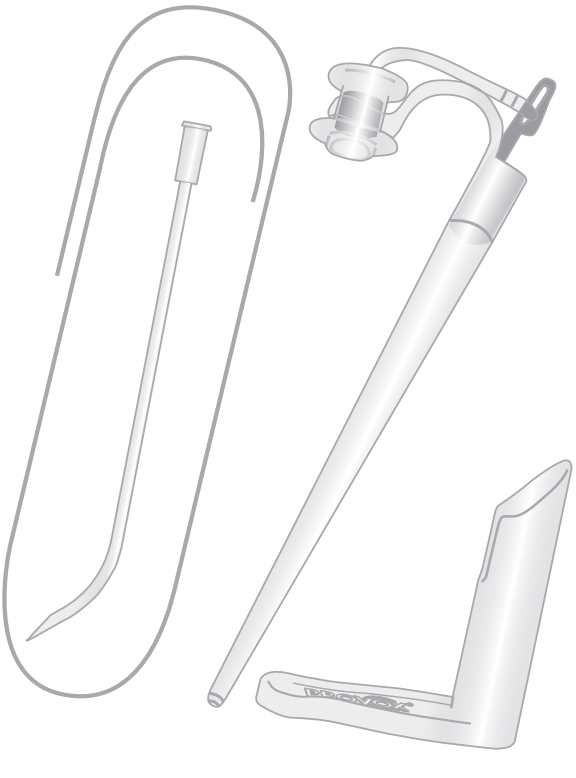
PROVOX® Vega™

Puncture Set

辅助发音管

穿刺套装（含普通辅助发音管）



MD Rx ONLY CE 0413

STERILE EO

42 °C 108 °F RT 2 °C 36 °F

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Due to local Chinese requirements, the text in the Intended use paragraph and the Overall description and product composition paragraph are not translated verbatim.

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Contents

Please see accompanying Illustration manual for illustrations referenced in this Instructions for Use.

Stomal airway management

Emergency situations

It is important that emergency personnel knows that you are a neck breather. This will help them determining that oxygen and rescue breathing need to be administered to your stoma and not to your mouth or nose.

We recommend that you and your clinician download the guidelines for rescue breathing from **www.atosmedical.com/rescuebreathing**

Elective situations

If you need to undergo a procedure that requires intubation (putting a breathing tube in your windpipe), it is very important that the anesthesiologist and the doctor who is performing the procedure are aware that you are a neck breather and that you are using a voice prosthesis. It is important for them to understand that the voice prosthesis should stay in place. If it is removed, fluids from your mouth, food pipe, or stomach may get into your windpipe.

It is very important that the intubation tube is inserted and removed carefully so that the voice prosthesis does not dislodge or come out.

1. Descriptive information

1.1 Intended Use

Provox Vega Puncture Set is a device for performing a primary or secondary tracheo-esophageal (TE) puncture in laryngectomized patients, with integrated placement of a Provox Vega voice prosthesis.

The Provox Vega voice prosthesis is a sterile single use indwelling voice prosthesis intended for voice rehabilitation after surgical removal of the larynx (laryngectomy). Cleaning of the voice prosthesis is performed by the patient while it remains in situ.

1.2 Overall description and product composition (结构及组成)

Provox Voice Prosthesis is composed of Silicone, Polyvinylidene Fluoride (PVDF) and Silicone adhesive.
The insertion system in the Provox Vega Puncture Set is composed of MethylMethacrylate Acrylonitrile Butadiene Styrene (MABS), Stainless steel, Polyamide (PA66) and epoxy glue, Thermoplastic Styrene-Ethylene/Butylene-Styrene (TPS-SEBS), polypropylene (PP), Polyvinylidene Fluoride (PVDF).
The insertion system in the Provox Vega and Provox Vega XtraSeal is composed of Polypropylene (PP), colorant, and Silicone oil.
Provox Flush in the Provox Accessories is composed of Silicone, Polypropylene (PP) and blue masterbatch; Provox Vega Plug in the Provox Accessories is made of Silicone.
Provox Voice Prosthesis and its set are sterilized by ethylene oxide. The product is for single use. The Provox accessories are non-sterile products.
The shelf life of package sterilization is 5 years.

1.3 Contraindications

Do not use the Provox Vega Puncture Set if the patient has anatomical abnormalities that may hinder safe puncturing of the TE wall or safe voice prosthesis placement (e.g., significant stenosis or significant fibrosis at the puncture site) as this may cause tissue damage.

Do not use the Provox Vega Puncture Set for secondary TE puncture if the patient suffers from severe trismus that precludes proper protection of the pharyngeal wall. Failure to protect the pharynx during puncture may lead to unintended trauma of the pharyngeal/ esophageal tissue.

1.4 Description of the device

The Provox Vega Puncture Set is a device for creating a primary or secondary TE puncture, with subsequent dilatation of that puncture to a width that facilitates placement of the included Provox Vega voice prosthesis. The Provox Vega voice prosthesis is preloaded on the Puncture Dilator, which is part of the device.

The Provox Vega Puncture Set is intended for single use only and the package contains the following sterile items in a blister package (Fig. 1):

- 1 Pharynx Protector (Fig. 1.1) made of transparent thermoplastic,
- 1 Puncture Needle (Fig. 1.2) made of stainless steel, Polyamide (PA66) and epoxy glue,
- 1 Guidewire (Fig. 1.3) made of pre-colored fluoroplastic,
- 1 Puncture Dilator with 1 preloaded Provox Vega voice prosthesis (Fig. 1.4). The Puncture Dilator is made of thermoplastic elastomer and polypropylene; and the Vega voice prosthesis is made of medical grade silicone rubber and fluoroplastic.

The preloaded Puncture Dilator contains the following functional characteristics and components:

- a dilator (Fig. 1.4.1),
- a dilator strap (Fig. 1.4.2) connecting the dilator and the voice prosthesis interface,
- a dilator loop (Fig. 1.4.3) constituting the voice prosthesis interface,
- a Wirelock (Fig. 1.4.4) containing interfaces to the voice prosthesis safety strap (Fig. 1.4.6) and to the Guidewire,
- a Provox Vega voice prosthesis (Fig. 1.4.5) with its safety strap (Fig. 1.4.6) connected to the Wirelock and oriented so that the tracheal flange (Fig. 1.4.7) of the voice prosthesis is facing towards the Wirelock.

The Provox Vega voice prosthesis contains a one-way valve that keeps the TE-puncture open for speech, while reducing the risk of fluids and food entering the trachea.

The Provox Vega voice prosthesis is not a permanent implant, and needs periodic replacement. The prosthesis is available in different diameters and several sizes.

The set also includes the following non-sterile items:

- 1 Instructions for use - Provox Vega Puncture Set (including 1 Illustration manual)
- 1 Provox Vega Patient's Manual
- 1 Provox Brush of a size corresponding to the voice prosthesis
- 1 Provox Brush Instructions for Use

1.5 Warnings

Pre-surgery

- **DO NOT** use the product if the package is damaged or opened. Unsterile product may cause infection.

- **DO NOT REUSE** and **DO NOT RESTERILIZE** by any method. This device is intended for single use only. Reuse may cause cross contamination. Cleaning and resterilization may cause structural damage to the device.
- **DO** proceed with great care if the patient has received radiotherapy with or without concurrent chemotherapy. These circumstances increase the risk of puncture-related complications (e.g., widening, granulation, atrophy). Therefore, ensure that the tissue integrity is sufficient for creation of a TE puncture.

During surgery

General

- **DO** ensure that the Pharynx Protector is inserted deep enough into the esophagus before performing primary TE puncture, by palpating the TE wall. Puncture without proper positioning of the Pharynx Protector may cause tissue damage.
- **DO** ensure that the Guidewire is inserted through the needle and through the lumen of the Pharynx Protector so that it does not damage the TE wall.
- **DO** ensure that the Puncture Needle is removed before removing the pharynx protector. The Puncture Needle may cause tissue damage without proper pharynx protection.
- **DO** ensure that the Puncture Dilator is mounted on the esophageal end of the Guidewire and not the tracheal. The dilatation should be performed in the posteroanterior direction. Dilatation in the wrong direction causes reversed placement of the voice prosthesis, which causes aspiration and inability to speak.
- **DO NOT** withdraw the Guidewire back through the Puncture Needle. Damage, shearing and/or scraping of the Guidewire may occur. If the Guidewire must be withdrawn, remove the Guidewire and the Puncture Needle simultaneously, as one unit, to prevent the Puncture Needle from damaging the Guidewire.
- **DO NOT** use toothed hemostats or other instruments that may damage the product.

