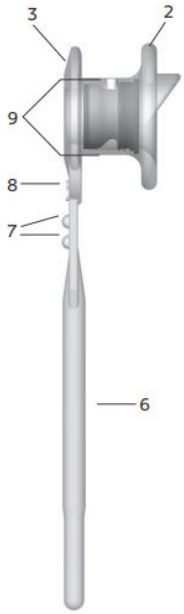
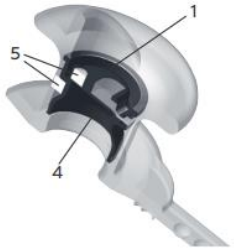
Product Information

Provox ActiValve





1. AV Flap; AV Hinge
2. Esophageal Flange
3. Tracheal Flange
4. Valve seat (AV Ring)
5. Interacting AV magnets in valve seat (AV Ring) and in valve flap
6. Safety strap
7. Direction identification knobs
8. Size information
9. Complete valve unit

Product description:

Provox ActiValve Voice Prosthesis is an unsterile single use one-way valve that keeps a TE-puncture open for speech, while reducing the risk of fluids and food entering the windpipe. It has two retention flanges and a blue ring that adds stability and an even sealing surface for the valve flap. The prosthesis is not a permanent implant and needs periodic replacement.

The device is made of medical grade silicone rubber and radio-opaque fluoroplastic. The outer diameter is 7.5mm (22.5Fr). Provox ActiValve is available in lengths 4.5, 6, 8, 10 and 12.5 mm and comes in different opening forces of the valve. The magnets in the ring and valve flap determine the opening force (the magnets are not adjustable). Since the opening forces are not apparent upon simple visual inspection the device comes with Provox ActiValve User Cards that also provide important information about the voice prosthesis.

The product includes the following non-sterile items: 2 Provox Brushes, 1 Provox Plug, 1 Provox ActiValve Lubricant, 1 Emergency Card, 2 Provox ActiValve User Cards, 1 Patient's instructions for use and 1 Clinician's instructions for use.

Product Information

Document ID:	PF003-01-TechInfo	**Edition:**	2.0

Manufacturer:
Atos Medical AB
Kraftgatan 8
SE-242 35 Hörby,Sweden

Classification:
MDD 93/42/EEC
Class IIb (2.1 Rule 5)

Intended Use:
Provox ActiValve is an unsterile indwelling voice prosthesis intended for anterograde insertion in a healed puncture for voice rehabilitation after total laryngectomy. The device is intended for patients who are experiencing early leakage with previous voice prostheses (device life less than 4-8 weeks). The device reduces the need for frequent replacements in a majority of users, but not in all.

Use specifications:

Intended medical indication
For voice rehabilitation in laryngectomized patients.

Intended patient population
Laryngectomized patients of any age.
Cognitive ability, by a clinician judged as sufficient.
Manual dexterity, by a clinician judged as sufficient.

Intended usage
Single use, prescription only.

Intended part of the body/type of tissue applied to or interacted with
Tracheostoma (during insertion); Mucosal tissue
Insertion system: Brief tissue contact (Insertion Tube) with tracheostoma, tracheoesophageal wall, trachea, esophagus and pharynx.
Voice prosthesis: In contact with the wall between the trachea and the esophagus.
Tracheal flange: In contact with the posterior wall of the trachea.
Esophageal flange: In contact with the anterior wall of the esophagus.

Intended user profile
Trained HCP (e.g., physician, nurse, SLP, clinician) for replacement of voice prosthesis.
Cleaning of the voice prosthesis is performed by the patient or caregiver, while it remains in situ.
Lay caregivers handle the medical device in home settings/nursing homes.

Intended conditions of use
Replacement of voice prosthesis is performed in outpatient hospital settings, on average 2-3 times per year.

