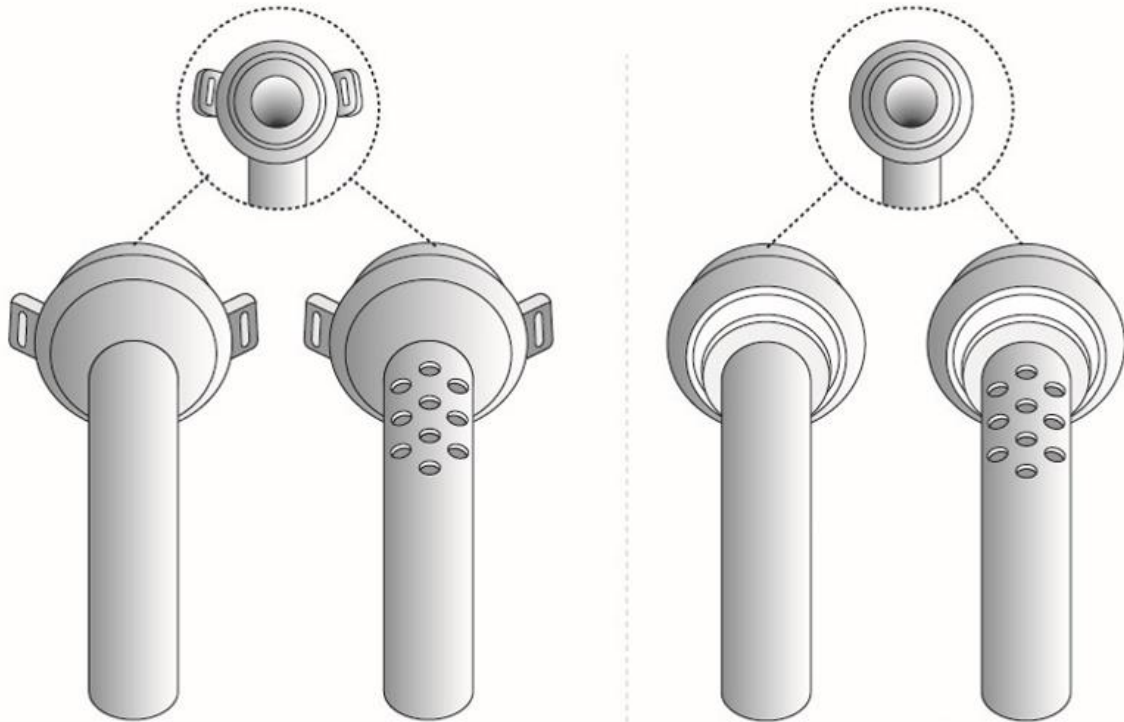


## Provox Life LaryTube



Standard

Fenestrated

Standard  
with Ring

Fenestrated  
with Ring

**Product description:**

Provox Life LaryTube is a tube made of medical grade silicone rubber. The purpose of the device is to create a comfortable and airtight fit between Provox Life LaryTube and the tracheostoma, and to provide attachment for devices from the Provox Life HME System and Provox Life Shower.

**Standard model and Ring model** can be fenestrated so that air can go through the voice prosthesis for voice prosthesis users. The holes are punched by using a biopsy punch.

**Standard model** – made for use with or without a voice prosthesis. Can be attached with a Provox TubeHolder, Provox LaryClip or Freevent Neckband.

**Fenestrated model** – made for voice prosthesis users. Can be attached with a Provox TubeHolder, Provox LaryClip or Freevent Neckband.

**Standard with Ring model** – made for use with or without a voice prosthesis. Can only be attached with a Provox Life Adhesive.

**Fenestrated with Ring model** – made for voice prosthesis users. Can only be attached with a Provox Life Adhesive.

**Document ID:** PF106-01-TechInfo

**Edition:** 3.0

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

**Classification: (EU)** IIb (Rule 5)  
**93/42/EEC**

**Intended Use:** Provox Life LaryTube is a single patient use device intended to provide attachment for Provox Life HME and accessories after total laryngectomy. For laryngectomized patients with a shrinking tracheostoma it is also used to maintain the tracheostoma for breathing.