Secondary puncture

- **DO NOT** use the included Pharynx Protector during Secondary punctures. It is only intended to be used during Primary punctures.
- **DO** ensure that the pharyngeal/esophageal tissue is adequately protected, e.g., by use of a rigid endoscope before performing secondary TE puncture.

Post surgery

Use of the voice prosthesis

Dislodgement or extrusion of the Provox Vega voice prosthesis from the TE puncture and subsequent ingestion, aspiration or tissue damage may occur. For further information about these events and how to prevent them, see section Adverse Events and Trouble Shooting Information below.

To reduce the risk of dislodgment or extrusion and its potential consequences:

- **DO** select the proper prosthesis size (i.e. length). A tight fit due to a too short voice prosthesis may cause tissue necrosis and extrusion.
- **DO** instruct the patient to only use genuine Provox accessories of corresponding size and diameter (e.g., Brush, Flush, Plug) for maintenance and to avoid all other kinds of manipulation.
- **DO** instruct the patient to consult a physician immediately if there are any signs of tissue edema and/or inflammation/infection.
- **DO** choose laryngectomy tubes or stoma buttons, if used, with a suitable shape that do not exert pressure on the prosthesis during use, or catch onto the tracheal flange of the prosthesis during insertion and removal of the tube or button.

1.6 Precautions

Always assess the suitability of the tissue in the area of the TE puncture. In cases with lacking suitability, e.g. due to excessive scar tissue or radiation fibrosis, proceed with great care and abort the procedure if dilatation of the TE puncture requires too much force.

- **DO** carefully assess patients with bleeding disorders or patients undergoing anticoagulant treatment for the risk of bleeding or hemorrhage, prior to secondary puncture and prosthesis placement.
- **DO** always use aseptic technique when handling the Puncture Set in order to reduce risk for infection.
- **DO** remove the Pharynx Protector before initiating dilatation. The voice prosthesis may get stuck inside the Pharynx Protector if attempting to complete the procedure without removing the Pharynx Protector.
- **DO** ensure that the Guidewire is adequately threaded and locked in position in the Wirelock. If proper locking is not achieved, the Guidewire may come loose from the Wirelock, causing failure to complete procedure.
- **DO** always proceed slowly and without using excessive force during dilatation and placement of the prosthesis. Tissue damage may otherwise occur.
- **DO** support the TE tissue during dilatation. Otherwise, rupture may occur. In case of a rupture of the TE tissue the TE puncture procedure should be abandoned and the rupture should be sutured immediately. TE puncture should only be repeated after proper healing of the tissues.
- **DO NOT** reload after the safety strap of the prosthesis has been cut off, as the safety mechanism in that case has been compromised, with risk for dislocation of the voice prosthesis during the procedure.

1.7 Adverse events and troubleshooting information

1.7.1 During use of the Puncture Set

(Sub-) mucosal injury

During puncture, the Puncture Needle or the Guidewire could cause a (sub) mucosal injury if the Pharynx Protector is not located in its correct position, or if the puncture is made incorrectly. In case of suspicion of (sub)mucosal damage, it is recommended that the patient receives a prophylactic course of postoperative antibiotics and is fed through a nasogastric tube or similar to allow healing.

Re-puncture

If the Pharynx Protector is not positioned appropriately when puncturing, or if, for any other reasons, there is need for re-puncture, the tissue should be assessed for possible sub-mucosal injury and the puncture procedure repeated with the Pharynx Protector positioned correctly.

Forgot to remove the Pharynx Protector

If the Puncture Dilator is connected to the Guidewire prior to removal of the Pharynx Protector, the procedure cannot be completed. If this occurs, detach the Puncture Dilator from the Guidewire and remove the Pharynx Protector. Also see Reloading below.

Reloading

In some cases, reloading of the Puncture Dilator may be necessary; e.g., if the voice prosthesis is pulled completely through the puncture during prosthesis placement. The reloading procedure is described in section 2.2.3 and illustrated in Fig. 4.

1.7.2 During use of the voice prosthesis

Dislodgement of the voice prosthesis– Dislodgement can be caused by infection and/or edema of the TE-puncture, granulation around the puncture or hypertrophic scarring around the puncture. Dislodgement might lead to aspiration or ingestion of the prosthesis. See below.

Aspiration of the prosthesis – Accidental aspiration of the voice prosthesis or other components of the voice rehabilitation system may occur. As with any other foreign body, complications from aspiration of a component may cause obstruction or infection. Immediate symptoms may include coughing, wheezing or other abnormal breathing sounds, dyspnea, and respiratory arrest, partial or inadequate air exchange and/or asymmetrical chest movement with respiration. Complications may include pneumonia, atelectasis, bronchitis, lung abscess, bronchopulmonary fistula and asthma.

If the patient can breathe, coughing may remove the foreign body. Partial airway obstruction or complete airway obstruction requires immediate intervention for removal of the object. If aspiration of the device is suspected, a CT scan of the lungs should be performed to confirm aspiration and locate the device. If the CT scan confirms aspiration of the device, the device may be retrieved endoscopically using a non-toothed grasping forceps.

The silicone housing of the Vega voice prosthesis can also be located endoscopically. On a CT scan and during endoscopy, the device may appear as a oval shape with an opening in the middle with an outer diameter of about 10-17 mm (the flanges of the device), or as a cufflink shape with a shaft length of 8, 10, 12.5 or 15 mm, depending on the size of the device. During endoscopy, reflections from the light source on the clear silicone rubber may be seen. Also, in prostheses that have been in situ for some time, white or yellow appearing Candida deposits may be visible on the device.

Ingestion of the prosthesis – Accidental ingestion of the voice prosthesis, or other components of the voice rehabilitation system, may occur. As with any other foreign body, the symptoms caused by ingestion of the prosthesis or a component of the voice rehabilitation system depends largely on size, location, degree of obstruction (if any) and the length of time it has been present. Ingested components that have remained in the lower esophagus may be removed by esophagoscopy or observed for a short period of time. The object may pass spontaneously into the stomach. Foreign bodies that pass into the stomach usually pass through the intestinal tract. Surgical removal of foreign bodies from the intestinal tract must be considered when bowel obstruction occurs, bleeding is present, perforation occurs or the object fails to pass through the intestinal tract.

Spontaneous passage of the device may be awaited for 4-6 days. The patient should be instructed to observe the stools for the ingested device. If the device does not pass spontaneously, or if there are signs of obstruction (fever, vomiting, abdominal pain) a gastroenterologist should be consulted. The silicone housing of the Vega voice prosthesis can be located and retrieved endoscopically. The device may be retrieved by using a non toothed grasping forceps. During endoscopy, the device may appear as a oval shape with an opening in the middle with an outer diameter of about 10-17 mm (the flanges of the device), or as a cufflink shape with a shaft length of 8, 10, 12.5 or 15 mm, depending on the size of the device. Reflections from the light source on the clear silicone rubber may be seen. In prostheses that have been in situ for some time, white or yellow appearing Candida deposits may be visible on the device.

Infection and/or edema of the TE-puncture – Infection, granulation formation and/or edema of the puncture may increase the length of the puncture tract. This may cause the prosthesis to be drawn inward and under the tracheal or esophageal mucosa. Inflammation or overgrowth of the esophageal mucosa may also cause the prosthesis to protrude from the puncture. Temporary replacement of the prosthesis by a prosthesis with a longer shaft is then advisable. If standard medical treatment does not resolve the infection, the prosthesis should be removed. In some cases stenting the puncture with a catheter might be considered. If the puncture closes spontaneously re-puncture for insertion of a new prosthesis may be required.

Granulation around the puncture – Formation of granulation tissue around the TE-puncture has been reported at an incidence of about 5%. Electrical, chemical, or laser cauterization of the area of granulation may be considered.

Granulation/Hypertrophic scarring around the puncture – Bulging of the tracheal mucosa over the tracheal flange may occur if the prosthesis is relatively short. This excess tissue may be removed by using a laser. Alternatively, a prosthesis with a longer shaft can be used.

