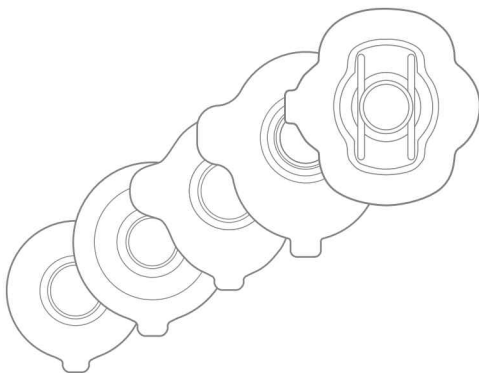
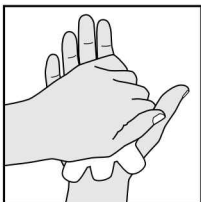


PROVOX[®] Adhesives

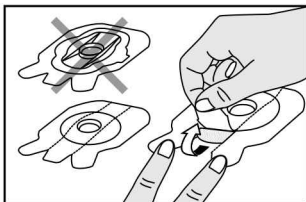


1. StabiliBase, StabiliBase OptiDerm

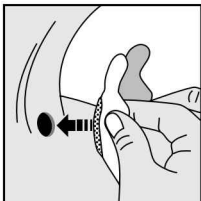
1.1



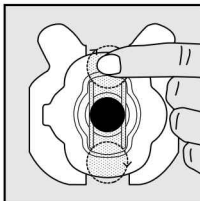
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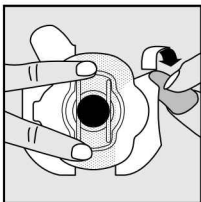
1.3



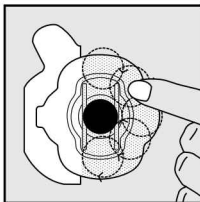
1.4



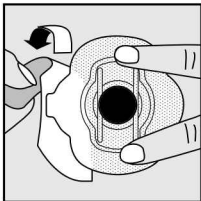
1.5



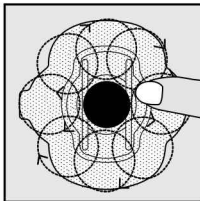
1.6



1.7

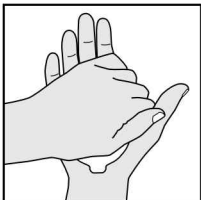


1.8

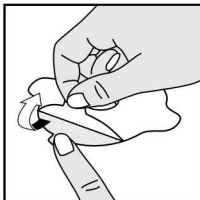


2. FlexiDerm, Regular, XtraBase, OptiDerm

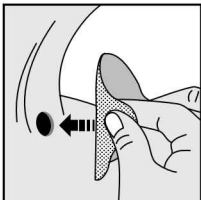
2.1



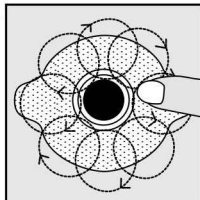
2.2



2.3



2.4



Intended use

The 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.

WARNINGS

- The adhesive may irritate the skin. Stop using the adhesive if skin irritation develops and consult your clinician.
- Do not use the Provox Adhesives during radiotherapy that is delivered to the area covered by the adhesive. Consult your clinician before you resume use of the adhesive after radiation therapy.
- Reuse will affect performance and may cause transfer of micro-organisms leading to infections.
- Only use genuine Provox devices intended for use with Provox Adhesives. Other devices may cause personal injury or damage to the products.

Instructions for use

Preparation

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.

Application

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.

Removal

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.

CAUTION:

- 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.

Disposal

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

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.

DEUTSCH

Verwendungszweck

Bei den Basisplatten Provox Adhesive handelt es sich um Einmalprodukte für laryngektomierte Patienten, die über ein Tracheostoma atmen. Die Basisplatten werden an der Haut rund um das Tracheostoma angebracht, um die Komponenten des Provox HME Systems zu befestigen.

WARNHINWEIS

- Die Basisplatte kann die Haut reizen. Im Falle von Hautreizungen ist die Anwendung der Basisplatte abbrechen und der zuständige Arzt zu konsultieren.
- Verwenden Sie die Basisplatte Provox Adhesive nicht während einer Strahlentherapie, die sich auf den von der Basisplatte abgedeckten Bereich richtet. Vor der weiteren Verwendung der Basisplatte nach erfolgter Strahlentherapie konsultieren Sie bitte den zuständigen Arzt.
- Durch Wiederverwendung wird die Funktion beeinträchtigt und es können Mikroorganismen übertragen werden, was Infektionen zur Folge haben kann.
- Verwenden Sie nur Original-Provox-Produkte, die zur Anwendung mit den Basisplatten Provox Adhesive vorgesehen sind. Andere Produkte können zu Verletzungen oder Produktbeschädigungen führen.

Gebrauchsanweisung

Vorbereitung

Überprüfen Sie die komplette Basisplatte auf Beschädigungen oder Risse. Reinigen Sie die Haut stets mit einem Provox Cleaning Towel und/oder Wasser und Seife und lassen Sie die Haut trocknen, bevor Sie die Basisplatte anbringen.