**Use specifications:** **Intended medical indication**  
Product for rehabilitation for patients breathing through a tracheostoma.

**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, Prescription only.

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

Tracheostoma.

**Intended user profile**

The product 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:

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: Continuous use.

Replacement rate: Max usage for 6 months. If device shows any signs of damage, it shall be replaced earlier. Replacement is performed by the patient, clinician or caregiver.

## Product Information

|                                     |  |
|-------------------------------------|--|
| <b>Contraindications:</b>           | Provox LaryTube is not intended to be used by patients that: <ul style="list-style-type: none"><li>• are under any form of mechanical ventilation.</li><li>• have damaged tracheostoma tissue.</li></ul> |
| <b>CE Mark:</b>                     | Yes. Devices are CE-marked.  |
| <b>GMDN code:</b>                   | 12292 (Laryngectomy tube)  |
| <b>Sterilization:</b>               | Non-sterile.   |
| <b>Raw material:</b>                | Tube: Silicone<br>Ring for Tube: Silicone with white masterbatch   |
| <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>                   | Provox Life LaryTube is single packed in a plastic bag of polyethylene. It is then packed together with instructions for use for Provox Life LaryTube in a cardboard box.                                |

**Devices under Basic UDI-DI: 7331791-LTU-0-000-0004-3L**

| REF  | Name   | UDI-DI        |
|------|--|---------------|
| 7409 | Provox Life LaryTube 8/27 Standard               | 7331791013874 |
| 7410 | Provox Life LaryTube 8/36 Standard               | 7331791013881 |
| 7411 | Provox Life LaryTube 8/55 Standard               | 7331791013898 |
| 7412 | Provox Life LaryTube 9/27 Standard               | 7331791013676 |
| 7413 | Provox Life LaryTube 9/36 Standard               | 7331791013683 |
| 7414 | Provox Life LaryTube 9/55 Standard               | 7331791013713 |
| 7415 | Provox Life LaryTube 10/27 Standard              | 7331791013904 |
| 7416 | Provox Life LaryTube 10/36 Standard              | 7331791013911 |
| 7417 | Provox Life LaryTube 10/55 Standard              | 7331791013928 |
| 7418 | Provox Life LaryTube 12/27 Standard              | 7331791013935 |
| 7419 | Provox Life LaryTube 12/36 Standard              | 7331791013942 |
| 7420 | Provox Life LaryTube 12/55 Standard              | 7331791013959 |
| 7421 | Provox Life LaryTube 8/36 Standard with Ring     | 7331791013966 |
| 7422 | Provox Life LaryTube 8/55 Standard with Ring     | 7331791013973 |
| 7423 | Provox Life LaryTube 9/36 Standard with Ring     | 7331791013690 |
| 7424 | Provox Life LaryTube 9/55 Standard with Ring     | 7331791013720 |
| 7425 | Provox Life LaryTube 10/36 Standard with Ring    | 7331791013980 |
| 7426 | Provox Life LaryTube 10/55 Standard with Ring    | 7331791013997 |
| 7427 | Provox Life LaryTube 12/36 Standard with Ring    | 7331791014000 |
| 7428 | Provox Life LaryTube 12/55 Standard with Ring    | 7331791014017 |
| 7429 | Provox Life LaryTube 8/36 Fenestrated            | 7331791014024 |
| 7430 | Provox Life LaryTube 8/55 Fenestrated            | 7331791014031 |
| 7431 | Provox Life LaryTube 9/36 Fenestrated            | 7331791013706 |
| 7432 | Provox Life LaryTube 9/55 Fenestrated            | 7331791013737 |
| 7433 | Provox Life LaryTube 10/36 Fenestrated           | 7331791014048 |
| 7434 | Provox Life LaryTube 10/55 Fenestrated           | 7331791014055 |
| 7435 | Provox Life LaryTube 12/36 Fenestrated           | 7331791014062 |
| 7436 | Provox Life LaryTube 12/55 Fenestrated           | 7331791014079 |
| 8048 | Provox Life LaryTube 8/36 Fenestrated with Ring  | 7331791014949 |
| 8049 | Provox Life LaryTube 8/55 Fenestrated with Ring  | 7331791014956 |
| 8050 | Provox Life LaryTube 9/36 Fenestrated with Ring  | 7331791014963 |
| 8051 | Provox Life LaryTube 9/55 Fenestrated with Ring  | 7331791014970 |
| 8052 | Provox Life LaryTube 10/36 Fenestrated with Ring | 7331791014987 |
| 8053 | Provox Life LaryTube 10/55 Fenestrated with Ring | 7331791014994 |
| 8054 | Provox Life LaryTube 12/36 Fenestrated with Ring | 7331791015007 |
| 8055 | Provox Life LaryTube 12/55 Fenestrated with Ring | 7331791015014 |