Protrusion/extrusion of the prosthesis – Protrusion of the prosthesis and subsequent spontaneous extrusion is sometimes observed during infection of the TE-puncture. Removal of the prosthesis is required to avoid dislodgement into the trachea. The puncture may close spontaneously secondary to the removal of the prosthesis. Re-puncture may be necessary for insertion of a new prosthesis.

Tissue damage – If the prosthesis is too short, too long, or is pushed frequently against the esophageal wall by a laryngectomy tube, stoma button, or the patients' finger, damage of the puncture, tracheal and/or esophageal tissues may occur. Inspect the conditions regularly to avoid severe damage.

Leakage through the valve – Leakage through the prosthesis may occur because:

- Candida overgrowth near the valve seat and valve flap may lead to incomplete closure of the valve flap, which causes leakage through the device. This is a normal event in prosthetic voice rehabilitation and an indication to replace the voice prosthesis.
- Stronger negative pressure in the PE-segment occurs during swallowing. To investigate this, transstomal inspection of the valve flap of the prosthesis should be performed during swallowing.

Leakage around the prosthesis – Transient leakage around the prosthesis may occur and may resolve spontaneously. The most common reason is that the prosthesis is too long, which is solved by inserting a shorter prosthesis. If the problem is not solved by inserting the correct length prosthesis, other factors that may affect tissue integrity in the area of the TE puncture (for example gastroesophageal reflux or thyroid function) should be considered, evaluated, and treated. In enlarged punctures with reduced retention strength other conventional treatment methods such as the injection of fillers (e.g., collagen) or temporary removal of the voice prosthesis, should be considered. If the leakage around the voice prosthesis is intractable, more conservative measures, such as surgical closure of the puncture may be necessary.

2. Instructions for Use

Please see accompanying Illustration manual for illustrations referenced in this Instructions for Use.

For a visual overview of the different procedures you can find links to video animations under the section headings below.

Caution: The videos do not replace nor do they set forth the complete contents of the Instructions for Use and /or Prescriber Information, and are not a substitute for reviewing the entire contents of the Instructions for Use. The videos are only intended to further enhance the understanding of the procedure after review of the Instructions for Use.

2.1 Preparation

Prior to the puncture always determine what size and diameter of voice prosthesis to use. The appropriate size and diameter depends on the anatomy of the patient, local medical practice and preference of the surgeon.

2.2 Operating instruction

Check the integrity of the sterile package. Do not use the product if the package is damaged or opened. Unsterile product may cause infection.

2.2.1 Primary puncture and prosthesis placement

www.atosmedical.com/primary-puncture

1. After removal of the larynx and creation of the tracheostoma, before closure of the pharynx, insert the Pharynx Protector in the open pharynx/esophagus (Fig. 2.1).
2. Verify the correct location for the TE puncture by palpating the inside of the trachea at the desired puncture site. The oblique front opening of the Pharynx Protector (or the slit on the upper side, depending on surgical technique) should be felt during palpation (Fig. 2.2).
3. Insert the Puncture Needle at the correct puncture site (about 8-10 mm from the edge of the tracheostoma) until the tip of the needle reaches the inner lumen of the Pharynx Protector (Fig. 2.3).
   If an endotracheal tube is in situ, this tube should be removed if it obstructs proper dilatation and integral placement of the voice prosthesis.
4. Insert the Guidewire into the hub of the Puncture Needle. Push the Guidewire through the needle until it extends approx. 20 cm out from the lumen of the Pharynx Protector (Fig. 2.4).
   WARNING: Always verify that the Guidewire comes out through the lumen of the Pharynx Protector. Otherwise there is a risk for (sub) mucosal damage and the procedure needs to be restarted (see Adverse Events and Troubleshooting Information as well as Instructions for Reload of the Puncture Set).
5. Remove the Puncture Needle (Fig. 2.5).
   CAUTION: Always remove the needle before removing the Pharynx Protector. There is a risk for damaging the esophageal tissue otherwise.
6. Remove the Pharynx Protector. Only the Guidewire should remain in situ before continuing (Fig. 2.6).
7. Insert the Guidewire extending from the esophageal side into the narrow end of the Puncture Dilator and push the Guidewire through the Puncture Dilator until it extends approx. 10 cm through the Puncture Dilator exit hole (Fig. 2.7).
8. Grab the tip of the Guidewire and insert it in the hole next to the exit hole (Fig. 2.8).
9. Tighten the Guidewire by pulling it from the narrow end of the Puncture Dilator and verify that it is secured to the Puncture Dilator (Fig. 2.9).
10. Using a continuous, smooth motion; dilate the puncture site by carefully pulling the Guidewire through the puncture. During dilatation, support the TE tissue (for example with two fingers) to reduce dilatation force. For better control, firmly grasp the Guidewire close to the Puncture Dilator (Fig. 2.10).
    CAUTION: Dilatation and integral placement of the voice prosthesis should be carried out in the anterior/caudal direction with limited lateral movement in order to limit the force applied to the TE wall.
11. In the same continuous, smooth motion, carefully pull the Guidewire, Puncture Dilator and the Puncture Dilator loop through the puncture. The Puncture Dilator loop folds the tracheal flange of the voice prosthesis as the loop is pulled over the flange and through the puncture. The tracheal flange unfolds in the trachea when the loop releases it (Fig. 2.11).
    Stop pulling immediately when the tracheal flange is released by the Puncture Dilator loop. If the tracheal flange does not unfold completely, it can be rotated in place using two non-toothed hemostats.
12. Grasp the tracheal flange of the voice prosthesis with a non-toothed hemostat, turn the prosthesis in the correct position, and cut the safety strap (Fig. 2.12).

2.2.2 Secondary puncture and prosthesis placement

www.atosmedical.com/secondary-puncture-and-prosthesis-placement

The Pharynx Protector (Fig. 1.1) included in the Provox Vega Puncture Set is not used during secondary puncture.

1. Choose an instrument (e.g., a rigid endoscope) which can function as;
   a. a protector when the needle is penetrating the TE wall and
   b. a guide for the correct location of the TE puncture and
   c. a means to facilitate a safe passage of the Guidewire when it is passed through the pharynx and out of the mouth.

   Introduce the instrument into the esophagus (Fig. 3.1). If an endotracheal tube is in situ, this tube should be removed if it obstructs proper dilatation and integral placement of the voice prosthesis.
   CAUTION: Always make sure that the instrument selected for pharynx protection does contains a lumen for safe passage of the Guidewire. Otherwise, there is risk for (sub) mucosal damage.
2. Verify the correct location of the instrument by palpating the trachea at the intended puncture site. For additional visual and/or transilluminated guidance, a flexible endoscope could be used (Fig. 3.2).
3. Insert the Puncture Needle at the correct puncture site (about 8-10 mm from the edge of the tracheostoma) until the tip of the needle reaches the inside wall of the instrument (Fig. 3.3).
4. Insert the Guidewire into the hub of the Puncture Needle. Push the Guidewire into the needle, up through the lumen of instrument until it extends approx. 20 cm out through the distal end of the instrument (Fig. 3.4).
   WARNING: Always verify that the Guidewire comes out through the lumen of the instrument chosen for pharynx protection. Otherwise there is a risk for (sub) mucosal damage and the procedure needs to be restarted (see Adverse Events and Troubleshooting Information as well as Instructions for Reload of the Puncture Set).
5. Remove the Puncture Needle (Fig. 3.5).
   CAUTION: Always remove the needle before removing the instrument. There is a risk for damaging the esophageal tissue otherwise.
6. Remove the instrument used for pharynx protection. Only the Guidewire should remain in situ before continuing (Fig. 3.6).
7. From the cranial side, insert the Guidewire into the narrow end of the Puncture Dilator and push the Guidewire until it extends approx. 10 cm through the Puncture Dilator exit hole (Fig. 3.7).
8. Grab the tip of the Guidewire and insert it in the hole next to the exit hole of the Puncture Dilator (Fig. 3.8).
9. Tighten the Guidewire by pulling it from the narrow end of the Puncture Dilator and verify that it is secured to the Puncture Dilator (Fig. 3.9).
   CAUTION: Ensure that the Guidewire is tightly secured in the Wirelock of the Puncture Dilator. If the Guidewire is not securely locked into the Wirelock, the Guidewire could separate from the Puncture Dilator and the Puncture Dilator may end up in the esophagus requiring

retrieval using additional instruments (e.g., laryngeal forceps).

