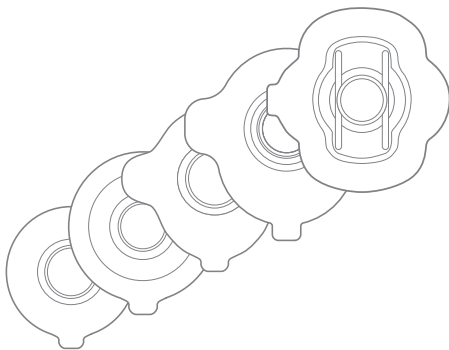


# PROVOX Adhesives

颈部造口底盘



## 1. StabiliBase 深凸稳固型

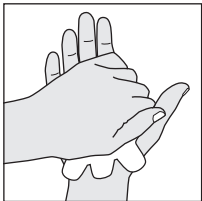


Figure 1.1

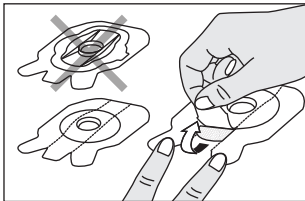


Figure 1.2

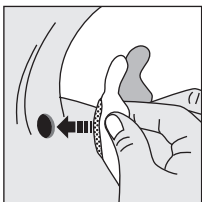


Figure 1.3

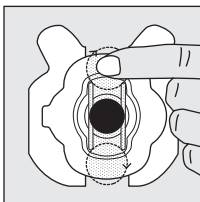


Figure 1.4

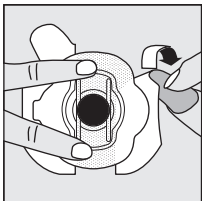


Figure 1.5

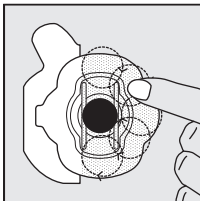


Figure 1.6

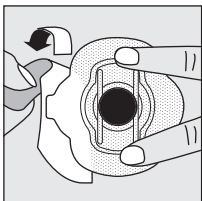


Figure 1.7

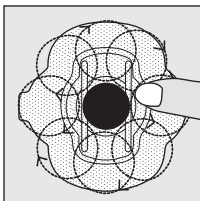


Figure 1.8

## 2. FlexiDerm 灵活型, XtraBase 微凸加固型, OptiDerm 柔肤型

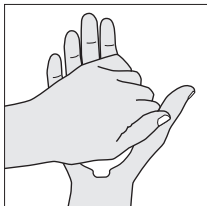


Figure 2.1

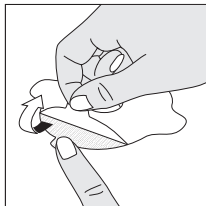


Figure 2.2

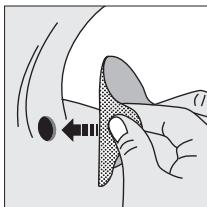


Figure 2.3

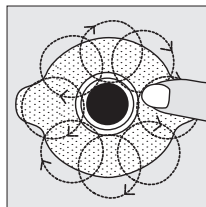


Figure 2.4

## **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。

## Provox Adhesive / 颈部造口底盘

Compatible Products; 相容产品

	Provox XtraBase 微凸加固型	Provox Stabilibase 深凸稳固型	Provox FlexiDerm 灵活型	Provox OptiDerm 柔肤型
Provox XtraFlow HME 热湿交换器	X	X	X	X
Provox XtraMoist HME 热湿交换器	X	X	X	X
Provox ShowerAid 颈部造口淋浴辅具	X	X	X	X
Provox Silicone Glue 颈部造口防漏硅胶	X	X	X	X
Provox Adhesive Remover 颈部造口黏胶祛除擦巾	X	X	X	X
Provox Skin Barrier 颈部造口皮肤保护膜	X	X	X	X
Provox Micron HME 热湿交换器	X	X	X	X
Provox BasePlate Adaptor 颈部造口底盘适配器	X	X	X	X
Provox Cleaning Towel 清洁湿巾	X	X	X	X
Provox LaryTube with Ring 环状喉管	X	X	X	X

## Contents

EN - ENGLISH..... 7

ZH - ZHCN..... 11

## 1. Intended Use

Provox Adhesives are single use devices intended for laryngectomized patients breathing through a tracheostoma. The devices are attached to the skin around the tracheostoma in order to provide attachment of components of the Provox HME System.

