Product Information

Provox® LaryTube™ Sizer Kit

Product description:

The Sizer Kit is a box which contains samples (“sizers”) of a variety of commercially available Provox LaryTubes. The sizes of these Sizers and actual Provox LaryTubes are the same. The size is indicated on the products and both diameter and length are indicated on the chart inside the 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 Sizer(s) and the storage box. After each sizing session, the Sizer(s) with its individual storage box must be cleaned, disinfected, dried and steam sterilized according to the accompanying "instructions for cleaning and sterilization".

Product Information

Document ID:	PF062-01-TechInfo	**Edition:**	2.0

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

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

Intended Use: The Provox LaryTube Sizer Kit is intended for use by the prescribing specialist to determine the size(s) of LaryTube that should be prescribed to the patient. The Sizer Kit should be used only by a prescribing specialist who has read the LaryTube Manual. A copy of that manual comes with the Sizer Kit. It can also be viewed on the Internet at www.atosmedical.com. The Sizer LaryTubes are intended for the sizing procedure only. After the correct size(s) have been determined, new LaryTube(s) shall be given to the patient for 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 LaryTubes 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. The Provox LaryTubes contained in the LaryTube Sizer Kit are not intended for patients requiring mechanical ventilation.

CE Mark: Yes. Device is CE-marked.

GMDN code: 12292 (Laryngectomy tube)

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.

Handling and storage: Store the product dry and away from sunlight at room temperature. Excursions permitted between 2 °C – 42 °C.

Product Information

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 Sizer Kit is single packed in a tamper-proof plastic bag together with a manual for the product, instructions for sterilization and a manual for the Provox LaryTube.

Product Information

Devices under Basic UDI-DI: 7331791-LTU-0-000-0003-3H

REF	Name	UDI-DI
7648	Provox LaryTube Sizer Kit	07331791005329

Atos Medical AB compatible products:

Range	BASIC UDI-DI
N/A	N/A

Document Approvals

Approved Date: 2023-10-23

Task: Approval Task Verdict: Approve	ABDALM Abdallah Almashharawi, Sustaining Engineer (abdallah.almashharawi-atosmedical@coloplast.com) Issuer 16-Oct-2023 07:34:12 GMT+0000

Task: Final Approval Verdict: Approve	ELIAND Elin Andersson, Associate Design Control & Usability Specialist (elin.andersson-atosmedical@coloplast.com) Technical / Specialist 23-Oct-2023 09:09:38 GMT+0000