10. Using a continuous, smooth motion; dilate the puncture site by carefully pulling the Guidewire through the puncture site until the thick end of the Puncture Dilator has passed the puncture. During dilatation, support the TE tissue (for example with two fingers) to reduce dilatation force. For better control, firmly grasp the Guidewire close to the Puncture Dilator (Fig. 3.10).
    CAUTION: Dilatation and integral placement of the voice prosthesis should be carried out in the anterior/caudal direction with limited lateral movement in order to limit the force applied to the TE wall.
11. In the same continuous, smooth motion, carefully pull the Guidewire, Puncture Dilator and the Puncture Dilator loop through the puncture. The Puncture Dilator loop folds the tracheal flange of the voice prosthesis as the loop is pulled over the flange and through the puncture. The tracheal flange unfolds in the trachea when the loop releases it (Fig. 3.11).
    Stop pulling immediately when the tracheal flange is released by the Puncture Dilator loop. If the tracheal flange does not unfold completely, it can be rotated in place using two non-toothed hemostats.
12. Grasp the tracheal flange with a non-toothed hemostat, turn the prosthesis in the correct position and cut the safety strap (Fig. 3.12).

2.2.3 Reload of the Puncture Set

www.atosmedical.com/reload-of-the-puncture-set

CAUTION: Reload of the Provox Vega Puncture Set must not be performed if the voice prosthesis safety strap has been cut or damaged during the first placement attempt.

If the procedure needs to be restarted the Provox Vega Puncture Set can be reloaded.
In order to reload the system:

1. Push the Guidewire from the narrow end of the Puncture Dilator until the Guidewire loosens from the Wirelock (Fig. 4.1-4.2).
2. Pull the Guidewire through the Puncture Dilator (Fig. 4.3).
3. Reload the Vega voice prosthesis in the Puncture Dilator ring (Fig. 4.4).
    WARNING: The safety strap and tracheal flange of the voice prosthesis must be oriented towards the Puncture Dilator strap and the Wirelock when it is inserted into the Puncture Dilator loop (Fig. 4.4).
4. If needed, the Guidewire can be straightened to facilitate reinsertion.
5. Proceed according to “2.2 Operating Instructions”.

2.3 Cleaning and sterilization

The surgical components in the puncture set, as well as the voice prosthesis, are provided sterile (EO) and are intended for single use only and can NOT be cleaned or resterilized.

After placement, the voice prosthesis requires regular cleaning by the patient while the prosthesis remains in situ (see prosthesis maintenance below).

2.4 Important patient information

Inform the patient that:

- After a prosthesis placement traces of blood may be found in the sputum.
- Occasionally, mild leakage through or around the prosthesis may occur in the first weeks after insertion of a prosthesis. This often resolves spontaneously and does not require immediate replacement of the prosthesis.
- Speech training sessions with a speech language pathologist are advised in order to acquire optimal voice sound, fluent speech, and optimal intelligibility.

Ensure that the patient understands to contact their clinician if:

- Any changes in the appearance of the material of the prosthesis or in the way it fits in the puncture occur.
- Leakage occurs during eating and/or drinking, and cleaning the prosthesis does not help. Provox Vega Plug can be used for temporary preventing leakage during eating and drinking until the device can be replaced.
- Speaking becomes difficult (requires higher effort) and cleaning does not help.
- There are any signs of inflammation or tissue change at or near the puncture tract.
- Bleeding or overgrowth of tissue around the device.
- Persistent pain or discomfort in the region of the Vega voice prosthesis.
- Chronic cough, trouble breathing, or blood in the mucus. These can be signs of a serious health conditions that requires medical attention.

Prosthesis maintenance:

CAUTION: Only use genuine Provox accessories that are intended for use with Provox Vega when cleaning the prosthesis.

The patient should clean the prosthesis at least twice a day and after each meal with the Provox Brush by inserting the brush into the prosthesis and moving it gently back and forth with a twisting movement. After the brush is removed it should be wiped with a gauze. The procedure can be repeated as often as necessary. For details and how to clean the brush see Instructions for Use that come with the Provox Brush. In addition to using the Provox Brush, the patient may also clean the Provox Vega voice prosthesis with the Provox Flush. The Provox Flush can be used with drinking water or air. For details and how to clean the Provox Flush see Instructions for Use that come with the Provox Flush.

Compatibility with antifungal substances

In most cases treatment with antifungal agents should not be indicated but may be considered as a preventive measure if excessive candida overgrowth occurs on the prosthesis.

An unknown variety of chemical substances may influence the material properties of the device. Therefore, the introduction of antifungal medicines or drugs directly to or within close proximity of the voice prosthesis should be carefully assessed.

Laboratory testing shows no negative influence on the function of the Vega voice prosthesis and components when using the following antifungal medications: Nystatin, Fluconazole and Mikonazol.

Cleaning and disinfection of the accessories

The accessories should be cleaned after each use and disinfected at least once a day according to their Instructions for Use. During hospitalization there is an increased risk of device contamination and patient infection. Therefore, during hospitalization, it is important to clean and disinfect the accessories immediately after use and again just before use, and rinse using sterile water, rather than tap water.

For details and how to clean the Provox Accessories see Instructions for Use that accompanies the Provox Accessories.

2.5 Device lifetime of the Provox Vega voice prosthesis

Depending on individual biological circumstances the device life varies, and it is not possible to predict the integrity of the device over a longer period of time. The material of the device will be

affected by e.g., bacteria and yeast, and the structural integrity of the device will eventually deteriorate.

Candida overgrowth of the prosthesis occurs in almost all patients. Radiotherapy, salivary content and dietary habits may influence how rapidly Candida can affect the silicone material and cause leakage through the prosthesis or other incompetence of the valve. Also see; Prosthesis maintenance under section 2.4 Important patient information.

The prosthesis is not a permanent implant, and requires periodic replacement. Depending on individual biological circumstances the device life varies, and it is not possible to predict the integrity of the device over a longer period of time. The prosthesis and especially the silicone material of the device will be affected by e.g., bacteria and Candida, and the structural integrity of the device will eventually deteriorate.

Indications for replacement of the Provox Vega voice prosthesis include leakage through the valve, blockage of the prosthesis, bacterial and candidal overgrowth leading to degradation of the materials and/or excessive pressure needed to obtain speech. Other reasons for earlier replacement could include medical indications such as problems with the puncture tract. Also see section 1.6 Adverse events and troubleshooting information / 1.6.2 During use of the voice prosthesis.

2.6 Disposal

After use, the product may be a potential biohazard. Handling and disposal should be carried out in agreement with medical practice and applicable national laws and legislations.

2.7 Accessories

Provox accessories are designed to be safe and effective for use with the Provox Vega voice prostheses. Do not use other devices since they may cause patient harm or product malfunction.

Accessories to maintain the device function (for patient use)
Provox Brush: is used by the patient to clean the inside of the prosthesis.
Provox Flush: An additional cleaning device for patient use that allows flushing of the prosthesis.
Provox Vega Plug: A tool for patient use that temporarily blocks the voice prosthesis.

Please see www.atosmedical.com or contact your local distributor for more info.

3. Product model

Model	Specification
8140-18	Provox Vega Puncture Set 17Fr 8mm
8141-18	Provox Vega Puncture Set 17Fr 10mm
8142-18	Provox Vega Puncture Set 17Fr 12.5mm
8143-18	Provox Vega Puncture Set 17Fr 15mm
8144-18	Provox Vega Puncture Set 20Fr 8mm
8145-18	Provox Vega Puncture Set 20Fr 10mm
8146-18	Provox Vega Puncture Set 20Fr 12.5mm
8147-18	Provox Vega Puncture Set 22.5Fr 8mm
8148-18	Provox Vega Puncture Set 22.5Fr 10mm
8149-18	Provox Vega Puncture Set 22.5Fr 12.5mm

4. Storage conditions

Store the product dry and away from sunlight at room temperature. Excursions permitted between 2°C - 42°C.

5. Reporting

Please note that any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the national authority of the country in which the user and/or patient resides.

6. Legal Agent and After-sales service information

Coloplast (China) Medical Devices Ltd.
Address: Unit1301-1306, 13th Floor, Building 1, No.5
Lido Huayuan Road, Chaoyang District,
Beijing
Agent contact information:
Tel: 010-5920 1888
Fax: 010-5920 1898
Coloplast Customer Service Hotline
Hotline: 400 700 7668
Website: www.coloplast.com.cn

7. Production date and validity

Please see the label for the production date; the shelf life of product is 5 years.

