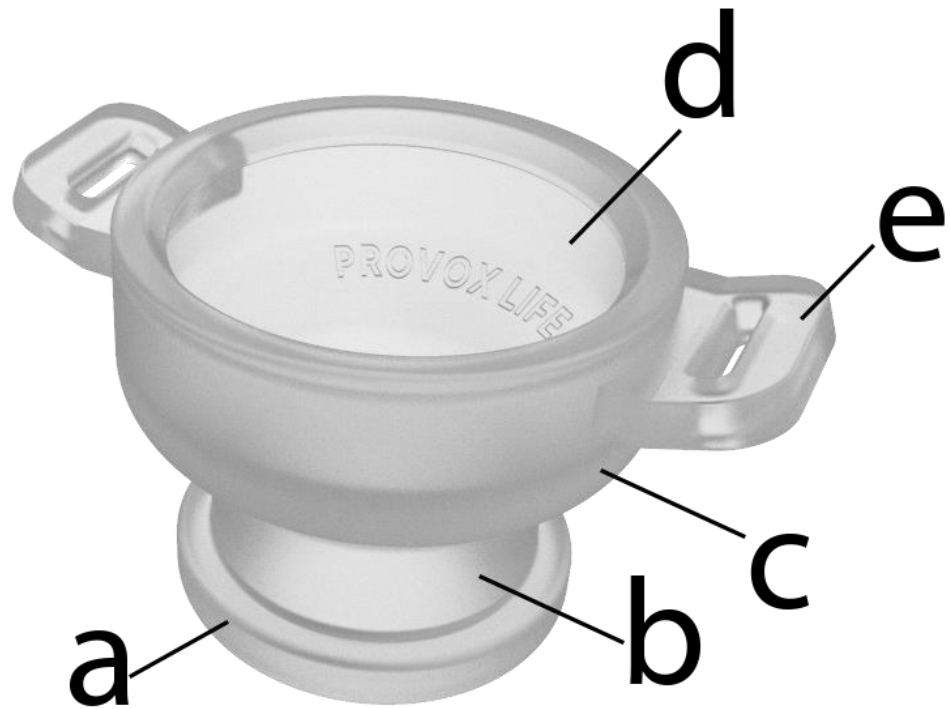


## Provox Life LaryButton



### Product description:

Provox Life LaryButton is a self-retaining tracheostoma button made of medical grade silicone rubber. The purpose of the device is to create a comfortable and airtight fit between Provox Life LaryButton and the tracheostoma and also to provide attachment for devices from Provox Life HME System. The device is delivered single packed, non-sterile and ready to use. The different parts of Provox Life LaryButton are:

- a) Retention Collar
- b) Shaft
- c) Shield (conical)
- d) HME and Accessory Holder
- e) Wings

**Document ID:** PF116-01-TechInfo

**Edition:** 2.0

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

**Classification: (EU)** IIb (2.1 Rule 5)  
**93/42/EEC**

**Intended Use:** Provox Life LaryButton is a single patient use self-retaining holder for Provox Life HMEs 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**

Provox Life LaryButton is a self-retaining holder for Provox Life HMEs and accessories after total laryngectomy. For laryngectomized patients with a shrinking tracheostoma, it is also used to maintain the tracheostoma for breathing.

Provox Life LaryButton is a single patient multiple use device prescribed by a clinician.

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

The device will contact intact skin and mucosal membrane and as external communicating device the contact mode with tissue is indirect via air.

**Intended user profile**

Patient, Health care professional (HCP), Lay caregiver

**Intended conditions of use**

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 the device shows any signs of damage, it shall be replaced earlier. Replacement is performed by the patient, clinician or caregiver.

**Contraindications:** Provox Life LaryButton is not intended to be used by patients that:

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

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

**GMDN code:** 14093 (Tracheostoma button)

## Product Information

<b>Sterilization:</b>	Non-Sterile
<b>Raw material:</b>	Provox Life LaryButton consists of transparent medical grade silicone rubber.
<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>	Devices are singled packed in a plastic bag made of polyethylene and then packed together with instructions for use in a cardboard box.

**Devices under Basic UDI-DI: 7331791-LTU-0-000-0005-3P**

REF	Name	UDI-DI
8040	Provox Life LaryButton 12/8	7331791015304
8041	Provox Life LaryButton 12/18	7331791015106
8042	Provox Life LaryButton 14/8	7331791015113
8043	Provox Life LaryButton 14/18	7331791015120
8044	Provox Life LaryButton 16/8	7331791015137
8045	Provox Life LaryButton 16/18	7331791015144
8046	Provox Life LaryButton 18/8	7331791015151
8047	Provox Life LaryButton 18/18	7331791015168

**Atos Medical AB compatible products:**

Range	BASIC UDI-DI
Provox TubeBrush	7331791-GEN-A-000-0001-E9
Provox Swab	7331791-GEN-A-000-0002-EC
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-0-000-0008-XZ
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-000-0000-E6
Stoma Sizing Guide	7331791-LTU-A-000-0001-JT

Document Approvals  
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