The Provox® System

Catalog 2008/2009

Let's talk about life®

ATOS MEDICAL

Past experience, continued innovations

At Atos Medical, we are always working with one foot in the past and one in the present, focusing on the future. We believe that our products need to be continuously tested and evaluated in order to know what to improve and what further demands the market might have. Everything we do is based on Evidence and Experience and that is how we maintain our leading position. The past is the key to our future actions.

We also act on present issues; designing and testing new products that fit with today's increasing demands for products that restore quality of life and technologies that address changing environmental conditions. As always, our development leads to the launch of sophisticated products that are backed by documentation, testing and adherence to high quality and performance standards.

Tommy Hedberg
CEO of Atos Medical

Evidence & Experience™

Contents

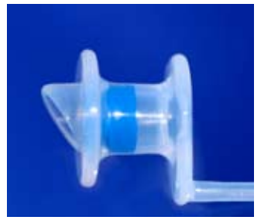
Provox® Voice Prostheses

The original Provox voice prosthesis was developed in 1988 to provide for low airflow resistance and extended device lifetime. The second-generation Provox prosthesis (Provox®2) was introduced in 1997. Based on the original Provox design, Provox2 allows bi-directional insertion, i.e. either anterograde insertion through the stoma or retrograde insertion through the pharynx and mouth.

The Provox ActiValve® is intended to help people who experience short prosthesis lifetime as the result of various biological conditions. Similarly to the Provox2, the Provox ActiValve allows for bi-directional replacement.

Provox® Voice Prosthesis (“Provox 1”)

The original Provox voice prosthesis is supplied with a Provox Guidewire for retrograde insertion.



Order information	Size	Rx	REF
Provox (1)	4.5 mm	Rx	7208
Provox (1)	6 mm	Rx	7200
Provox (1)	8 mm	Rx	7201
Provox (1)	10 mm	Rx	7202
Provox (1) Starter Kit	see right	Rx	7220

Sterile, for single use.
Includes: 1 Provox Voice Prosthesis, 1 Provox Guidewire, 1 Scalpel, 1 Provox Brush.

Provox® (1) Starter Kit

- 1 each of Provox Voice Prosthesis 6, 8, 10 mm (7200, 7201, 7202)
- 1 Provox Trocar (7203)
- 1 Provox Pharynx Protector (7210)
- 1 Set of Provox Brushes – 6 pcs (7204)
- 1 Provox Plug (7205)

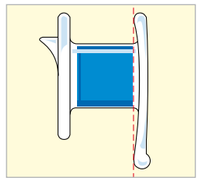
From the Department of Otolaryngology -Head and Neck Surgery, Helsinki University Central Hospital, Helsinki, Finland:

“We performed a retrospective chart review of 95 patients (88 men and 7 women; mean age, 63.5 years) who underwent insertion of a voice prosthesis in the period 1992 to 2002. Eighty-one percent (77/95) of the patients underwent a primary prosthesis insertion at the time of laryngectomy. A head and neck surgeon, a laryngologist, and a speech therapist rated the long-term tracheoesophageal speech of 78% (74/95) of the patients as good or average. The main causes for replacement of the device were obstruction, leakage or inadequate size of the prosthesis, and granulation or leakage around the fistula. According to our 10-year experience, use of the Provox prosthesis is an effective method of postlaryngectomy voice rehabilitation, and it continues to be our preferred method of voice restoration in the majority of cases.”

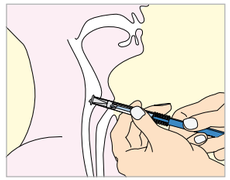
Makitie AA, Niemensivu R, Juvas A, Aaltonen LM, Back L, Lehtonen H: Postlaryngectomy voice restoration using a voice prosthesis: a single institution’s ten-year experience. Ann Otol Rhinol Laryngol. 2003 Dec;112(12):1007-10.

Provox®2 Voice Prosthesis

Provox2 is a low-resistance, indwelling silicone voice prosthesis that can be inserted:
- immediately after TE puncture (primary or secondary), without the need for temporary stenting. This retrograde insertion method is to be performed by a physician using the Provox Guidewire.
- as a replacement prosthesis for the Provox(1) or other voice prosthesis.
- in an anterograde manner using the single-use insertion tool. This preferred method can be performed by any trained health care professional.



The slightly concave shape of the tracheal flange of the Provox2 voice prosthesis helps ensure a proper fit even if the fistula size changes slightly.



The stable flanges of the Provox2 voice prosthesis facilitate immediate confirmation of whether the device is correctly in place.

Features

- **low airflow resistance**
- **easy maintenance**
- **safe placement**
- **detectable in x-ray**
- **high success rate**

Provox®2 Starter Kit contains:

1 each of Provox2 Voice Prostheses (7216-7219 and 7221)
1 Provox Trocar (7203)
1 Provox Pharynx Protector (7210)
1 Provox Guidewire (7215)
1 Provox Measure (7270)
1 Set of Provox Brushes – 6 pcs (7204)
1 Provox Plug (7205)
1 Provox Flush (7206)
1 Provox2 Training Kit (7222)

Order information	Size	Rx	REF
Provox2	4.5 mm	Rx	7216
Provox2	6 mm	Rx	7217
Provox2	8 mm	Rx	7218
Provox2	10 mm	Rx	7219
Provox2	12.5 mm	Rx	7221
Provox2	15 mm	Rx	7224
Provox2 Training Kit			7222
Provox2 Starter Kit	see left	Rx	7223

Sterile, for single use. Includes: 1 Provox2 Voice Prosthesis, 1 single-use insertion tool, 1 Provox Brush.
A Provox2 Training Kit is available to practice anterograde insertion.

From the long-term prospective clinical trial of Provox ActiValve at the Netherlands Cancer Institute, Amsterdam:

"Prototype testing and the long-term clinical trial confirmed that the new valve material remained free of Candida growth and that the use of magnets can prevent inadvertent opening of the valve during swallowing and/or deep inhalation.

This resulted in a highly significant increase in device lifetime in the 18 laryngectomized patients in the prospective trial (14-fold increase on average, range 3-39-fold; p < 0.001). Lubrication with special medical-grade fluoridated silicone oil is favorable in patients who experience possible adhesion of the valve to the valve seat."

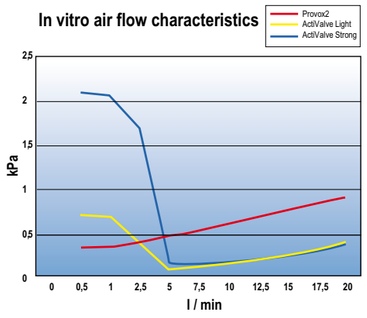
Literature reference
Hilgers FJM, Ackerstaff AH, Balm AJM, Van Den Brekel MWM, Tan IB, Persson J-O: A New Problem-solving Indwelling Voice Prosthesis, Eliminating the Need for Frequent Candida- and "Underpressure"-related Replacements: Provox ActiValve. Acta Otolaryngol (Stockh.), 2003 Oct; 123:972-979.

Provox ActiValve®

Provox ActiValve is designed for those who experience **short device lifetime** of Provox(1) or Provox2, caused by:
• early leakage through the prosthesis due to excessive candida growth.
• inadvertent opening (and thus leakage) of the valve during swallowing or deep inhalation as the result of negative pressure building in the esophagus and/or thorax.
To help prevent excessive candida overgrowth, the valve flap and valve seat of the Provox ActiValve prosthesis are made of a **candida resistant** material. To help **prevent inadvertent opening,** the valve and valve-seat of the Provox ActiValve contain magnets which are available in three opening forces: Light, Strong and XtraStrong.
The Provox ActiValve should be considered after a patient has experienced approximately 5 consecutive short durations of use of Provox (1) or Provox2 prostheses (shorter than 4 to 8 weeks).
Provox ActiValve is NOT intended for primary or secondary insertion at the time of surgery.

