PROVOX®

Coming Home®

Figure 1

Fig.1.1

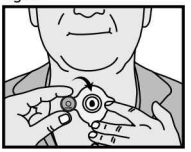


Fig.1.2

Fig.1.3

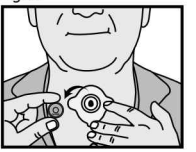


Figure 2

Fig. 2.1

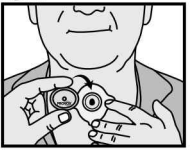


Fig. 2.2

Fig. 2.3

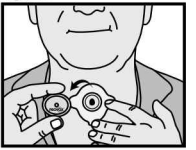
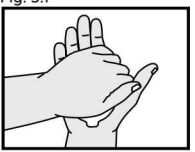


Figure 3

Fig. 3.1



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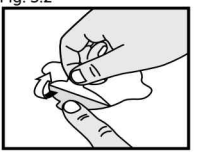

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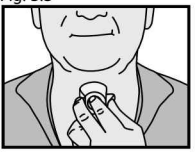

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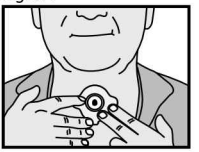


Fig. 3.5

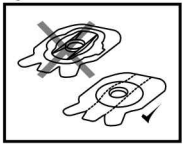


Fig. 3.6

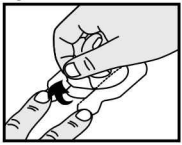


Fig. 3.7

Fig. 3.8

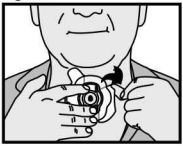


Fig. 3.9

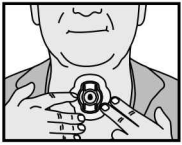


Figure 4

Fig. 4.1

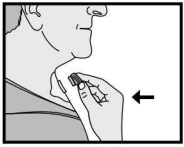


Fig. 4.2

Fig. 4.3

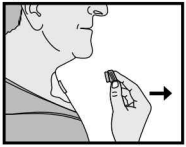


Fig.

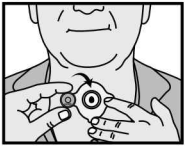


Fig. 4.5

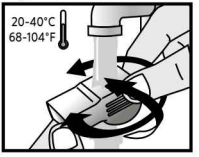
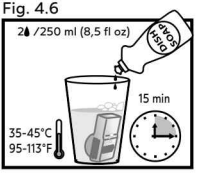


Fig. 4.6



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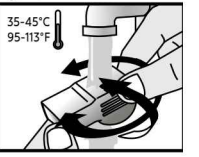


Fig. 4.8

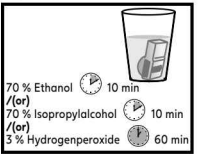
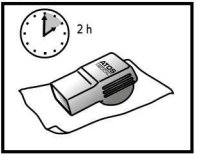


Fig. 4.9



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.

Patents and trademarks

Provox®, Provox® Luna® and Coming Home® are registered trademarks owned by Atos Medical AB, Sweden.
Micron HME™, FlexiDerm™, OptiDerm™, StabiliBase™, XtraHME™, XtraMoist™, XtraFlow™ and ShowerAid™ are trademarks of Atos Medical AB.
For information about protective rights (e.g. patents), please refer to our web page www.atosmedical.com/patents.

Intended use

Provox® Coming Home® is an assortment of products and information for newly laryngectomized persons. It provides guidance on product use, lung rehabilitation, and stoma care at home.

How to use Provox Coming Home

The products included are selected for the first days or weeks at home after a Total Laryngectomy. See instructions on how to use the different products below. Additional information that may be relevant for you can be found in the Coming Home Booklet.

Disposal

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

User assistance information

For additional help or information, please see Contact card provided.

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.

Provox® XtraHME™

Provox XtraMoist and Provox XtraFlow

Intended use

Provox XtraHME Cassette is a single use, specialized device intended for patients breathing through a tracheostoma. It is a heat and moisture exchanger (HME) that heats and humidifies inhaled air by retaining heat and moisture from exhaled air in the device. It partially restores lost breathing resistance. For patients with a voice prosthesis or surgical speech fistula it may also facilitate voicing.

How to use Provox XtraHME

Attach and remove

Place the HME in the holder of your attachment device (e.g. Provox Adhesive or Provox LaryTube) and breathe normally (Fig. 1.1).

To remove the HME, hold the attachment device in place with two fingers and remove the HME from the holder (Fig. 1.3).

Speaking with a voice prosthesis

If you have a voice prosthesis and you have been cleared to use it for speaking, the lid of Provox XtraHME can be pressed down with your finger to occlude the stoma for speaking. After releasing the finger pressure, the lid opens and you can breathe (Fig. 1.2).

