Technical Info / Material Data Sheet

Document ID: PF002-01-TechInfo	Edition: 05

REF Number	7216, 7217, 7218, 7219, 7221, 7224
Product Name	Provox® 2 Voice Prosthesis
Models:	6 sizes; lengths 4.5 mm, 6 mm, 8 mm, 10 mm, 12.5 mm and 15 mm.
Classification: (MDD 93/42/EEC)	IIb (2.4 Rule 8)
CE Mark:	Yes
GMDN code:	42533 (Tracheoesophageal speech valve, indwelling)
Produced by:	Atos Medical AB Kraftgatan 8 P.O. Box 183 242 22 Hörby Sweden
Intended Use:	The Provox 2 Voice Rehabilitation System is intended for use in surgical, prosthetic voice restoration after total laryngectomy. The prosthesis may be inserted by the physician at the time of the total laryngectomy (primary puncture), or at a later date (secondary puncture), or may be used to replace the present prosthesis.
Description:	The Provox 2 voice prosthesis is a hinged valve with two retention collars, made of medical grade silicon rubber. A rigid blue ring sits inside the prothesis, adding stability and providing an even sealing surface for the valve flap. The ring can also be seen in an X-ray.
Sterilization:	EO-sterilization
Raw material:	Prosthesis: Silicone and Polyvinylidene fluoride (PVDF) Insertion system: Polypropylene (PP)
Latex information	Not manufactured with natural rubber latex.
Biological origin:	The device is not manufactured with any materials derived from human or animal source.
Handling and storage:	Keep dry and away from sunlight. Temperature limit 2 - 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:	5 years after manufacturing

Technical Info / Material Data Sheet

Packaging: The Provox 2 voice prosthesis is packed together with the Insertion Tool in a blister package made of PETG film and a top film. It is then packed in a cardboard box together with a non-sterile Provox Brush and instructions for use (clinician/patient).

Reviewed by:

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Vice President QA&RA

2016-04-14

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Date

Approved by:

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Vice President Design & Development

2016-04-14

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Date

Document No.: **QMC-730-115-en** Issue No.: 06 Valid from: 2014-12-12 Time stamp: 2016-04-11 13:06 File name: PF002-01-TechInfo

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Approved:	DD	Jon Berg - JONBER	2021-03-01 - 12:37
Released:	QA	Sara Dahl - X-SARDAH	2021-03-01 - 13:11

This document has been electronically signed by the persons above.

Product Information

Provox ActiValve®

Product description:
The Provox ActiValve voice prosthesis has a one-way valve and two retention flanges. A rigid blue ring sits inside the prosthesis, adding stability and providing an even sealing surface for the valve flap. The blue ring and valve flap can be seen on X-ray. Magnets in the ring and valve flap determine the force needed to open the valve (the magnets are not adjustable). Provox ActiValve comes in different opening forces.

Document No: 10000043691 Edition: 09 Release date: 2021-03-01

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Product Information

Document ID: PF003-01-TechInfo **Edition:** 09

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

Classification: (EU) 2017/745 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 (i.e. indications for use; conditions or diseases to be treated):
Intended for anterograde insertion in a healed puncture for voice rehabilitation after total laryngectomy.

- Intended patient population (e.g. age, health, condition):
Age: Any age
Gender: Male and female with a bias towards males
Weight: Representative of overall human population
Health and condition: Medium to poor. Post-operative adverse effects, post (chemo)-radiation therapy adverse effects, common history of alcohol and tobacco abuse.

- Intended usage:
Non-reusable single use device inserted at hospital/clinic after prescription.

- Intended part of the body/type of tissue applied to or interacted with:
Primary interaction (short and long term): Tracheoesophageal wall, tracheoesophageal puncture
Secondary interaction (transient): Trachea, esophagus, pharynx, skin.

- Intended user profile (e.g. patient, nurse, physician, surgeon):
(Insertion of the Provox ActiValve) Typically an SLP or other clinical professional experienced in voice prosthesis maintenance.
(Subject user of Provox ActiValve) Male or female that have been subject for partial or total laryngectomy (surgical removal of the voice box) due to malignious cancer, neck trauma or other indication where the patient is deemed eligible, by the surgeon or clinical professional, for tracheoesophageal voice rehabilitation. Within this general subject group, the typical Provox ActiValve user may experience discomfort from early leakage (short device life) due to biofilm growth and/or underpressure.

