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## 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.

# 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.

## Product Information

<b>CE Mark:</b>	Yes. Devices are CE-marked.
<b>GMDN code:</b>	42533 (Tracheoesophageal speech valve, indwelling)
<b>Sterilization:</b>	Yes, EO-sterilization
<b>Raw material:</b>	Prosthesis: Silicone and Polyvinylidene fluoride (PVDF) Insertion system: Polypropylene (PP)
<b>Latex information:</b>	Not manufactured with natural rubber latex
<b>Biological origin:</b>	The device is not manufactured with materials derived from human or animal source.
<b>Handling and storage:</b>	Store the product dry and away from sunlight at room temperature. Excursions permitted between 2°C - 42°C.
<b>Waste handling and disposal:</b>	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.
<b>Hazardous components:</b>	None
<b>Expiration date:</b>	5 years after manufacturing.
<b>Packaging:</b>	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.

**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

# 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

# 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