Order information	Size	Rx	REF
Provox ActiValve Light	4.5 mm	Rx	7150
Provox ActiValve Light	6 mm	Rx	7151
Provox ActiValve Light	8 mm	Rx	7152
Provox ActiValve Light	10 mm	Rx	7153
Provox ActiValve Light	12.5 mm	Rx	7154
Provox ActiValve Strong	4.5 mm	Rx	7160
Provox ActiValve Strong	6 mm	Rx	7161
Provox ActiValve Strong	8 mm	Rx	7162
Provox ActiValve Strong	10 mm	Rx	7163
Provox ActiValve Strong	12.5 mm	Rx	7164
Provox ActiValve XtraStrong	4.5 mm	Rx	7165
Provox ActiValve XtraStrong	6 mm	Rx	7166
Provox ActiValve XtraStrong	8 mm	Rx	7167
Provox ActiValve XtraStrong	10 mm	Rx	7168
Provox ActiValve XtraStrong	12.5 mm	Rx	7169
Provox ActiValve Lubricant (replacement)		-	7149

Non sterile, for single use.
Includes: 1 Provox ActiValve Voice Prosthesis, 1 single-use insertion tool, 2 Provox Brush, 1 Provox ActiValve Lubricant, 1 User Card.



Provox ActiValve Light, in case of early candida overgrowth. Provox ActiValve Strong, in case of negative pressure in the PE segment.

Provox® NID™ Voice Rehabilitation System

For nearly two decades, clinicians from all over the world have known that our indwelling Provox voice prosthesis offers excellent function, reliability, and safety. However, many of you have asked for a convenient version that patients can insert, remove, and clean themselves while preserving key features and the proven quality of the Provox.

You asked and we listened. Atos Medical is pleased to offer the Provox NID.

Provox® NID™ Voice prosthesis

- **Patients may insert, remove and clean the device themselves.**
- **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 possible with dedicated cleaning tools.**
- **Variety of sizes.**

Provox NID 17 FR	Size	Rx	REF	Provox NID 20 FR	Size	RX	REF
Provox NID 17	6 mm	Rx	7101	Provox NID 20	6 mm	Rx	7111
Provox NID 17	8 mm	Rx	7102	Provox NID 20	8 mm	Rx	7112
Provox NID 17	10 mm	Rx	7103	Provox NID 20	10 mm	Rx	7113
Provox NID 17	12 mm	Rx	7104	Provox NID 20	12 mm	Rx	7114
Provox NID 17	14 mm	Rx	7105	Provox NID 20	14 mm	Rx	7115
Provox NID 17	18 mm	Rx	7106	Provox NID 20	18 mm	Rx	7116
Inserter of corresponding size included. Non sterile, ready for use. For single patient use.							

Provox® NID™ Accessories

Provox® Dilator 17 / 20

The Provox Dilator is designed to facilitate replacement and insertion of the Provox NID prosthesis. It serves to keep the fistula tract open after removal of and/or prior to the insertion of the Provox NID. Also, a small circular ridge helps to keep the Provox Dilator in place and reduces the tendency of it sliding out. Included in the Starter Kit and available separately.

Order information	Rx	REF
Provox Dilator 17	Rx	7122
Provox Dilator 20	Rx	7123
Non-sterile, ready for use. For single patient use.		

Provox® Brush

The Provox brush design is based on our long experience with indwelling Provox prostheses, and is a valuable maintenance tool for in-situ and ex-situ cleaning. Included in the Starter Kit and available separately.

Order information	Quantity	REF
Provox Brush. For use with Provox NID 20, 6-10 mm.	set of 6	7204
Provox Brush XL. Extra long version for use with Provox NID 20, 12-18 mm.	set of 6	7225
Non-sterile, ready for use. For single patient use. 7126 and 7127 have been replaced by 7204 and 7225.		

Provox® Flush 17 / 20

The Provox Flush is a dedicated maintenance device for cleaning the inner lumen of the Provox NID prosthesis by using clean water or air. Included in the Starter Kit and available separately.

Order information	Rx	REF
Provox Flush 17	Rx	7124
Provox Flush 20	Rx	7125
Non-sterile, ready for use. For single patient use.		

Provox® NID™ Storage Box

The Provox NID Storage Box helps to keep the Provox NID prosthesis and accessories clean, and fits into a normal-sized pocket for convenient storage and transport. Included in the Starter Kit and available separately.

Order information	REF
Provox NID Storage Box	7128
Non-sterile, ready for use. For single patient use.	

Provox® NID™ Starter Kit

For greater convenience and economy, all accessories are provided in a handy starter kit.

Order information	Rx	REF
Provox NID 17 Starter Kit, 6-10 mm. Containing Dilator 17; Brush (set of 6); Flush 17; Storage Box	Rx	7131
Provox NID 17 Starter Kit 12-18 mm. Containing Dilator 17; Brush XL (set of 6); Flush 17; Storage Box	Rx	7132
Provox NID 20 Starter Kit, 6-10 mm. Containing Dilator 20; Brush (set of 6); Flush 20; Storage Box.	Rx	7133
Provox NID 20 Starter Kit, 12-18 mm. Containing Dilator 20; Brush XL (set of 6); Flush 20; Storage Box.	Rx	7134
Non-sterile, ready for use. For single patient use.		

Professional Accessories

Provox® Trocar with Cannula

This instrument is used for making primary or secondary TE punctures. The Provox Trocar is preferred to a scalpel, because it **creates a round fistula** and the surrounding **tissue remains intact**. After the trocar is withdrawn, the Provox Guidewire is inserted through the cannula.

Order information	Quantity	REF
Provox Trocar	1 pc	7203
Instrument steel, non sterile, reusable, sterilizable.		

Provox® Pharynx Protector

The Provox Pharynx Protector helps **protect the pharyngeal walls** from accidental piercing during primary TE puncture. It can also reduce the risk of injury to the surgeon.

Order information	Quantity	REF
Provox Pharynx Protector	1 pc	7210
Provox Pharynx Protector O-Ring	1 pc	7209
Instrument steel, non sterile, reusable, sterilizable.		

Provox® Guidewire

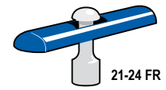
The Provox Guidewire **enables retrograde insertion** of Provox(1) and Provox2 prostheses. The tip contains a retainer slit into which the security string of the prosthesis is held. There is also a stop on the guidewire shaft to allow extraction of the old prosthesis (after the tracheal flange has been cut off). The guidewire is not intended for pulling the prosthesis into the TE-fistula; a non-toothed hemostatic forceps is recommended for this procedure.

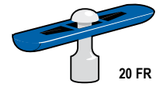
Order information	Quantity	REF
Provox Guidewire	1 pc	7215
Sterile, for single use.		

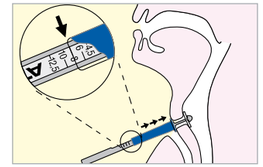
Provox® Measure

The Provox Measure is used to check the length (corresponding to **prosthesis size**) of TE fistulas. The correct prosthesis size is important to minimize the risk of complications and should always be checked when replacing a prosthesis. The single-use flanges of Provox Measure can be attached to the instrument in two different ways, facilitating measurement of fistulas made for different voice prosthesis diameters.

Note: Do not use in 16 Fr fistulas without prior dilation to at least 20 Fr!



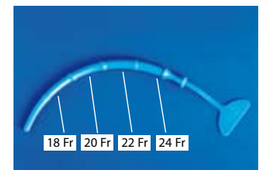




After reading the scale, the Provox Measure is removed by tilting.

Order information	Quantity	Size	REF
Provox Measure	1 pc	One size	7270
Provox Measure Flanges	5 pcs	One size	7271
Provox Measure instrument: Non sterile, reusable, sterilizable. Comes with 5 Provox Measure Flanges. Provox Measure Flanges: Non sterile, for single use.			

Provox® Dilator



The Provox Dilator is used for up sizing the diameter of a TE fistula by **stepwise dilation**
• when changing from a smaller to a larger diameter prosthesis.
• for temporary stenting of a TE- fistula; irrespective of type and diameter of the voice prosthesis used.
• in case of a shrunken fistula, i.e. after the rare event of a lost voice prosthesis.
A retention collar at the end of each section **prevents** that section **from sliding back** to the preceding thinner section.
Diameter at tip: 15 Fr (increases to 24 Fr in one device).
Steps: 18, 20, 22, 24 Fr.