**Atos Medical AB compatible products:**

| Range                                 | BASIC UDI-DI              |
|---------------------------------------|---------------------------|
| Provox Brush                          | 7331791-GEN-A-000-0001-E9 |
| Provox TubeBrush                      | 7331791-GEN-A-000-0001-E9 |
| Provox Swab                           | 7331791-GEN-A-000-0002-EC |
| Provox Life Standard Adhesive         | 7331791-ADH-0-000-0001-CT |
| Provox Life Standard Adhesive Round   | 7331791-ADH-0-000-0001-CT |
| Provox Life Standard Adhesive Oval    | 7331791-ADH-0-000-0001-CT |
| Provox Life Standard Adhesive Plus    | 7331791-ADH-0-000-0001-CT |
| Provox Life Sensitive Adhesive        | 7331791-ADH-0-000-0001-CT |
| Provox Life Sensitive Adhesive Round  | 7331791-ADH-0-000-0001-CT |
| Provox Life Sensitive Adhesive Oval A | 7331791-ADH-0-000-0001-CT |

| Range                                 | BASIC UDI-DI              |
|---------------------------------------|---------------------------|
| Provox Life Sensitive Adhesive Oval B | 7331791-ADH-0-000-0001-CT |
| Provox Life Sensitive Adhesive Plus   | 7331791-ADH-0-000-0001-CT |
| Provox Life Stability Adhesive        | 7331791-ADH-0-000-0001-CT |
| Provox Life Night Adhesive            | 7331791-ADH-0-000-0001-CT |
| Provox Life Go HME                    | 7331791-HME-0-000-0001-XC |
| Provox Life Home HME                  | 7331791-HME-0-000-0001-XC |
| Provox Life Energy HME                | 7331791-HME-0-000-0001-XC |
| Provox Life Protect HME               | 7331791-HME-0-000-0001-XC |
| Provox Life Night HME                 | 7331791-HME-0-000-0001-XC |
| Provox Life FreeHands HME             | 7331791-HME-0-000-0001-XC |
| Provox Life Shower                    | 7331791-ADH-A-000-0001-UB |
| Provox LaryClip                       | 7331791-LTU-A-000-0001-JT |
| Provox TubeHolder                     | 7331791-GEN-A-000-0000-E6 |
| Provox Life BasePlate Adaptor         | 7331791-HME-A-000-0005-FB |
| FreeVent Neckband                     | 7331791-GEN-A-000-0005-EM |

Document Approvals  
Approved Date: 2024-07-11

|  |   |
|--|---|
| Task: Approval Task<br>Verdict: Approve  | SEHRBJNC Carolina Johansson, Sustaining Engineer<br>(carolina.johansson-atosmedical@coloplast.com)<br>Issuer<br>05-Jul-2024 04:57:37 GMT+0000             |
| Task: Approval Task<br>Verdict: Approve  | ABDALM Abdallah Almashharawi, Senior Sustaining Engineer<br>(abdallah.almashharawi-atosmedical@coloplast.com)<br>Quality<br>05-Jul-2024 06:54:37 GMT+0000 |
| Task: Final Approval<br>Verdict: Approve | KARNIL Karolina Nilsson, Head of Regulatory Affairs<br>(karolina.nilsson-atosmedical@coloplast.com)<br>Regulatory<br>11-Jul-2024 12:55:14 GMT+0000        |