Quality Management System

Technical Info / Material Data Sheet

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Karolina Nilsson - KARNIL	2019-06-10 - 10:01
Reviewed:	QA	John Wennborg - JOHWEN	2019-06-10 - 11:07
Approved:	DD	Jon Berg - JONBER	2019-06-10 - 12:31
Released:	DD	Daniel Åberg - DANABE	2019-11-28 - 11:20

This document has been electronically signed by the persons above.

Document ID: PF060-01-Techinfo	Edition: 06

REF Number 8140, 8141, 8142, 8143, 8144, 8145, 8146, 8147, 8148, 8149.

Product Name

REF	Denomination
8140	Provox® Vega Puncture Set 17Fr 8mm
8141	Provox® Vega Puncture Set 17Fr 10mm
8142	Provox® Vega Puncture Set 17Fr 12.5mm
8143	Provox® Vega Puncture Set 17Fr 15mm
8144	Provox® Vega Puncture Set 20Fr 8mm
8145	Provox® Vega Puncture Set 20Fr 10mm
8146	Provox® Vega Puncture Set 20Fr 12.5mm
8147	Provox® Vega Puncture Set 22.5Fr 8mm
8148	Provox® Vega Puncture Set 22.5Fr 10mm
8149	Provox® Vega Puncture Set 22.5Fr 12.5mm

Models: Diameters 17, 20 and 22.5 Fr, each available in lengths 8, 10 and 12.5 mm. The 17 Fr is also available in length 15 mm. Total of 10 variants.

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

CE Mark: Yes

GMDN code: 42533 (Tracheoesophageal speech valve, indwelling)

(U)DI code:

REF	Denomination	EAN code
8140	Provox Vega Puncture Set 17Fr 8mm	7331791005114
8141	Provox Vega Puncture Set 17Fr 10mm	7331791005121
8142	Provox Vega Puncture Set 17Fr 12.5mm	7331791005138
8143	Provox Vega Puncture Set 17Fr 15mm	7331791005145
8144	Provox Vega Puncture Set 20Fr 8mm	7331791005152
8145	Provox Vega Puncture Set 20Fr 10mm	7331791005169
8146	Provox Vega Puncture Set 20Fr 12.5mm	7331791005176
8147	Provox Vega Puncture Set 22.5Fr 8mm	7331791005183
8148	Provox Vega Puncture Set 22.5Fr 10mm	7331791005190
8149	Provox Vega Puncture Set 22.5Fr 12.5mm	7331791005206

Produced by:
Atos Medical AB
Kraftgatan 8
P.O. Box 183
242 22 Hörby
Sweden

Document No: 10000040330 Edition: 06 Release date: 2019-11-28

Released

Technical Info / Material Data Sheet

Intended Use: The Provox Vega Puncture Set is intended for creation of a tracheoesophageal puncture for placement of a preloaded Provox Vega voice prosthesis as the time of the puncture.

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 Illustrations Vega Puncture Set, 1 pc Provox Vega Patient's Manual and 1 pc Instructions for Use Provox Brush.

Sterilization: EO-sterilization.

Raw material: Prosthesis: Silicone and Polyvinylidene fluoride (PVDF).
Insertion system: Methyl Methacrylate Acrylonitrile Butadiene Styrene (MABS), stainless steel, 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 any materials derived from human or animal source (MEDDEV 2.4/1 rev. 9 Rule 17).

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.

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 outer package is a cardboard box. The instructions for use – Provox Vega Puncture Set, Provox Vega Patient's Manual and Provox Brush Instructions for Use are accompanying documents.

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Product Information

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Issued:	DD	Daniel Åberg - DANABE	2021-12-03 - 16:02
Reviewed:	QA	Karolina Nilsson - KARNIL	2021-12-03 - 16:43
Approved:	DD	Jon Berg - JONBER	2021-12-03 - 16:47
Released:	DD	Daniel Åberg - DANABE	2021-12-17 - 09:19

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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

Released

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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	-

Document No: 10000046793 Edition: 03 Release date: 2021-12-17

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Issued:	QA	Sara Dahl - X-SARDAH	2021-03-01 - 11:23
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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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Product Information

- 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).

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

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

Product Information

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Issued:	QA	Alexandra Holmberg - ALEHOL	2020-10-26 - 13:44
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Approved:	DD	Jon Berg - JONBER	2020-10-26 - 15:15
Released:	QA	Alexandra Holmberg - ALEHOL	2020-11-02 - 13:23

This document has been electronically signed by the persons above.

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.

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Released

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Product Information

Document ID:	PF003-02-TechInfo **Edition: 07**
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** 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. **Intended part of the body/type of tissue applied to or interacted with** Tracheostoma (during application): Mucosal membrane in esophagus and trachea. **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.
Contraindications:	None
CE Mark:	Yes, the devices are CE marked.
GMDN code:	62094 (Tracheoesophageal speech valve, indwelling, non-sterile)
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.
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.