## 2. Overall Description and Product Composition

Provox Adhesives consist of a baseplate with an adaptor, adhesive tape and peeloff liner. The devices are made of polymer materials and are non-sterile. The devices can be used together with Provox HMEs, Provox Shower Aid or Provox Baseplate Adaptor. When used, the adhesive is attached on intact skin around the tracheostoma. After application a Provox HME, Provox Shower Aid or a Provox Baseplate Adaptor can be attached to the adhesive adaptor, see instruction for use section.

## 3. Description of the Device

Provox Adhesives are adhesives for everyday use, they are designed to ensure an airtight attachment for the Provox HME system components. The adhesives consist of an adapter and an adhesive part with peel-off liners.

**Provox FlexiDerm** is a soft, flexible and acrylic based adhesive with strong adhesive properties.

**Provox XtraBase** is an acrylic based adhesive with strong adhesive properties. It has a concave base which can be especially suitable for somewhat deep tracheostomas.

**Provox StabiliBase** is an acrylic based adhesive with strong adhesive properties. It has a firm base with vertical stabilizing bars that provides support to the tracheostoma during speech. The design of the StabiliBase adapter can be especially suitable for deep tracheostomas. The peel-off liner is divided into three sections to facilitate application to the skin.

**Provox OptiDerm** is made of a hydrocolloid material that is suitable for sensitive skin. For example, dependent on clinical suitability and continued tolerance, it can be used postoperatively and during and after radiotherapy. The hydrocolloid material is commonly used in wound care and one of its main characteristics is that it absorbs wound fluids. When the material has absorbed fluids it becomes white and depending on the amount of secretions it can become jelly-like and it will no longer stick to the skin. Please note that the material may also absorb mucus coming from the stoma, and therefore it remains very important to always wipe and clear the mucus away from your adhesive and stoma area after you cough.

## 4. Contraindications

None.

## 5. Warnings

- Do not use Provox FlexiDerm, Provox StabiliBase or Provox XtraBase directly after laryngectomy.
- The use of Provox Adhesives need to be assessed both on an individual basis and reviewed regularly through the course of radiotherapy treatment.
- Reuse will affect performance and may cause transfer of micro-organisms leading to infections.
- Only use Provox Adhesives with compatible HMEs and accessories.

## 6. Precautions

- The adhesive may irritate the skin. Stop using the adhesive if skin irritation develops and consult your clinician.
- When cleaning the skin from residual glue, prevent particles/fluids from entering the tracheostoma.
- When using OptiDerm in the postoperative period or on sensitive skin, it should be removed very slowly and carefully.

## 7. How to Use

### Prepare

Inspect that the adhesive is not damaged or has tears in the adhesive or around the base plate. Always clean the skin with a Provox Cleaning Towel and/or soap and water and let the skin dry before applying the adhesive.

### Apply

If needed, you can apply skin protection products, like Provox Skin Barrier or adhesive supporting products such as Provox Silicone Glue (read the Instructions for Use accompanying the product). For guidance on how to apply, see figures 1.1 - 1.8 and 2.1 - 2.4.

### Remove

Peel the adhesive off gently, using the finger lift tab. An adhesive remover, e.g. Provox Adhesive Remover (read the Instructions for Use accompanying the product), may be helpful for removing adhesives. Always clean the skin with a Provox Cleaning Towel and/or soap and water after removal. Dry the area carefully.