8. Registration certificate number of medical devices

Certificate number of medical devices: 国械注进20223130609

9. Technical requirements for medical devices

Technical requirement number for medical devices: 国械注进20223130609

10. Edition of Instruction for Use

Article number: 11615, Edition date: 2026-03-19

11. Registration and Manufacturer company

Atos Medical AB
Registration & Manufacturer location: Kraftgatan 8, SE-242 35 Hörby, Sweden
Registration & Manufacturer contact: +46 (0)415 198 00 • info@atosmedical.com
Production location: Kraftgatan 8, SE-242 35 Hörby, Sweden
Country of origin: Sweden

有关本使用说明中提及的插图，请参阅随附的插图手册。

造口气道管理

紧急情况

紧急医护人员要清楚知道您是依靠颈部造口呼吸的患者，这一点很重要。这将帮助他们做出正确的判断，将氧气和人工呼吸应用到造口上，而不是口或鼻子上。

我们建议您和您的医生从 **www.atosmedical.com/rescuebreathing** 下载人工呼吸指南。

可选择的情况

如果您需要接受插管手术（在气管中插入一根呼吸管），进行手术的麻醉师和医生要了解您是依靠颈部造口呼吸的患者并正在使用辅助发音管，这一点非常重要。重要的是他们要清楚明白辅助发音管应保持原本的位置。如果辅助发音管被移除，液体可能会从您的嘴、食管或胃进入气管。

在插入和拔出插管时要小心操作，不要让辅助发音管移位或脱出，这一点非常重要。

1. 描述性信息

1.1 适用范围

该产品在食管与气管间建立单向气流通道，用于手术去除喉头（喉切除术）患者的发音重建。

1.2 结构及组成

辅助发音管由硅胶、聚偏二氟乙烯（PVDF）、有机硅粘合剂组成。其穿刺套装中的输送系统由甲基丙烯酸甲酯 (MABS)、不锈钢、聚酰胺 (PA66) 和环氧胶
、热塑性苯乙烯 - 乙烯 / 丁烯 - 苯乙烯 (TPS-SEBS)、聚丙烯 (PP)、聚偏二氟乙烯 (PVDF) 组成，其替换套装中的推置系统由聚丙烯 (PP)、着色剂和聚丙烯 (PP)、硅油组成。其附件冲洗器由硅胶、聚丙烯 (PP)、蓝色母粒组成；塞子由硅胶组成。辅助发音管及其套装为环氧乙烷灭菌，一次性使用。附件为非灭菌。包装灭菌有效期为 5 年。

1.3 禁忌症

如果患者出现可能阻碍气管食道壁安全穿刺或辅助发音管安全置放的解剖结构异常（例如，穿刺部位处显著狭窄或显著纤维化），请勿使用辅助发音管穿刺套装因为这可能造成组织损伤。

如果患者患有会妨碍咽壁适当保护的严重牙关紧闭症，请勿使用 Provox Vega 辅助发音管穿刺套装进行喉全切术后气管食道穿刺。在穿刺期间，如未能保护咽部，可能导致咽部 / 食道组织出现非预期创伤。

1.4 器械说明

Provox Vega 辅助发音管穿刺套装是一种建立喉全切术中或喉全切术后气管食道穿刺口的器械，可在穿刺后将穿刺口扩张至有助于内附 Provox Vega 辅助发音管置放的宽度。Provox Vega 辅助发音管预装在属于器械组成部分的穿刺扩张器上。

Provox Vega 辅助发音管穿刺套装仅供一次性使用，包装含有以下置于泡罩包装内的无菌物品（图 1）：

- 1 个咽保护器（图 1.1），由甲基丙烯酸甲酯 (MABS) 制成，
- 1 根穿刺针（图 1.2），由不锈钢、聚酰胺 (PA66) 和环氧胶制成。
- 1 根导丝（图 1.3），由聚偏二氟乙烯制成，
- 1 个穿刺扩张器，附有 1 个预装的 Provox Vega 辅助发音管（图 1.4）。穿刺扩张器是由热塑性苯乙烯 - 乙烯 / 丁烯 - 苯乙烯 (TPS-SEBS) 制成；Vega 辅助发音管是由硅胶和聚偏二氟乙烯制成。

预装的穿刺扩张器包含以下功能特点和组件：

- 一个扩张器（图 1.4.1），
- 一个连接扩张器和辅助发音管界面的扩张器束带（图 1.4.2），
- 一个构成辅助发音管界面的扩张器环圈（图 1.4.3），
- 一个线锁（图 1.4.4），含有连接辅助发音管安全带（图 1.4.6）和导丝的界面，
- 一个 Provox Vega 辅助发音管（图 1.4.5），附有连接到线锁并且经定向使辅助发音管气管侧轮缘（图 1.4.7）朝向线锁的安全带（图 1.4.6）。

Provox Vega 辅助发音管包含一个使气管食道穿刺口保持打开的单向阀，让患者能够在发声的同时降低液体和食物进入气管的风险。

Provox Vega 辅助发音管并非永久性植入器械，需要定期更换。辅助发音管有不同直径和多种尺寸可选。

穿刺套件还包含以下非无菌物品：

- 1 本使用说明 — Provox Vega 辅助发音管穿刺套装（包括 1 本插图手册）
- 1 本 Provox Vega 辅助发音管患者操作手册
- 1 个尺寸符合辅助发音管设计的 Provox Brush（Provox 清洁刷）
- 1 本 Provox Brush（Provox 清洁刷）使用说明

1.5 警告

手术前

- 如果包装已破损或开启，**请勿**使用产品。非无菌产品可能造成感染。
- **请勿利用任何**方法重复使用或**重复灭菌**。本器械仅限单次使用。重复使用可能造成交叉污染。清洁和重复灭菌可能对器械造成结构性损害。
- 如果患者已经接受放射治疗（不管是否同时接受化疗），**继续**进行时务必小心。这些状况会增加与穿刺有关的并发症风险（例如，变宽、形成肉芽、萎缩）。因此，确保足够的组织完整性以便建立气管食道穿刺口。

手术期间

一般信息

- 在执行喉全切术中气管食道穿刺前，**务必**通过触摸气管食道壁确保咽保护器在食道中插入足够的深度。如果咽保护器未能适当定位，穿刺可能造成组织损害。
- **务必**确保将导丝透过穿刺针和咽保护器的内腔插入，使其不会损害气管食道壁。
- **务必**确保在取下咽保护器前先移除穿刺针。如无适当的咽部保护，穿刺针可能会造成组织受损。

- **务必**确保穿刺扩张器装配在导丝的食道端而不是气管端。扩张应朝后前方向进行。朝错误的方向扩张会造成辅助发音管的反向放置，导致吸入以及无法说话。
- **切勿**透过穿刺针将导丝撤回。否则，可能会发生导丝损坏、剪切和 / 或刮削。如果必须撤回导丝，则将导丝和穿刺针作为一个整体同时取出，以避免穿刺针损坏导丝。
- **切勿**使用齿状止血钳或其他可能损坏产品的器械。

喉全切术后穿刺

- **切勿**在喉全切术后穿刺期间使用内附的咽保护器。仅限喉全切术中穿刺期间使用。
- **务必**确保咽部 / 食道组织受到充分保护，例如在执行喉全切术后气管食道穿刺前使用硬式内窥镜。

手术后

辅助发音管的使用

Provox Vega 辅助发音管可能从气管食道穿刺口移位或脱出，随后可能引起误吞、误吸或组织伤害。有关这些事件以及如何加以预防的更多信息，请参阅以下的“不良事件和故障排除信息”章节。

要降低移位或脱出的风险以及其潜在后果：

- **务必选择**适当的辅助发音管尺寸（例如长度）。因辅助发音管太短而造成的过度紧合可能导致组织坏死和器械脱出。
- **务必**叮嘱患者只使用相应尺寸和直径的 Provox 原厂配件（清洁刷、冲洗器、塞子）进行维护，并避免任何其他的使用方式。
- **务必**叮嘱患者在发现任何组织水肿和 / 或发炎 / 感染的迹象时立即咨询医生。
- **务必选择**合适的喉切除管或造口钮（若使用）形状，以免在使用过程中挤压到辅助发音管或在插入和移除喉切除管或造口钮时卡住辅助发音管的气管侧轮缘。

