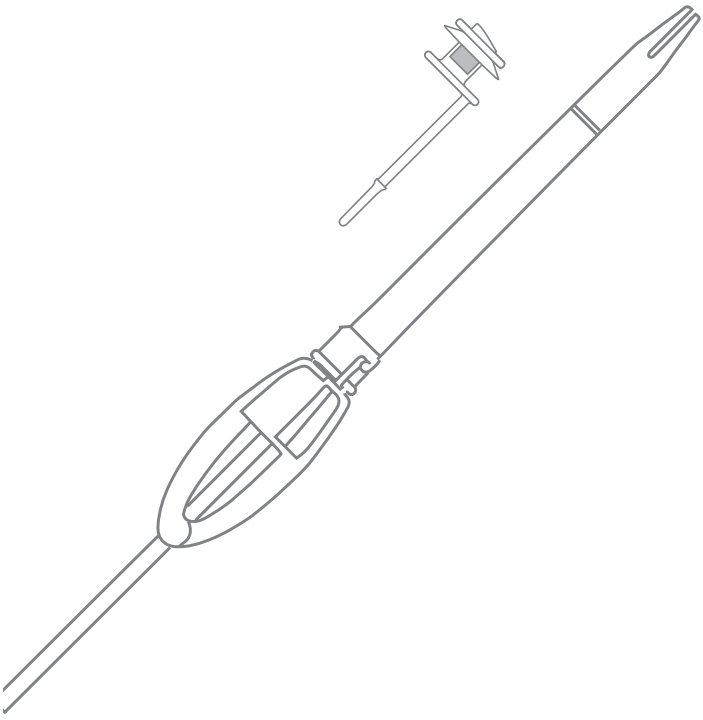
PROVOX® Vega™ XtraSeal™

辅助发音管
替换套装（含加封辅助发音管）

IFU

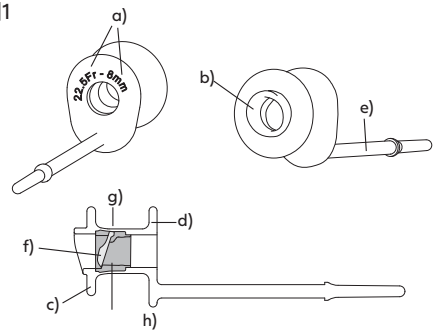


MD Rx ONLY 0413

STERILE EO

42 °C 108 °F RT
2 °C 36 °F

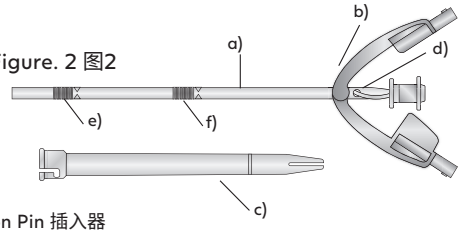
Figure. 1 图1



Provox® Vega XtraSeal™ voice prosthesis 加封辅助发音管

a) Size information (shaft diameter and length between flanges) 尺寸信息
b) Prosthesis Hood 辅助发音管罩
c) Esophageal Flange 食管侧轮缘
d) Tracheal Flange 气管侧轮缘
e) Safety Strap 安全带
f) Valve Flap 阀瓣
g) Prosthesis Shaft 辅助发音管轴
h) Radio-opaque fluoroplastic Valve Seat 不透射线氟塑料阀座

Figure. 2 图2



a) Insertion Pin 插入器
b) Folding Tool 折叠工具
c) Insertion Tube 输送管
d) Attachment Slot 连接槽孔
e) Distal grip surface 远端抓握表面
f) Proximal grip surface 近端抓握表面