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- Intended conditions of use (i.e. environment including hygienic requirements, frequency of use, location, mobility):
At the time of, and in the environment of, voice prosthesis maintenance and/or change in a clinical setting.
Environments of use for the Provox ActiValve Voice Prosthesis include – hospitals, sub-acute care institutions and home.
For the Provox Loading Tube and Inserter the environments of use include – hospitals and sub-acute care institutions.

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, the devices are CE marked.

GMDN code: 42533 (Tracheoesophageal speech valve, indwelling)

Sterilization: Non-sterile

Raw material: Prosthesis: Silicone, Polyvinylidene fluoride (PVDF), Magnet
Insertion system: Polypropylene (PP)
Lubricant: Fluor silicone fluid
Brush: Polypropylene (PP), Polyamide (PA), Stainless steel
Plug: Silicone

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).

Product Information

Devices under Basic UDI-DI: 7331791-VPS-0-00I-0001-NT

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-GEN-A-000-0004-EJ
Provox Brushes	7331791-VPS-A-000-0001-E9
Provox Flush	7331791-VPS-A-000-0001-RK
Provox Plug	7331791-VPS-A-000-0004-RU

Document No: 10000043691 Edition: 09 Release date: 2021-03-01

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Approved:	DD	Jon Berg - JONBER	2021-03-04 - 16:47
Released:	QA	Sara Dahl - X-SARDAH	2021-03-12 - 13:39

This document has been electronically signed by the persons above.

Product Information

Provox® ActiValve® Lubricant

Product description:

Provox ActiValve Lubricant is a medical grade silicone oil to be used with Provox ActiValve Voice Prosthesis. It shall be applied as a thin film on the inner lumen of Provox ActiValve voice prosthesis to help prevent occasional temporary blockage of the valve.

Document No: 10000045683 Edition: 08 Release date: 2021-03-12

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Product Information

Document ID:	PF003-02-TechInfo **Edition:** 08
Manufacturer:	Atos Medical AB Kraftgatan 8 SE-242 35 Hörby,Sweden
Classification: (EU) 2017/745	IIb
Intended Use:	For use with Provox ActiValve only. Lubricating the inner lumen of the Provox ActiValve prosthesis helps to prevent sticking of the valve that might otherwise occur e.g. after sleep.
Use specifications:	**Intended medical indication** Intended for use with Provox ActiValve for voice rehabilitation in laryngectomized patients. **Intended patient population** Male and female of any age. Cognitive ability, by a clinician judged as sufficient. Manual dexterity, by a clinician judged as sufficient. **Intended usage** Daily use to lubricate the voice prosthesis. **Intended part of the body/type of tissue applied to or interacted with** Primary interaction (short and long term): Tracheoesophageal wall, tracheoesophageal puncture. Secondary interaction (transient): Trachea, esophagus, pharynx, skin **Intended user profile** Trained clinician (e.g. physician, SLP) for lubrication of voice prosthesis after insertion. Lubrication of the voice prosthesis is performed by the patient while it remains in situ.
Contraindications:	None
CE Mark:	Yes, the devices are CE marked.
GMDN code:	42533 (Tracheoesophageal speech valve, indwelling)
Sterilization:	Non-sterile
Raw material:	Fluorosilicone fluid.
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.

Product Information

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 Lubricant is contained in a dropper bottle made of low-density polyethylene and a closure made of polypropylene. The bottle is packed in a plastic bag and then in a carboard box.

Devices under Basic UDI-DI: 7331791-GEN-A-000-0004-EJ

REF	Name	UDI-DI
7149	Provox ActiValve Lubricant	07331791000515

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox ActiValve	7331791-VPS-0-00I-0001-NT

Technical Info / Material Data Sheet

Document ID: PF004-01-TechInfo | Edition: 05

REF Number	7101-7106, 7111-7116
Product Name	Provox® NID™
Models:	2 model diameters; 17 Fr (5.67 mm) and 20 Fr (6.67 mm). 6 model lengths; 6, 8, 10, 12, 14 and 18 mm.
Classification: (MDD 93/42/EEC)	IIb (2.1 Rule 5)
CE Mark:	Yes
GMDN code:	44412 (Tracheoesophageal speech valve, nonindwelling)
Produced by:	Atos Medical AB Kraftgatan 8 P.O. Box 183 242 22 Hörby Sweden
Intended Use:	The Provox NID voice rehabilitation system is intended for use in prosthetic voice rehabilitation after total laryngectomy only by patients who have been trained in the use of the device and, as assessed by the clinician who prescribes the device, have demonstrated the ability to understand and consistently follow Instructions for Use without clinician supervision. The Provox NID is intended for single patient use.
Description:	Provox NID is a non-indwelling voice prosthesis for patients who are capable of handling the exchange and maintenance of a voice prosthesis independently of a clinician or physician. The prosthesis is available in two outer shaft diameters (17 and 20 French) and several lengths.
Sterilization:	Non-sterile.
Raw material:	Prosthesis: Silicone and Polyvinylidene flouride (PVDF). Medallion with thread: Silicone and polypropylene (PP). Inserter: Polypropylene (PP).
Latex information	Not manufactured with natural rubber latex.
Biological origin:	The device is not manufactured with any materials derived from human or animal source.
Handling and storage:	Keep dry and away from sunlight. Temperature limit 2 - 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:	5 years after manufacturing.