## 8. Product model

Model	Specification
7253-18	Provox Adhesive FlexiDerm Round (20 pcs)
7254-18	Provox Adhesive FlexiDerm Oval (20 pcs)
7331-18	Provox Adhesive FlexiDerm Plus (20 pcs)
7255-18	Provox Adhesive OptiDerm Round (20 pcs)
7256-18	Provox Adhesive OptiDerm Oval (20 pcs)
7332-18	Provox Adhesive OptiDerm Plus (20 pcs)
7289-18	Provox StabiliBase (15 pcs)
7265-18	Provox XtraBase Adhesive (20 pcs)

## 9. Storage conditions

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

## 10. Manufacturer and filing company

Filing & Manufacturer company: Atos Medical AB

Filing & Manufacturer location: Kraftgatan 8, SE-242 35 Hörby, Sweden

Filing & Manufacturer contact: +46 (0415 198 00 • info@atosmedical.com

Production location: Kraftgatan 8, SE-242 35 Hörby, Sweden

Country of origin: Sweden

## 11. Edition of Instruction for Use

Article number: 11617, Edition date: 2024-09-04.

## 12. Disposal

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

### **13. 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.

### **14. 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](http://www.coloplast.com.cn)

### **15. Production date and validity**

Please see the label for the production date; the shelf life of product is 3 years.

### **16. Filing certificate number of medical devices**

Filing certificate number of medical devices: 国械备 20230011

### **17. Technical requirements for medical devices**

Technical requirement number for medical devices: 国械备 20230011

## 1. 预期用途 / 适用范围

用于将颈造口热湿交换器、颈部造口底盘适配器或淋浴辅具卡入底盘接口内侧。声称颈造口热湿交换器可加热和加湿吸入的空气，淋浴辅具可防止颈造口进水。

## 2. 产品描述 / 结构及组成

由底盘接口及与其连接的圆盘、粘合贴和背衬组成。

采用高分子材料制成。为非无菌提供产品。可与颈造口热湿交换器、颈部造口淋浴辅具或颈部造口底盘适配器配合使用，使用时先将粘合贴贴于颈部造口周围完整皮肤上，固定后将配合使用的颈造口热湿交换器、颈部造口淋浴辅具或颈部造口底盘适配器卡入底盘接口内侧。

## 3. 设备说明

Provox Adhesive (Provox 颈部造口底盘) 是日常使用的颈部造口底盘，可用于确保 Provox HME System (Provox 热湿交换器) 组件的气密连接。颈部造口底盘由底盘接口和带背衬的粘合贴圆盘组成。

Provox FlexiDerm (Provox 灵活型) 是一种柔软且柔韧的丙烯酸基颈部造口底盘，具有很强的粘合性。

Provox XtraBase (Provox 微凸加固型) 是一种丙烯酸基颈部造口底盘，具有很强的粘合性。它的凹形底盘特别适合用于较深的气管造口。

Provox StabiliBase (Provox 深凸稳固型) 是一种丙烯酸基颈部造口底盘，具有很强的粘合性。它有一个经特殊设计的带有垂直稳定杆的硬底，可在说话过程中为气管造口提供支持。StabiliBase 适配器的设计特别适合用于较深的气管造口。剥离垫片分为三部分，便于贴敷于皮肤。

Provox OptiDerm (Provox 柔肤型) 由水状胶质材料制成，适合敏感皮肤使用。例如，根据临床适用性和持续耐受性，它可以用于术后以及放疗期间和放疗后。水状胶质材料通常用于伤口护理，这种材料的主要特点是可以吸收伤口积液。当材料吸收积液后，就会变成白色，而根据分泌物的数量，它会变成果冻状，与皮肤分离。请注意，该材料也可能吸收来自造口的粘液，因此在咳嗽后，请一律擦拭干净粘合贴和造口位置的粘液，这点不容忽视。

## 4. 禁忌症

无。

## 5. 警告

- 不要在喉切除术后直接使用 Provox FlexiDerm (Provox 灵活型)、Provox StabiliBase(Provox 深凸稳固型) 或 Provox XtraBase (Provox 微凸加固型)。
- Provox Adhesive (Provox 颈部造口底盘) 的使用需要根据个人情况进行评估, 并在放射治疗期间定期复查。
- 重复使用将会影响性能, 并可能传播微生物, 进而导致感染。
- 仅将 Provox Adhesive (Provox 颈部造口底盘) 与兼容的热湿交换器和配件一起使用。

