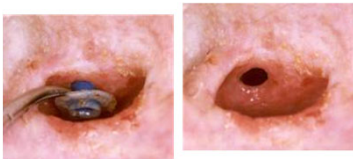
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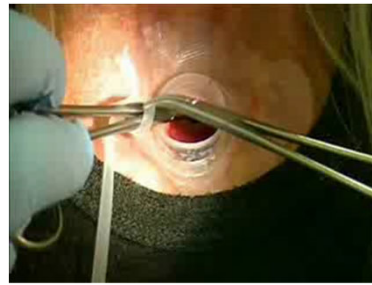
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Provox XtraFlange is a rapid solution to manage leakage around the voice prosthesis

- Placed on tracheal side of voice prosthesis
- Can be applied in situ
- Safety medallion to prevent product in trachea
- 17Fr, 20Fr, 22.5Fr
- Can also be used with Provox Vega XtraSeal



Courtesy of Netherlands Cancer Institute



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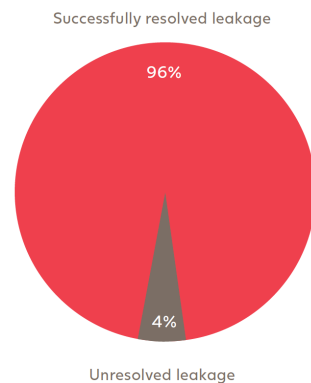
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Provox Vega XtraSeal solved peripheral leakage in 96% of the patients

Study method

- 13 patients, 26 replacements
- Consecutive cohort of patients seen in the outpatient clinic with periprosthetic leakage were included
- Only one Provox Vega XtraSeal needed replacement due to periprosthetic leakage

Study results



Petersen JF, Lansaat L, Hilgers F, Brekel MVD. Solving periprosthetic leakage with a novel prosthetic device. Laryngoscope. 2018;129(10):2299-302

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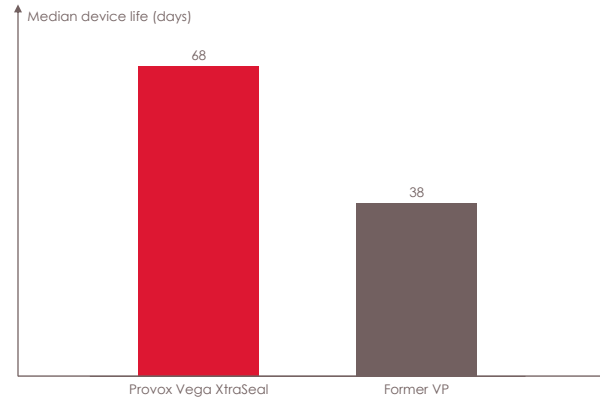
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Provox Vega XtraSeal median device lifetime was 68 days, compared to 38 days of the former voice prosthesis

Study method

- 13 patients, 26 replacements
- Consecutive cohort of patients seen in the outpatient clinic with periprosthetic leakage were included
- Median device lifetime of Provox Vega XtraSeal was 68 days (95% CI 56–80). Median device lifetime of the former VP before placement of the first Provox Vega XtraSeal was 38 days (95% CI 1–76)

Study results



Petersen JF, Lansaat L, Hilgers F, Brekel MVD. Solving periprosthetic leakage with a novel prosthetic device. *Laryngoscope*. 2018;129(10):2299-302

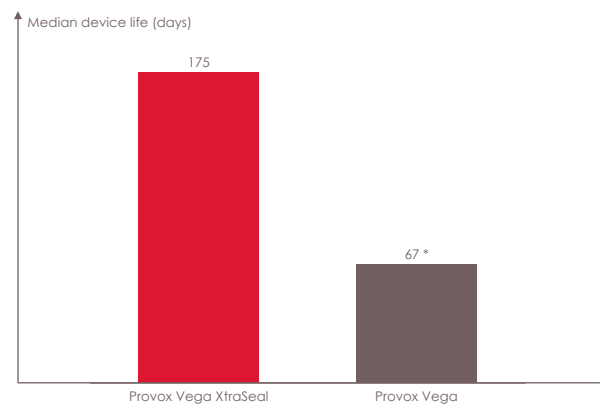
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Provox Vega XtraSeal median device lifetime was 175 days, compared to 67 days of Provox Vega