CONTRAINDICATIONS

This device shall not be used by patients who are unable to handle or remove the device themselves when needed, unless the patient is under constant supervision of a clinician or a trained caregiver. For example: patients who are unable to move their arms, patients with decreased levels of consciousness, or patients with diseases that put them at a risk for unpredictable periodic loss of consciousness.

WARNING

Be careful not to exert pressure on the lid of the HME unintentionally. Unintentional closing of the lid may cause difficulty in breathing.

PRECAUTIONS

- Always test the function of Provox XtraHME prior to use. The top lid should immediately return to its open position after releasing the pressure.
- Do not disassemble Provox XtraHME since this will interfere with its proper function.
- Do not reuse Provox XtraHME or attempt to rinse it with water or any other substance. This will substantially reduce the function of the HME. It also increases the risk of potential infections since e.g. bacteria may start to grow in the foam.
- Do not use Provox XtraHME longer than 24 hours. This will increase the risk of potential infections since e.g. bacteria may start to grow in the foam.

Provox® Micron HME™

Provox Micron HME is not available in all countries. In the US and Canada, this product is available on prescription only.

Intended use

Provox Micron HME is a heat and moisture exchanger (HME) and air filtration device for laryngectomized patients. Provox Micron HME partially restores

lost breathing resistance. For patients with a voice prosthesis or surgical speech fistula it may also facilitate voicing.
Provox Micron HME is intended to be used with the attachment devices in Provox HME System.

How to use Provox Micron HME

Attach and remove

Provox Micron HME can easily be attached (Fig. 2.1) and removed (Fig. 2.3) from Provox HME System attachment devices when needed. Provox Micron HME helps to filter inhaled air through consistent normal use. Thereby, small airborne particles, e.g., bacteria, viruses, dust and pollen are restricted from passing through the device into the lungs. In order to get good protection, make sure that the seal is airtight by closing Provox Micron HME and check for leakage. **Note:** Provox Micron is not intended to be used as a Personal Protective Equipment during work that requires breathing protection.

Speaking with a voice prosthesis

If you have a voice prosthesis and you have been cleared to use it for speaking, the lid of Provox Micron HME can be pressed down with your finger to occlude the stoma for speaking. After releasing the finger pressure, the lid opens and you can breathe (Fig. 2.2).

CONTRAINDICATIONS

This device shall not be used by patients who are unable to handle or remove the device themselves when needed, unless the patient is under constant supervision of a clinician or a trained caregiver. For example: patients who are unable to move their arms, patients with decreased levels of consciousness, or patients with diseases that put them at a risk for unpredictable periodic loss of consciousness.

WARNING

Be careful not to exert pressure on the lid of the HME unintentionally. Unintentional closing of the lid may cause difficulty in breathing.

PRECAUTIONS

- Provox Micron HME provides good protection through consistent normal use, as long as there is no air leakage. However, since there are other pathways for e.g. viruses and bacteria to enter the human body, total protection can never be guaranteed.
- The same device must not be used for more than 24 hours after initial use. This can increase the risk for infection due to growth of e.g. bacteria.

- Do not wash and re-use the device. Washing the HME impairs the filtering- and HME functions.
- Do not disassemble Provox Micron HME. Disassembly will destroy its function. Do not administer medicated nebulizer treatment over the device since the medication can be deposited in the device.
- Do not use humidifiers or heated humidified oxygen over the device since the HME will become too wet.
- Replace Provox Micron HME when needed. To ensure its proper function, the same device must not be used for more than **24 hours** after initial use.

Provox® Adhesives

Provox® OptiDerm™, Provox® FlexiDerm™ and Provox® StabiliBase™

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 Provox HME System.

How to use a Provox Adhesive

Provox OptiDerm

To apply the adhesive to your skin, first make sure the skin is clean and dry. Pre-warm the adhesive between your hands to improve the adhesion. Then remove the back liner and apply Provox OptiDerm around your stoma. Gently massage the adhesive onto the skin to improve adherence (Fig. 3.1 - 3.4).

Remove Provox OptiDerm when it is loose or dirty. Carefully remove the adhesive from the skin, using the finger lift tab. **Caution:** When using Provox OptiDerm in the post-operative period or on sensitive skin, it should be removed very slowly and carefully. When cleaning the skin from e.g. residual glue, prevent particles/fluids from entering your stoma.

