

# Product Information

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Niki Svensson - NIKSVE	2022-12-19 - 11:36
Reviewed:	QA	Sofia Thomasson - SOFTHO	2022-12-19 - 11:42
Approved:	QA	Elin Andersson - ELIAND	2022-12-22 - 15:47
Released:	QA	Niki Svensson - NIKSVE	2023-03-16 - 13:32

This document has been electronically signed by the persons above.



### Product description:

The Sizer Kit is a box which contains samples, (Sizers.) of commercially available Provox LaryButtons. The sizes of these Sizers and actual Provox LaryButtons are the same and are indicated on the products themselves and in the bottom of the outer storage box. Each Sizer in the Sizer Kit is stored in an individual removable polypropylene box. This makes it possible for the prescribing specialist to remove the individual storage boxes with the Sizers from the outer storage box individually. This allows for hygienic handling of both the Sizers and the storage boxes. After each sizing session, the Sizer(s) with its individual storage box(es) must be cleaned, disinfected, dried and steam sterilized according to the accompanying Instructions for cleaning and sterilization. The outer storage box must also be cleaned if contaminated. The Sizer LaryButtons and their individual removable storage boxes are thereafter put back at the appropriate position as indicated in the bottom of the outer storage box

# Product Information

**Document ID:** PF032-01-TechInfo **Edition:** 04

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

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

**Intended Use:** The Provox® LaryButton Sizer Kit is intended for use by the prescribing clinician to determine the size(s) of LaryButton that should be prescribed to the patient. The Sizer Kit should be used only by a prescribing clinician who has read the LaryButton Manual. A copy of that manual comes with the Sizer Kit. It can also be viewed on the Internet at [www.atosmedical.com](http://www.atosmedical.com). The Sizer LaryButtons are intended for the sizing procedure only. After the correct size(s) have been determined a new LaryButton(s) shall be prescribed to the patient for actual use.

**Use specifications:** **Intended medical condition**  
 Laryngectomized patient.

**Intended patient population**

Gender: Male and female.  
 Age: Typical average age for a laryngectomy is 65 years.

**Intended usage**

The Sizer LaryButtons are intended for the sizing procedure only.

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

**Intended user profile**

Prescribing clinician.

**Intended conditions of use**

Only to be used in clinical environment.

**Contraindications:** The Sizer Kit in itself does not have specific contraindications. Do not use the Provox LaryButton, or use it only with special care, in cases of tracheostoma tissue problems such as damaged mucous membrane, granulation tissue formation, and vulnerability with a higher tendency to bleed. The Provox LaryButton may be contraindicated for patients with bleeding disorders or undergoing anticoagulant treatment.

**CE Mark:** Yes. Device is CE-marked.

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

**Sterilization:** Non-sterile, steam sterilizable

**Raw material:** Silicone, polypropylene

**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

**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 LaryButton Sizer Kit is single packed in a tamper-proof plastic bag made of polypropylene together with one IFU for the product, one IFU for Provox LaryButton and one IFU for cleaning and sterilization.

Document No: 10000038474 Edition: 04 Release date: 2023-03-16

Released

# Product Information

**Devices under Basic UDI-DI: 7331791-LTU-0-000-0001-3B**

REF	Name	UDI-DI
7690	Provox LaryButton Sizer Kit	7331791002779

**Atos Medical AB compatible products:**

Range	BASIC UDI-DI
N/A	N/A