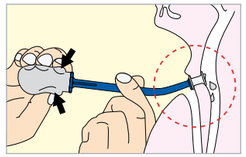
Order information	Quantity	Size	REF
Provox Dilator	1 pc	One size	7211
Silicone, non sterile, reusable, sterilizable.			

User Accessories

Once a Provox Voice Prosthesis is in place, it usually requires little care. However, daily cleaning may help maintain device function and prolong its lifetime.

Provox® Flush

The Provox Flush is a cleaning device with several attractive features.
Use both hands when using the device to ensure a watertight fit between the tip and lumen of the prosthesis.
In experimental studies, the regular use of the Provox Flush has shown **a prolongation of device lifetime** of voice prostheses, even if only used with air.



The Provox Flush can be a valuable addition to the regular use of the Provox Brush.

Features:

- **comfortable use**
- **allows flushing fresh water (under slight pressure) through the lumen of the prosthesis, thereby**
  - **helping to clean the prosthesis from debris and crusts**
  - **flushing away mucus from the pharynx and esophagus**

Order information	Quantity	Size	REF
Provox Flush	1 pc	20 Fr	7206
Non sterile, reusable. Can be boiled. For single patient use.			

An in vitro study about the use of Provox Flush. From the University of Groningen, the Netherlands:

"This study shows that use of the Provox Flush has a cleansing effect, especially on Provox2 voice prostheses, and furthermore suggests that daily airflow through voice prostheses as part of a daily maintenance scheme reduces biofilm formation and can be expected to prolong the life of these devices."

Free RH, Van der Mei HC, Elving GJ, Van Weissenbruch R, Albers FW, Busscher HJ: Influence of the Provox Flush, blowing and imitated coughing on voice prosthetic biofilms in vitro. Acta Otolaryngol. 2003 May;123(4):547-51.

Provox® Brush

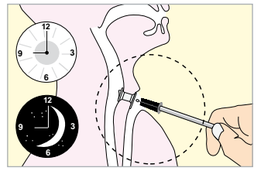
The Provox Brush is made for cleaning the inside of the Provox voice prosthesis without removing it from the TE-fistula, and works as follows:

- Insert the brush into the prosthesis and gently move it back and forth with a twisting motion.
- After removal, clean the brush with gauze.
- Repeat the procedure as often as necessary.
- After use, clean the brush with water, and store it dry for the next use.

Each brush may be used for a maximum period of 1 month. Available in two lengths.

The design of the Provox Brush has recently been updated to allow for even easier handling. New features include:

- Safety wings on the brush shaft that help prevent accidental aspiration of the Provox Brush
- Blue shaft and ball tip for improved visibility
- For improved hygiene, the Provox Brush can be boiled (max. 5 min each time) and disinfected in 70% ethanol or 2% hydrogen peroxide (max 5 min each time)
- Hexagonal rear end for improved application of the Provox Plug
- Reference number and size indication on the safety wings

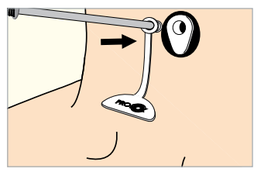


The brush shaft may be slightly bent to reach the voice prosthesis better.

Order information	Quantity	Size	REF
Provox Brush	6 pcs	4.5-10 mm	7204
Provox Brush XL	6 pcs	12-15 mm	7225
Non sterile, reusable.			

Provox® Plug

The Provox Plug is a first-aid tool for **temporarily stopping leakage** through the prosthesis. The plug is inserted into the opening of the Provox voice prosthesis with the help of the non-bristled end of a Provox Brush. The medallion end can be taped to the skin if desired. Although speech is not possible while the Provox Plug is in place, it is possible again after removal of the plug by pulling on the safety strap.



The Provox Plug can also be helpful to find out whether leakage occurs through or around the prosthesis.

Order information	Quantity	Size	REF
Provox Plug	1 pc	One size	7205
Non sterile, reusable. For single patient use. Includes one Provox Brush.			

Provox® HME System™

A heat and moisture exchanger heats and moisturizes inhaled air and restores breathing resistance to a great extent. It retains about 60% of the humidity in the airways that would otherwise be lost by breathing through an open tracheostoma. Users experience fewer problems with coughing and mucus production. This improves sleep – and the quality of life. Provox HME is based on a simple mechanism that is documented as safe and hygienic.

Provox® HME Cassette

The Provox HME cassette is the core of Atos Medical's product line for effective pulmonary rehabilitation following a total laryngectomy. It features multiple functions.
Provox HME Cassettes are available in two versions:

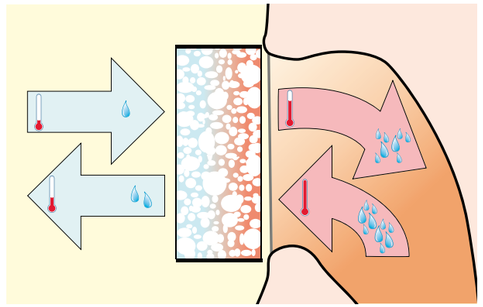
- **Normal,** intended for all-day use.
- **HiFlow,** for lower airflow resistance, e.g. for physical activity, or when adapting to one's first HME.

The Provox HME Cassette fits both the Provox Adhesive base plates and the Provox LaryTubes. The HiFlow version is recommended for the latter.

An HME is most effective when worn day and night. It usually **takes some weeks** until the pulmonary symptoms improve. During the first days of use, there may be increased mucus production.

Features:

- **heat and moisture exchanger (HME)**
- **facilitates manual stoma occlusion with the help of a simple lid/spring-valve mechanism, thereby improving speech as well as hygiene**
- **beneficial side openings that enable airtight closure of the stoma even when the HME is covered by clothing, which means that:**
  – the HME can be discreetly hidden
  – there will be no wet stains on the clothing

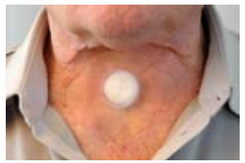


The HME acts like a condenser and helps to protect the airways.

Order information	Quantity	Rx	REF
Provox HME Cassette Normal	20 pcs	Rx	7240
Provox HME Cassette HiFlow	20 pcs	Rx	7241
Non sterile, for single use (max. 24 hours).			

Provox® HME Let's Start sample bag

Provox HME Let's start sample bag allows the user to test all different base plates and cassettes for some days, facilitating to make an informed choice for larger supplies.



The earlier the patient starts using an HME after surgery, the easier it is to adapt. HMEs are often introduced the day after surgery, and, attached by an OptiDerm base plate or a Provox LaryTube. In these cases, external humidifiers may no longer be needed.

Order information	Pieces	Products	Rx	REF
Provox HME Let's Start sample bag	1	of each Provox Adhesives (7251-7256 and 7265)	Rx	7257
	5	of each Provox HME Cassettes (7240 and 7241)		
	1	unit of Provox Cleaning Towels (7244)		
Non sterile, for single use (max. 24 hours).				

From a USA-based multi-center study about heat and moisture exchangers:

"RESULTS: Compliance was 73% (n = 59); decrease in coughing, 68%; sputum production, 73%; forced expectoration, 60%; and need for stoma cleaning, 52% of these 59 patients. Regarding daily cough expectoration frequency, a statistically significant decrease (P < 0.0001) was found between the first and last trial weeks. Regarding influence on voice quality, 46% of regular users reported improvement in intelligibility, 30% in loudness, 37% in fluency, and 40% in telephone intelligibility. Fourteen patients (19%) reported skin irritation, with discontinuation of 7 patients.…

In conclusion, the most obvious results of this study - the decrease in pulmonary symptoms and the improvement in voice quality - are a carbon copy of the results found in the several studies from the Netherlands Cancer Institute and more recently in the United Kingdom and Spain. As a whole, these results, although obvious to the study participants, were viewed together as an improvement in the postoperative quality of life.

With an improved quality of life, participants indicated they were more willing to communicate, slept better, and generally felt better about themselves and that the number of attempts to speak increased. Although not a part of the study, spouses and friends volunteered observations similar to those of the study participants.