Technical Info / Material Data Sheet

Packaging:

Provox NID is packed together with NID Inserter in a blister package made of PETG film and a top film made of spun-bonded polyethylene. It is then packed in a carton box containing the blister package and instructions for use.

Reviewed by:

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Vice President QA&RA

2014-05-20

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Date

Approved by:

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Vice President Design Control

2014-05-20

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Date

Product Information

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	DD	Daniel Åberg - DANABE	2021-12-03 - 16:02
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Approved:	DD	Jon Berg - JONBER	2021-12-03 - 16:47
Released:	DD	Daniel Åberg - DANABE	2021-12-17 - 09:19

This document has been electronically signed by the persons above.

Product description:

An electrolarynx is a battery-powered artificial larynx that is externally applied on undamaged skin and intended for use in the absence of the larynx or the inability to use the larynx to produce sound.

Document No: 1000046793 Edition: 03 Release date: 2021-12-17

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Product Information

Document ID: PF121-01-TechInfo **Edition:** 03

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

Classification: (EU) 2017/745 Class 1, Rules 5 & 13

Intended Use: An electrolarynx is a battery-powered artificial larynx that is externally applied and intended for use in the absence of the ability to use the larynx to produce sound. When held against the skin in the area of the voicebox, or by insertion of a tube in the oral cavity (with an oral adapter), the device generates mechanical vibrations which resonate in the oral and nasal cavities and can be modulated by the tongue and lips in a normal manner, thereby allowing the production of speech.

Use specifications:

Intended medical indication:
Voice rehabilitation for patients without the ability to use the larynx to produce sound

Intended patient population:

Male and female of any age.

Cognitive ability, by a clinician judged as sufficient.

Manual dexterity, by a clinician judged as sufficient.

Intended usage:

Multiple use and for demonstration use. Available over-the-counter.

Intended user profile:

The device is supposed to be handled by the patient but is also handled by physicians, trained nurses, SLPs, clinicians and caregivers.

Intended conditions of use;

Environment: Home, indoor and outdoor use (for optimal battery life within temperature 5°C to 25°C; 15% to 93% relative humidity).

Outpatient clinic use. Hospital use.

Frequency of use: Daily use or upon need.

Contraindications: The device should only be used in accordance with the Instructions for Use. Users without the physical, cognitive, or mental ability required to operate the device themselves, should not use the device independently and should only use it if they are under sufficient supervision of a clinician or a trained caregiver. The device should not be directly applied over frail neck tissue with weak blood vessels. This can cause tissue damage or bleeding. Patients with this condition should only use the device when they have been specifically instructed by their clinician about how to use the device and where to safely apply it

CE Mark: Yes. Devices are CE-marked.

GMDN code: 34857 Artificial larynx

Sterilization: Non-sterile

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Product Information

Raw material:	Acrylonitrile butadiene styrene, Polycarbonate and Aluminium
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:	To maintain optimal battery life, maintain the following environmental conditions: -20°C to +25°C; 0% to 45% relative humidity
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:	Electrolarynx devices contain a magnet that may interfere with pacemakers or other implantable devices. Consult with your physician before use. Maintain a minimum distance of 6"/16cm between your electrolarynx and any implanted devices. If interference between the devices is suspected, discontinue use and consult with your physician
Expiration date:	Expected service life 1- 5 years depending on use frequency and care taken to prevent wear and damage.
Packaging:	One Electrolarynx, Lanyard, Sound head, Oral Adaptor, Oral Tube Varity Pack and a Power cord are packed in a cardboard box.

