The Provox evolution

The Provox legacy
In 1986, Atos Medical was founded by two Swedish brothers, one an engineer and one an entrepreneur, whose ambition to develop and produce medical devices – led to the birth of the first Provox voice prosthesis in 1990.

Through the years, Atos Medical has become a world leader in laryngology products. Today, our Provox brand has gained a reputation for high-quality products. Provox has grown into a complete system for laryngectomees, in which the core are two products – the Provox HME and the Provox voice prosthesis.

Airflow pioneers
The Provox voice prosthesis was born from the idea of offering laryngectomees better voices, in response to the growing dissatisfaction that laryngectomees expressed.

20 years after the launch of the first incarnation of Provox, Atos Medical proudly presents the third generation of indwelling prostheses, Provox Vega, developed to make speaking and cleaning even better for its users. Since entering the market, Provox Vega has proved to offer the best voicing capabilities and easiest maintenance for users all over the world.

First-class lung rehabilitation
Using an HME is key in lung rehabilitation after laryngectomy and very important in order to avoid unnecessary pulmonary deterioration. Atos Medical is a provider of HMEs since 1995 and the new Provox XtraHME is superior in humidification and airflow, is easy to occlude and offers several features for discreet usage.
Core products
Provox voice prostheses
Speciality voice prostheses
Provox HME system
HME attachments

Accessories
Voice prostheses – accessories for professionals
Voice prostheses – user accessories
Accessories for HME attachments
Accessories for tracheostoma support
Educational resources
Ordering Information

6  9  10  14  18  20  22  25  26  28
Speaking and breathing

The Provox system has been developed to meet every demand a laryngectomee might have, with voice restoration and lung rehabilitation in focus.

We offer three core product lines – the Provox voice prostheses, Provox HMEs and Provox Attachments. This strong assortment of products is continuously perfected to offer better voice qualities, airflow, and adhesive qualities, and we are now introducing Provox Vega and Provox XtraHME.

Provox® Vega™

Our finest voice prosthesis yet, with proven excellence in voice quality, in cleaning results and in low speaking effort. Read more about Provox Vega on page 6.
Provox attachment devices

The Provox System consists of a large variety of attachment devices for placing an HME in front of the stoma. Atos Medical is a pioneer in this field, and we continuously strive to develop new patient-friendly methods, all based on evidence and experience. Read more about Provox attachments on page 14.

Provox® XtraHME™

Offers enhanced airflow and humidification in a very small and discreet design. Read more about Provox XtraHME on page 10.
Provox® Vega™ – the third generation

The third generation Provox voice prosthesis is a state-of-the-art voice prosthesis and insertion device system that addresses the issues of voice quality, device maintenance and clinical comfort. The Provox Vega Voice Prosthesis is produced in three diameters and six lengths.

### Provox® Vega™ voice prosthesis

Studies have shown:

**Voice quality improvements**
- Both clinicians and Provox Vega users perceived significant improvements in voice quality.

**Effortless speaking**
- Speaking with a Provox Vega voice prosthesis was less effortful.

**Easy and effective cleaning**
- The Provox Vega users found it easy to keep the voice prosthesis clean and they perceived the cleaning to be effective.
Provox® SmartInserter™

Smooth tip
- The SmartInserter has a smooth, soft and webbed tip.

Clinical hygiene
- The SmartInserter is delivered sterile and has no loose parts, assuring hygienic insertion.

No assembly or folding
- The Provox Vega is pre-loaded inside the SmartInserter and is ready to use straight from the box.

Preferred insertion
- Clinical studies show that the SmartInserter was the clinicians’ preferred insertion method for the majority of insertions.

Highlights from clinical studies, clinician feedback
Provox Vega speech samples were perceived by clinicians in blinded ratings to be significantly:

✓ Less strained
✓ Easier to understand
✓ Sounded less effortful
✓ Had a better voice quality

Highlights from clinical studies, patient feedback
Patient perceptions

Best voice quality
- 72% Provox Vega
- 14% Other Prosthesis
- 14% Undecided

Lowest speaking effort
- 51% Provox Vega
- 29% Other Prosthesis
- 20% Undecided

Easiest to clean
- 72% Provox Vega
- 14% Other Prosthesis
- 14% Undecided

Preferred voice prosthesis
- 76% Provox Vega
- 20% Other Prosthesis
- 7% Undecided

For ordering information, please see on page 28
Provox®2

Provox2 was introduced in 1997 to meet the demands for anterograde and retrograde insertion as well as lower airflow resistance for the user. Provox2 can be inserted immediately after TE puncture (primary or secondary), without the need for temporary stenting. It can also be inserted in an anterograde manner using the single-use insertion tool, which is the preferred method. Provox2 presents more sizes (lengths) than the first Provox voice prosthesis.

Benefits:
- Low airflow resistance.
- Easy maintenance.
- Anterograde placement made possible.