Study method

- 20 laryngectomized patients, with 218 replacements
- Prospective case-crossover study
- Median lifetime: Provox Vega 67 days, Provox XtraSeal 175 days ($p=0.012$)
- Main conclusion: Provox Vega reduces the number of changes due to periprosthetic leakage, thus increasing lifetime of VP

Study results



* Significant

Mayo-Yanez M, Cabo-Varela I, Suanzes-Hernandez J, Calvo-Henriquez C, Chiesa-Estomba C, Herranz-Gonzalez-Botas J. Use of double flange voice prosthesis for periprosthetic leakage in laryngectomized patients: a prospective case-crossover study. *Clin Otolaryngol*. 2020 Feb 3 [Epub ahead of print].

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Atos Provox ActiValve

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Provox ActiValve for early leakage due to excessive biofilm formation and/or underpressure

Key design features

- Fluoroplastic valve seat and valve flap
- Supported by magnets
 - Light
 - Strong
 - XtraStrong
- Diameter: 22.5 Fr
- Lengths: 4.5, 6, 8, 10, 12.5 mm



Key benefits

- Significantly longer average device life
- Manages early central leakage due to biofilm
- Manages central leakage due to underpressure

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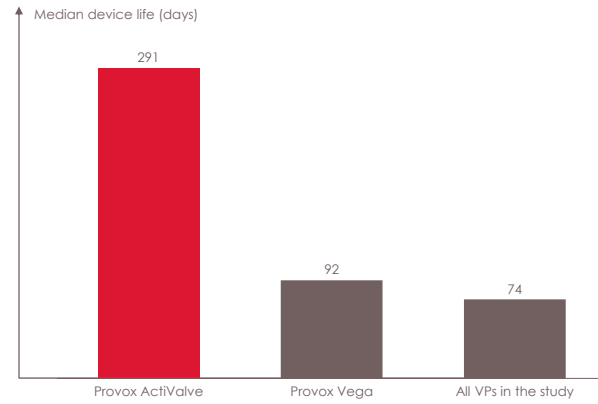
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Provox ActiValve had significantly longest median device life for users experiencing early leakage through VP

Study method

- 102 patients using 749 voice prostheses
- Prospective, non-randomized study
- First prostheses used intraoperatively were excluded, since it is known that their service life can be disproportionately long
- Provox ActiValve had significantly longer device life compared to all other voice prostheses for users experiencing early leakage through VP (median 291 days vs 74 days; $p < 0.0001$)

Study results



Kress P, Schafer P, Schwerdtfeger FP, Rosler S. Are modern voice prostheses better? A lifetime comparison of 749 voice prostheses. Eur Arch Otorhinolaryngol. 2014;271(1):133-40

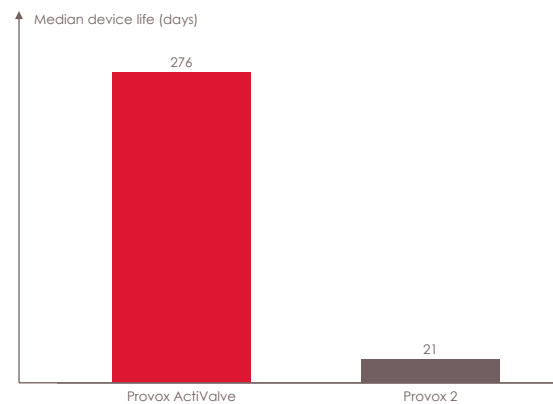
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Provox ActiValve average 16-fold longer device life when replacements due to 'underpressure' or biofilm

