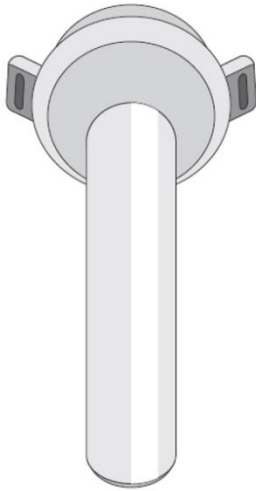
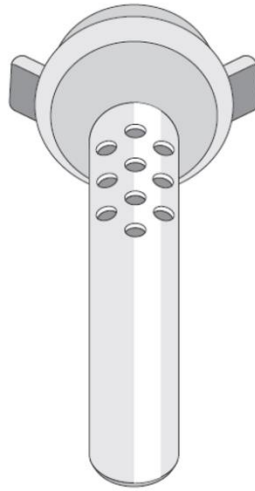


Provox® LaryTube™

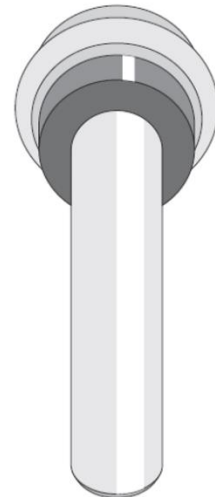
Provox LaryTube



Provox LaryTube, Fenestrated



Provox LaryTube with Ring



Product description:

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

The Standard model and the Ring version can be fenestrated so that air can go through the voice prosthesis for voice prosthesis users.

Standard versions – made for use with or without a voice prosthesis. Can be attached with a Provox TubeHolder or Provox LaryClip.

Fenestrated versions – for voice prosthesis users. Can be attached with a Provox TubeHolder or Provox LaryClip.

Ring versions – made for use with or without a voice prosthesis.

Document ID: PF011-02-TechInfo **Edition:** 2.0

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

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

Intended Use: The Provox LaryTube is a holder for devices in the Provox HME System intended for vocal and pulmonary rehabilitation after total laryngectomy. For patients with a shrinking tracheostoma it is also used to maintain the tracheostoma for breathing. The Provox LaryTube is intended for single patient use.

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: Home use (normal daily environment without any or environmental restrictions regarding temperature, moisture etc.).
Outpatient clinic use. Hospital use.
Frequency of use: Continuous use.
Replacement rate: Max use of 6 months. Replacement is performed by the patient, clinician or caregiver.

Contraindications: Provox LaryTube is not intended to be used by patients that:

- are under any form of mechanical ventilation.
- have damaged tracheal or tracheostoma tissue.

CE Mark: Yes. Devices are CE-marked.

GMDN code: 12292 (Laryngectomy tube)

Sterilization: Non-sterile

Raw material: LaryTube: Silicone
Ring: Silicone with blue masterbatch

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 LaryTube is packed in a plastic bag of polyethylene. The product and instructions for use are packed in a cardboard box.

Devices under Basic UDI-DI: 7331791-LTU-0-000-0002-3E

REF	Name	UDI-DI
7601FR	Provox LaryTube 8/27	7331791002083
7602FR	Provox LaryTube 8/36	7331791002106
7603FR	Provox LaryTube 8/55	7331791002120
7605FR	Provox LaryTube 9/27	7331791002144
7606FR	Provox LaryTube 9/36	7331791002168
7607FR	Provox LaryTube 9/55	7331791002182
7609FR	Provox LaryTube 10/27	7331791002205
7610FR	Provox LaryTube 10/36	7331791002229
7611FR	Provox LaryTube 10/55	7331791002243
7613FR	Provox LaryTube 12/27	7331791002267
7614FR	Provox LaryTube 12/36	7331791002281
7615FR	Provox LaryTube 12/55	7331791002304
7624FR	Provox LaryTube 8/36 with Ring	7331791002328
7625FR	Provox LaryTube 8/55 with Ring	7331791002342
7626FR	Provox LaryTube 9/36 with Ring	7331791002366
7627FR	Provox LaryTube 9/55 with Ring	7331791002380
7628FR	Provox LaryTube 10/36 with Ring	7331791002403
7629FR	Provox LaryTube 10/55 with Ring	7331791002427
7630FR	Provox LaryTube 12/36 with Ring	7331791002441
7631FR	Provox LaryTube 12/55 with Ring	7331791002465
7637FR	Provox LaryTube 8/36, Fenestrated	7331791002489
7638FR	Provox LaryTube 8/55, Fenestrated	7331791002502
7640FR	Provox LaryTube 9/36, Fenestrated	7331791002526
7641FR	Provox LaryTube 9/55, Fenestrated	7331791002540
7643FR	Provox LaryTube 10/36, Fenestrated	7331791002564
7644FR	Provox LaryTube 10/55, Fenestrated	7331791002588
7646FR	Provox LaryTube 12/36, Fenestrated	7331791002601
7647FR	Provox LaryTube 12/55, Fenestrated	7331791002625

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox Adhesive	7331791-ADH-0-000-0000-CQ
Provox BasePlate Adaptor	7331791-HME-A-000-0003-F5
Provox Brush	7331791-VPS-A-000-0003-RR
Provox FreeHands HME Cassette	7331791-HME-0-000-0003-XJ
Provox LaryClip	7331791-LTU-A-000-0001-JT
Provox Micron HME	7331791-HME-0-000-0002-XF
Provox ShowerAid	7331791-ADH-A-000-0000-U8
Provox Swab	7331791-GEN-A-000-0002-EC
Provox TubeBrush	7331791-GEN-A-000-0001-E9
Provox TubeHolder	7331791-GEN-A-000-0000-E6
Provox XtraHME	7331791-HME-0-000-0000-X9

Document Approvals
Approved Date: 2023-10-24

Task: Approval Task Verdict: Approve	ABDALM Abdallah Almashharawi, Sustaining Engineer (abdallah.almashharawi-atosmedical@coloplast.com) Issuer 23-Oct-2023 10:05:08 GMT+0000
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Task: Final Approval Verdict: Approve	ELIAND Elin Andersson, Associate Design Control & Usability Specialist (elin.andersson-atosmedical@coloplast.com) Technical / Specialist 24-Oct-2023 09:27:50 GMT+0000
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