Provox(1)

The original Provox voice prosthesis was launched 1990. It was a landmark in reliability, safety and voice quality. The design set the standard for all future Provox voice prostheses, the basic characteristics – the firm blue ring (the valve seat), medical grade silicone, smooth surface, flanges that offer a controlled retention force and optimal airflow for easy voicing – all continuously perfected in the following generations of Provox voice prostheses.

Benefits:
- Low airflow resistance.
- Easy maintenance.
- To be placed and replaced in a retrograde manner.
Provox® ActiValve®

Provox ActiValve is designed for those who experience short prosthesis lifetime (less than 4 – 8 weeks) caused by early leakage through the prosthesis or negative pressure in the pharynx/esophagus during swallowing or inhalation. The valve and valve-seat of the Provox ActiValve contain magnets that prevent inadvertent opening.

Benefits:
- Reduces the need for frequent replacements in a majority of users who experience short device lifetime.
- Available in three opening forces: Light, Strong and XtraStrong.

Provox® NiD™ – the home care voice prosthesis

The Provox NiD is designed to meet the demand for a Provox non-indwelling voice prosthesis. Available only in limited parts of the world.

Benefits:
- Patients may insert, remove and clean the device themselves.
- Safe – the Provox NiD is attached to a strong polypropylene cord with a safety medallion that is too wide to fall into the tracheostoma.
- Low airflow resistance.
- In-situ cleaning is possible with dedicated cleaning tools.
- Variety of sizes and lengths.
The Heat and Moisture Exchanger (HME) plays a central part in lung rehabilitation after laryngectomy. It heats and moisturizes inhaled air, something that is not done when breathing through an unprotected tracheostoma. The media inside the HME cassette traps heat and moisture from the exhaled air. This heat and moisture is then returned to the inhaled air.

The first Provox HME Cassettes were introduced in 1995. The Provox HME has set the standard, and it is the most extensively clinically tested HME for laryngectomees in the world.

**Provox XtraHME™**

We are proud to present the next generation of HME Cassettes: the Provox XtraHME. Now with even better humidification, from which many patients breathing through a tracheostoma will benefit. The Provox XtraHME is available in two versions:

**XtraMoist™** HME has capacities close to normal nasal function. The humidification is improved and the XtraMoist maintains good airflow for easy breathing.

**XtraFlow™** HME is focusing on providing superior airflow, while still getting good humidification.

When to use XtraFlow or XtraMoist

**XtraMoist**

For accustomed users and immediately after a total laryngectomy.

**XtraFlow**

For non-acclimated users and during exercise.
Benefits of using an HME
Many users experience the following:

- Reduced mucus production
- Reduced coughing
- Improved pulmonary function
- Improved speech
- Hygienic stoma occlusion
- Improved quality of life

Patient feedback
HME Normal user:
How do you perceive XtraMoist HME?

- Better: 61%
- Worse: 9%
- No difference: 30%

HME HiFlow user:
How do you perceive XtraFlow HME?

- Better: 76%
- Worse: 4%
- No difference: 20%

For ordering information, please see on page 28
Provox® FreeHands HME® – for hands-free speech

The Provox FreeHands HME combines a Heat and Moisture Exchanger (HME) with an easy-to-operate automatic tracheostoma valve that allows speaking without manual stoma closure.

The Provox FreeHands HME is best used with a Provox XtraBase self-adhering base plate, but it can also be attached to any other Provox Adhesive base plate, a Provox LaryButton or a Provox LaryTube cannula with ring (which itself is held by a base plate). If needed, by simply rotating the Provox FreeHands HME while it is in place, a user can turn the automatic speech function on or off.

To match individual needs, the Provox FreeHands HME is available with three easy-to-replace membranes, each with different closing resistances.

The FreeHands HME cassettes are specially made to fit the FreeHands valve unit (housing) or the HME Cap, and they are different from the regular HME cassettes.

Benefits:
• Allows speaking without manual stoma closure.
• Minimal handling and maintenance, e.g. using the enclosed cleaning container.
• Discreet design: small and with side openings, allowing the user to cover the Provox FreeHands HME with clothing.

Note: Do not use the FreeHands HME cassettes separately!
**Provox® Micron HME – viral and bacterial filtration**

Provox Micron HME is the world’s first HME for laryngectomees that is combined with an highly effective bacterial and viral filter. Without compromising pulmonary rehabilitation and user friendliness, we have combined our HME with a very effective electrostatic filter, which filters charged particles.

Provox Micron HME, addresses the risk of transfer of airborne pathogens and could be valuable for laryngectomees in need of improved health safety. The integral filter helps to filter small airborne particles, e.g. bacteria, viruses, dust and pollen. The HME part of the Micron is clinically proven to improve the airway climate. It is compatible with the Provox System, and it can be attached by using the Provox Adhesive Baseplates, Provox LaryTube and Provox LaryButton.

**Benefits:**
- Same benefits as for Provox HME.
- High filtration efficiency of bacteria and viruses (≥99.8%).
- Fits all the attachment devices in the Provox System.