Product Information

Operating principles:	The general principle of operation and mode of action for all voice prostheses is that they are one-way valves that allow air from the lungs to pass to the esophagus and pharynx for speech, and prevent liquids, food-debris and saliva to enter the airway. In tracheoesophageal speech, pulmonary air is directed through the voice prosthesis that is placed in a surgically created puncture in between the trachea and the esophagus. The pulmonary air generates mucosal vibrations in the pharyngoesophageal (PE) segment and thereby produces sound.
Contraindications:	Provox ActiValve is NOT intended: • for insertion in a freshly made puncture, • to be in place during MRI-examination (Magnetic Resonance Imaging), or during Radiation Therapy
CE Mark:	Yes. Devices are CE-marked.
GMDN code:	42533 (Tracheoesophageal speech valve, indwelling)
Sterilization:	Non-sterile.
Raw material:	Prosthesis: Silicone, Polyvinylidene fluoride (PVDF), Magnet, Silicone adhesive*, Epoxy glue (direct and indirect contact with the patient) Insertion system: Polypropylene (PP), Blue masterbatch, Silicone fluid Lubricant: Fluorosilicone fluid (direct contact with the patient) Brush: Polypropylene (PP), Blue masterbatch, Polyamide (PA), Styrenic Block Copolymer based thermoplastic, Stainless steel (direct contact with the patient) Plug: Silicone (direct contact with the patient) *)MSDS: MED-1137
Latex information:	Not manufactured with natural rubber latex
Biological origin:	The device is not manufactured with materials derived from human or animal source.
Handling and storage:	Store the product dry and away from sunlight at room temperature. Excursions permitted between 2°C - 42°C.
Waste handling and disposal:	Waste handling and disposal should be carried out in agreement with medical practice and applicable national laws and legislations. Used product may be a potential biohazard.
Hazardous components:	None.
Expiration date:	3 years after manufacturing.
Packaging:	Provox ActiValve is packed together with the Insertion Tool in a blister package made of PETG film and a top film made of spun-bonded polyethylene. They are then packed in a cardboard box containing the blister package, Provox ActiValve Lubricant, Provox Brushes, Provox Plug, Provox ActiValve User Cards, Emergency card and instructions for use (clinician/patient).

Document Number: VV-0544244 Status: Effective Version: 2.0
Name: PF003-01-TECHINFO Provox ActiValve

Product Information

Devices under Basic UDI-DI: 7331791-VPS-0-000-0001-A3

REF	Name	UDI-DI
7150	Provox ActiValve Light 4.5 mm	07331791000522
7151	Provox ActiValve Light 6 mm	07331791000539
7152	Provox ActiValve Light 8 mm	07331791000546
7153	Provox ActiValve Light 10 mm	07331791000553
7154	Provox ActiValve Light 12.5 mm	07331791000560
7160	Provox ActiValve Strong 4.5 mm	07331791000577
7161	Provox ActiValve Strong 6 mm	07331791000584
7162	Provox ActiValve Strong 8 mm	07331791000591
7163	Provox ActiValve Strong 10 mm	07331791000607
7164	Provox ActiValve Strong 12.5 mm	07331791000614
7165	Provox ActiValve XtraStrong 4.5 mm	07331791000621
7166	Provox ActiValve XtraStrong 6 mm	07331791000638
7167	Provox ActiValve XtraStrong 8 mm	07331791000645
7168	Provox ActiValve XtraStrong 10 mm	07331791000652
7169	Provox ActiValve XtraStrong 12.5 mm	07331791000669

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox ActiValve Lubricant	7331791-VPS-A-000-0013-RW
Provox Brushes	7331791-VPS-A-000-0003-RR
Provox Flush	7331791-VPS-A-000-0001-RK
Provox Plug	7331791-VPS-A-000-0004-RU
Provox Measure	7331791-VPS-A-00R-0005-BK
Provox Dilator	7331791-VPS-A-00R-0007-BR
Provox GuideWire	7331791-VPS-A-0E0-0006-5Z

Document Approvals
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