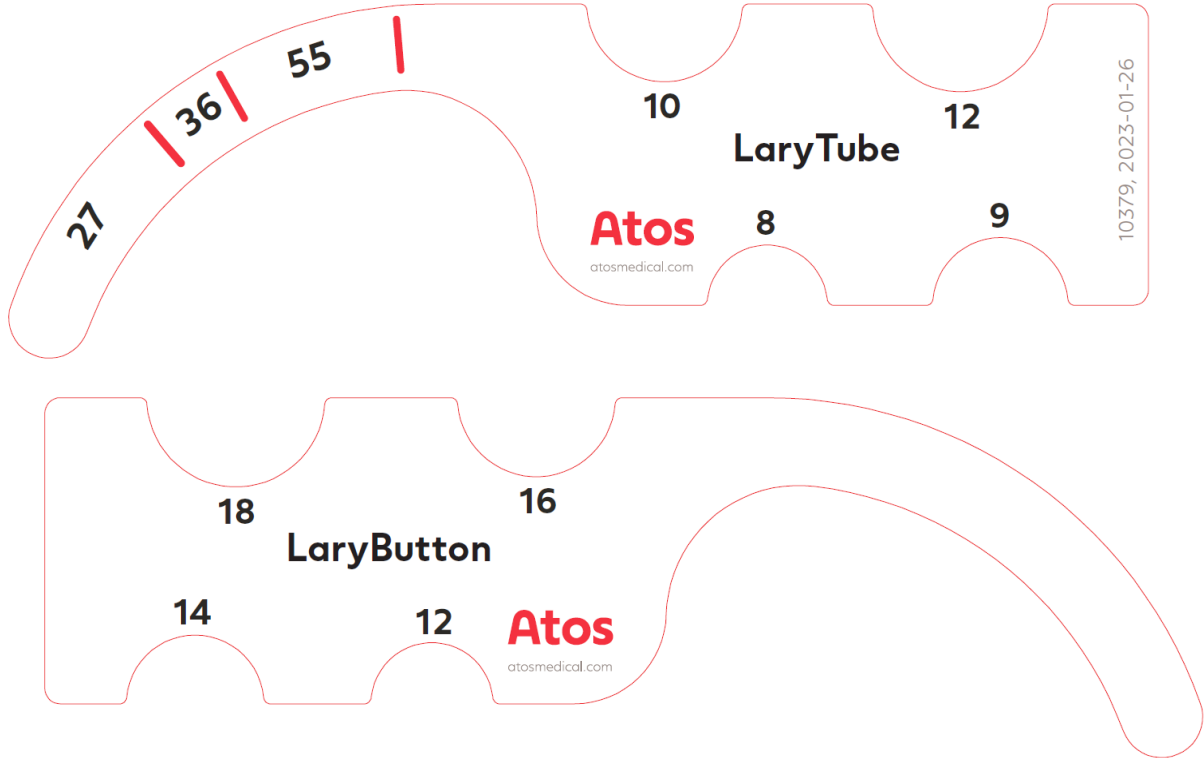


Stoma Sizing Guide



Product description:

Stoma Sizing Guide is a guide made of laminated paper and marked with indicators. It is delivered non-sterile and ready for use.

Document ID: PF118-01-TechInfo

Edition: 2.0

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

Classification: (EU) Class I, Rule 5
2017/745

Intended Use: Stoma Sizing Guide is a single use device intended to help the prescribing clinician determine which size of LaryTube or LaryButton in the Provox and Provox Lif range respectively should be prescribed to the patient. Stoma Sizing Guide is intended to be used by a prescribing clinician who has read the IFU for Provox and Provox Life LaryTube and LaryButton respectively. Stoma Sizing Guide can also be used by patients to monitor the stoma size.

Use specifications: **Intended medical indication**
Patients breathing through a tracheostoma using LaryTube or LaryButton for pulmonary rehabilitation.

Intended patient population
For patients breathing through a tracheostoma after total laryngectomy.

Intended usage
Single use, Prescription only.

Intended part of the body/type of tissue applied to or interacted with
Tracheostoma. The device will contact intact skin and mucosal membrane.

Intended user profile
The product is supposed to be handled by prescribing clinician and patient.

Intended conditions of use
Outpatient clinic use. Hospital use.
Frequency of use: Transient, Normally intended for use for less than 60 minutes.
Replacement rate: N/A, Single use only.
Home use (normal daily environment without any hygienical or environmental restrictions).

Contraindications: No known contraindications

CE Mark: Yes. Devices are CE-marked.

GMDN code: 65811 (Tracheostoma sizer)

Sterilization: Non-sterile.

Raw material: Paper laminated with a Polypropylene-film

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:	2 years after manufacturing.
Packaging:	5 x 10 pcs of Stoma Sizing Guide are packed in a LDPE plastic bags, which is then packed in a cardboard box together with an IFU.

Devices under Basic UDI-DI: 7331791-LTU-0-000-0006-3S

REF	Name	UDI-DI
7135	Stoma Sizing Guide	7331791015366

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox Life LaryTube	7331791-LTU-0-000-0004-3L
Provox Life LaryButton	7331791-LTU-0-000-0005-3P
Provox LaryTube	7331791-LTU-0-000-0002-3E
Provox LaryButton	7331791-LTU-0-000-0000-38

Document Approvals
Approved Date: 2023-10-23

Task: Approval Task Verdict: Approve	NIKI.SVENSSON Niki Svensson, Sustaining Engineer (niki.svensson-atosmedical@coloplast.com) Issuer 19-Oct-2023 06:00:07 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 23-Oct-2023 06:25:27 GMT+0000
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