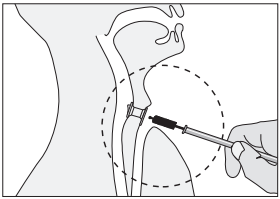
PROVOX Brush

清洁刷

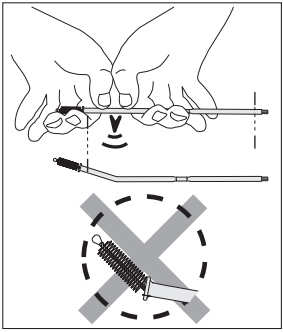
IFU

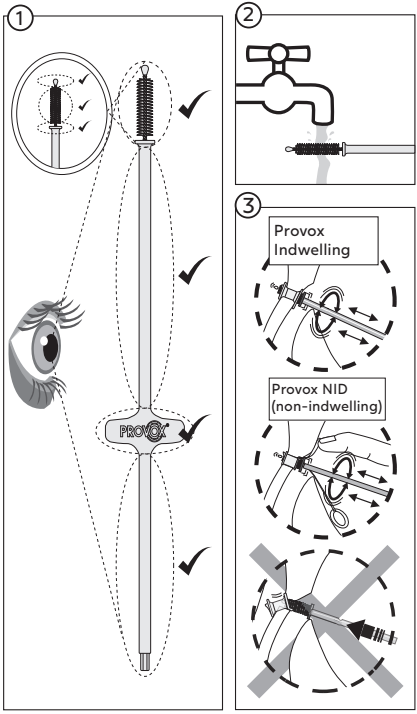
NON STERILE

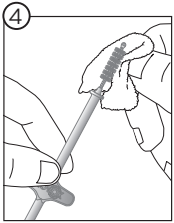
42 °C
108 °F
RT
2 °C
36 °F



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					




1
2
3
Provox
Indwelling
Provox NID
(non-indwelling)
PROVOX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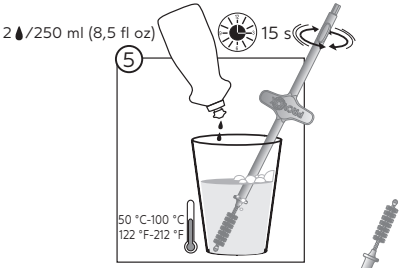
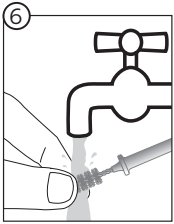

2 ♦/250 ml (8,5 fl oz)
15 s
5
50 °C-100 °C
122 °F-212 °F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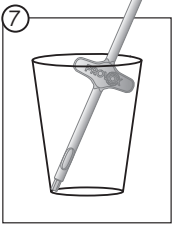
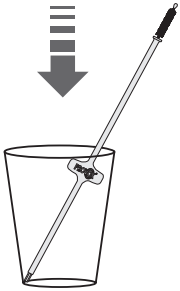

7

8

70% Ethanol 10 min
or
70% Isopropylalcohol 10 min
or
3% Hydrogenperoxide 60 min



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.

免责声明

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Intended Use

Provox Brush is a single patient use device intended for cleaning Provox Voice Prosthesis, for insertion of Provox Plug and Provox Vega Plug, for applying lubricant and anti-candida agents, and for cleaning of fenestration holes on Provox LaryTubes. The product is intended for use by the patient.

Before Use

Always inspect the Provox Brush (fig.1) to make sure that it is not broken or worn out.

Before each use, make sure that
- the protective tip is not cracked or loose.
- the bristles do not appear worn or are loose.
- the wires are not bent or broken.
- the entire handle is not cracked or broken and that the safety wings have not been removed.

If any defects are found, the brush must be discarded.

Cleaning and Disinfection

Clean the Provox Brush after each use according to fig. 4-7 using drinking water.

Disinfect the Provox Brush (fig. 8) with one of the following methods:
- Ethanol 70% for 10 minutes
- Isopropylalcohol 70% for 10 minutes
- Hydrogenperoxide 3% for 60 minutes

Do not use the device until it is completely dry.

Note: Always clean and disinfect before use.

Precautions:

- The device is intended for single patient use only. Reuse in another patient may cause cross contamination.
- Do not clean or disinfect by any other method as this might cause product damage and injury.

Disposal

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

Product Model

Model	Specification
8404-18	Provox Brush Long
8425-18	Provox Brush Long XL

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.

Edition of Instruction for Use

Article number: 11699, Edition date: 2026-04-07.

Manufacturer

Atos Medical AB
Kraftgatan 8, SE-242 35 Hörby, Sweden
Contact: +46 (0)415 198 00 • info@atosmedical.com
Country of origin: Thailand

预期用途

用于清洁安装的Provox 辅助发音管和 LaryTube（气管套管） 上的开窗孔，其远端可用于插入Provox Vega Plug 塞子并将其放入辅助发音管。

使用前

务必检查 Provox Brush（Provox 清洁刷，图 1），确保其没有损坏或磨损。

每次使用前，请确保：
- 防护尖端没有破裂或松动。
- 刷毛没有出现磨损或松脱。
- 金属丝没有弯曲或损坏。
- 整个手柄没有破裂或损坏，保护翼没有被取下。

如果发现任何缺陷，必须丢弃清洁刷。

清洁和消毒

每次使用后，按照图 4-7 所示使用饮用水清洁 Provox Brush（Provox 清洁刷）。

使用以下方法之一对 Provox Brush（Provox 清洁刷，图 8）进行消毒：
- 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

本设备完全干燥前请勿使用。
注：使用前务必进行清洁和消毒。

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。
- 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。

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	规格
8404-18	Provox 清洁刷（长款）
8425-18	Provox 清洁刷（超长款）

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

生产日期和有效期

请参阅标签了解生产日期；产品的有效期为 5 年。

说明书版本号

说明书版本编号：11699，说明书修订日期：2024/02/14。

制造商

生产企业：Atos Medical AB 欧拓适医疗有限责任公司
住所：Kraftgatan 8, SE-242 35 Hörby，Sweden
联系方式：+46 (0)415 198 00 • info@atosmedical.com
原产地：泰国

符号的解释

Manufacturer; 制造商

Country of manufacture with date of manufacture;
制造国家/地区及制造日期

Use-by date; 使用期限

LOT

Batch code; 批次代码

REF

Product reference number; 产品编号

NON STERILE

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。

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

Instructions for use; 使用说明书

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

Indicates that the product is in compliance with European legislation for medical devices; 表示本产品符合欧洲医疗器械法规

Recycling guidelines; 回收指南

11699, 01
2026-04-07

Atos
atosmedical.com

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