Product Information

Devices under Basic UDI-DI: 7331791-ELX-0-A00-0001-VJ

REF	Name	UDI-DI
7438	Provox SolaTone Plus	7331791015823
7439	Provox TruTone Emote	7331791015830
7444	Provox TruTone Plus	7331791015571

Atos Medical AB compatible products:

Range	BASIC UDI-DI
None	-

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Approved:	DD	Diana Tieger - DIATIE	2022-07-05 - 13:26
Released:	QA	Elin Andersson - ELIAND	2022-09-20 - 09:10

This document has been electronically signed by the persons above.

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Product Information

Provox® Vega™ / Vega™ XtraSeal™ w. Insertion System

Product description:

Provox Vega and Vega XtraSeal with Insertion System consists of a voice prosthesis (Provox Vega or Provox Vega XtraSeal), an insertion system and a Provox Brush.

Provox Vega and Provox Vega XtraSeal are a one-way valve (prostheses) that keeps a TE-puncture open for speech, while reducing the risk of fluids and food entering the trachea. Provox Vega voice prostheses are not permanent implants, and needs periodic replacement.

Provox Vega XtraSeal has an additional enlarged esophageal flange that is intended to solve problems with leakage around the voice prosthesis.

The prosthesis is available in different diameters and several lengths.

The device is made of medical grade silicone rubber and fluoroplastic.

Document No: 10000030449 Edition: 02 Release date: 2022-09-20

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Product Information

Document ID: PF057-06-TechInfo **Edition:** 02

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

Classification: (EU) (MDD/93/42/EEC) Class IIb (2.4 rule 8)

Intended Use: Provox Vega Voice Prosthesis is a sterile single use indwelling voice prosthesis intended for voice rehabilitation after surgical removal of the larynx (laryngectomy). Cleaning of the voice prosthesis is performed by the patient while it remains in situ.

The Provox Insertion System is a sterile single use device intended for anterograde replacement of the Provox Vega Voice Prosthesis. This replacement procedure is carried out by a medical professional in accordance with local or national guidelines.

The Provox Insertion System is not intended to be used for insertion of a voice prosthesis in a freshly made puncture

Use specifications:

Intended medical indication
For voice rehabilitation in laryngectomized patients.

Intended patient population
Male and female 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 membrane.
Insertion system: Brief tissue contact (Insertion Tube) with tracheostoma, tracheoesophageal wall, trachea, esophagus and pharynx.
Voice prosthesis: In contact with 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 clinician (e.g. physician, SLP) for replacement of voice prosthesis. Cleaning of the voice prosthesis is performed by the patient while it remains in situ.

Intended conditions of use
Home and hospital use. Replacement of voice prosthesis is performed in outpatient hospital settings, on average 4 times per year.

Contraindications: There are no known contraindications for use or replacement of the Provox Vega voice prosthesis among patients already using prosthetic voice rehabilitation.

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Product Information

CE Mark:	Yes. Devices are CE-marked.
GMDN code:	42533 (Tracheoesophageal speech valve, indwelling)
Sterilization:	Yes, EO-sterilization
Raw material:	Prosthesis: Silicone and Polyvinylidene fluoride (PVDF) Insertion system: Polypropylene (PP)
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:	5 years after manufacturing.
Packaging:	The Provox Vega / Vega XtraSeal with Provox Insertion System is packed in a blister package made of PETG film and with a Tyvek (spun-bounded polyethylene) top film. It is then packed in a cardboard box together with a non-sterile Provox Brush and instructions for use.