1.6 注意事项

务必评估气管食道穿刺口区域中组织的适合性。在缺乏适合性的情况下（例如，由于过度的疤痕组织或放射性纤维化），继续进行时务必小心，如果气管食道穿刺口的扩张需要太大力量，则中止程序。

- 在喉全切术后穿刺和辅助发音管置放前，**务必**仔细评估有出血性疾病或接受抗凝血治疗的患者发生出血或大出血的风险。
- 处理穿刺套件时，**务必**始终采用无菌技术，以降低感染风险。
- 开始扩张前，**务必**取下咽保护器如果在未取下咽保护器的情况下试图完成程序，辅助发音管可能会卡在咽保护器。
- **务必**确保导丝充分穿过并在线锁中锁定到位。如未能适当锁定，导丝可能会从线锁松脱，导致程序无法完成。
- 在扩张和辅助发音管置放期间，**务必**始终缓慢进行并且不要过度施力。否则，可能发生组织损伤。
- 在扩张期间，**务必**支撑气管食道组织。否则，可能发生破裂。如果气管食道组织发生破裂，应放弃气管食道穿刺程序，并且应立即缝合破裂处。气管食道穿刺只能在组织完全愈合后才能再次进行。
- 当辅助发音管的安全带被剪断后，**切勿**重装。因为在此情况下，安全机制已经受到影响，在程序期间会存在辅助发音管错位的风险。

1.7 不良事件和故障排除信息

1.7.1 使用穿刺套件期间

黏膜（下）伤害

在穿刺期间，如果咽保护器没有处于正确的位置，或者如果未正确穿刺，则穿刺针或导丝可能造成黏膜（下）伤害。如果怀疑黏膜（下）损伤，建议让患者接受术后抗生素的预防性治疗疗程，并通过鼻胃管或类似的导管喂食使伤口愈合。

重新穿刺

如果咽保护器在穿刺时未适当放置，或因任何其他理由而需要重新穿刺，应评估是否伤害到黏膜下的组织，并且在咽保护器正确定位的情况下重复穿刺程序。

忘记取下咽保护器

如果在取下咽保护器之前，将穿刺扩张器连接到导丝，则无法完成程序。如果发生这种情况，将穿刺扩张器从导丝拆除，并且取下咽保护器另请参阅下面的“重装”。

重装

在某些情况下，可能需要重装穿刺扩张器；例如，如果在辅助发音管置放期间，辅助发音管被完全拉过穿刺口。重装程序如第 2.2.3 节所述，图解说明见图 4。

1.7.2 使用辅助发音管期间

辅助发音管的移位 — 气管食道穿刺口感染和 / 或浮肿、穿刺口周围肉芽形成或穿刺口周围肥厚性疤痕可能会引起移位。移位可能导致吸入或吞入辅助发音管。参见下文。

辅助发音管的吸入 — 可能发生辅助发音管或发音重建系统其他组件的意外吸入。如同任何其他异物一样，意外吸入组件的并发症可造成阻塞或感染。即时的症状可能包括咳嗽、喘鸣或其他异常的呼吸声音、呼吸困难和呼吸骤停、部分或不充分的气体交换和 / 或不对称的胸腔呼吸动作。并发症可能包括肺炎、肺膨胀不全、支气管炎、肺脓疡、支气管肺瘘和气喘。

如果患者可以呼吸，可尝试咳嗽咳出异物。呼吸道部分或完全阻塞时需要立即进行介入治疗以取出异物。如果怀疑吸入器械，则应执行肺部 CT 扫描以确认是否吸入并找到器械。如果 CT 扫描确认吸入器械，则可以透过内窥镜利用无齿抓取器将其取出。

辅助发音管的硅胶外壳也可以透过内窥镜找到。在 CT 扫描和内窥镜检查过程中，器械可能显示为中间有开口、外径大约 10-17 mm（器械的轮缘）的椭圆形状，或具有 8、10、12.5 或 15 mm 轴长度的袖扣形状，具体取决于器械的尺寸。在内窥镜检查过程中，可能会看见光源照在透明硅橡胶上形成的反射。此外，在已经处于原位一段时间的辅助发音管中，白色或黄色的念珠菌沉积物可能会出现在器械上。

辅助发音管的吞入 — 可能发生辅助发音管或发音重建系统其他组件的意外吞入。与吞入任何其他异物一样，吞入辅助发音管或发音重建系统组件造成的症状在很大程度上取决于尺寸、位置、阻塞程度（如发生阻塞的话）以及存在时间的长短。留在下食道的吞入组件可以利用食管镜取出或者观察一段短的时间。物体可能会自行进入胃部。进入胃部的异物通常会往下进入肠道。当发生肠阻塞、出现流血、发生穿孔或物体无法通过肠道时，必须考虑用外科手术从肠道取出异物。

您可以选择等待 4 到 6 天，让器械自行通过。应嘱咐患者观察排便是否排出吞入的器械。如果器械没有自行排出，或者有阻塞的迹象（发烧、呕吐、腹痛），应咨询肠胃科医生。辅助发音管的硅胶外壳也可以透过内窥镜找到并取出。器械可以利用无齿抓取器取出。在内

窥镜检查过程中，器械可能显示为中间有开口、外径大约 10-17 mm（器械的轮缘）的椭圆形状，或具有 8、10、12.5 或 15 mm 轴长度的袖扣形状，具体取决于器械的尺寸。可能会看见光源照在透明硅橡胶上形成的反射。在已经处于原位一段时间的辅助发音管中，白色或黄色的念珠菌沉积物可能会出现在器械上。

气管食道穿刺口感染和 / 或浮肿 — 穿刺口感染、肉芽形成和 / 或浮肿可能增加穿刺道的长度。这可能造成辅助发音管往内拉以及往气管或食道黏膜下拉。食道黏膜发炎或增生也可能造成辅助发音管从穿刺口突出。如发生此种情况，建议用具有较长轴的辅助发音管暂时替换此辅助发音管。如果标准的医疗方法无法解决感染，则应取出辅助发音管。在某些情况下，可以考虑用导管在穿刺口做支架。如果穿刺口自行闭合，则可能需要重新穿刺，以插入新的辅助发音管。

穿刺口周围形成肉芽 — 据报告气管食道穿刺口周围形成肉芽组织的发生率约为 5%。可以考虑在形成肉芽的区域进行电气、化学药物或激光烧灼治疗。

穿刺口周围形成肉芽 / 肥厚性疤痕 — 如果辅助发音管相对较短，则气管黏膜可能在气管侧轮缘上膨出。多余的组织可以通过激光去除。或者，可以使用带有较长轴的辅助发音管。

辅助发音管的突出 / 脱出 — 辅助发音管的突出和之后的自行脱出有时会在气管食道穿刺口感染期间观察到。需要取出辅助发音管，以防止其移位进入气管内。穿刺口可能在辅助发音管取出后自行闭合。对于新辅助发音管的插入，可能需要重新穿刺。

组织损伤 — 如果辅助发音管过短、过长或经常通过喉切除管、造口钮或用患者的手指推到食道壁上，则可能会对穿刺口、气管和 / 或食道组织造成伤害。定期检查各种情况以避免严重的损伤。

经由活阀渗出的泄漏 — 有可能发生经辅助发音管渗出的泄漏，其原因是：
- 阀座和阀瓣附近的念珠菌增生可能导致阀瓣无法完全闭合，从而造成经由器械渗出的泄漏。这是辅助发音管发音重建中的正常事件，表明应该更换辅助发音管。
- 吞咽期间，在咽食管段内出现较强的负压。要查明原因，应在吞咽过程中通过造口对辅助发音管的阀瓣进行检查。

辅助发音管周围的泄漏 — 辅助发音管周围可能会发生短暂泄漏，并且可能自行解决。最常见的原因是辅助发音管过长，可以插入较短的辅助发音管来解决问题。如果插入正确长度的辅助发音管无法解决问题，应该考虑、评估是否有其他的因素影响气管食道穿刺口区域的组织完整性（例如，胃食道返流或甲状腺功能）并加以处理。在滞留强度降低的扩大穿刺口，应考虑注射填充剂（例如胶原蛋白）或暂时取下辅助发音管等其他传统治疗方法。如果辅助发音管周围的泄漏非常棘手，可能需要采取更保守的措施（例如，采用外科手术方式闭合穿刺口）。