2.2 Preparation 准备

Figure. 3 图3

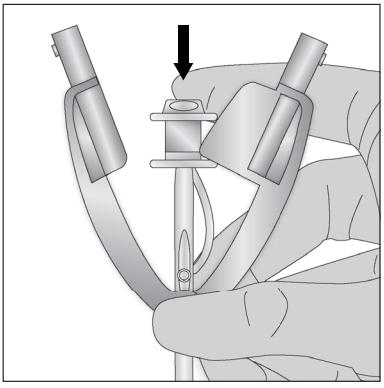


Figure. 4 图4

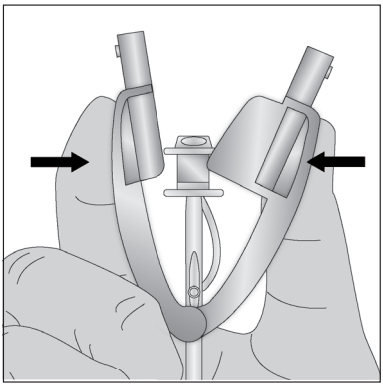
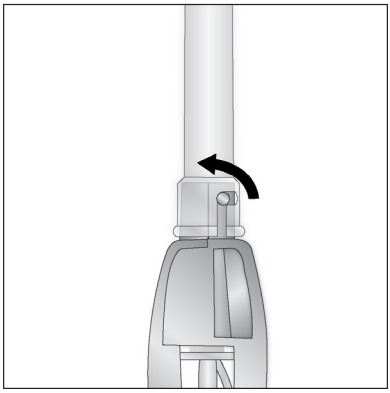
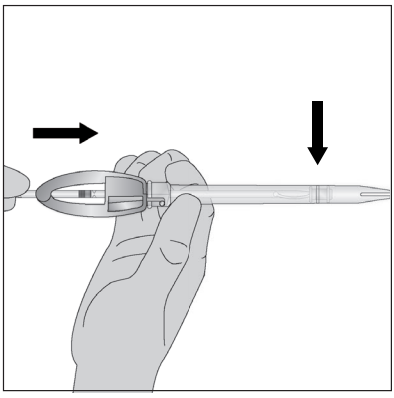


Figure. 5 图5



2.3.1 Method 1 System Insertion 方法1 系统插入法
Figure. 6 图6



2.3 Overshoot Insertion 过度超出插入法
Figure. 7 图7

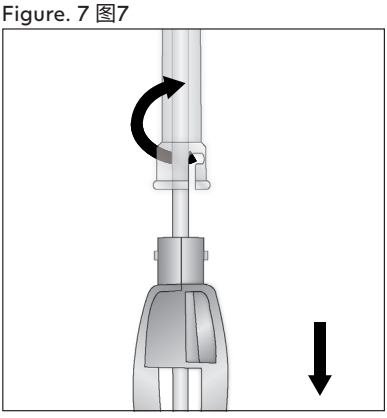


Figure. 8 图8

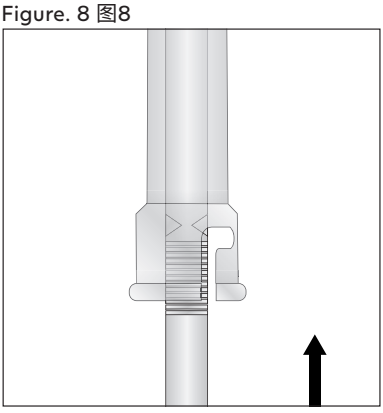


Figure. 9 图9

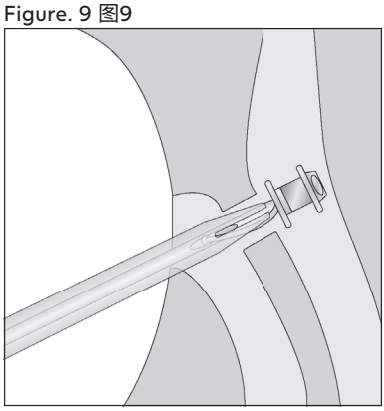
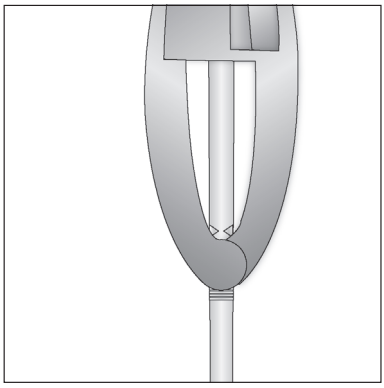
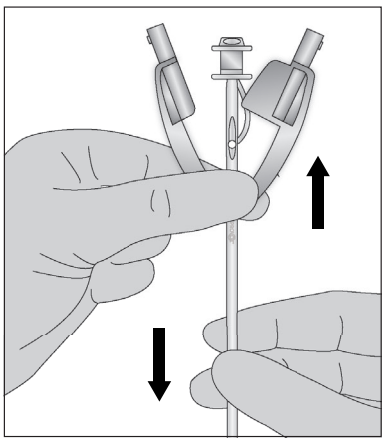