Provox FlexiDerm

To apply the adhesive to your skin, first make sure the skin is clean and dry. If needed, you can apply skin protection products (described below). Then remove the back liner and apply Provox FlexiDerm around your stoma. Gently massage the adhesive onto the skin to improve adherence (Fig. 3.2 – 3.4).
Remove Provox FlexiDerm when it has become loose or dirty. Carefully remove the adhesive from the skin, using the finger lift tab. An adhesive remover (described below) may be helpful for removing adhesives or glue. Always clean the skin with a Provox Cleaning Towel and/or soap and water after use of an adhesive remover. Dry the area carefully. **Caution:** When cleaning the skin from e.g. residual glue, prevent particles/fluids from entering your stoma.

Provox StabiliBase

To apply the adhesive to your skin, first make sure the skin is clean and dry. If needed, you can apply skin protection products (described below). Then remove the center piece of the back-liner (Fig. 3.5, 3.6). Apply the adhesive to the skin around your stoma (Fig. 3.7), and then remove the side pieces of the back liner (Fig. 3.8). Gently massage the adhesive onto the skin to improve adherence (Fig. 3.9).

Remove Provox StabiliBase when it has become loose or dirty. Carefully remove the adhesive from the skin, using the finger lift tab. An adhesive remover (described below) may be helpful for removing adhesives or glue. Always clean the skin with a Provox Cleaning Towel and/or soap and water after use of an adhesive remover. Dry the area carefully. **Caution:** When cleaning the skin from e.g. residual glue, prevent particles/fluids from entering your stoma.

WARNINGS

- The adhesive may irritate the skin. Stop using the adhesive if skin irritation develops and consult your clinician.
- Do not use 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 of the adhesive, by yourself or someone else, may cause transfer of micro-organisms which can lead to infections.
- Reuse may also cause reduced efficiency of the adhesive properties which can lead to air leakage during speech and reduced efficiency of the attached HME.
- Only use genuine Provox system components that are intended for use with Provox Adhesives. Other devices may cause personal injury or damage to the products.

Skin protection

Intended use

Skin protection products can improve the adhesion of Provox adhesives and protects the skin by forming a thin, protective barrier.

How to use Skin Protection products

Application:

The skin should be clean and dry prior to application of the product. Apply a uniform coating over the entire area around your stoma. Wait for the product to dry (approximately 30 seconds). If you miss an area that you intended to cover, wait until the original area of application has dried, then reapply to the missed area.
For maximum protection, an optional second coating may be applied and allowed to dry before applying the adhesive.
If the product is applied to an area with skin folds or other skin-to-skin contact, make sure that skin-contact areas are separated to allow the coating to thoroughly dry before returning to normal position.

PRECAUTIONS

- For external use only.
- Keep out of the reach of children.
- Avoid contact with eyes. In the case of accidental contact, flush eyes well with water.
- Do not apply directly to open wounds.
- Should redness or other signs of irritation appear, discontinue use.
- Hold breath while applying skin protection as inhalation can irritate the airways.
- Be careful that the liquid does not drip into the stoma.

Adhesive Remover

Intended use

Adhesive Remover is used for removal of adhesives and glue residue from skin.

How to use Adhesive Remover

Apply the product on top of the adhesive. Grasp the finger lift tab and apply more of the product at the edge and underneath the adhesive. Carefully remove the adhesive and adhesive residue from the skin. Clean the skin with Provox Cleaning Towel or water and soap afterwards.

PRECAUTIONS

- For external use only.
- Keep out of reach of children.
- Avoid contact with eyes. In the case of accidental contact, flush eyes well with water.
- Do not apply to open wounds or mucous membranes.
- Vapor may be harmful - use with adequate ventilation.
- Hold breath while applying adhesive remover as inhalation can irritate the airways.
- Be careful that the liquid does not drip into the stoma.
- Flammable. Do not use near heat, sparks or open flame.
- If swallowed, do not induce vomiting. Call physician.
- Avoid contact with painted/finished surfaces.

Provox® ShowerAid

Intended use

Provox ShowerAid is used to temporarily replace the HME during showering. The ShowerAid can be placed in all Provox appliance holders.

How to use Provox ShowerAid

Attach and remove

Prior to entering the shower, remove the HME and insert Provox ShowerAid with the opening facing down. After showering, remove Provox ShowerAid and insert an HME (Fig. 4.1 – 4.4).

Cleaning and disinfection

Clean the device after each use (Fig. 4.5 – 4.7). Disinfect monthly using 70% Ethanol or Isopropylalcohol for 10 minutes or 3% Hydrogenperoxide for 60 minutes (Fig. 4.8 – 4.9). When the device shows signs of damage, it must be discarded. Replace Provox ShowerAid at least yearly.

WARNINGS

- Single patient use only. Reuse between patients may cause cross-contamination.
- Do not bathe or swim, the device does not prevent water from entering the stoma.