The majority of patients were very positive about this pulmonary protection and rehabilitation system to the point they have continued to use the HME beyond the conclusion of the study. As one patient observed, "If you can replace the voice with an artificial voice prosthesis, it makes sense to replace the nose with an artificial moistening and heating device."

Ackerstaff AH, Fuller D, Irvin M, Maccracken E, Gaziano J, Stachowiak L: Multicenter study assessing effects of heat and moisture exchanger use on respiratory symptoms and voice quality in laryngectomized individuals. Otolaryngol Head Neck Surg 2003; 129:705-712.

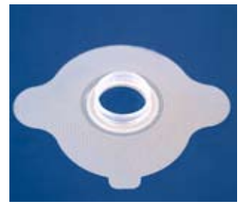
Provox® Adhesives

Provox® Adhesives

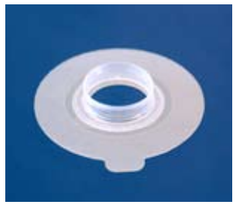
OptiDerm™ is intended for patients with sensitive skin or if the skin is not yet healed properly, e.g. after surgery and/or irradiation. OptiDerm absorbs moisture, is gentle to the skin and needs less frequent replacement. Average durability: 36 hours.

FlexiDerm™ is very flexible and has the strongest adhesive properties. It 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.

Regular is a transparent adhesive. It is less flexible and adhesive than FlexiDerm. It leaves less residual glue, is easier to handle and more comfortable to use. This adhesive is recommended for persons with a regular (normal) stoma and skin. Average durability: 24 hours.

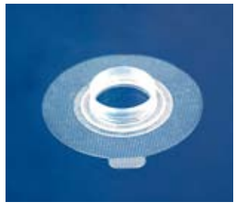


OptiDerm Oval

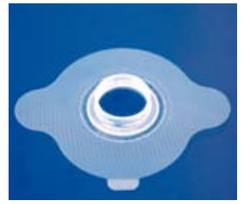


OptiDerm Round

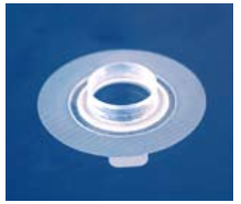
FlexiDerm Oval



FlexiDerm Round



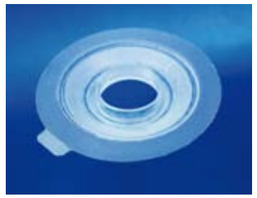
Regular Oval



Regular Round

Order information	Quantity	REF
FlexiDerm Oval	20 pcs	7254
FlexiDerm Round	20 pcs	7253
OptiDerm Oval	20 pcs	7256
OptiDerm Round	20 pcs	7255
Regular Oval	20 pcs	7252
Regular Round	20 pcs	7251
Non sterile, for single use.		

Provox® XtraBase®



Provox XtraBase is a unique, 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 alike. But thanks to its special shape and controlled elasticity, Provox XtraBase helps in many cases to achieve an optimized fit and even longer durability.

This may be most beneficial in case of

- having a deep stoma
- using an automatic tracheostoma valve (Provox FreeHands HME)

Beyond that, Provox XtraBase may improve stoma attachment in many other cases where firm skin contact is desired.

Order information	Quantity	REF
Provox XtraBase	20 pcs	7265
Non sterile, for single use.		

Accessories for tracheostoma attachment

Proper skin preparation is essential for users of automatic tracheostoma valves. Users of regular Provox HME also benefit from optimal cleaning around the tracheostoma.

Remove™

This product is used to remove medical tape and any residue left behind from the application of base plates (from silicone glue). It is recommended that Remove first be applied directly on top of a base plate where it penetrates the material (best with Provox FlexiDerm). After use, the skin is oily and has to be cleaned (water and non-oily soap or Provox Cleaning Towel) before using a new adhesive.

Order information	Quantity	REF
Remove	50 pcs	403100
Non sterile, for single use.		

Provox® Cleaning Towel

Provox Cleaning Towels remove oil from the skin. They are alcohol-based and non-perfumed.

Order information	Quantity	REF
Provox Cleaning Towel	200 pcs	7244
(20 resealable pouches of 10). Non sterile, for single use.		

Skin-Prep™

Skin-Prep improves the stickiness of our adhesive baseplates by forming a thin protective barrier on the skin.

Order information	Quantity	REF
Skin-Prep	50 pcs	420400
Non sterile, for single use.		

Provox® Silicone Glue

Provox Silicone Glue is a liquid glue for skin application that cures on contact with the air. Long-term use may cause skin irritation and does not work for everybody. The use of Skin-Prep before application of silicone glue is normally recommended.

Order information	Quantity	REF
Provox Silicone Glue	40 ml	7720
Bottle with brush cap, non sterile. For multiple application.		

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. It has many built-in features that makes it easy to use, and it requires only minimal handling and maintenance.

The Provox FreeHands HME enables voice prosthesis users to have all benefits of an HME combined with hands-free speech.

Provox® FreeHands HME®

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 or a Provox LaryTube cannula with ring (which itself is held by a base plate). All features of the Provox FreeHands HME are **designed for maximum discretion**: the small size, the transparent color and the side openings (which allow the device to be covered with clothing).

If needed, by simply rotating the Provox FreeHands HME while 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 clinician should adjust the device for the user by choosing a suitable membrane and checking the proper function of the adjustable cough-relief valve.

A dedicated cleaning container facilitates the maintenance of the reusable valve unit.

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

Note: Do not use the FreeHands HME cassettes separately!

Order information	Quantity	Rx	REF
Provox FreeHands HME (starter kit)		Rx	7710
Provox FreeHands Kit (Includes 25 pcs HME cassettes)	1 pc	Rx	7710-01
Provox FreeHands HME Cassette	(20 pcs)	Rx	7712
Provox FreeHands Speech Valve Membrane, light (white dot) (includes 1 pc 7719)	1 pc	Rx	7713
Provox FreeHands Speech Valve Membrane, medium (blue dot) (includes 1 pc 7719)	1 pc	Rx	7714
Provox FreeHands Speech Valve Membrane, strong (green dot) (includes 1 pc 7719)	1 pc	Rx	7715
Provox FreeHands Cleaning and Storage Box	1 pc		7718
Provox FreeHands HME Adjustment Kit (1 safety screwdriver and 1 membrane replacement forceps)			7719
Provox FreeHands HME Replacement Device (Valve only)		Rx	7722
Provox FreeHands HME Replacement Device (Valve with light membrane)		Rx	7716
Provox FreeHands HME Replacement Device (Valve with medium membrane)		Rx	7717
Provox FreeHands HME Replacement Device (Valve with strong membrane)		Rx	7721

Provox® FreeHands HME® Starter Kit

Provox® FreeHands HME® Starter Kit contains:

1 valve unit (housing) with a medium (blue dot) membrane
5 FreeHands HME Cassettes (7712)
2 Provox XtraBase (7265)
1 Adjustment Kit (7719)
1 Speech Valve Membrane, light (white dot) (7713)
1 Speech Valve Membrane, strong (green dot) (7715)
1 Cleaning and Storage Box (7718)
5 Skin-Prep tissues

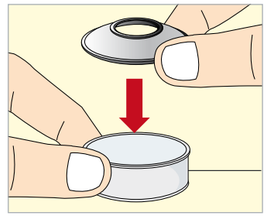
Order information	Rx	REF
Provox FreeHands HME Starter Kit	Rx	7710
Containing all above mentioned.		

Provox® HME Cap™

The Provox HME Cap is a dome-shape titanium ring that allows use of the special FreeHands HME cassettes without the Provox FreeHands HME valve unit. This can be convenient, e.g. **for night use** or if no regular Provox HME cassettes are available.

The HME Cap is snapped onto a FreeHands HME cassette and then used like a regular Provox HME cassette. Although the HME Cap lacks the benefits of a lid/spring valve mechanism and side openings (found in regular Provox HME cassettes), it does allow the stoma to be closed manually for speech.

Note: Do not use the FreeHands HME cassettes separately!



The Provox HME Cap is firmly attached to the FreeHands HME cassette and then inserted into the adhesive base plate holder. After a maximum use time of 24 hours, the cassette must be replaced.

