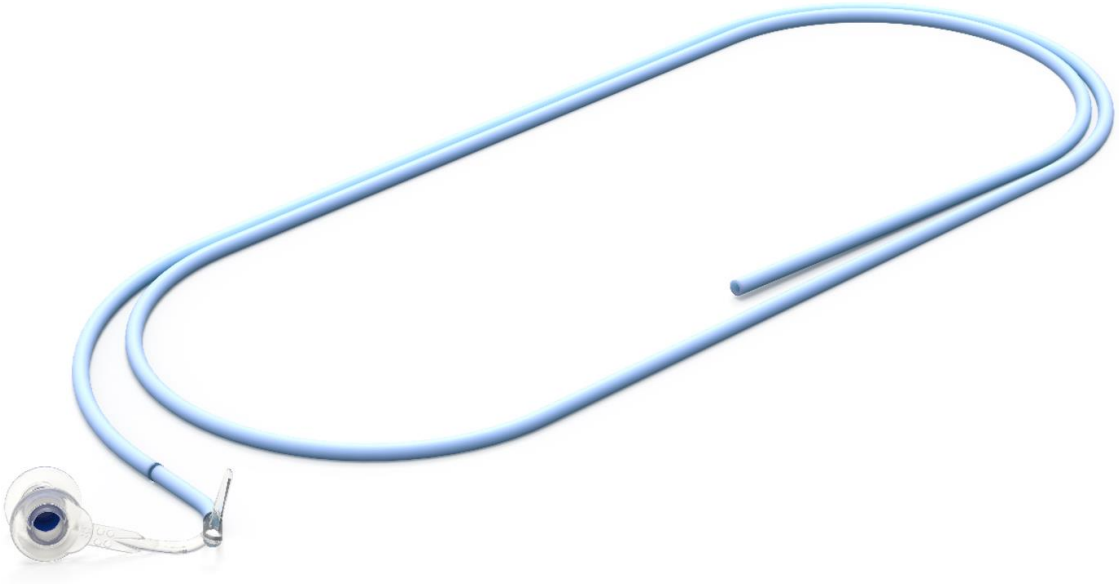
# Product Information

## Provox® GuideWire



**Product description:**

Provox GuideWire is a sterile single use insertion device intended for placement of a sterile Provox indwelling voice prosthesis, and for retrograde replacement of a Provox indwelling voice prosthesis. Provox GuideWire consists of a tube made of a PVC plastic material and a connector for attachment of a Provox indwelling voice prosthesis safety strap made of nylon plastic material (Polyamide).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# Product Information

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| **Document ID:** | PF024-01-TechInfo | **Edition:** | 2.0 |

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

**Classification: (EU) 93/42/EEC**
Class IIa (Rule 6)

**Intended Use:**
The Provox GuideWire is a sterile single use insertion device intended for placement of a sterile Provox indwelling voice prosthesis after total laryngectomy (primary or secondary puncture), or for retrograde replacement of a Provox indwelling voice prosthesis.

**Use specifications:**

**Intended medical indication**
Facilitate retrograde insertion of a voice prosthesis in laryngectomized patients.

**Intended patient population**
Laryngectomized patients of any age.

**Intended usage**
Single use. Prescription only.
**Intended part of the body/type of tissue applied to or interacted with**
Primary interaction (transient): Tracheoesophageal wall.
Secondary interaction (transient): Trachea, esophagus, pharynx, mouth.

**Intended user profile**
Health care professional (HCP) including medical staff such as physician, nurse, SLP, and clinician.

**Intended conditions of use**
Placement of voice prosthesis is performed at the time of, and in the environment of, the procedure of tracheoesophageal puncture, e.g. the operating theatre or in an outpatient clinic. No environmental restrictions regarding temperature, moisture, hygiene, lighting and working position. Potential high stress level. Both daytime and nighttime.

**Contraindications:**
Do not use if the patient has anatomical abnormalities, e.g. significant pharyngeal stenosis above the puncture site or severe trismus. Significant pharyngeal stenosis may preclude insertion of the voice prosthesis. Severe trismus may preclude proper protection of the pharyngeal wall during secondary puncture leading to harm of the esophageal tissue.

**CE Mark:**
Yes. Devices are CE-marked.

**GMDN code:**
65394 Tracheoesophageal speech valve guidewire.

**Sterilization:**
EO-sterilization.

**Raw material:**
PVC Tubing: Polyvinyl chloride (PVC) with blue masterbatch.
Joint and Tip: Polyamide (PA) without masterbatch.

**Latex information:**
Not manufactured with natural rubber latex.

**Biological origin:**
The device is not manufactured with materials derived from human or animal source.

# Product Information

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| **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 Guidewire is packed in a sterile bag made of paper and polyester/polypropylene laminate. It is then packed in a cardboard box together with instructions for use. |

**Devices under Basic UDI-DI:** 7331791-VPS-A-OEO-0006-5Z

| REF | Name | UDI-DI |
|---|---|---|
| 7215 | Provox GuideWire | 7331791000867 |

**Atos Medical AB compatible products:**

| Range | BASIC UDI-DI |
|---|---|
| Provox Vega | 7331791-VPS-0-0E0-0002-N2 |
| Provox Vega XtraSeal | 7331791-VPS-0-0E0-0004-N8 |
| Provox2 Voice Prosthesis | 7331791-VPS-0-0E0-0005-NB |
| Provox ActiValve | 7331791-VPS-0-000-0001-A3 |

Document Approvals
Approved Date: 2023-11-15

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|---|---|
| Task: Approval Task<br>Verdict: Approve | ABDALM Abdallah Almashharawi, Sustaining Engineer<br>(abdallah.almashharawi-atosmedical@coloplast.com)<br>Issuer<br>31-Oct-2023 09:52:34 GMT+0000 |

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| Task: Final Approval<br>Verdict: Approve | ELIAND Elin Andersson, Design Control & Usability Engineering Specialist<br>(elin.andersson-atosmedical@coloplast.com)<br>Technical / Specialist<br>15-Nov-2023 07:59:50 GMT+0000 |