2. 使用说明

有关本使用说明中提及的插图，请参阅随附的插图手册。

如需要不同程序的可视化概述，您可以在下面的章节标题下找到相关视频动画的链接。

注意： 视频不能替代并且没有详细阐述使用说明和 / 或处方者信息的全部内容，观看视频并不能代替阅读使用说明的整个内容。视频仅用于在阅读使用说明之后，进一步加深对程序的理解。

2.1 准备

在穿刺之前，务必确定要使用的辅助发音管尺寸和直径。适当的尺寸和直径取决于患者的解剖结构、当地的医疗惯例和外科医生的偏好。

2.2 操作说明

检查无菌包装的完整性。如果包装已破损或开启，请勿使用产品。非无菌产品可能造成感染。

2.2.1 喉全切术中穿刺和辅助发音管置放

www.atosmedical.com/primary-puncture

1. 喉头切除和气管造口建立后，在咽部闭合之前，将咽保护器插入开放的咽部 / 食道内（图 2.1）。
2. 通过触摸所需穿刺部位的气管内部，确认气管食道穿刺口是否处于正确位置。在触摸期间，应可感觉到咽保护器的前侧倾斜开口（或上侧狭缝；取决于手术方法）（图 2.2）。
3. 在正确的穿刺部位处（离气管造口边缘约 8-10 mm）插入穿刺针，直到穿刺针尖端触及咽保护器的内腔为止（图 2.3）。
   若气管内管处于原位，而该气管内管妨碍正常的扩张和辅助发音管的整体置放，则应该取下该内管。
4. 将导丝插入穿刺针的针座内。推送导丝穿过穿刺针，直到延伸出去距离咽保护器的内腔约 20 cm 为止（图 2.4）。
   警告： 务必确认导丝穿过咽保护器的内腔出来。否则会有黏膜（下）损伤的风险以及需要重新开始程序（参阅“不良事件和故障排除信息”以及“重装穿刺套件”说明）。
5. 取下穿刺针（图 2.5）。
   注意： 取下咽保护器前，务必先移除穿刺针。否则有损伤食道组织的风险。
6. 取下咽保护器。继续操作前，只有导丝应留在原位（图 2.6）。
7. 插入导丝，从食道侧延伸到穿刺扩张器的狭窄端，并推送导丝穿过穿刺扩张器，直到穿过穿刺扩张器的出口孔延伸大约 10 cm 为止（图 2.7）。
8. 抓握导丝的尖端，并将其插入出口孔旁的孔中（图 2.8）。
9. 通过穿刺扩张器的狭窄端拉动导丝加以拉紧，并确认导丝固定至穿刺扩张器（图 2.9）。
10. 采用连续、平稳的动作；通过小心拉动导丝穿过穿刺口来扩张穿刺部位。扩张期间，支撑气管食道穿刺口组织（例如用两根手指）以降低扩张力。为了取得更好的控制，抓稳导丝靠近穿刺扩张器（图 2.10）。
    注意：辅助发音管的扩张和整体置放应以有限的侧向移动朝前 / 后方向进行，以限制施用于气管食道壁的力度。
11. 以同样连续、平稳的动作，经穿刺口小心拉出导丝、穿刺扩张器和穿刺扩张器环。将穿刺扩张器环拉过气管侧轮缘并经过穿刺口时，穿刺扩张器环会折起辅助发音管的气管侧轮缘。当扩张器环释放气管侧轮缘时，轮缘会在气管内展开（图 2.11）。
    当穿刺扩张器环释放气管侧轮缘时，应立刻停止拉动。如果气管侧轮缘没有完全展开，可使用两把无齿止血钳转动它。
12. 用无齿止血钳抓握辅助发音管的气管侧轮缘，将辅助发音管转至正确的位置，并且切断安全带（图 2.12）。

2.2.2 喉全切术后穿刺和辅助发音管置放

www.atosmedical.com/secondary-puncture-and-prosthesis-placement

Provox Vega 辅助发音管穿刺套装内附的咽保护器(图 1.1)不会在喉全切术后穿刺期间使用。

1. 选择一个可以起到如下作用的器械（例如硬式内窥镜）：
   a. 一个当穿刺针穿透气管食道壁时的保护器
   b. 正确定位气管食道穿刺口位置的导引器
   c. 将导丝穿过咽部从口腔出来时使其能安全通过的一个方式。
   将器械引入食道中（图 3.1）。若气管内管处于原位，而该气管内管妨碍正常的扩张和辅助发音管的整体置放，则应该取下该内管。
   注意：务必确保选择用于咽部保护的器械含有使导丝安全通过的内腔。否则，有造成黏膜（下）损伤的风险。
2. 通过触摸预期穿刺部位的气管，确认器械的正确位置。如需额外的视觉和 / 或透光导引，可以使用软式内窥镜（图 3.2）。
3. 在正确的穿刺部位处（离气管造口边缘约 8-10 mm）插入穿刺针，直到穿刺针的尖端到达器械的内壁为止（图 3.3）。
4. 将导丝插入穿刺针的针座内。将导丝推送入穿刺针，通过器械的内腔往上推，直到伸出器械远端约 20 cm 为止（图 3.4）。
   警告：务必确认导丝伸出选择用于咽部保护的器械的内腔。否则会有黏膜（下）损伤的风险以及需要重新开始程序(参阅“不良事件和故障排除信息”以及“重装穿刺套件”说明)。
5. 取下穿刺针（图 3.5）。
   注意：取下器械前，务必先移除穿刺针。否则有损伤食道组织的风险。
6. 取下用于咽部保护的器械。继续操作前，只有导丝应留在原位（图 3.6）。
7. 从颅骨侧将导丝插入穿刺扩张器的狭窄端，并推送导丝直到其穿过穿刺扩张器的出口孔延伸大约 10 cm 为止（图 3.7）。
8. 抓握导丝的尖端，并将其插入穿刺扩张器的出口孔旁的孔中（图 3.8）。
9. 通过穿刺扩张器的狭窄端拉动导丝加以拉紧，并确认导丝固定至穿刺扩张器（图 3.9）。
   注意：确保导丝紧密固定于穿刺扩张器的线锁中。如果导丝没有固定锁入线锁中，则导丝可能与穿刺扩张器分离，而后者最后可能落到食道中，需要使用额外的器械（例如喉钳）取出。
10. 采用连续、平稳的动作；通过小心拉动导丝穿过穿刺部位来扩张穿刺部位，直到穿刺扩张器的厚端超过穿刺口为止。扩张期间，支撑气管食道穿刺口组织（例如用两根手指）以降低扩张力。为了取得更好的控制，抓稳导丝靠近穿刺扩张器（图 3.10）。
    注意：辅助发音管的扩张和整体置放应以有限的侧向移动朝前 / 后方向进行，以限制施用于气管食道壁的力度。
11. 以同样连续、平稳的动作，经穿刺口小心拉出导丝、穿刺扩张器和穿刺扩张器环。将穿刺扩张器环拉过气管侧轮缘并经过穿刺口时，穿刺扩张器环会折起辅助发音管的气管侧轮缘。当扩张器环释放气管侧轮缘时，轮缘会在气管内展开（图 3.11）。
    当穿刺扩张器环释放气管侧轮缘时，应立刻停止拉动。如果气管侧轮缘没有完全展开，可使用两把无齿止血钳转动它。
12. 用无齿止血钳抓握气管侧轮缘，将辅助发音管转至正确的位置，并且切断安全带（图 3.12）。

2.2.3 重装穿刺套件

www.atosmedical.com/reload-of-the-puncture-set

注意：如果辅助发音管安全带在首次尝试置放时已经切断或受损，则不得进行 Provox Vega 辅助发音管穿刺套装的重装。

如果需要重新开始程序，则可以重装辅助发音管穿刺套装。要重装系统：

1. 从穿刺扩张器的狭窄端推送导丝，直到导丝从线锁松开为止（图 4.1-4.2）。
2. 拉动导丝穿过穿刺扩张器（图 4.3）。
3. 将辅助发音管重装于穿刺扩张器环中（图 4.4）。
   警告：将辅助发音管的安全带和气管侧轮缘插入穿刺扩张器环圈时，必须朝穿刺扩张器束带和线锁定向（图 4.4）。
4. 如有需要，可以将导丝拉直以帮助重新插入。
5. 依照“2.2 操作说明”继续进行操作。