Order information	Quantity	Rx	REF
Provox HME Cap matt titanium	1 piece	Rx	7730
Reusable, non sterile.			
Provox FreeHands HME Cassette	20 pcs	Rx	7712
Non sterile, for single use only.			

Tracheostoma Support

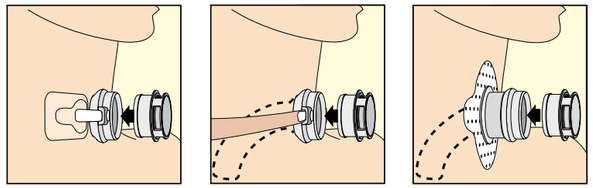
The Provox® LaryTube™ allows the use of Provox HME Cassettes and helps laryngectomees with an unstable or deep stoma to achieve pulmonary protection and rehabilitation. Provox LaryTubes also allow immediate post-operative use of an HME. Patients with highly sensitive skin, e.g. during the radiotherapy period, can use Provox LaryTube when no adhesive can be used. Provox LaryTubes are made of soft, flexible, yet sufficiently rigid silicone. The conical, anatomical shape helps to assure an optimal seal around the stoma.

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 Provox Brush (7204), normally used for cleaning Provox voice prostheses, is also suitable for cleaning the fenestrations of the LaryTube.

- The **Standard version, made for use without 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 only used during the night or with the Provox FreeHands HME to support the stoma seal.



The Standard and Fenestrated LaryTube devices are secured by Provox TubeHolder or Provox LaryClip. The LaryTube with Ring is held by an adhesive base plate.

LaryTube	Rx	Standard	ID	OD	L	REF	Fenestrated	ID	OD	L	REF	with Ring	ID	OD	L	REF
LaryTube 8/27	Rx		9.5	12.0	27	7601		-	-	-	-		-	-	-	-
LaryTube 8/36	Rx		9.5	12.0	36	7602		9.5	12.0	36	7637		9.5	12.0	36	7624
LaryTube 8/55	Rx		9.5	12.0	55	7603		9.5	12.0	55	7638		9.5	12.0	55	7625
LaryTube 9/27	Rx		10.5	13.5	27	7605		-	-	-	-		-	-	-	-
LaryTube 9/36	Rx		10.5	13.5	36	7606		10.5	13.5	36	7640		10.5	13.5	36	7626
LaryTube 9/55	Rx		10.5	13.5	55	7607		10.5	13.5	55	7641		10.5	13.5	55	7627
LaryTube 10/27	Rx		12.0	15.0	27	7609		-	-	-	-		-	-	-	-
LaryTube 10/36	Rx		12.0	15.0	36	7610		12.0	15.0	36	7643		12.0	15.0	36	7628
LaryTube 10/55	Rx		12.0	15.0	55	7611		12.0	15.0	55	7644		12.0	15.0	55	7629
LaryTube 12/27	Rx		13.5	17.0	27	7613		-	-	-	-		-	-	-	-
LaryTube 12/36	Rx		13.5	17.0	36	7614		13.5	17.0	36	7646		13.5	17.0	36	7630
LaryTube 12/55	Rx		13.5	17.0	55	7615		13.5	17.0	55	7647		13.5	17.0	55	7631
		Provox LaryTube Standard includes: 5 HiFlow Cassettes (7241).					Provox LaryTube Fenestrated includes: 5 HiFlow Cassettes (7241) and 1 Provox Brush (7204).					Provox LaryTube with Ring includes: 5 HiFlow Cassettes (7241), 1 FlexiDerm Oval (7254).				

ID = inner diameter, OD = outer diameter, L= length (in mm).

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 for other rehabilitation devices of the Provox System including the regular HME cassettes and the Provox FreeHands HME.

The main difference between the LaryButton and LaryTube is that the LaryButton is self-retaining in the stoma. Once inserted, it remains in position, taking advantage of the tissue elasticity of the tracheal opening which helps to hold it in place and provide an airtight seal. Of course it also helps to prevent the tracheostoma from shrinking.

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

The Provox LaryButton is particularly well-suited for patients with a circumferential skin fold around the tracheostoma (so called “lip”), however other users may also benefit.

To allow for proper selection and sizing, the Provox LaryButton Sizer Kit contains sterilizable and reusable buttons of all lengths and sizes.

Key features:

Effective

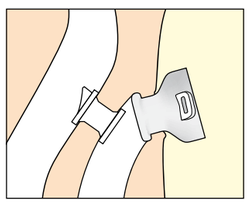
The conical shape facilitates a tight fit as it allows the Provox LaryButton to be situated close to the stoma.

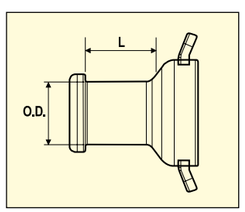
Compatible

The Provox LaryButton is intended to be worn in combination with the Provox HME System with optimal fit and stability.

Soft

The Provox LaryButton is constructed from soft silicon material and is atraumatically shaped to reduce negative side-effects such as stoma irritation and bleeding.





Order information	Rx	OD	L	REF
Provox LaryButton 12/8	Rx	12	8	7671
Provox LaryButton 14/8	Rx	14	8	7672
Provox LaryButton 16/8	Rx	16	8	7673
Provox LaryButton 18/8	Rx	18	8	7674
Provox LaryButton 12/18	Rx	12	18	7685
Provox LaryButton 14/18	Rx	14	18	7686
Provox LaryButton 16/18	Rx	16	18	7687
Provox LaryButton 18/18	Rx	18	18	7688
Non sterile, for single patient use. Maximum device lifetime 6 months.				
Provox LaryButton Sizer Kit	Rx			7690
Non sterile, reusable, sterilizable (Sizer Buttons and inner boxes).Outer tray can be cleaned in instrument washer.				
OD = outer diameter, L= length (in mm).				

Barton-Mayo Tracheostoma Button*

The Barton-Mayo Tracheostoma Button (Mayo Clinic) was developed to provide leakproof tracheostoma valve retention for near-total laryngectomy and total laryngectomy patients.

Some of the advantages of using a Barton-Mayo Tracheostoma Valve include:

Features:

- **Can be used with an HME (Heat and Moisture Exchanger).**
- **Enhances speech with “hands-free” stoma occlusion.**
- **Another option for positive stoma sealing.**
- **Reduces stoma contractions with a wide range of sizes available.**

Please note: Not for sale in Canada!

Order info	Size	Models	Diameter (mm)	Length (mm)	Rx	REF
Barton-Mayo Tracheostoma Button	9	Short Regular Long	13.5	15 22 30	Rx	ENBMB091 ENBMB092 ENBMB093
Barton-Mayo Tracheostoma Button	10	Short Regular Long	15.0	15 22 30	Rx	ENBMB101 ENBMB102 ENBMB103
Barton-Mayo Tracheostoma Button	12	Short Regular Long	17.0	15 22 30	Rx	ENBMB121 ENBMB122 ENBMB123
Barton-Mayo Tracheostoma Button	14	Short Regular Long	19.0	15 22 30	Rx	ENBMB141 ENBMB142 ENBMB143
Barton-Mayo Sizing Kit						ENBMBKIT

* Manufactured by Medical Innovations International, Inc., USA.

Conversion chart

Barton-Mayo™ Button				Provox LaryButton		
REF		Diameter	Length	REF	Diameter	Length
9	Short	13.5	15	7671	12	8
	Regular	13.5	22	7685	12	18
	Long	13.5	30			
10	Short	15.0	15	7672	14	8
	Regular	15.0	22	7686	14	18
	Long	15.0	30			
12	Short	17.0	15	7673	16	8
	Regular	17.0	22	7687	16	18
	Long	17.0	30			
14	Short	19.0	15	7674	18	8
	Regular	19.0	22	7688	18	18
	Long	19.0	30			

Provox® LaryClip™

The new patented Provox LaryClip is a two-piece system that helps to optimize the airtight attachment of the Provox LaryButton and the Provox LaryTube to the stoma.

