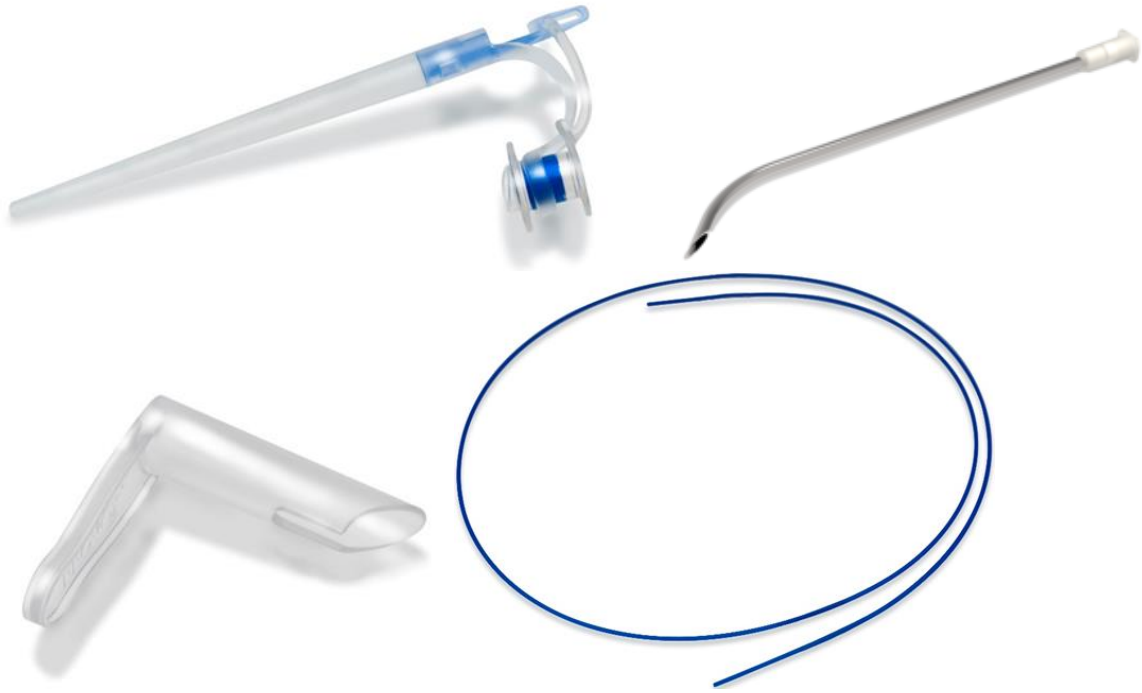


Provox® Vega Puncture Set



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.

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

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

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

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.

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.

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
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