Figure. 10 图10



2.4 Assembly and reloading 组装和重新安装

Figure. 11 图11



2.5 Finalization 完成

Figure. 12 图12

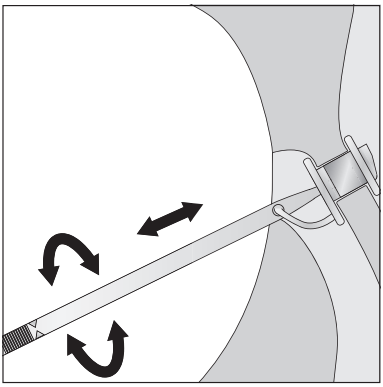


Figure. 13 图13

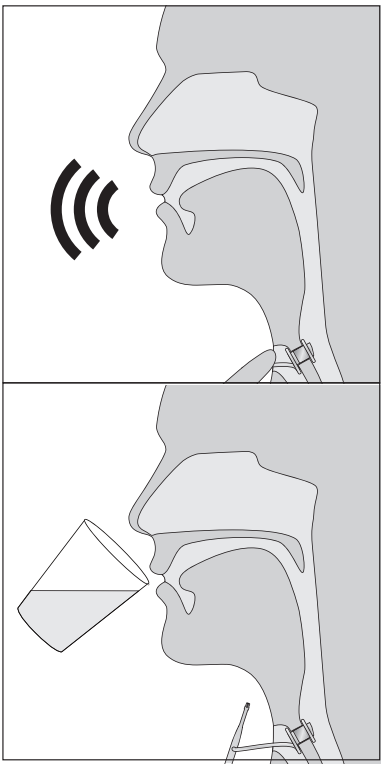
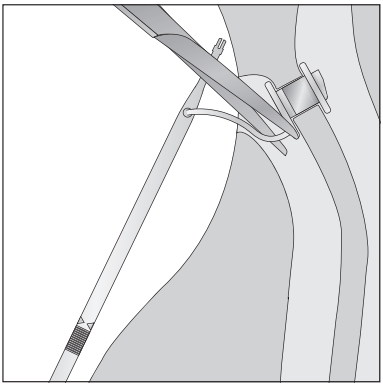


Figure. 14 图14



Disclaimer

Atos Medical offers no warranty - neither expressed nor implied - to the purchaser hereunder as to the lifetime of the product delivered, which may vary with individual use and biological conditions. Furthermore, Atos Medical offers no warranty of merchantability or fitness of the product for any particular purpose.

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

Provox® Vega™ XtraSeal™

1. Descriptive information

1.1 Intended use

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.

The Provox Insertion System is a sterile single use device intended for anterograde replacement of the Provox Vega Voice Prosthesis. This replacement procedure is carried out by a medical doctor or a trained medical professional in accordance with local or national guidelines.

The Provox Insertion System is not intended to be used for insertion of a voice prosthesis in a freshly made puncture.

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 Description of the device General

The Provox Vega is a one-way valve (prosthesis) that keeps a 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 (Fig. 1) is available in different diameters and several lengths.
Provox Vega XtraSeal has an additional enlarged esophageal flange that is intended to solve problems with leakage around the voice prosthesis.
The device is made of medical grade silicone rubber and fluoroplastic.

Provox Vega XtraSeal package
The Provox Vega XtraSeal package contains the following items:

- 1 Provox Vega XtraSeal voice prosthesis, pre-assembled in a single use Insertion System, sterile (Fig. 2)
- 1 Provox Brush of a size corresponding to the voice prosthesis, non-sterile
- 1 Provox Vega XtraSeal Clinician's manual
- 1 Provox Vega Patient's manual
- 1 Provox Brush Instructions for Use

1.4 CONTRAINDICATIONS

There are no known contraindications for use or replacement of a Provox Vega voice prosthesis among patients already using prosthetic voice rehabilitation.

1.5 WARNINGS

- **Dislodgement or extrusion of the Provox Vega voice prosthesis** from the TE puncture and subsequent ingestion, aspiration or tissue damage may occur. A foreign body in the airway may cause severe complications such as acute respiratory distress and/or respiratory arrest.
- **Select the proper prosthesis size.** A tight fit may cause tissue necrosis and extrusion.
- **Instruct the patient to consult a physician** immediately if there are any signs of tissue edema and/or inflammation/infection.
- **Instruct the patient to consult a physician** if leakage through or around the voice prosthesis occurs. Leakage may cause aspiration pneumonia.
- **If used, choose laryngectomy tubes or stoma buttons** with a suitable shape that do not exert pressure on the prosthesis or catch onto the tracheal flange of the prosthesis during insertion and removal of the laryngectomy tube or stoma button. This may lead to severe tissue damage and/or accidental ingestion of the prosthesis.
- **Instruct the patient to use only genuine Provox accessories** of corresponding size (Brush, Flush, Plug) for maintenance and to avoid all other kinds of manipulation.
- **Re-use and re-processing** may cause cross-contamination and damage to the device, which could cause patient harm.

1.6 PRECAUTIONS

- Carefully assess any patient with bleeding disorders or who is undergoing anticoagulant treatment for the risk of bleeding or hemorrhage prior to placement or replacement of the prosthesis.
- Inspect the package before use. If the package is damaged or opened, do not use the product.
- Always use aseptic technique when handling the prosthesis in order to reduce infection risk.