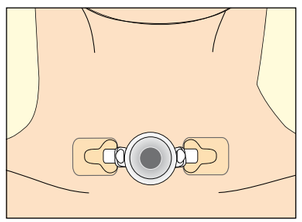
It consists of a square adhesive base and a hook-and-loop clip that allows for optimal fit to the wings of the Provox LaryButton and LaryTube.

When the adhesive Base is attached to the skin at both sides of the stoma and is eventually removed due to loss of its stickiness, the Clip part can be removed and re-attached as needed.

Key features:

- **Increases the usability of the Provox LaryButton**
- **Simple touch fasten/unfasten solution**
- **Strong FlexiDerm adhesive properties**
- **May be taped to the most optimal area to the skin around the stoma**
- **An alternative to the use of neckbands**

Order information	Quantity	REF
Provox LaryClip	1 set: 8 pcs LaryClip, 40 pcs LaryClip Base	7669
Non sterile, for single patient use.		



Other Accessories

Provox® FenestrationPunch

The Provox Fenestration Punch is used for making small fenestrations in the LaryTube at the desired location.

Order information	Quantity	REF
Provox FenestrationPunch	1 pc	7654
Non sterile, reusable, sterilizable.		

Provox® TubeBrush

New design for easier handling and improved hygiene.

Order information	Size Ø	Quantity	REF
Provox TubeBrush	9 mm	6 pcs	7660
Provox TubeBrush	13 mm	6 pcs	7661
Non sterile, reusable.			

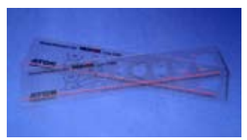
Provox® TubeHolder

The new Provox TubeHolder has been developed exclusively for use with the Provox LaryTube and Provox LaryButton.

The integrated clip connectors allow for optimal fit to the wings of the Provox LaryTube and LaryButton, which reduces the physical stress on the soft silicone material.

Order information	Quantity	REF
Provox TubeHolder	1 pc	7668
Non sterile, reusable.		

StomaMeasure



The plastic StomaMeasure is a ruler that can be used to estimate the diameter of the tracheostoma.

Order information	Quantity	REF
StomaMeasure for LaryTube	1 pc	7807
Non sterile.		

Provox® ShowerAid

The Provox ShowerAid is used with Provox Adhesives (FlexiDerm or Regular). Used as a temporary replacement for a Provox HME Cassette while taking a shower.

Note: Do not use with OptiDerm!

Order information	Quantity	REF
Provox ShowerAid	1 pc	7260
Non sterile, for single patient use, boilable. Includes: 1 Provox FlexiDerm Oval Adhesive (7254).		

Provox® BasePlate Adaptor

The Provox BasePlate Adaptor allows the attachment of other devices with ISO 15 mm standard connectors to a Provox Adhesive base plate or Provox LaryTube cannula.

Order information	Quantity	REF
Provox BasePlate Adaptor	1 pc	7263
Non sterile, for single patient use.		

Educational Material

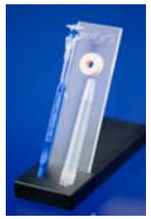
At Atos Medical, we seek to increase awareness and knowledge regarding postlaryngectomy rehabilitation options. The following material we offer as a courtesy to the dedicated professional.

Provox®2 Training Kit

Essential for practicing the Provox2 insertion/replacement method ex vivo. Contains 1 Inserter Pin, 3 Loading Tubes, 1 (demo) Provox2, 8 mm, 1 Instructions for Use.

Order information	Includes	REF
Provox2 Training Kit	1 Inserter Pin, 3 Loading Tubes, 1 (demo) Provox2 8 mm, 1 Instructions for Use.	7222

Artificial Fistula Model



Model Provox2

Model NID

For practice and demonstration of the Provox, Provox2 and Provox NID insertion and replacement methods.

Order information	REF
Artificial Fistula Model Provox2	7286
Includes: 1 Provox2 prosthesis 8 mm and 1 inserter.	
Artificial Fistula Model NID	7129
Includes: 1 Provox NID prosthesis 8 mm/17 French and 1 inserter.	

Life as a Laryngectomee Brochure

Introduction to post-laryngectomy rehabilitation. Explains the rationale behind products. Available in several languages.

Order information	REF
Life as a laryngectomee	7962US

Instructional CD:s and DVD:s

Various instructional CD:s and DVD:s.

Order information	REF
A practical guide to post-laryngectomy rehabilitation – including the Provox System (CD-ROM)	ISBN 90-75575-05-X
Provox HME DVD	7969-N
Picture CD-ROM	7819
Olfaction CD	ISBN 90-75575-07-6
Secondary Puncture DVD (Spanish/English)	Please contact us for further information
Provox Instructional Movies (NTSC)	7861-N
For Windows and Macintosh.	

Starter Kits

Provox® HME Let's Start sample bag

- **1 of each Provox Adhesives (7251-7256 and 7265)**
- **5 of each Provox HME Cassettes (7240 and 7241)**
- **1 unit of Provox Cleaning Towels (7244)**

Order information	Rx	REF
Provox HME Let's Start sample bag	Rx	7257

Provox® FreeHands HME®

- **1 valve unit (housing) with a medium (blue dot) membrane**
- **5 FreeHands HME Cassettes (7712)**
- **2 Provox XtraBase (7265)**
- **1 Adjustment Kit (7719)**
- **1 Speech Valve Membrane, light (white dot) (7713)**
- **1 Speech Valve Membrane, strong (green dot) (7715)**
- **1 Cleaning and Storage Box (7718)**
- **5 Skin-Prep tissues**

Order information	Rx	REF
Provox FreeHands HME	Rx	7710

Provox®2 Starter Kit

- **1 each of Provox2 Voice Prostheses (7216-7219 and 7221)**
- **1 Provox Trocar (7203)**
- **1 Provox Pharynx Protector (7210)**
- **1 Provox Guidewire (7215)**
- **1 Provox Measure (7270)**
- **1 Set of Provox Brushes – 6 pcs (7204)**
- **1 Provox Plug (7205)**
- **1 Provox Flush (7206)**
- **1 Provox2 Training Kit (7222)**

Order information	Rx	REF
Provox2 Starter Kit	Rx	7223

Provox® (1) Starter Kit

- **1 each of Provox Voice Prosthesis 6, 8, 10 mm (7200, 7201, 7202)**
- **1 Provox Trocar (7203)**
- **1 Provox Pharynx Protector (7210)**
- **1 Set of Provox Brushes – 6 pcs (7204)**
- **1 Provox Plug (7205)**

Order information	Rx	REF
Provox Starter Kit	Rx	7220

Prescription Devices

Caution:

United States federal law restricts devices identified herein with the symbol "Rx" to sale, distribution and use by or on order of a physician or licensed health care provider.
The availability of these devices without prescription outside the United States may vary from country to country.

User Manual and Prescriber Information

This catalog does not replace nor does it set forth the complete contents of the User Manual and/or Prescriber Information for the products in this catalog, and is not a substitute for reviewing and understanding that important information. Therefore, before prescribing and/or using any of the products included in this catalog, please review the entire contents of the respective User Manual and/or Prescriber Information.
User Manuals and Prescriber Informations are available online at www.atosmedical.com. In the United States, you may also obtain a copies by calling 1-800-217-0025, sending a Fax to 1-414-227-9033 or an e-mail to info.us@atosmedical.com, or writing to Atos Medical Inc., 11390 W. Theodore Trecker Way, West Allis, WI 53214-1135, U S A.
Information in French is available online at www.atosmedical.com.

Limited Warranty:

Atos Medical makes no warranty, either expressed or implied, as to the lifetime of the product delivered to the purchaser hereunder, which may vary with individual use and biological conditions. Further, Atos Medical makes no warranty of merchantability or fitness of the product for any particular purpose.

Please Note:

The persons depicted in this document have agreed to be photographed for purposes of illustration only.
The Provox Catalog in French is available online at www.atosmedical.com.

