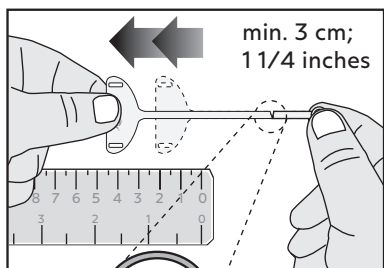
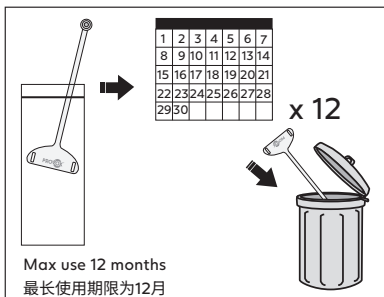


PROVOX[®]

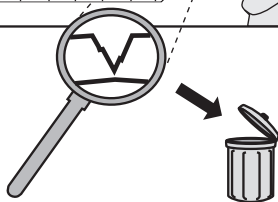
Vega[™] Plug

辅助发音管
塞子



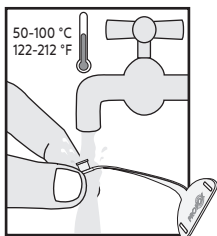


1.

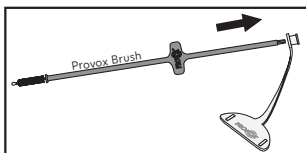


The original length is 1 1/4 inches (about 7 centimeters). Pull the strap at least 3 centimeters. If there is any breakage, please discard it.

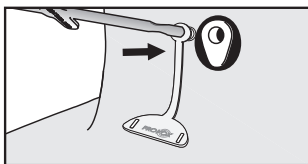
本来长度1 1/4英寸(约7厘米), 拉动带子至少3厘米; 如有断裂, 请丢弃。



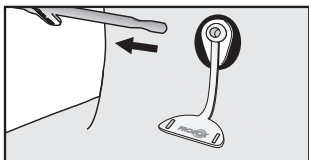
2. Rinse the insertion end of the device.
冲洗塞子的插入端



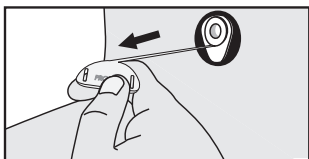
3. Secure Provox Vega Plug by using Provox Brush.
用Provox Brush清洁刷将塞子固定



4. Insert Provox Vega Plug into the lumen
of the prosthesis
正对辅助发音管并插入小孔



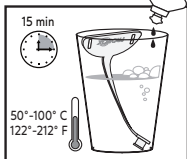
5. Remove Provox Brush.
移除Provox Brush清洁刷



6. Pull the end of the plug and slightly to
remove the Plug.
稍微用力拉塞子在体外的一端可将塞子取下

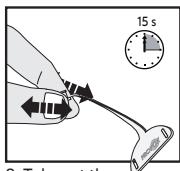
2 / 250 ml (8,5 fl oz)

Dishsoap



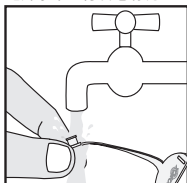
7. Two drops of mild soap adding to 250ml water for soaking and cleaning.

2滴洗洁精/清洗剂滴入250毫升水中进行浸泡清洗

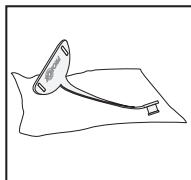


8. Take out the device after 15 mins.

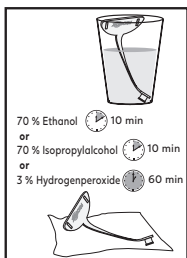
15分钟后取出



9. Rinse the device in water
流动的水冲洗



10. Let the device dry
晾干



11. Soak in 70% ethanol for 10 minutes, or soak in 70% isopropanol for 10 minutes, or soak in 3% hydrogen peroxide solution for 60 minutes.