Study method

- 32 laryngectomized patients
- Patients experiencing a short Provox2 device lifetime (median 21 days)
- Retrospective assessment of device lifetime and indications for replacement
- Provox ActiValve had in average 16-fold longer device life in patients requiring replacements due to 'underpressure' or biofilm ($p < 0.001$)

Study results



Soolsma J, Van den Brekel MW, Ackerstaff AH, Balm AJ, Tan B, Hilgers FJ. Long-term results of Provox ActiValve, solving the problem of frequent candida- and "underpressure"-related voice prosthesis replacements. Laryngoscope. 2008;118(2):252-7

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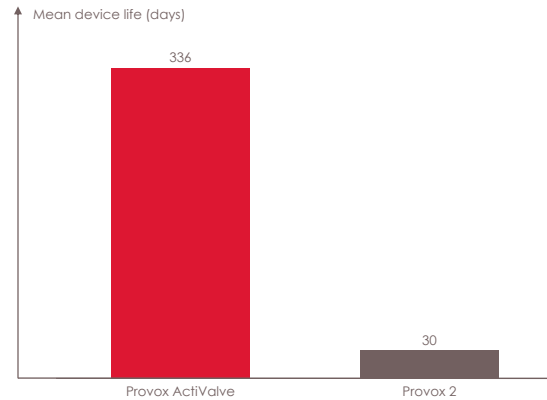
Provox ActiValve average 14-fold longer device life when replacements due to 'underpressure' or biofilm

Study method

- 18 laryngectomized patients
- Patients experiencing a short Provox2 device lifetime (mean 30 days)
- Prospective trial
- Provox ActiValve had in average 14-fold longer device life compared to Provox 2 in patients requiring replacements due to 'under pressure' or candida (range 3-39-fold, $p < 0.001$)

Hilgers FJ, Ackerstaff AH, Balm AJ, Van den Brekel MW, Bing Tan I, Persson JO. A new problem-solving indwelling voice prosthesis, eliminating the need for frequent Candida- and "underpressure"-related replacements: Provox ActiValve. *Acta Otolaryngol.* 2003 Oct;123(8):972-9

Study results



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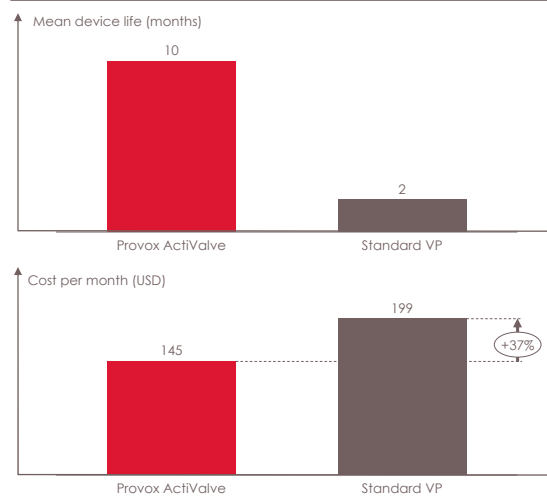
Provox ActiValve average 500% longer device life in patients experiencing below-average device life. Cost per month for standard voice prostheses +37% (USD)

Study method

- 11 laryngectomized patients
- Prospective study, patients experiencing below-average VP device lifetime were studied
- Patients followed average 30.45 months (range 14.70-43.49 months), in total of 31 VPs
- Increase in device life of more than 500%, going from mean 1.93 months with standard indwelling device to 10.30 months with Provox ActiValve
- Cost per month with Provox ActiValve 144.51 USD, and for standard indwelling voice prosthesis 198.62 US. Cost included devices and clinician visit cost (100 USD per visit), but excluded brush, flush, nystatin, lubricant

Graville DJ, Palmer AD, Andersen PE, Cohen JL. Determining the Efficacy and Cost-Effectiveness of the ActiValve: Results of a Long-term Prospective Trial. *The Laryngoscope* 2011; 121(4):769-776.

Study results



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