Patents and Trademarks:

Provox®, Provox® ActiValve®, Provox® FreeHands HME®, Provox® StomVent®, Provox® XtraBase® and Let's talk about life® are registered trademarks owned by Atos Medical AB, Sweden. Provox® HME Cap™, Provox® LaryTube™, Provox® LaryClip™ and Provox® LaryButton™ are trademarks owned by Atos Medical AB, Sweden.
Remove™ and Skin-Prep™ are trademarks owned by Smith & Nephew Inc., U.S.A.
Provox®, Provox®2, Provox ActiValve®, Provox® HME, Provox® FreeHands HME®, Provox® HME Cap™, Provox® XtraBase®, Provox® StomVent®, TrachPhone® and Provox® NID™ are protected by patents (US 5.314.470; US 5.976.151; US 5.738.095; US 6.422.235; US 5.042.468; JP 3.553.955) and other patents and patents and design registrations pending.

Reference list

Provox® Voice Prostheses

New peer-reviewed publications:

Boscolo-Rizzo P, Marchiori C, Gava A, Da Mosto MC. The impact of radiotherapy and GERD on in situ lifetime of indwelling voice prostheses. Eur Arch Otorhinolaryngol 2007 November 16 [Epub ahead of print]

Schwandt LQ, Van Weissenbruch R, Van Der Mei HC, Busscher HJ, Albers FWJ. Effect of dairy products on the lifetime of Provox2 voice prosthesis in vitro and in vivo. Head &Neck 2005; 27: 471-477

Lam PK, Ho WK, Ho AC, Ng RW, Yuen AP, Wei WI. Long-term performance of indwelling tracheoesophageal speaking valves in Chinese patients undergoing laryngectomy. Archives of Otolaryngology- Head and Neck Surgery 2005 November;131(11):954-8.

Štajner-Katušić S, Horga D, Mušura M, Globlek D. Voice and Speech after total laryngctomy. Clinical Linguistics and Phonetics 2006; 20(2/3): 195-203.

Schwandt LQ, Tjong-Ayong HJ, van Weissenbruch R, der Mei HC, Albers FW. Differences in aerodynamic characteristics of new and dysfunctional Provox 2 voice prostheses in vivo. European Archives of Otorhinolaryngology 2006 June;263(6):518-23.

Kummer P, Chahoud M, Schuster M, Eysholdt U, Rosanowski F. [Prosthetic voice rehabilitation after laryngectomy : Failures and complications after previous radiation therapy.]. HNO 2006 April;54(4):315-22

Bien S, Okla S. [Analysis of complications after surgical voice and speech rehabilitation in laryngectomized patients. Problems related to implantation and change of voice prosthesis]. Otolaryngologia Polska 2006;60(2):129-34.

Terada T, Saeki N, Toh K et al. Voice rehabilitation with Provox2 voice prosthesis following total laryngectomy for laryngeal and hypopharyngeal carcinoma. Auris Nasus Larynx 2007 March;34(1):65-71.

Gonzalez Poggioli N, Gonzalez-Botas JH, Vazquez Barro JC, Novoa J, V, Martinez VJ. [Phonation fistulas today]. Acta Otorrinolaringol Esp 2007 March;58(3):110-2.

Bremke M, Werner JA, Lichtenberger G, Folz BJ. [Chronic aspiration secondary to a Staffieri fistula: Succesful therapy with Provox voice prosthesis. Laryngorhinootologie 2007

Boscolo-Rizzo P, Zanetti F, Carpenè S, Da Mosto MC. Long-term results with tracheoesophageal voice prosthesis: Primary versus secondary TEP. European Archives of Otorhinolaryngology 2008 Jan; 265(1): 73-77.

Padhya TA, Athavale SM, Morgan JM, McCaffrey TV. An alternative approach for secondary tracheoesophageal puncture in the difficult laryngectomy neck. The Laryngoscope 2008 Feb; 118(2): 266-269.

Soolsma J, Van Den Brekel MW, Ackerstaff AH, Malm AJ, Tan B, Hilgers FJ. Long-term results of Provox ActiValve, solving the problem of frequent Candida- and "Underpressure"-related voice prosthesis replacements. The Laryngoscope 2008 Feb; 118(2): 252-257.

Ramalingam WVBS, Chikara D, Rajagopal G, Mehta AR, Sarkar S. Tracheo-esophageal puncture (TEP) for voice rehabilitation in laryngectomized patients Blom-Singer vs Provox: Our experience. Medical Journal of the Armed Forces India 2007; 63(1): 15-18.

Selected earlier publications:

Nagarkar AN, Gupta AK: A comparative analysis of speech in postlaryngectomised cases. Gazz Med Ital Arch Sci Med. 2005: 164/3 (191-194)

Ng RW, Lam P, Wong BY. Insertion of Provox2 voice prosthesis using the anterograde technique immediately after the secondary tracheoesophageal puncture. J Laryngol Otol. 2005 Dec;119(12):988-90.

Markowski J, Gierek T, Paluch J, Wardas P: The use of the vocal prosthesis Provox 2 for speech rehabilitation after total laryngectomy Otolaryngol Pol. 2005;59(3):373-7. [Article in Polish]

Hancock K, Houghton B, Van As-Brooks CJ, Coman W: First clinical experience with a new non-indwelling voice prosthesis (Provox NID) for voice rehabilitation after total laryngectomy. Acta Otolaryngol. 2005 Sep;125(9):981-90.

Morshed K, Golabek W, Szymanski M, Olszanski W: Speech rehabilitation using Provox voice prosthesis. Otolaryngol Pol. 2005;59(2):225-8. [Article in Polish]

Demir D, Suoglu Y, Emin H, Guven M, Kiyak E: Factors that affect in situ lifetime of Provox voice prosthesis. Kulak Burun Bogaz Ihtis Derg. 2004;13(5-6):126-31. [Article in Turkish]

Ameye D, Honraet K, Loose D, Vermeersch H, Nelis H, Remon JP: Effect of a buccal bioadhesive nystatin tablet on the lifetime of a Provox silicone tracheoesophageal voice prosthesis. Acta Otolaryngol. 2005 Mar;125(3):304-6.

Kummer P, Chahoud M, Schuster M, Eysholdt U, Rosanowski F: Prosthetic voice rehabilitation after laryngectomy Failures and complications after previous radiation therapy. HNO. 2005 May 4; [Epub ahead of print] [Article in German]

Globlek D, Simunjak B, Ivkic M, Hedjever M: Speech and voice analysis after near-total laryngectomy and tracheoesophageal puncture with implantation of Provox 2 prosthesis. Logoped Phoniatr Vocol. 2004;29(2):84-6.

Trussart C, Lawson G, Remacle M: Voice prostheses: long-term follow-up retrospective study (three- to sixteen-year follow-up of 22 patients). Rev Laryngol Otol Rhinol (Bord). 2003;124(5):299-304.

Scheuermann K, Delank KW: Perforation of the esophagus with a mediastinal abscess. HNO. 2005 Jan;53(1):66-70. [Article in German]

Makitie AA, Niemensivu R, Juvas A, Aaltonen LM, Back L, Lehtonen H: Postlaryngectomy voice restoration using a voice prosthesis: a single institution's ten-year experience. Ann Otol Rhinol Laryngol. 2003 Dec;112(12):1007-10.

Hilgers FJ, Ackerstaff AH, Balm AJ, Van den Brekel MW, Bing Tan I, Persson JO: A new problem-solving indwelling voice prosthesis, eliminating the need for frequent Candida- and "underpressure"-related replacements: Provox ActiValve. Acta Otolaryngol 2003 Oct;123(8):972-9.

Free RH, Van der Mei HC, Elving GJ, Van Weissenbruch R, Albers FW, Busscher HJ: Influence of the Provox Flush, blowing and imitated coughing on voice prosthetic biofilms in vitro. Acta Otolaryngol 2003 May;123(4):547-51.

Op de Coul BMR, Hilgers FJM, Balm AJM, Tan IB, van den Hoogen FJA, van Tinteren H: A decade of post-laryngectomy vocal rehabilitation in 318 patients: A single institution's experience with consistent application of Provox® indwelling voice prostheses. Arch Otolaryngol Head Neck Surg 2000 Nov;126(11):1320-8.

BalleVH, Rindsø L, Thomsen JC. Primary speech restoration at laryngectomy by insertion of voice prosthesis – 10 years experience. Acta Otolaryngol 2000; Suppl 543:244-245.