2. Instructions for use

2.1 Choose size of the Voice prosthesis

Be sure to use a Provox Vega XtraSeal voice prosthesis of the proper shaft diameter and length. Provox Vega XtraSeal is available in different length/diameter combinations.

- **Selecting shaft diameter**
  The clinician should determine the proper diameter of the prosthesis appropriate for the patient.
  If the selected diameter is larger than the previous prosthesis the tract must be dilated, using the Provox Dilator, appropriate to the diameter of the prosthesis being inserted.
  If a prosthesis with a smaller shaft diameter is inserted, observe and ensure that the puncture shrinks to the appropriate diameter.
- **Selecting shaft length**
  To select the correct length, you may use the current prosthesis as its own measuring device.
  If there is too much (i.e. 3 mm /~0.12 inches, or more) space between the Tracheal Flange of the old prosthesis and the mucosal wall, a shorter prosthesis should be used.
  If the prosthesis sits too tight, a longer prosthesis should be used.
  Note: The shaft of Provox Vega XtraSeal is ca 1 mm shorter than the size indicated due to the enlarged esophageal flange.

2.2 Preparation

(Fig. 3-6)
Position voice prosthesis

1. Ensure the Voice Prosthesis is properly positioned on the Insertion Pin, firmly attached, and with the tip of the pin positioned all the way into the blue ring of the voice prosthesis (Fig. 3).

Fold the esophageal flange

2. Verify that the Insertion Pin is correctly positioned with the Folding Tool (The Pin shall be snapped into the Folding Tool).
3. Squeeze the Folding Tool together with two fingers (Fig. 4).
4. Attach the Insertion Tube while keeping the Folding Tool closed and twist the Insertion Tube until it locks in place (Fig. 5).

Load

5. Push the Insertion Pin forward until the voice prosthesis is aligned with the visible ring on the Insertion Tube (Fig. 6).

Remove the old voice prosthesis

6. Remove the current (old) prosthesis is from the TE-puncture by pulling it out with a non-toothed hemostat. Alternatively, at the clinician's discretion, the tracheal flange of the prosthesis can be grasped with forceps and cut off. The rest of the prosthesis is then pushed into the esophagus for passage through the intestinal tract. The patient's history of any intestinal diseases should be taken into account before using this method.

Prepare the puncture (optional)

7. The puncture may be dilated to prepare for the insertion of the voice prosthesis. This is usually not necessary but may facilitate insertion in patients with angled or tight punctures that easily collapse.

2.3 Insertion, Anterograde replacement procedure

(Fig. 7-10)
CAUTION: Provox Vega XtraSeal with enlarged esophageal flange must be placed using the overshooting technique to ensure the additional enlarged esophageal flange and the esophageal flange both deploy inside the esophageal lumen. Overshooting means that the whole prosthesis is deployed in the esophagus and then retracted to the intended position.

1. **Remove the Folding Tool (Optional)**
   After the prosthesis has been pushed into the Insertion Tube, remove the Folding Tool by unlocking and disconnecting it from the Insertion Tube (Fig. 7).
2. **Enter the TE-puncture**
   Hold the Provox Insertion System by the Insertion Tube. Enter the puncture with the Insertion Tube Tip. Proceed with care if you encounter resistance. If there is resistance, dilatation and/or lubrication can ease the insertion.
3. **Insert the voice prosthesis**

Hold the Insertion Tube stable with one hand and push the Insertion Pin with the other hand beyond the Proximal grip surface, (Fig. 8). At this point voice prosthesis is fully deployed in the esophagus, (Fig.9).
If overshoot insertion is performed with the Folding Tool kept assembled, push the Insertion Pin beyond the Distal grip surface, (Fig.10). At this point the voice prosthesis is fully deployed in the esophagus, (Fig. 9).

4. **Release the voice prosthesis**
Pull the Insertion Tube straight out from the puncture. The prosthesis remains in the esophagus; still firmly attached to the Insertion Pin. Grasp the tracheal flange with a non-toothed hemostat and pull/rotate the voice prosthesis into place.
5. **Finalize the procedure**
After insertion, finalize the procedure as described below in section 2.5.

2.4 Assembly and reloading the Provox Insertion System

If the first attempt to insert the Provox Vega XtraSeal into the TE-puncture was unsuccessful, it is possible to reload the voice prosthesis into the Provox Insertion System.