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Product Information

Devices under Basic UDI-DI: 7331791-VPS-0-0E0-0002-N2

REF	Name	UDI-DI
4270	Provox Vega 17Fr 4mm	07331791012136
4271	Provox Vega 17Fr 6mm	07331791012143
4272	Provox Vega 17Fr 8mm	07331791012150
4273	Provox Vega 17Fr 10mm	07331791012167
4274	Provox Vega 17Fr 12.5mm	07331791012174
4275	Provox Vega 17Fr 15mm	07331791012181
4276	Provox Vega 20Fr 4mm	07331791012198
4277	Provox Vega 20Fr 6mm	07331791012204
4278	Provox Vega 20Fr 8mm	07331791012211
4279	Provox Vega 20Fr 10mm	07331791012228
4280	Provox Vega 20Fr 12.5mm	07331791012235
4281	Provox Vega 20Fr 15mm	07331791012242
4282	Provox Vega 22.5Fr 4mm	07331791012259
4283	Provox Vega 22.5Fr 6mm	07331791012266
4284	Provox Vega 22.5Fr 8mm	07331791012273
4285	Provox Vega 22.5Fr 10mm	07331791012280
4286	Provox Vega 22.5Fr 12.5mm	07331791012297
4287	Provox Vega 22.5Fr 15mm	07331791012303
8270	Provox Vega 17Fr 4mm	07331791010743
8270-18	Provox Vega 17Fr 4mm	07331791013034
8271	Provox Vega 17Fr 6mm	07331791010750
8271-18	Provox Vega 17Fr 6mm	07331791013041
8272	Provox Vega 17Fr 8mm	07331791010767
8272-18	Provox Vega 17Fr 8mm	07331791013058
8273	Provox Vega 17Fr 10mm	07331791010774
8273-18	Provox Vega 17Fr 10mm	07331791013065
8274	Provox Vega 17Fr 12,5mm	07331791010781
8274-18	Provox Vega 17Fr 12,5mm	07331791013072
8275	Provox Vega 17Fr 15mm	07331791010798
8275-18	Provox Vega 17Fr 15mm	07331791013089
8276	Provox Vega 20Fr 4mm	07331791010804
8276-18	Provox Vega 20Fr 4mm	07331791013096
8277	Provox Vega 20Fr 6mm	07331791010811
8277-18	Provox Vega 20Fr 6mm	07331791013102
8278	Provox Vega 20Fr 8mm	07331791010828
8278-18	Provox Vega 20Fr 8mm	07331791013119
8279	Provox Vega 20Fr 10mm	07331791010835
8279-18	Provox Vega 20Fr 10mm	07331791013126
8280	Provox Vega 20Fr 12,5mm	07331791010842
8280-18	Provox Vega 20Fr 12,5mm	07331791013133
8281	Provox Vega 20Fr 15mm	07331791010859
8281-18	Provox Vega 20Fr 15mm	07331791013140
8282	Provox Vega 22,5Fr 4mm	07331791010866
8282-18	Provox Vega 22,5Fr 4mm	07331791013157
8283	Provox Vega 22,5Fr 6mm	07331791010873
8283-18	Provox Vega 22,5Fr 6mm	07331791013164
8284	Provox Vega 22,5Fr 8mm	07331791010880
8284-18	Provox Vega 22,5Fr 8mm	07331791013171
8285	Provox Vega 22,5Fr 10mm	07331791010897

Released
Document No: 10000030449 Edition: 02 Release date: 2022-09-20

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Product Information

REF	Name	UDI-DI
8285-18	Provox Vega 22,5Fr 10mm	07331791013188
8286	Provox Vega 22,5Fr 12,5mm	07331791010903
8286-18	Provox Vega 22,5Fr 12,5mm	07331791013195
8287	Provox Vega 22,5Fr 15mm	07331791010910
8287-18	Provox Vega 22,5Fr 15mm	07331791012327