70%的乙醇浸泡10分钟,或者70%的异丙醇浸泡10分钟,也可以用3%的过氧化氢溶液浸泡60分钟。

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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1. Descriptive Information

1.1 Intended use

Provox Vega Plug is intended to seal the inner lumen of Provox Vega voice prosthesis and therefore stop leakage of both air and fluids through the voice prosthesis.

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

None.

1.4 WARNINGS

None.

1.5 Description of the device

Provox Vega Plug is a first-aid tool for temporarily stopping leakage through a Provox Vega voice prosthesis. The device is inserted into the opening of the Provox Vega voice prosthesis and hence blocking any leakage through the valve.

1.6 Precaution

Provox Vega Plug is intended for single patient use. Reuse in another patient may cause cross contamination.

2. Instructions for use

2.1 Operation instruction

Check device integrity prior to each use by pulling the strap see fig. 1.

For instructions on how to use the product, please see fig. 2-6.

2.2 Cleaning and disinfection

Clean the Provox Vega Plug after each use, or if it is changed during use according to Fig. 7-10.

Fig. 8; Rub the device between your fingers for 15 seconds.

DO NOT use any water other than drinking water to clean and rinse the device.

Disinfect the Provox Vega Plug at least once a day if it is removed (Fig. 11) with one of the following methods:

- Ethanol 70% for 10 minutes
- Isopropylalcohol 70% for 10 minutes
- Hydrogenperoxide 3% for 60 minutes

CAUTION: DO NOT clean or disinfect by any other method as this might cause product damage and injury.

If the Provox Vega Plug looks dirty or has air dried in an area with a risk of contamination the device should be both cleaned and disinfected before use.

A risk of contamination could exist if the device has been dropped on the floor or if it has been in contact with a pet, someone with a respiratory infection, or any other gross contamination.

During hospitalization it is important to both clean and disinfect the Provox Vega Plug after use but also before use since there is an increased risk of infection and contamination. In a hospital it is better to use sterile water for cleaning and rinsing, rather than drinking water.

2.3 Disposal

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

3. Product model

Model	Specification
8119-18	17Fr
8129-18	20Fr
8139-18	22.5Fr

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: 11704, 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

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

无。

1.4 警告

无。

1.5 器械说明

Provox Vega 塞子是一种急救工具，可暂时阻止物质经由 Provox Vega 辅助发音管泄漏。

该装置会插入 Provox Vega 辅助发音管的开口，从而阻止任何物质经过阀门外泄。

1.6 注意事项

Provox Vega 塞子仅供单一患者使用。重复使用在其他患者身上可能引起交叉感染。

2. 使用说明

2.1 操作说明

每次使用前应试着拉动带子以确认完整无缺，详见图 1。

产品详细使用说明见图 2-6。

2.2 清洁和消毒

每次使用后或在使用期间更换时，根据图 7-10 清洁 Provox Vega 塞子。

图 8，在手指之间摩擦该装置 15 秒。

不要使用饮用水以外的其他任何水来清洗和冲洗装置

若拿下，每天至少一次使用下列方法之一对 Provox Vega 塞子进行消毒 (图 11):

- 70% 乙醇浸泡 10 分钟
- 70% 异丙醇浸泡 10 分钟
- 3% 过氧化氢浸泡 60 分钟

注意：请勿使用其他任何方法清洁或消毒，否则可能导致产品损坏和相关人员受伤。

若发现 Provox Vega 塞子 脏污或曾被置于存在污染风险处晾干，使用前应对其进行清洁和消毒。

如果设备掉地，或者与宠物、呼吸道感染者或任何其他肉眼可见的污染物接触，那么设备可能已被污染。

在住院期间，由于设备的感染和污染风险会增加，请务必在使用前以及使用后对 Provox Vega 塞子 进行清洁和消毒。在医院环境中，使用消毒水而非饮用水进行清洁和冲洗可获得更好的效果。

2.3 弃置

弃置使用过的医疗器械时，请务必遵循生物危害相关的医疗惯例和国家要求。

3. 产品型号

型号	规格
8119-18	17Fr
8129-18	20Fr
8139-18	22.5Fr

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：11704，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



Non-sterile; 未灭菌



Single Patient – multiple use; 供一位患者多次使用;



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

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2026-03-19

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