Document No: 10000045683 Edition: 07 Release date: 2020-11-02

Product Information

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:

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

Document No: 10000045683 Edition: 07 Release date: 2020-11-02

Technical Info / Material Data Sheet

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:

.....

Vice President Design Control

2014-05-20

.....

Date

Atos Medical Your voice

Quality Management System

Technical Info / Material Data Sheet

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:		Alexandra Holmberg - ALEHOL	2017-10-19 - 10:31
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Approved:	DD	Mikael Melefors - SEHRBSGM	2017-10-19 - 16:21
Released:		Alexandra Holmberg - ALEHOL	2018-02-02 - 14:20

This document has been electronically signed by the persons above.

Document ID: PF057-06 TechInfo	Edition: 01

REF Number 4270-4305, 8270-8305

Product Name Provox® Vega 17Fr, Provox® Vega 20Fr and Provox® Vega 22.5Fr
Provox® Vega XtraSeal 17Fr, Provox® Vega XtraSeal 20Fr and
Provox® Vega XtraSeal 22.5Fr

Models: Diameter 17, 20 and 22.5 Fr, each available in the lengths 4, 6, 8, 10, 12.5 and 15 mm and each size available also as XtraSeal model.

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

CE Mark: Yes

GMDN code: 42533 (Tracheoesophageal speech valve, indwelling, sterile)

Released

Document No: 10000030449 Edition: 01 Release date: 2018-02-02

(U)DI code:

REF Number	Denomination	EAN code
4270	Provox Vega 17Fr 4mm	7331791012136
4271	Provox Vega 17Fr 6mm	7331791012143
4272	Provox Vega 17Fr 8mm	7331791012150
4273	Provox Vega 17Fr 10mm	7331791012167
4274	Provox Vega 17Fr 12.5mm	7331791012174
4275	Provox Vega 17Fr 15mm	7331791012181
4276	Provox Vega 20Fr 4mm	7331791012198
4277	Provox Vega 20Fr 6mm	7331791012204
4278	Provox Vega 20Fr 8mm	7331791012211
4279	Provox Vega 20Fr 10mm	7331791012228
4280	Provox Vega 20Fr 12.5mm	7331791012235
4281	Provox Vega 20Fr 15mm	7331791012242
4282	Provox Vega 22.5Fr 4mm	7331791012259
4283	Provox Vega 22.5Fr 6mm	7331791012266
4284	Provox Vega 22.5Fr 8mm	7331791012273
4285	Provox Vega 22.5Fr 10mm	7331791012280
4286	Provox Vega 22.5Fr 12.5mm	7331791012297
4287	Provox Vega 22.5Fr 15mm	7331791012303
8270	Provox Vega 17Fr 4mm	7331791010743
8271	Provox Vega 17Fr 6mm	7331791010750
8272	Provox Vega 17Fr 8mm	7331791010767
8273	Provox Vega 17Fr 10mm	7331791010774
8274	Provox Vega 17Fr 12,5mm	7331791010781
8275	Provox Vega 17Fr 15mm	7331791010798
8276	Provox Vega 20Fr 4mm	7331791010804
8277	Provox Vega 20Fr 6mm	7331791010811
8278	Provox Vega 20Fr 8mm	7331791010828
8279	Provox Vega 20Fr 10mm	7331791010835
8280	Provox Vega 20Fr 12,5mm	7331791010842
8281	Provox Vega 20Fr 15mm	7331791010859
8282	Provox Vega 22,5Fr 4mm	7331791010866
8283	Provox Vega 22,5Fr 6mm	7331791010873
8284	Provox Vega 22,5Fr 8mm	7331791010880
8285	Provox Vega 22,5Fr 10mm	7331791010897
8286	Provox Vega 22,5Fr 12,5mm	7331791010903
8287	Provox Vega 22,5Fr 15mm	7331791010910

