PROVOX Flush

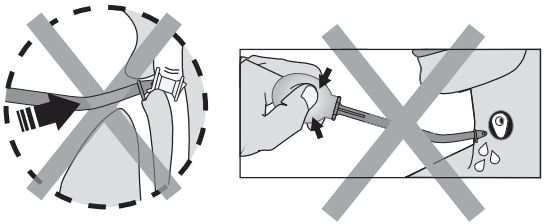
辅助发音管
冲洗器

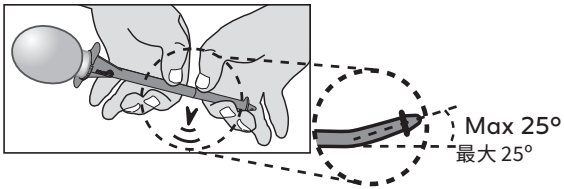
IFU

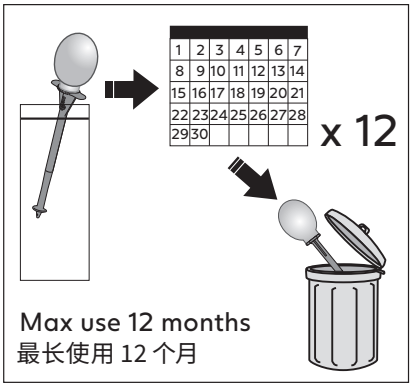
MD

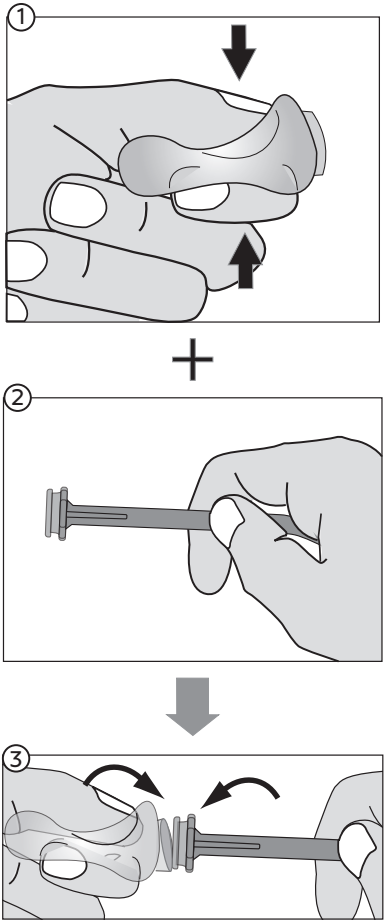
NON STERILE

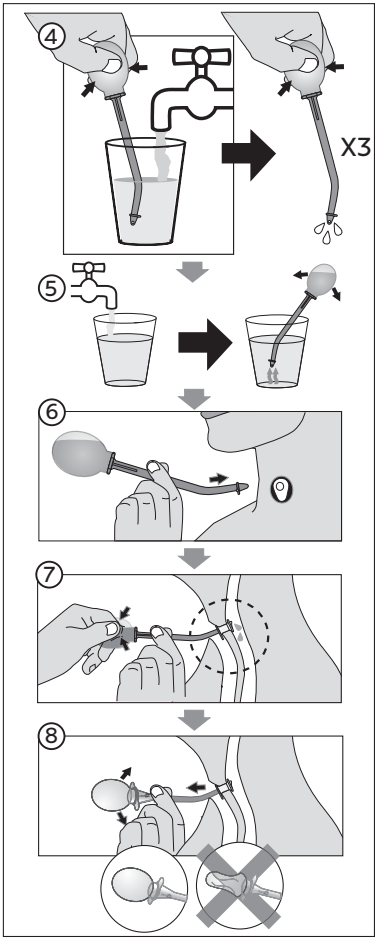
42 °C
108 °F
RT
2 °C
36 °F

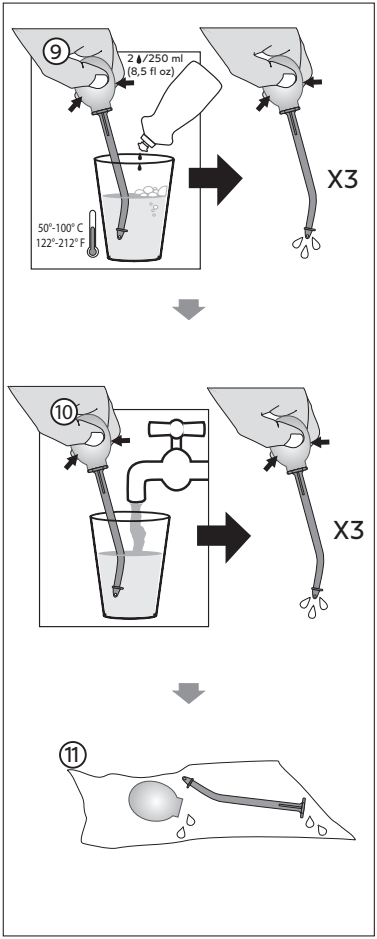



Max 25°
最大 25°

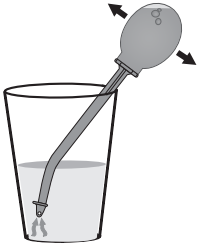

1 2 3 4 5 6 7
8 9 10 11 12 13 14
15 16 17 18 19 20 21
22 23 24 25 26 27 28
29 30
x 12
Max use 12 months
最长使用 12 个月