## 6. 注意事项

- 颈部造口底盘可能会刺激皮肤。如果发生皮肤刺激, 请停止使用颈部造口底盘并咨询医生。
- 清洁皮肤上的残胶时, 应防止微粒 / 液体进入气管造口。
- 在术后或敏感皮肤使用柔肤型时, 将其移除时应非常缓慢和小心。

## 7. 使用说明

### 准备

检查粘合贴是否损坏或粘合贴或底盘周围是否有撕裂。始终使用 Provox Cleaning Towel (Provox 清洁湿巾) 和 / 或肥皂和水清洁皮肤, 并在皮肤干燥后再使用粘合贴。

### 涂敷

如果需要, 您可以涂抹皮肤保护产品, 如 Provox Skin Barrier (Provox 颈部造口皮肤保护膜) 或颈部造口底盘辅助产品, 如 Provox Silicone Glue (Provox 颈部造口防漏硅胶) (请参阅产品随附的使用说明书)。有关涂敷手法指南, 请参阅图 1.1 至 1.8 以及 2.1 至 2.4。

### 移除

用手指向上提起耳片, 轻轻撕下粘合贴。粘合贴去除剂, 例如 Provox Adhesive Remover (Provox 颈部造口黏胶祛除擦巾) ( 请参阅产品随附

的使用说明书)，可能有助于去除粘合贴。移除后，请务必使用 Provox Cleaning Towel (Provox 清洁湿巾) 和 / 或肥皂和水清洁皮肤。仔细擦干相关部位。

## 8. 产品型号

型号	规格
7253-18	颈部造口底盘灵活正圆型 (20 个)
7254-18	颈部造口底盘灵活椭圆型 (20个)
7331-18	颈部造口底盘灵活加大型 (20个)
7255-18	颈部造口底盘柔肤正圆型 (20个)
7256-18	颈部造口底盘柔肤椭圆型 (20个)
7332-18	颈部造口底盘柔肤加大型 (20个)
7289-18	颈部造口底盘深凸稳固型 (15个)
7265-18	颈部造口底盘微凸加固型 (20个)

## 9. 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。

## 10. 备案人 / 生产企业

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

备案人住所 / 生产企业住所：Kraftgatan 8, SE-242 35 Hörby, Sweden

备案人联系方式 / 生产企业联系方式

+46 (0415 198 00 • info@atosmedical.com

生产地址：Kraftgatan 8, SE-242 35 Hörby, Sweden

原产地：瑞典

## 11. 使用说明书版本

说明书版本编号：11617，说明书修订日期：2024-09-04

## 12. 处置

在处置用过的医疗器械时，请始终遵循有关生物危害的医疗实践和国家要求。

## 13. 事故报告

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。

## 14. 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](http://www.coloplast.com.cn)

## 15. 生产日期和使用期限

见包装标签产品有效期：三年

## 16. 医疗器械备案号

备案编号：国械备 20230011

## 17. 医疗器械技术要求编号

产品技术要求编号：国械备 20230011

## 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



Keep away from sunlight and keep dry; 怕晒,怕雨



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



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

**XXXXX, NN**  
**YYYY-MM-DD**

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

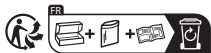
YYYY-MM-DD = Date of issue; 發行日期; 发布日期

**UK\***  
**CA**

UK Conformity Assessed (UKCA) marking; 英國合格評定 (UKCA) 標誌; 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

\* Not applicable for China



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

\* Not applicable for China





11617, 01  
2024-09-04

**Atos**  
atosmedical.com



Atos Medical AB  
Kraftgatan 8, SE-242 35 Hörby, Sweden  
Tel: +46 (0)415 198 00 • [info@atosmedical.com](mailto:info@atosmedical.com)

Atos and the Atos logo are trademarks of Coloplast A/S.  
© 2024 Coloplast A/S. All rights reserved.