Document No: 10000030449 Edition: 01 Release date: 2018-02-02

REF Number	Denomination	EAN code
4288	Provox Vega XtraSeal 17Fr 4mm	7331791011771
4289	Provox Vega XtraSeal 17Fr 6mm	7331791011788
4290	Provox Vega XtraSeal 17Fr 8mm	7331791011795
4291	Provox Vega XtraSeal 17Fr 10mm	7331791011801
4292	Provox Vega XtraSeal 17Fr 12.5mm	7331791011818
4293	Provox Vega XtraSeal 17Fr 15mm	7331791011825
4294	Provox Vega XtraSeal 20Fr 4mm	7331791011832
4295	Provox Vega XtraSeal 20Fr 6mm	7331791011849
4296	Provox Vega XtraSeal 20Fr 8mm	7331791011856
4297	Provox Vega XtraSeal 20Fr 10mm	7331791011863
4298	Provox Vega XtraSeal 20Fr 12.5mm	7331791011870
4299	Provox Vega XtraSeal 20Fr 15mm	7331791011887
4300	Provox Vega XtraSeal 22.5Fr 4mm	7331791011894
4301	Provox Vega XtraSeal 22.5Fr 6mm	7331791011900
4302	Provox Vega XtraSeal 22.5Fr 8mm	7331791011917
4303	Provox Vega XtraSeal 22.5Fr 10mm	7331791011924
4304	Provox Vega XtraSeal 22.5Fr 12.5mm	7331791011931
4305	Provox Vega XtraSeal 22.5Fr 15mm	7331791011948
8288	Provox Vega XtraSeal 17Fr 4mm	7331791010927
8289	Provox Vega XtraSeal 17Fr 6mm	7331791010934
8290	Provox Vega XtraSeal 17Fr 8mm	7331791010941
8291	Provox Vega XtraSeal 17Fr 10mm	7331791010958
8292	Provox Vega XtraSeal 17Fr 12.5mm	7331791010965
8293	Provox Vega XtraSeal 17Fr 15mm	7331791010972
8294	Provox Vega XtraSeal 20Fr 4mm	7331791010989
8295	Provox Vega XtraSeal 20Fr 6mm	7331791010996
8296	Provox Vega XtraSeal 20Fr 8mm	7331791011009
8297	Provox Vega XtraSeal 20Fr 10mm	7331791011016
8298	Provox Vega XtraSeal 20Fr 12.5mm	7331791011023
8299	Provox Vega XtraSeal 20Fr 15mm	7331791011030
8300	Provox Vega XtraSeal 22.5Fr 4mm	7331791011047
8301	Provox Vega XtraSeal 22.5Fr 6mm	7331791011054
8302	Provox Vega XtraSeal 22.5Fr 8mm	7331791011061
8303	Provox Vega XtraSeal 22.5Fr 10mm	7331791011078
8304	Provox Vega XtraSeal 22.5Fr 12.5mm	7331791011085
8305	Provox Vega XtraSeal 22.5Fr 15mm	7331791011092

Produced by: Atos Medical AB
Kraftgatan 8
P.O. Box 183
242 22 Hörby
Sweden

Intended Use: 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.

The Provox Insertion System is a sterile single use device intended for

Document No: 10000030449 Edition: 01 Release date: 2018-02-02

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.

Description: Provox Vega voice prosthesis is an indwelling, low resistance voice prosthesis intended for voice restoration after surgical removal of the larynx.
The Provox Insertion System is a single-use replacement device intended for anterograde insertion only.
Provox Vega XtraSeal has an additional enlarged esophageal flange that is intended to solve problems with leakage around the voice prosthesis.
The products include 1pc Provox Brush.

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 limits 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

Packaging: The Provox Vega 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.

Release date: 2018-02-02
Edition: 01
Document No: 10000030449

Technical Info / Material Data Sheet

Document ID: PF057-01-TechInfo	Edition: 10

REF Number	8110-8115, 8120-8125, 8130-8135, 7770-7787
Product Name	Provox® Vega 17, Provox® Vega 20 and Provox® Vega 22.5 Provox® Vega XtraSeal 17Fr, Provox® Vega XtraSeal 20Fr and Provox® Vega XtraSeal 22.5Fr
Models:	Diameter 17, 20 and 22.5 Fr, each available in the lengths 4, 6, 8, 10, 12.5 and 15 mm and each size available also as XtraSeal model.
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 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 SmartInserter 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 doctor or a trained medical professional in accordance with local or national guidelines. The Provox SmartInserter is not intended to be used for insertion of a voice prosthesis in a freshly made puncture.
Description:	Provox Vega voice prosthesis is an indwelling, low resistance voice prosthesis intended for voice restoration after surgical removal of the larynx. The prosthesis comes preloaded into the SmartInserter, ready for immediate insertion. The SmartInserter is a single-use replacement device intended for anterograde insertion only. Provox Vega XtraSeal has an additional enlarged esophageal flange that is intended to solve problems with leakage around the voice prosthesis. The products includes 1pc Provox Brush.
Sterilization:	EO-sterilization
Raw material:	Prosthesis: Silicone and Polyvinylidene fluoride (PVDF) Insertion system: Polypropylene (PP) and Polyoxymethylene (POM)
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.

Document No: 10000016595 Edition: 10 Release date: 2016-09-21

Technical Info / Material Data Sheet

Hazardous components: None

Expiration date: 5 years after manufacturing

Packaging: The Provox Vega with SmartInserter 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.

Reviewed by:

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Vice President QA&RA

2016-04-29

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Date

Approved by:

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Vice President Design & Development

2016-05-03

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Date

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