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**TrachPhone® – for users of tracheostomy or endotracheal tubes**

TrachPhone is an HME that is intended for spontaneously breathing patients having either a tracheostomy or an endotracheal tube.

TrachPhone contains a valve with a spring that can easily be occluded with a finger to facilitate speech. After releasing the finger, the valve will open automatically. TrachPhone also has a valve for forced inspiration/expiration or suctioning, and a built-in oxygen port.

Connections: 15 mm female connector for ET tube or tracheostomy tube. 4 mm connector for supplemental oxygen supply, use appropriate size of oxygen tubing.

**Benefits:**
- Enables speech for users of tracheostomy or endotracheal tubes.
- Integrated oxygen connector.
- Light-weight, only 2.9 g, placing minimal stress on tracheostomy or tracheal tube.
- Small and compact design.
- Integrated suction port.
- In case of coughing or blockage, a suction port acts as a relief valve.
- Standard 15 mm connector complies with EN 1281-1.
HME attachments

Differences in anatomy and skin types are relevant when finding a suitable means of attaching the HME of choice. In addition, the chosen HME may also indicate what type of attachment to use. The Provox System offers a complete range of attachment possibilities, for finding the optimal combination.

Provox® XtraBase®

Provox XtraBase is a convex, self-adhering base plate designed specifically for deep and/or irregular stomas. The adhesive properties of the popular FlexiDerm base plate and Provox XtraBase are similar. But thanks to its special shape and controlled elasticity, Provox XtraBase helps in many cases to achieve an optimized fit and even longer durability. For patients with deep stomas or users of Provox FreeHands HME.

- Especially suitable for hands-free speaking valves.
- Improves fitting in deep or irregular stomas.
- Strong adhesion - similar to FlexiDerm.
OptiDerm™
Intended for patients with sensitive skin or skin that has not yet healed properly, e.g. after surgery and/or irradiation. OptiDerm absorbs moisture, is gentle to the skin and requires less frequent replacement. Average durability: 36 hours.

Benefits:
• Can be placed immediately post-op.
• Skin-friendly, for irritated skin.
• Gentle and durable.

FlexiDerm™
Very flexible and has the strongest adhesive properties. FlexiDerm is especially suitable for patients with a deep and/or irregular stoma, or those who prefer a very soft and flexible adhesive. Due to the type of glue used, any residual glue should be removed with a suitable skin cleanser. Average durability: 48 hours.

Benefits:
• Flexible and strong.
• Strongest adhesive properties.
• Normally the longest-lasting.

Regular
A transparent adhesive. This adhesive is recommended for persons with a regular (normal) stoma and skin. Average durability: 24 hours.

Benefits:
• Leaves less residual glue.
• Easier to handle.
• More comfortable to use.

NB: for maximum satisfaction, ensure that the user knows how to prepare the stoma and take care of the skin. See page 22 for accessories.
Provox® LaryButton™

The Provox LaryButton is a short, self-retaining silicone tracheal cannula. It maintains the opening of the tracheostoma and acts as a holder e.g. for HME cassettes and the Provox FreeHands HME. Once inserted, it remains in position and it also helps to prevent the tracheostoma from shrinking.

If needed, the wings that are attached to the outer rim of the Provox LaryButton may be used to secure the button with a Provox LaryClip or a Provox TubeHolder in order to avoid accidental dislodgement.

- Attaches tightly to the stoma thanks to its conical shape.
- Well suited for patients with a circumferential skin fold around the tracheostoma (a so-called “lip”).
- Beneficial for sensitive stomas due to the soft silicone and atraumatic shape.
- Compatible part of the Provox system.

To allow for proper selection and sizing, the Provox LaryButton Sizer Kit contains sterilizable and reusable buttons for individual fitting.
**Provox® LaryTube™**

The Provox LaryTube is a soft laryngectomy tube. A key feature that distinguishes the Provox LaryTube from traditional laryngectomy tubes is that it can hold a Provox HME cassette and/or Provox FreeHands HME. For use with or without a voice prosthesis.

Available in three versions:
- **The Fenestrated version**, designed for use in combination with a voice prosthesis. Several small fenestrations are preferred over a single large one in order to prevent locking and accidental dislocation of the voice prosthesis.
- **The Standard version**, made for use without a voice prosthesis or when customized fenestration with the FenestrationPunch is preferred.
- **The LaryTube with Ring version**, to be worn with an adhesive base plate. Recommended if a cannula is used only during the night, or with the Provox FreeHands HME to support the stoma seal.

- Allows for immediate post-operative use of an HME.
- Compatible with all Provox HMEs.
- No adhesive required, which makes the LaryTube suitable for users with sensitive skin or during the radiotherapy period.
- Maintains an open stoma in patients with shrinking stomas.

To allow for proper selection and sizing, the Provox LaryTube Sizer Kit contains sterilizable and reusable tubes for individual fitting.

The Provox LaryTubes and Provox LaryButtons can be secured with Provox LaryClip and Provox TubeHolder. See page 25.

For ordering information, please see on page 29.