1
2
3

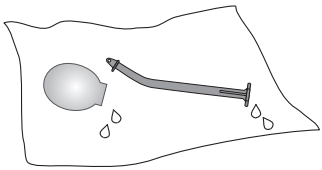

④
X3
⑤
⑥
⑦
⑧


9
2 ∕250 ml
(8,5 fl oz)
50°-100° C
122°-212° F
X3
10
X3
11

⑫



70% Ethanol
70% 乙醇
10 min
10 分钟
or / 或
70% Isopropylalcohol
70% 异丙醇
10 min
10 分钟
or / 或
3% Hydrogenperoxide
3% 过氧化氢
60 min
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.

免责声明

欧拓适医疗有限责任公司不向买方提供本协议项下所交付产品的使用期限的任何保证——无论是明示的还是默示的——使用期限可能因个人使用情况和生物条件的不同而有所不同，此外，欧拓适医疗有限责任公司不保证产品的适销性或适合于任何特定用途。

Contents

Intended Use

Provox Flush is intended to be used to flush drinking water or air through the inner lumen of a Provox voice prosthesis for cleaning purposes. The Provox Flush is intended for both home and clinical use by patient or clinician.

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, 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.

Contraindications

None.

Warnings

- The flush is only recommended for patients with sufficient manual dexterity, acceptable vision and satisfactory cognitive ability.

Description of the Device

- Provox Flush is intended to be used to flush drinking water or air through the inner lumen of a Provox voice prosthesis for cleaning purposes.
- The Provox Flush is intended for both home and clinical use by patient or clinician.

Precaution

• The device is intended for single patient use only. Reuse in another patient may cause cross contamination.

Instructions for Use

For instructions how to use the device, see fig. 1-8.

Cleaning and Disinfection

Clean the Provox Flush after each use according to fig. 9-11. Do not use any water other than drinking water to clean and rinse the device.

Disinfect the Provox Flush at least once a day (fig. 12) 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 Flush 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 Flush 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.

Disposal

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

Product Model

Model
8109-18

Storage Conditions

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

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.

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

Production Date and Validity

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

Registration Certificate Number of Medical Devices

Certificate number of medical devices: 国械注进 20223130609

Technical Requirements for Medical Devices

Technical requirement number for medical devices: 国械注进20223130609

Edition of Instruction for Use

Article number: 11703, Edition date: 2024-06-04

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

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。

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、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。

禁忌症

无。

警告

- 仅建议具备足够的动手能力、合格的视力和令人满意的认知能力的患者进行冲洗操作。

器械说明

- Provox Flush（冲洗器）设计用于使用饮用水或空气对 Provox 辅助发音管内腔进行冲洗。
- Provox Flush（冲洗器）适用于患者或临床医生在家庭和临床环境中使用。

注意事项

- 本设备仅供单一患者使用。多患者共用可能造成交叉污染。

使用说明

设备的使用说明请参见图 1-8。

清洁和消毒

每次使用后，按照图 9-11 所示清洁 Provox Flush（冲洗器）。请勿使用饮用水之外的任何液体来清洁和冲洗本设备。

采用如下方法之一（图 12），每天至少对 Provox Flush（冲洗器）消毒一次：

- 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 Flush（冲洗器）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 Flush（冲洗器）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。

处置

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。

产品型号

型号
8109-18

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。

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。

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

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。

医疗器械注册证编号

注册证编号：国械注进 20223130609

医疗器械技术要求编号

产品技术要求编号：国械注进 20223130609

说明书版本号

说明书版本编号：11703，说明书修订日期：2024/06/24

生产企业和注册人

注册人名称 / 生产企业名称：Atos Medical AB 欧拓适医疗有限责任公司
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

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。

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

Medical Device; 医疗器械

Instructions for use; 使用说明书

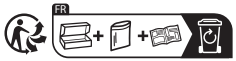
Caution, consult instructions for use; 警告，参阅使用说明书

UK Conformity Assessed (UKCA) marking;
英国合格评定（UKCA）标志;

UK Responsible Person
Atos Medical UK Ltd Tottle Road
Cartwright House
Nottingham
Nottinghamshire NG2 1RT
England United Kingdom

CE

Indicates that the product is in compliance with European legislation for medical devices; 法国 Triman 标志和分类信息



Triman symbol and Infotri for France;
法国 Triman 标志和分类信息;

Recycling guidelines; 回收指南;

XXXXX, NN
YYYY-MM-DD

XXXXX, NN = Reference number, Version number;
参考编号, 版本号

YYYY-MM-DD = Date of issue; 发布日期

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11703, 03
2024-06-24

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atosmedical.com

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