Devices under Basic UDI-DI: 7331791-VPS-0-0E0-0004-N8

REF	Name	UDI-DI
4288	Provox Vega XtraSeal 17Fr 4mm	07331791011771
4289	Provox Vega XtraSeal 17Fr 6mm	07331791011788
4290	Provox Vega XtraSeal 17Fr 8mm	07331791011795
4291	Provox Vega XtraSeal 17Fr 10mm	07331791011801
4292	Provox Vega XtraSeal 17Fr 12.5mm	07331791011818
4293	Provox Vega XtraSeal 17Fr 15mm	07331791011825
4294	Provox Vega XtraSeal 20Fr 4mm	07331791011832
4295	Provox Vega XtraSeal 20Fr 6mm	07331791011849
4296	Provox Vega XtraSeal 20Fr 8mm	07331791011856
4297	Provox Vega XtraSeal 20Fr 10mm	07331791011863
4298	Provox Vega XtraSeal 20Fr 12.5mm	07331791011870
4299	Provox Vega XtraSeal 20Fr 15mm	07331791011887
4300	Provox Vega XtraSeal 22.5Fr 4mm	07331791011894
4301	Provox Vega XtraSeal 22.5Fr 6mm	07331791011900
4302	Provox Vega XtraSeal 22.5Fr 8mm	07331791011917
4303	Provox Vega XtraSeal 22.5Fr 10mm	07331791011924
4304	Provox Vega XtraSeal 22.5Fr 12.5mm	07331791011931
4305	Provox Vega XtraSeal 22.5Fr 15mm	07331791011948
8288	Provox Vega XtraSeal 17Fr 4mm	07331791010927
8288-18	Provox Vega XtraSeal 17Fr 4mm	07331791013218
8289	Provox Vega XtraSeal 17Fr 6mm	07331791010934
8289-18	Provox Vega XtraSeal 17Fr 6mm	07331791013225
8290	Provox Vega XtraSeal 17Fr 8mm	07331791010941
8290-18	Provox Vega XtraSeal 17Fr 8mm	07331791013232
8291	Provox Vega XtraSeal 17Fr 10mm	07331791010958
8291-18	Provox Vega XtraSeal 17Fr 10mm	07331791013249
8292	Provox Vega XtraSeal 17Fr 12.5mm	07331791010965
8292-18	Provox Vega XtraSeal 17Fr 12.5mm	07331791013256
8293	Provox Vega XtraSeal 17Fr 15mm	07331791010972
8293-18	Provox Vega XtraSeal 17Fr 15mm	07331791013263
8294	Provox Vega XtraSeal 20Fr 4mm	07331791010989
8294-18	Provox Vega XtraSeal 20Fr 4mm	07331791013270
8295	Provox Vega XtraSeal 20Fr 6mm	07331791010996
8295-18	Provox Vega XtraSeal 20Fr 6mm	07331791013287
8296	Provox Vega XtraSeal 20Fr 8mm	07331791011009
8296-18	Provox Vega XtraSeal 20Fr 8mm	07331791013294
8297	Provox Vega XtraSeal 20Fr 10mm	07331791011016
8297-18	Provox Vega XtraSeal 20Fr 10mm	07331791013300
8298	Provox Vega XtraSeal 20Fr 12.5mm	07331791011023
8298-18	Provox Vega XtraSeal 20Fr 12.5mm	07331791013317
8299	Provox Vega XtraSeal 20Fr 15mm	07331791011030

Document No: 10000030449 Edition: 02 Release date: 2022-09-20

Product Information

REF	Name	UDI-DI
8299-18	Provox Vega XtraSeal 20Fr 15mm	07331791013324
8300	Provox Vega XtraSeal 22.5Fr 4mm	07331791011047
8300-18	Provox Vega XtraSeal 22.5Fr 4mm	07331791013331
8301	Provox Vega XtraSeal 22.5Fr 6mm	07331791011054
8301-18	Provox Vega XtraSeal 22.5Fr 6mm	07331791013348
8302	Provox Vega XtraSeal 22.5Fr 8mm	07331791011061
8302-18	Provox Vega XtraSeal 22.5Fr 8mm	07331791012723
8303	Provox Vega XtraSeal 22.5Fr 10mm	07331791011078
8303-18	Provox Vega XtraSeal 22.5Fr 10mm	07331791013362
8304	Provox Vega XtraSeal 22.5Fr 12.5mm	07331791011085
8304-18	Provox Vega XtraSeal 22.5Fr 12.5mm	07331791013379
8305	Provox Vega XtraSeal 22.5Fr 15mm	07331791011092
8305-18	Provox Vega XtraSeal 22.5Fr 15mm	07331791012334