Ahmad I, Kumar BN, Radford K, O'Connell J, Batch AJG: Surgical voice restoration following ablative surgery for laryngeal and hypopharyngeal carcinoma. J Laryng Otol, Jul 2000; 114:522-525.

Ackerstaff AH, Hilgers FJ, Meeuwis CA, van der Velden LA, van den Hoogen FJ, Marres HA, Vreeburg GC, Manni JJ: Multi-institutional assessment of the Provox®2 voice prosthesis. Arch Otolaryngol Head Neck Surg 1999 Feb;125(2):167-73.

Laccourreye O, Menard M, Crevier-Buchman L, Couloigner V, Brasnu D: In situ lifetime, causes for replacement, and complications of the Provox® voice prosthesis. Laryngoscope 1997 Apr;107(4):527-30.

Aust MR, McCaffrey TV: Early speech results with the Provox® [1] prosthesis after laryngectomy. Arch Otolaryngol Head Neck Surg 1997 Sep;123(9):966-8.

Hilgers FJM, Ackerstaff AH, Balm AJM, Tan IB, Aaronson NK, Persson JO. Development and clinical evaluation of a second-generation voice prosthesis (Provox®2) designed for anterograde and retrograde insertion. Acta Otolaryngol 1997; 117: 889-896.

Hilgers FJM, Balm AJM: Long-term results of vocal rehabilitation after total laryngectomy with the low-resistance, indwelling Provox® voice prosthesis. Clin. Otolaryngol.1993, 18:517-523.

Hilgers FJM, Cornelissen MW, Balm AJM. Aerodynamic characteristics of the Provox® low-resistance, indwelling voice-prosthesis. Eur Archs ORL 1993; 250: 375-378.3.

Hilgers FJM, Schouwenburg PF. A new low-resistance, self-retaining prosthesis (Provox®) for voice rehabilitation after total laryngectomy. Laryngoscope 1990; 100, 1202-1207.

Provox® HME and Provox FreeHands HME

New peer-reviewed publications:

Hamade, R., Hewlett, N., & Scanlon, E. (2006). A quantitative and qualitative evaluation of an automatic occlusion device for tracheoesophageal speech: the Provox FreeHands HME. Clin Linguist Phon., 20, 187-193.

Hilgers, F. J. & Ackerstaff, A. H. Development and evaluation of a novel tracheostoma button and fixation system (Provox LaryButton and LaryClip adhesive) to facilitate hands-free tracheoesophageal speech. Acta Otolaryngologica 2006 Dec; 126(11): 1218-1224

Zuur JK, Muller SH, Sinaasappel M. Hart GA, Van Zandwijk N, Hilgers FJ. Influence of heat and moisture exchanger respiratory load on transcutaneou oxygenation in laryngectomized individuals: a randomized cross-over study. Head & neck 2007 Dec; 29(12): 1102-1110

Zuur JK, Muller SH, De Jongh FH, Vand Der Horst MJ, Shehata M, Van Leeuwen J, Sinaasappel M, Hilgers FJ. A newly developed tool for intra-tracheal temperature and humidity assessment in laryngectomized individuals: the Airway Climate Explorer (ACE). Medical & Biological Engineering & Computing 2007 Aug; 45(8):737-745. Epub 2007 Jul 13.

Lorenz KJ, Ackerstaff AH, Hilgers FJM, Maier H. Hands-free speech after surgical voice rehabilitation with a Provox® voice prosthesis: experience with the Provox® Freehands™ HME tracheostoma valve system. European Archives of Otorhinolaryngology 2007 Feb; 264(2):151-157.

Selected earlier publications:

FJM Hilgers, AH Ackerstaff. Development and evaluation of a novel tracheostoma button and fixation system (Provox LaryButton and LaryClip adhesive) to facilitate hands free tracheoesophageal speech. Acta Otolaryngol (Stockh), in press.

Op de Coul BM, Ackerstaff AH, van As-Brooks CJ, van den Hoogen FJ, Meeuwis CA, Manni JJ, Hilgers FJ. Compliance, quality of life and quantitative voice quality aspects of hands-free speech. Acta Otolaryngol. 2005 Jun;125(6):629-37.

Zuur JK, Muller SH, de Jongh FH, van Zandwijk N, Hilgers FJ: The physiological rationale of heat and moisture exchangers in post-laryngectomy pulmonary rehabilitation: a review. Eur Arch Otorhinolaryngol. 2006 Jan;263(1):1-8. Epub 2005 Jul 7.

Tervonen H, Back L, Juvas A, Rasanen P, Makitie AA, Sintonen H, Roine RP, Vilkman E, Aaltonen LM: Automatic speaking valve in speech rehabilitation for laryngectomized patients. Eur Arch Otorhinolaryngol. 2005 Oct;262(10):816-20. Epub 2005 Mar 1

Ackerstaff AH, Fuller D, Irvin M, Maccracken E, Gaziano J, Stachowiak L: Multicenter study assessing effects of heat and moisture exchanger use on respiratory symptoms and voice quality in laryngectomized individuals. Otolaryngol Head Neck Surg. 2003 Dec;129(6):705-12

Hilgers FJ, Ackerstaff AH, Van As CJ, Balm AJ, Van den Brekel MW, Tan IB: Development and clinical assessment of a heat and moisture exchanger with a multi-magnet automatic tracheostoma valve (Provox FreeHands HME) for vocal and pulmonary rehabilitation after total laryngectomy. Acta Otolaryngol 2003 Jan;123(1):91-9

Herranz Gonzalez-Botas J, Suarez T, Garcia Carreira B, Martinez Moran A. Experience with the HME-Provox® Stomafilter in laryngectomized patients. Acta Otorrinolaringol Esp 2001 Apr;52(3):221-5 [Spanish]

van As CJ, Hilgers FJM, Koopmans-van Beinum FJ, Ackerstaff AH. The influence of stoma occlusion on aspects of alaryngeal speech. Acta Otolaryngol 1998; 118: 732-738.

Ackerstaff AH, Hilgers FJM, Balm AJM, Tan IB. Long term compliance of laryngectomized patients with a specialized pulmonary rehabilitation device, Provox® [HME] Stomafilter. Laryngoscope 1998; 108: 257-260.

Hilgers FJM, Ackerstaff AH, Balm AJM, Gregor RT. A new heat and moisture exchanger with speech valve (Provox® [HME] Stomafilter). Clin Otolaryngol 1996; 21: 414-418.

Ackerstaff AH, Hilgers FJM, Aaronson NK, de Boer MF, Meeuwis CA, Knegt PPM, Spoelstra HAA, van Zandwijk N, Balm AJM. Heat and moisture exchangers as a preventative treatment option in the rehabilitation of laryngectomized patients. Clin Otolaryngol 1995; 20: 504-509

Ackerstaff AH, Hilgers FJM, Aaronson NK, Balm AJM, van Zandwijk N. Improvements in respiratory and psychosocial functioning following total laryngectomy by the use of a heat and moisture exchanger (HME). Ann Otol Rhinol Laryngol 1993; 102: 878-883.

Hilgers FJM, Aaronson NK, Ackerstaff AH, Schouwenburg PF, van Zandwijk N. The influence of a heat and moisture exchanger (HME) on the respiratory symptoms after total laryngectomy. Clin Otolaryngol 1991; 16: 152-156.

The above references represent a selection. For more information contact Atos Medical AB or your local representative.

More about the Provox System, including trouble shooting:
www.provoxweb.info

More about rehabilitation of olfaction after total laryngectomy:
www.hoofdhals.nki.nl/olfaction/Start.aspx

*Insurance coverage, payment, co-payments, deductibles and other restrictions vary depending on patient's policy and medical need.

ATOS MEDICAL

Head office:
Atos Medical AB
P.O. Box 183, SE-242 22 Hörby, Sweden
Tel: +46 (0)415 198 00 • Fax: +46 (0)415 198 98
info@atosmedical.com • www.atosmedical.com

Sales Office in the US:
Atos Medical Inc.
11390 W. Theodore Trecker Way, West Allis, WI 53214-1135, U S A
Tel: 1-800 217 0025 • Fax: 1-414 227 9033
info.us@atosmedical.com • www.atosmedical. com • www.atosdirect.com