Position voice prosthesis

1. Mount the voice prosthesis with the tracheal side facing down on top of the Insertion Pin.
2. Attach the Safety Strap by leading it through the Attachment Slot from either side.
3. Ensure the Voice Prosthesis is properly positioned on the Insertion Pin, firmly attached and with the tip of the pin positioned all the way into the blue ring of the voice prosthesis (Fig. 3). Connect the Folding Tool.
4. Guide the Insertion Pin through the opening in the Folding Tool until it clicks in place. Pull the pin until the pin is snapped into the Folding Tool. (Fig. 11). The Provox Insertion System is now ready for preparation. Continue the preparation as described above in section 2.2.

CAUTION: Do not reload more than twice. If the Provox Vega voice prosthesis shows any signs of damage, do not use the voice prosthesis.

2.5 Finalize the procedure

After insertion:

Ensure proper fit

1. Ensure the proper position of the voice prosthesis by rotating and gently pulling the Insertion Pin (Fig. 12). The prosthesis is in an ideal position when the Safety Strap is pointing downwards.
CAUTION: Confirm that both esophageal flanges have deployed entirely in the lumen of the esophagus. No part of the enlarged esophageal flange should be visible alongside the shaft of the voice prosthesis and when rotated the voice prosthesis should move freely. Rotating the voice prosthesis while at the same time slightly pushing it towards the esophagus can help to unfold the enlarged flange completely. In case of uncertainty, use flexible endoscopy to confirm proper placement inside the esophagus.

Test proper function

2. Brush the Provox Vega with the Provox Brush. Test proper function of the prosthesis by asking the patient to speak and by observing that the prosthesis does not leak while the patient drinks water (Fig. 18).

Cut the Safety Strap

3. After ensuring the voice prosthesis is placed correctly, cut off the Safety Strap so that it is flush with the Tracheal Flange (Fig. 14). The voice prosthesis is now ready for use.

3. Important patient information

3.1 General information

Ensure that the patient understands to contact their clinician if:

- There is leakage through or around the prosthesis (coughing and/or change of mucus color).
- Speaking becomes difficult (higher effort and/or voice sounds more strained).
- There are any signs of inflammation or tissue changes at the puncture site or the stoma region (pain, redness, heat, swelling, traces of blood on the brush after brushing).

Also inform the patient that:

- After a prosthesis replacement traces of blood may be found in the sputum. This may come from granulation tissue on the edges of the TE puncture.
- The Provox Vega Plug can be used to temporarily stop leakage through the voice prosthesis.
- Speech Training Sessions with a trained clinician are advised in order to acquire optimal voice sound, fluent speech, and optimal intelligibility.

3.2 Prosthesis maintenance

Instruct the patient when and how to clean the Provox Vega XtraSeal voice prosthesis. Cleaning the prosthesis at least twice a day can help prolong the device life.

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

- Brushing the prosthesis with the Provox Brush twice a day will help to remove mucus and food remnants from the prosthesis.

- Flushing the prosthesis with the Provox Flush also helps to clean debris and mucus from the prosthesis, can help increase the life of the device.
  Note: The Provox Flush is intended for use only by patients who, as assessed by the clinician who prescribes the device, have demonstrated ability to understand and consistently follow the instructions for use without clinician supervision.
- Some dietary measures, like the daily intake of yogurt or butter milk containing lactobacilli, are considered to be helpful against excessive Candida growth.

For detailed information on how to clean a Provox Vega, please see Instructions for each accessory.

4. Additional information

4.1 Compatibility with MRI, X-ray and radiation therapy

Provox voice prostheses have been tested and found to be compatible with Magnetic Resonance Imaging (tested up to 3 Tesla), X-ray and radiation therapy (tested up to 70 Gy). The prosthesis can be left in the TE-puncture during the examination/ therapy session. Note that the radio-opaque valve seat is visible on X-ray.

4.2 Device lifetime

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.

Laboratory testings of simulated usage for a test period of 12 months show that, in the absence of bacteria and yeasts, the device will maintain its structural integrity for this time period. The device has not been tested for usage beyond 12 months. Usage beyond this limit is under the sole discretion of the prescriber.

4.3 Disposal

Always follow medical practice and national requirements regarding biohazards when disposing of a used medical device.

4.4 Compatibility with antifungal medicine

Laboratory tests show only minor negative influence on the function of the Provox Vega voice prosthesis and components when using the following antifungal medications: Nystatin, Fluconazole, Mikonazol.