Provox Vega

Provox Vega XtraSeal

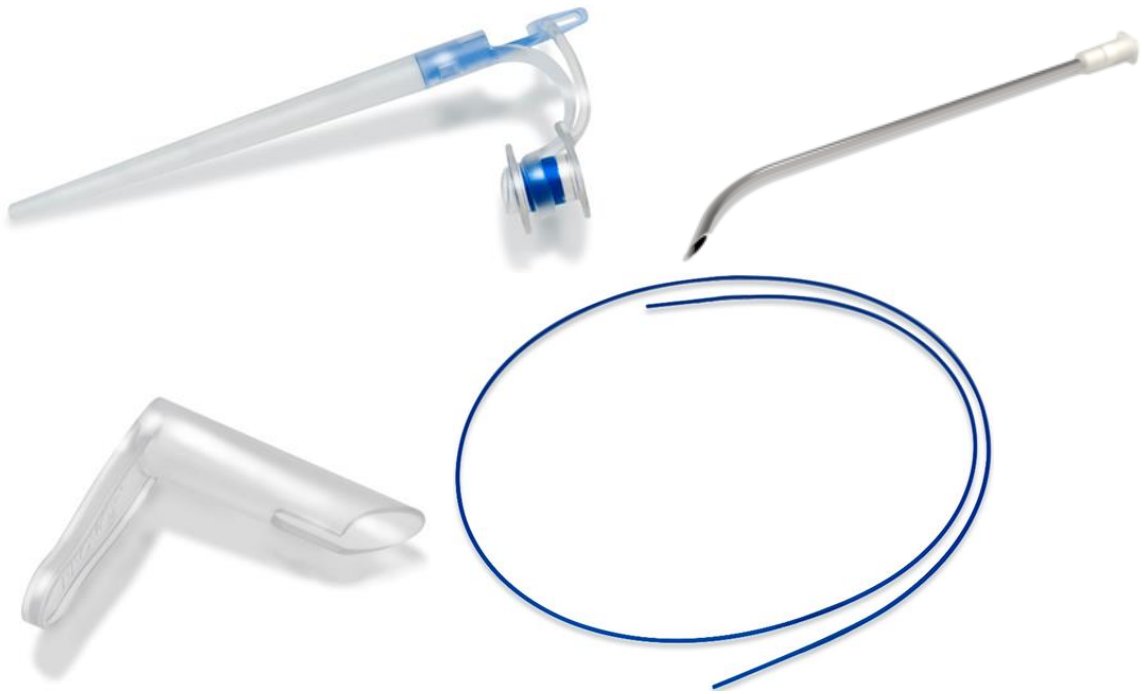
Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox Brush	7331791-VPS-A-000-0003-RR
Provox Capsule (only compatible with Provox Vega)	7331791-VPS-A-000-0000-RG
Provox Dilator	7331791-VPS-A-00R-0007-BR
Provox Flush	7331791-VPS-A-000-0001-RK
Provox GuideWire	7331791-VPS-A-0E0-0006-5Z
Provox Measure	7331791-VPS-A-00R-0005-BK
Provox Vega Plug	7331791-VPS-A-000-0004-RU
Provox XtraFlange	7331791-VPS-A-0E0-0008-67
Provox TwistLock (only compatible with Provox Vega)	7331791-VPS-A-000-0009-SB

Document No: 10000030449 Edition: 02 Release date: 2022-09-20

Product Information

Provox® Vega Puncture Set



Product description:

The Provox Vega Puncture Set is a device for creating a primary or secondary TE puncture, with subsequent dilatation of that puncture to a width that facilitates placement of the included Provox Vega voice prosthesis. The Provox Vega voice prosthesis is preloaded in the Puncture Dilator, which is part of the device.

The Provox Vega Puncture Set is intended for single use only.

The product also includes 1 pc Provox Brush, 1 pc Instructions for use Provox Vega Puncture Set, 1 pc Instructions for use Illustrations Vega Puncture Set, 1 pc Provox Vega Patient's Manual and 1 pc Instructions for Use Provox Brush.

Product Information

Document ID:	PF060-01-TechInfo	**Edition:**	1.0

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

Classification:
MDD 93/42/EEC
IIb (2.4, Rule 8)

Intended Use:
Provox Vega Puncture Set is a device for performing a primary or secondary tracheoesophageal (TE) puncture in laryngectomized patients, with integrated placement of a Provox Vega voice prosthesis.

The Provox Vega voice prosthesis is a sterile single use indwelling voice prosthesis intended for voice rehabilitation after surgical removal of the larynx (laryngectomy). Cleaning of the voice prosthesis is performed by the patient while it remains in situ.

Product Information

Use specifications:

Intended medical indication
To facilitate speech in laryngectomized patients.

Intended patient population
Laryngectomized patients of any age and with sufficient manual dexterity and cognitive ability to maintain and use a voice prosthesis.

Intended usage
Single use. Prescription only.

Intended part of the body/type of tissue applied to or interacted with
Primary interaction (short and long term): Tracheoesophageal wall.
Secondary interaction (transient): Trachea, esophagus, pharynx, mouth.

Intended user profile
ENT surgeons, Health care professionals (HCPs), Patients, Lay caregivers

Intended conditions of use
Placement of voice prosthesis is performed at the time of, and in the environment of, tracheoesophageal puncture (hospital use or outpatient hospital use). The voice prosthesis is used by the patient and lay caregiver while it remains in situ in home settings.

Hospital use
No environmental restrictions regarding temperature, moisture, hygiene, lighting and working position. Potential high stress level. Both daytime and nighttime.

Outpatient hospital use
No environmental restrictions regarding temperature, moisture, hygiene, lighting and working position. Potential high stress level. Daytime.

Home use
No environmental restrictions regarding temperature and moisture. Potential low conditions regarding hygiene, lighting, stress level and working position. Both daytime and nighttime.

Frequency of use: Single use item. Provox Vega Puncture Set is used once to create the puncture and place the voice prosthesis. The voice prosthesis is not a permanent implant and requires periodic replacement depending on individual biological circumstances.

