Checklist Voice prosthesis replacement

Assessment leakage

Assess with (colored) drinking water (suction ready to prevent aspiration)

- Central leakage (through VP)
- Peripheral leakage (around VP)
- Central and peripheral leakage

Required materials

- Brush
- Suction equipment
- Hemostats/forceps (non toothed)
- Headlamp
- Gloves
- Scissor or stitch cutter
- Voice prosthesis, different lengths
- Provox Vega XtraSeal
- Provox XtraFlange
- (Colored) Drinking water

Central leakage

Normal/expected: on average >2 mths in situ

Clean voice prosthesis with Provox Brush.

Optional: Deep clean VP (brush/flush with lukewarm water/gentle suction).[1]

Repeat assessment with (colored) drinking water.

Early: on average <2 mths in situ

Clean voice prosthesis with Provox Brush.

Optional: Deep clean VP (brush/flush with lukewarm water/ gentle suction).[1]

Repeat assessment with (colored) drinking water.

System Insertion Guide, Provox Vega and Provox Vega XtraSeal:

System Insertion Guide, Overshooting Provox Vega and Provox Vega XtraSeal:

Tube Insertion Guide, Provox Vega and Provox Vega XtraSeal:

Placement of Provox ActiValve:

Central leakage > 2 mths (standard replacement)

Check length (IFU 2.1)

Gently pull tracheal flange of VP in situ forward using e.g. forceps (tip: after checking length, remove VP using e.g. forceps with mild force).

> 2 mm shaft length visible: replace with VP one size down (e.g. 6mm instead of 8mm).

After insertion of VP: check correct placement of VP by rotating with brush or non-toothed forceps.

Clean valve with brush.

Check for leakage (colored fluid/water), check voice, cut safety strap with with insertion pin still attached.

≤ 2mm shaft visible: correct size. Replace with VP same analogous size (tip: ask the patient to open mouth to prevent swallowing during insertion of the VP).

After insertion of VP: check correct placement of VP by rotating with brush or non-toothed forceps.

Clean valve with brush or suction device.

Check for leakage (colored fluid/water), check voice, cut safety strap with with insertion pin still attached.

(Repeated) Central leakage < 2 mths

Caused by biofilm (visual inspection of removed VP)

Review and repeat education on VP cleaning and maintenance with the patient, including use of Provox Brush and Provox Flush.

Consider Provox ActiValve Light, or prescribe anti-candida medication.

Please note, Provox ActiValve is only available in 22.5Fr.

Caused by negative pressure

Negative pressure: inadvertent opening of the valve flap causing central leakage. Use scope to observe valve flap opening whilst breathing or swallowing. Listen for audible clicks.

If yes: consider Provox ActiValve Strong.

Depending on recurrence of complaints, Provox ActiValve XtraStrong might be considered.

For sizing, see standard replacement (also IFU 2.1).

Reference:
1. Parrilla C, Longobardi Y, Paludetti G, Marenda ME, D'Alatri L, Bussu F, Scarano E, Galli J. A one-year time frame for voice prosthesis management. What should the physician expect? Is it an overrated job? Acta Otorhinolaryngol Ital. 2020 Aug;40(4):270-276.

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- Provox XtraFlange
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Peripheral leakage

Check length (IFU 2.1)

Gently pull forward tracheal flange of VP in situ using e.g. forceps.

Tip: after checking length, remove VP using e.g. forceps and mild force.

Too long (>2mm shaft size visible, see standard replacement). Replace with a shorter VP please at shaft: (one shaft size down).

Repeat leakage assessment with colored liquid.

Enlarged puncture (atrophy)

Note: always assess and manage cause enlargement with adequate medical treatment (e.g reflux, recurrence, malnutrition, RT, thyroid)

Provox Vega XtraSeal if VP has to be replaced (e.g. VP in situ > 2 mths) or if puncture is too wide to ensure adequate retention of standard VP.

Note: for insertion of Provox Vega XtraSeal, always use overshoot technique, with gentle pulling tracheal flange through puncture with rotating movement (IFU 2.3.3).

Repeat assessment with colored liquid.

Still leakage: consider additional placement of Provox XtraFlange.

Provox XtraFlange if no need for replacement VP (eg < 2 mths in situ). Note: contraindicated if puncture is too wide to ensure adequate retention of VP (IFU).

Repeat leakage assesment with colored liquid.

Still leakage: consider replacement with Provox Vega XtraSeal.

Hypertrophy TE puncture (granulation, extrusion)

Replace VP, upsize two shaft lengths (e.g. 10 mm instead of 6 mm): use overshoot technique to ensure correct position of esophageal flange.

Puncture shape: too wide or oval shaped TE puncture

Provox XtraFlange and/or Provox Vega XtraSeal.

Still leakage: consider purse-string suture or injectables.

Still leakage: consider removal of VP and let puncture shrink. Manage nutritional needs and aspiration risk.

High intrapharyngeal pressure

Assess swallowing (eg videofluoroscopy) and esophageal stricture/ stenosis.

Provox XtraFlange and/or Provox Vega XtraSeal (as for enlarged puncture). Note: for insertion of Provox Vega XtraSeal, always use overshoot technique, with gentle pulling tracheal flange through puncture with rotating movement (IFU 2.3.3).

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