5. Product model

Model	Specification
8288-18	Provox Vega XtraSeal 17Fr 4mm
8289-18	Provox Vega XtraSeal 17Fr 6mm
8290-18	Provox Vega XtraSeal 17Fr 8mm
8291-18	Provox Vega XtraSeal 17Fr 10mm
8292-18	Provox Vega XtraSeal 17Fr 12.5mm
8293-18	Provox Vega XtraSeal 17Fr 15mm
8294-18	Provox Vega XtraSeal 20Fr 4mm
8295-18	Provox Vega XtraSeal 20Fr 6mm
8296-18	Provox Vega XtraSeal 20Fr 8mm
8297-18	Provox Vega XtraSeal 20Fr 10mm
8298-18	Provox Vega XtraSeal 20Fr 12.5mm
8299-18	Provox Vega XtraSeal 20Fr 15mm
8300-18	Provox Vega XtraSeal 22.5Fr 4mm
8301-18	Provox Vega XtraSeal 22.5Fr 6mm
8302-18	Provox Vega XtraSeal 22.5Fr 8mm
8303-18	Provox Vega XtraSeal 22.5Fr 10mm
8304-18	Provox Vega XtraSeal 22.5Fr 12.5mm
8305-18	Provox Vega XtraSeal 22.5Fr 15mm

6. Storage conditions

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

7. 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.

8. 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

9. Production date and validity

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

10. Registration certificate number of medical devices

Certificate number of medical devices: 国械注进20223130609

11. Technical requirements for medical devices

Technical requirement number for medical devices: 国械注进20223130609

12. Edition of Instruction for Use

Article number: 11612, Edition date: 2026-03-19.

13. 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

简体中文

Provox® Vega ™ XtraSeal ™

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 器械说明

一般信息

Provox Vega 辅助发音管是一个单向阀（辅助发音管），让气管食道穿刺口保持开启以便说话，同时降低食物和液体进入气管的风险。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（图 1）有不同直径和多种长度可选。
Provox Vega XtraSeal 加封辅助发音管具有额外的加大食管侧轮缘，适用于解决辅助发音管周围的渗漏问题。
该器械由医用级硅橡胶和氟塑料制成。

Provox Vega XtraSeal 辅助发音管替换套装（含加封辅助发音管）包装
Provox Vega XtraSeal 辅助发音管替换套装（含加封辅助发音管）包装包含下列物品：

- 1 个预组装于单次使用的 Insertion System（推置系统）中的 Provox Vega XtraSeal 加封辅助发音管，无菌（图 2）
- 1 个尺寸符合辅助发音管设计的 Provox Brush（清洁刷），非无菌
- 1 本 Provox Vega XtraSeal 加封辅助发音管医生操作手册
- 1 本 Provox Vega 辅助发音管患者操作手册
- 1 本 Provox Brush（清洁刷）使用说明

1.4 禁忌症

在已使用辅助发音管发音重建的患者中，使用或更换 Provox Vega 辅助发音管并无任何已知的禁忌症。

1.5 警告

- 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。气道中的异物可能引起严重的并发症，例如急性呼吸窘迫和 / 或呼吸停止。
- 选择合适的辅助发音管尺寸。过紧的器械可能造成组织坏死和器械脱出。
- 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。
- 叮嘱患者在发现辅助发音管内或其周围有渗漏时咨询医生。渗漏可能引起吸入性肺炎。
- 选择合适的喉切除管或造口钮（若使用）形状，以免在插入和移除喉切除管或造口钮时挤压到辅助发音管或卡住辅助发音管的气管侧轮缘。这可能引起严重的组织损伤和 / 或误吞辅助发音管。
- 叮嘱患者只使用相应尺寸的 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。
- 重复使用和重复加工处理可导致交叉污染和器械损坏，并可能因此而对患者造成伤害。

1.6 注意事项

- 在置放或更换辅助发音管前，请谨慎评估有出血性疾病的患者或正接受抗凝血治疗的患者发生出血或大出血的风险。
- 请于使用前检查包装。若包装受损或已开启，请勿使用此产品。
- 为降低感染风险，请于处理辅助发音管时始终采用无菌技术。

2. 使用说明

2.1 选择辅助发音管的尺寸

确保使用具有合适轴直径和长度的 Provox Vega XtraSeal 加封辅助发音管。Provox Vega XtraSeal 加封辅助发音管具有不同长度 / 直径组合。

- 选择轴直径
  医生应确定适用于患者的合适辅助发音管直径。

如果所选用的辅助发音管的轴直径比之前使用的辅助发音管大，则必须使用适合待插入辅助发音管直径的 Provox Dilator 扩张器扩大穿刺口。
如果插入较小轴直径的辅助发音管，观察并确认穿刺口的直径缩到适当的大小。