Product Information

Contraindications:	Do not use the Provox Vega Puncture Set if the patient has anatomical abnormalities that may hinder safe puncturing of the TE wall or safe voice prosthesis placement (e.g., significant stenosis or significant fibrosis at the puncture site) as this may cause tissue damage. Do not use the Provox Vega Puncture Set for secondary TE puncture if the patient suffers from severe trismus that precludes proper protection of the pharyngeal wall. Failure to protect the pharynx during puncture may lead to unintended trauma of the pharyngeal/ esophageal tissue.
CE Mark:	Yes. Devices are CE-marked
GMDN code:	42533 (Tracheoesophageal speech valve, indwelling)
Sterilization:	EO-sterilization
Raw material:	Prosthesis: Silicone and Polyvinylidene fluoride (PVDF). Insertion system: Methyl Methacrylate Acrylonitrile Butadiene Styrene (MABS), stainless steel, polyamide 66 (PA66), thermoplastic styrene-ethylene/butylene-styrene (TPS-SEBS), Polypropylene (PP) and Polyvinylidene fluoride (PVDF). Brush: Stainless steel, Polyamide (PA), Polypropylene (PP) with blue masterbatch
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:	5 years after manufacturing.
Packaging:	The Provox Vega Puncture Set is packed in a PETG blister package with a spun-bounded polyethylene top film. The blister package is packed in a sterile bag. The Brush is packed in a plastic bag of polyethylene. The patient items are packed in a plastic bag of LDPE. The outer package is a cardboard box. The instructions for use Provox Vega Puncture Set, Instructions for use illustrations Provox Vega Puncture Set, Provox Vega Patient's Manual and Provox Brush Instructions for Use are accompanying documents.

Product Information

Devices under Basic UDI-DI: 7331791-VPS-0-0EI-0003-2Y

REF	Name	UDI-DI
8140	Provox Vega Puncture Set 17Fr 8mm	07331791005114
8141	Provox Vega Puncture Set 17Fr 10mm	07331791005121
8142	Provox Vega Puncture Set 17Fr 12.5mm	07331791005138
8143	Provox Vega Puncture Set 17Fr 15mm	07331791005145
8144	Provox Vega Puncture Set 20Fr 8mm	07331791005152
8145	Provox Vega Puncture Set 20Fr 10mm	07331791005169
8146	Provox Vega Puncture Set 20Fr 12.5mm	07331791005176
8147	Provox Vega Puncture Set 22.5Fr 8mm	07331791005183
8148	Provox Vega Puncture Set 22.5Fr 10mm	07331791005190
8149	Provox Vega Puncture Set 22.5Fr 12.5mm	07331791005206
8140-18	Provox Vega Puncture Set 17Fr 8mm	07331791013584
8141-18	Provox Vega Puncture Set 17Fr 10mm	07331791013591
8142-18	Provox Vega Puncture Set 17Fr 12.5mm	07331791012952
8143-18	Provox Vega Puncture Set 17Fr 15mm	07331791012969
8144-18	Provox Vega Puncture Set 20Fr 8mm	07331791012976
8145-18	Provox Vega Puncture Set 20Fr 10mm	07331791012983
8146-18	Provox Vega Puncture Set 20Fr 12.5mm	07331791012990
8147-18	Provox Vega Puncture Set 22.5Fr 8mm	07331791012310
8148-18	Provox Vega Puncture Set 22.5Fr 10mm	07331791013010
8149-18	Provox Vega Puncture Set 22.5Fr 12.5mm	07331791013027

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox Brush	7331791-VPS-A-000-0003-RR
Provox Brush XL	7331791-VPS-A-000-0003-RR
Provox Brush Long	7331791-VPS-A-000-0003-RR
Provox Brush Long XL	7331791-VPS-A-000-0003-RR
Provox Flush	7331791-VPS-A-000-0001-RK
Provox Vega Plug	7331791-VPS-A-000-0004-RU

Document Approvals
Approved Date: 2023-11-23

Task: Approval Task Verdict: Approve	SEHRBJNC Carolina Johansson, Sustaining Engineer (carolina.johansson-atosmedical@coloplast.com) Issuer 17-Nov-2023 14:49:05 GMT+0000

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Task: Final Approval Verdict: Approve	KARNIL Karolina Nilsson, Head of Regulatory Affairs (karolina.nilsson-atosmedical@coloplast.com) Regulatory 23-Nov-2023 06:59:26 GMT+0000