2.3 清洁和灭菌

穿刺套件中的外科组件以及辅助发音管以无菌方式 (EO) 提供，并且仅限单次使用，不得清洁或重复灭菌。

放置后，辅助发音管需要在维持于原位的情况下由患者定期清洁（参阅下面的辅助发音管维护）。

2.4 重要的患者信息

告知患者可能发生下列情况：

- 辅助发音管置放后，痰液中可能会发现血迹。
- 在辅助发音管插入后的最初几周，可能偶尔会发现辅助发音管或其周围有轻微的泄漏。但这通常可自行解决，无需立即更换辅助发音管。
- 建议参考语言病理学家指导的语言训练课，以实现最佳的说话声音、流畅说话和最佳的语言清晰度。

确保患者知道在以下情况下要联系医生：

- 辅助发音管材料的外观发生任何变化或装入穿刺口的方式发生改变。
- 在食用和 / 或饮用期间发生泄漏，而清洁辅助发音管没有帮助。饮食期间，可以使用塞子暂时防止泄漏，直到可以更换器械为止。
- 说话变得困难（需要更加费力）并且在清洁后没有帮助。
- 在穿刺道内或附近存在发炎或组织变化的任何迹象。
- 器械周围的组织出血或增生。
- 辅助发音管置放部位发生持续的疼痛或不适。
- 慢性咳嗽、呼吸困难或黏液带血。这些可能是需要医疗护理的严重健康问题的先兆。

辅助发音管维护：

注意：仅可使用适用于 Provox Vega 辅助发音管的原厂 Provox 配件清洁辅助发音管。

患者每天至少应该使用 Provox Brush（Provox 清洁刷）清洁辅助发音管两次，在每餐后也应进行清洁，方法是将刷子插入辅助发音管内，以扭转的动作来回轻轻地移动刷子。刷子取出后，应当用纱布加以擦拭。可以根据需要，重复程序多次。有关详细信息以及如何清洁刷子的说明，请参阅 Provox Brush（Provox 清洁刷）随附的使用说明。除了使用 Provox Brush（Provox 清洁刷）外，患者也可以利用 Provox Flush（Provox 冲洗器）清洁辅助发音管。Provox Flush（Provox 冲洗器）可以与饮用水或空气一起使用。有关详细信息以及如何清洁 Provox Flush（Provox 冲洗器）的说明，请参阅 Provox Flush（Provox 冲洗器）随附的使用说明。

与抗真菌药物的相容性
在大多数的情况下，不应使用抗真菌药物进行治疗，但如果在辅助发音管上发生念珠菌过度增生的现象，则应考虑作为预防措施。

各样未知的化学物质可能会影响器械的材料特性。因此，应小心评估抗真菌药物是否可直接用在辅助发音管上或其邻近区域。

实验室测试显示，当使用以下抗真菌药物时，对辅助发音管及其组件的功能并无不良的影响：Nystatin、Fluconazole 和 Mikonazol。

配件的清洁和消毒
每次使用配件后应立即清洁，并且每天至少依照其使用说明消毒一次。住院期间，器械受污染和患者受到感染的风险增加。因此，住院期间务必要在使用后立即清洁和消毒配件，并在准备使用前再度清洁和消毒，并且以无菌水（而不是自来水）清洗。

有关详细信息以及如何清洁 Provox 配件的说明，请参阅 Provox 配件随附的使用说明。

2.5 Provox Vega 辅助发音管的器械寿命

器械寿命因个人生理情况而异，并且不可能预测器械在使用较长时间后的完整性。器械的材质将受细菌和酵母等的影响，而其结构完整性终将降低。

几乎所有患者的辅助发音管都会发生念珠菌增生。放射治疗、唾液腺内含物和饮食习惯可能会影响念珠菌如何快速地影响硅胶材料以及造成经由辅助发音管渗出泄漏或活阀的其他功能不全。另请参阅“2.4 重要的患者信息”一节中的“辅助发音管维护”。

辅助发音管并非永久性植入器械，需要定期更换。器械寿命因个人生理情况而异，并且不可能预测器械在使用较长时间后的完整性。辅助发音管（特别是器械的硅胶材质）将受细菌和念珠菌等的影响，而其结构完整性终将降低。

Provox Vega 辅助发音管更换的适用范围包括经由活阀渗出的泄漏、辅助发音管堵塞、细菌和念珠菌增生导致材质变差和 / 或说话需要过度压力。早期更换的其他理由可能包括医学上的适应症，例如穿刺道发生问题。另请参阅“1.6 不良事件和故障排除信息”/“1.6.2 使用辅助发音管期间”等章节。

2.6 弃置

产品使用后，可能变成一种潜在的生物危害。应当依照医疗惯例和适用的国家法律和法规进行处理和弃置。

2.7 配件

Provox 配件的设计旨在与 Provox Vega 辅助发音管安全且有效的配合使用。请勿使用其他器械，因为它们可能造成患者伤害或产品故障。

维持器械功能的配件（供患者使用）
Provox Brush（清洁刷）：由患者用来清洁辅助发音管的内侧。
Provox Flush（冲洗器）：患者用来冲洗辅助发音管的另一种清洁器械。
Provox Vega Plug（塞子）：患者用来暂时堵住辅助发音管的一种工具。

如需更多信息，请访问 www.atosmedical.com 或联系您当地的经销商。

3. 产品型号

型号	规格
8140-18	Provox Vega Puncture Set 17Fr 8mm
8141-18	Provox Vega Puncture Set 17Fr 10mm
8142-18	Provox Vega Puncture Set 17Fr 12.5mm
8143-18	Provox Vega Puncture Set 17Fr 15mm
8144-18	Provox Vega Puncture Set 20Fr 8mm
8145-18	Provox Vega Puncture Set 20Fr 10mm
8146-18	Provox Vega Puncture Set 20Fr 12.5mm
8147-18	Provox Vega Puncture Set 22.5Fr 8mm
8148-18	Provox Vega Puncture Set 22.5Fr 10mm
8149-18	Provox Vega Puncture Set 22.5Fr 12.5mm

4. 储存条件

在室温下储存产品，且存放于阴凉干燥处。温度偏差介于 2° C 至 42° C 之间。

5. 报告

请注意，发生任何与设备有关的严重事故时，应向制造商以及用户和 / 或患者所在国家 / 地区的主管部门报告。

6. 中国大陆地区代理人及售后服务机构

代理人名称 / 售后服务单位：康乐保（中国）医疗用品有限公司
代理人住所：北京市朝阳区丽都花园路 5 号院 1 号楼 13 层 1301-1306 单元
代理人联系方式：
电话：010-5920 1888
传真：010-5920 1898
康乐保客户服务热线
热线电话：400 700 7668
网址：www.coloplast.com.cn

7. 生产日期和使用期限

请参阅标签了解生产日期；产品的有效期为 5 年。

8. 医疗器械注册证编号

注册证编号：国械注进 20223130609

9. 医疗器械技术要求编号

产品技术要求编号：国械注进 20223130609

10. 说明书版本号

说明书版本编号：11615，说明书修订日期：2026/03/19

11. 生产企业和注册人

注册人名称 / 生产企业名称：欧拓适医疗有限责任公司 Atos Medical AB
注册人住所 / 生产企业住所：Kraftgatan 8, SE-242 35 Hörby，Sweden
注册人联系方式 / 生产企业联系方式 : +46 (0)415 198 00 • info@atosmedical.com
生产地址 : Kraftgatan 8, SE-242 35 Hörby，Sweden
原产地：瑞典

符号的解释

Manufacturer; 制造商

Date of manufacture; 生产日期

Use-by date; 使用期限

Batch code; 批次代码

Product reference number; 产品编号

Do not re-use; 不得二次使用

Sterilized using ethylene oxide; 经环氧乙烷灭菌

Do not use if package is damaged; 包装破损切勿使用

Keep away from sunlight and keep dry; 怕雨，怕晒

Storage temperature limit; 储存温度限制

Store at room temperature. Temporary deviations within the temperature range (max-min) are allowed; 室温下存放。允许温度范围内（最高-最低）的暂时偏差

Caution, consult instructions for use; 警告，参阅使用说明书

Instructions for use; 使用说明书

Medical Device; 医疗器械

Instructions for use intended for clinician; 临床医生使用说明书

Instructions for use intended for patient; 患者使用说明书

Prescription; 凭处方购买（仅适用于美国）

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