- 选择轴长度
  为了选择正确的长度，您可使用目前的辅助发音管作为其自身的度量参考。
  如果旧辅助发音管的气管侧轮缘和黏膜壁之间有太多空隙（即 3 mm/ 约 0.12 英寸或以上），则应使用较短的辅助发音管。
  若辅助发音管卡得过紧，则应使用较长的辅助发音管。
  注：由于加大食管侧轮缘的关系，Provox Vega XtraSeal 加封辅助发音管的轴比指定的尺寸大约短 1 mm。

2.2 准备

（图 3-6）
组装辅助发音管

1. 确保辅助发音管正确组装在插入器上并已牢固连接，插入器的尖端完全通入辅助发音管的蓝色环中（图 3）。

折叠食管侧轮缘

2. 确认插入器已与折叠工具正确组装（插入器应卡入到折叠工具中）。
3. 使用两个手指将折叠工具压合（图 4）。
4. 保持折叠工具闭合，连接输送管并旋转直至其锁定到位（图 5）。

装填

5. 向前推动插入器直到辅助发音管与输送管上的可见环对齐（图 6）。

取出旧的辅助发音管

6. 使用无齿止血钳从气管食道穿刺口拔出当前（旧的）辅助发音管。或者，经医生判断，可用镊子夹住辅助发音管的气管侧轮缘并剪掉。然后将辅助发音管的剩余部分推入食管以穿过肠道。在使用此方法之前应考虑患者的任何肠道疾病病史。

准备穿刺口（可选）

7. 可对穿刺口进行扩张以准备插入辅助发音管。通常这不是必须进行的程序，但对于穿刺口有角度或较紧而容易坍塌的患者，可能有助于插入。

2.3 插入、顺行更换程序

（图 7-10）
注意：具有加大食管侧轮缘的 Provox Vega XtraSeal 加封辅助发音管必须用过度超出技术更换，以确保额外的加大食管侧轮缘和一般食管侧轮缘都在食管腔内展开。过度超出是指整个辅助发音管先在食管中展开，然后退回到预定位置。

1. 取下折叠工具（可选）
   在将辅助发音管推入输送管后，将折叠工具从输送管解锁并断开连接，将折叠工具取下（图 7）。
2. 伸入气管食道穿刺口
   握住 Provox Insertion System（Provox 推置系统）的输送管。将输送管尖端伸入穿刺口。如果遇到阻力则小心地推进。在有阻力的情况下，扩口和 / 或润滑可有助于插入。
3. 插入辅助发音管
   用一只手稳住输送管，另一只手推动插入器直到越过近端抓握表面（图 8）。此时，辅助发音管在食管中完全展开（图 9）。
   如果在装配着折叠工具的情况下执行过度超出插入，则推进插入器直至越过远端抓握表面（图 10）。此时，辅助发音管在食管中完全展开（图 9）。
4. 释放辅助发音管
   将输送管从穿刺口直接拔出。辅助发音管留在食管内，仍牢固地与插入器连接。使用无齿止血钳夹住气管侧轮缘，并将辅助发音管牵扯 / 旋转到位。
5. 完成程序
   插入后，按照下文第 2.5 节的说明完成程序。

2.4 组装和重新安装 Provox Insertion System（Provox 推置系统）

如果首次尝试将 Provox Vega XtraSeal 加封辅助发音管插入气管食道穿刺口未成功，可以重新将辅助发音管装填到 Provox Insertion System（Provox 推置系统）。

组装辅助发音管

1. 将辅助发音管安装在插入器的顶部，使气管侧朝下。
2. 连接安全带：将安全带从任一侧穿过连接槽孔。
3. 确保辅助发音管正确组装于插入器上并已牢固连接，插入器的尖端完全通入辅助发音管的蓝色环中（图 3）。连接折叠工具。
4. 将插入器穿过折叠工具的开口直到其卡入到位。牵拉插入器直到插入器卡入到折叠工具中。（图 11）。Provox Insertion System（Provox 推置系统）现已做好准备。继续按照上文第 2.2 节的描述进行准备工作。

注意：请勿重新装填超过两次。如果 Provox Vega 辅助发音管有任何损坏的迹象，请勿使用。

2.5 完成程序

插入之后：
确保正确就位

1. 旋转并轻拉插入器确保辅助发音管正确就位（图 12）。当安全带朝下时辅助发音管处于理想位置。
   注意：确认两个食管侧轮缘都已在食管腔内完全展开。从辅助发音管轴的任何地方都不应该看得到加大食管侧轮缘的任何部分，旋转辅助发音管时也应该能自由移动。旋转辅助发音管的同时轻轻将其推至食道可帮助完全展开加大轮缘。若不确定，使用软式内窥镜确认已适当置入食管内。

