

Provox Plug / Provox Vega Plug



Provox Plug



Provox Vega Plug

Product description:

The Provox Plug / Provox Vega Plug is a first-aid tool for temporarily stopping leakage through the voice prosthesis. The device is inserted into the opening of the Provox / Provox Vega voice prosthesis and hence blocking any leakage through the valve. The medallion end can be taped to the skin if desired.

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Edition: 2.0

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

Classification: IIa (2.1, Rule 5)
MDD 93/42/EEC

Intended Use:

Provox Plug:

Provox Plug is intended to seal the inner lumen of Provox2 voice prostheses and Provox ActiValve and therefore stop leakage of both air and fluids through the voice prosthesis.

Provox Vega Plug:

Provox Vega Plug is intended to seal the inner lumen of Provox Vega voice prosthesis and therefore stop leakage of both air and fluids through the voice prosthesis.

Use specifications: **Intended medical indication**

Provox Vega Plug:

Provox Vega Plug is intended to seal the inner lumen of Provox Vega voice prosthesis and therefore stop leakage of both air and fluids through the voice prosthesis

Provox Plug:

Provox Plug is intended to seal the inner lumen of Provox2 voice prosthesis and Provox ActiValve and therefore stop leakage of both air and fluids through the voice prosthesis.

Intended patient population

Patients of any age.

Cognitive ability, by a clinician judged as sufficient.

Manual dexterity, by a clinician judged as sufficient.

Intended usage

Single patient multiple use, Over-the-counter.

Intended part of the body/type of tissue applied to or interacted with

Introduced in the lumen of a voice prosthesis that is placed in a TE puncture.

Intended user profile

Health care professionals, patients, and lay caregivers.

Intended conditions of use

Environment: Home use.

Frequency of use: Intermittently.

Replacement rate: May be used for a maximum period of 12 months. If the device shows any signs of damage, it must be replaced earlier.

Replacement is performed by the patient, healthcare professionals or caregiver.

Operating principles

The Provox Plug and the Provox Vega Plug are placed in the lumen of the Provox indwelling voice prosthesis from the tracheal side. The Plug is attached to the Provox Brush (opposite end to brush head) which is introduced through the tracheostoma and into the voice prosthesis. When the plug is placed in the voice prosthesis, the brush is removed. The product fulfills its intended use by mechanically sealing the inner lumen of the prosthesis.

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

CE Mark: Yes. Devices are CE-marked.

GMDN code: 62119 (Tracheoesophageal speech valve occlude, non-valved).

Sterilization: Non-sterile.

Raw material: Silicone

Latex information: Not manufactured with natural rubber latex.

Product Information

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:	Provox Plug / Provox Vega Plug is separately packed in a LDPE plastic bag together with one Provox Brush and two instructions for use (Provox Plug/Provox Vega Plug and Provox Brush).

Devices under Basic UDI-DI: 7331791-VPS-A-000-0004-RU

REF	Name	UDI-DI
7205	Provox Plug	07331791000782
8119	Provox Vega Plug 17	07331791005947
8129	Provox Vega Plug 20	07331791005954
8139	Provox Vega Plug 22.5	07331791005961
8119-18	Provox Vega Plug 17	07331791013775
8129-18	Provox Vega Plug 20	07331791013782
8139-18	Provox Vega Plug 22.5	07331791013799



Provox Plug (one size)



Provox Vega Plug (comes in three different sizes)

Atos Medical AB compatible products:

Range	Plug	Vega Plug	BASIC UDI-DI
Provox ActiValve	X		7331791-VPS-0-00I-0001-NT
Provox NID	X		7331791-VPS-0-00I-0000-NQ
Provox Vega		X	7331791-VPS-0-0EI-0002-2V
Provox Vega XtraSeal		X	7331791-VPS-0-0EI-0004-33
Provox2 Voice Prosthesis	X		7331791-VPS-0-0EI-0005-36

Document Approvals
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Task: Approval Task Verdict: Approve	HUABOD Adrienn Bodonyi, Product Support Specialist (huabod@coloplast.com) Issuer 05-Feb-2025 15:01:34 GMT+0000
Task: Final Approval Verdict: Approve	SOFTHO Sofia Thomasson, Regulatory Affairs Professional (sofia.thomasson-atosmedical@coloplast.com) Regulatory 06-Feb-2025 07:04:24 GMT+0000