测试正常功能

2. 使用清洁刷洗刷 Provox Vega 辅助发音管。请患者说话，并在患者饮水时观察辅助发音管是否有渗漏，以此测试辅助发音管的正常功能（图 18）。

剪掉安全带

3. 在确保辅助发音管放置正确之后，从气管侧轮缘外缘处剪断安全带（图 14）。辅助发音管现已准备好可供使用。

3. 重要的患者信息

3.1 一般信息

确保患者知道在以下情况下要联系医生：

- 辅助发音管内或其周围有渗漏（咳嗽和 / 或粘液颜色改变）。
- 说话困难（更为费力和 / 或声音听起来更为紧张）。
- 在穿刺部位或造口区域出现发炎或组织变化的迹象（疼痛、红肿、发热、肿胀、刷洗后刷子留有血迹）。

还应告知患者可能发生下列情况：

- 更换辅助发音管后可能在痰液中发现血迹。这可能是来自于气管食道穿刺口边缘的肉芽组织。
- 塞子可用于暂时堵塞辅助发音管内的渗漏。
- 建议参加受过培训的医生指导的语言训练课程，以实现最佳的说话声音、流畅说话和最佳的语言清晰度。

3.2 辅助发音管维护

指导患者何时及如何清洁 Provox Vega XtraSeal 加封辅助发音管。每天至少清洁两次辅助发音管有助于延长器械寿命。

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

- 每天使用清洁刷刷洗两次辅助发音管有助于清除辅助发音管上的粘液和食物残渣。
- 使用冲洗器冲洗辅助发音管也可清除辅助发音管上的残留物和粘液，从而有助于延长器械寿命。
  注：冲洗器仅适合经开具此器械处方的医生评估能够在不需要医生监督的情况下理解并始终遵循使用说明的患者使用。
- 部分饮食措施，例如每天摄取含有乳酸菌的乳酪或酸奶，被视为有助于抵抗念珠菌过度生长。

有关如何清洁 Provox Vega 辅助发音管的详细信息，请参阅每个配件的说明。

4. 其他信息

4.1 与 MRI、X 射线和放射治疗的相容性

Provox 辅助发音管经过测试，发现与磁共振成像（测试磁感应强度达 3 特斯拉）、X 射线和放射治疗（测试剂量达 70 Gy）兼容。在检查 / 治疗期间辅助发音管可留在气管食道穿刺口内。请注意，不透射线的阀座在 X 射线中可见。

4.2 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。

实验室曾进行为期 12 个月的模拟使用测试，其结果显示，若在无细菌和酵母的情况下，器械可在 12 个月内维持结构完整性。实验室未对器械超过 12 个月的使用期进行测试。是否使用超过此期限需由开处方者决定。

4.3 弃置

弃置使用过的医疗设备时，请务必遵循生物危害相关的医疗惯例和国家要求。

4.4 与抗真菌药的相容性

实验室测试显示，下列抗真菌药对 Provox Vega 辅助发音管及其组件的功能仅具有轻微的负面影响：Nystatin、Fluconazole、Mikonazol。

5. 产品型号

型号	规格
8288-18	Provox Vega XtraSeal 17Fr 4mm
8289-18	Provox Vega XtraSeal 17Fr 6mm
8290-18	Provox Vega XtraSeal 17Fr 8mm
8291-18	Provox Vega XtraSeal 17Fr 10mm
8292-18	Provox Vega XtraSeal 17Fr 12.5mm
8293-18	Provox Vega XtraSeal 17Fr 15mm
8294-18	Provox Vega XtraSeal 20Fr 4mm
8295-18	Provox Vega XtraSeal 20Fr 6mm
8296-18	Provox Vega XtraSeal 20Fr 8mm
8297-18	Provox Vega XtraSeal 20Fr 10mm
8298-18	Provox Vega XtraSeal 20Fr 12.5mm
8299-18	Provox Vega XtraSeal 20Fr 15mm
8300-18	Provox Vega XtraSeal 22.5Fr 4mm
8301-18	Provox Vega XtraSeal 22.5Fr 6mm
8302-18	Provox Vega XtraSeal 22.5Fr 8mm
8303-18	Provox Vega XtraSeal 22.5Fr 10mm
8304-18	Provox Vega XtraSeal 22.5Fr 12.5mm
8305-18	Provox Vega XtraSeal 22.5Fr 15mm

6. 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。

7. 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。

8. 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

9. 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。

10. 医疗器械注册证编号

注册证编号：国械注进 20223130609

11. 医疗器械技术要求编号

产品技术要求编号：国械注进 20223130609

12. 说明书版本号

说明书版本编号：11612，说明书修订日期：2026/3/19

13. 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

MD

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

Rx
ONLY

Prescription; 凭处方购买（仅适用于美国）

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2026-03-19

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