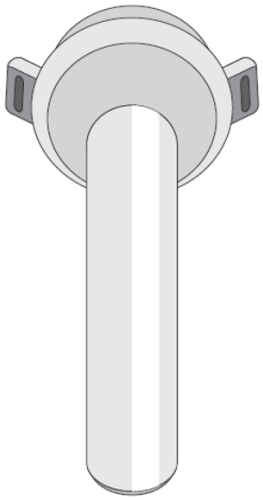
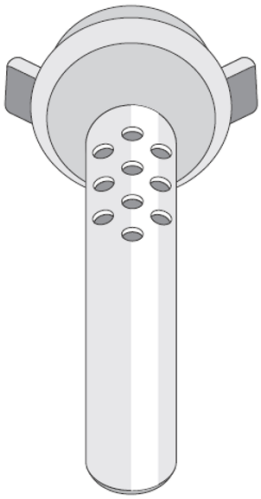
Product Information

Provox® LaryTube™

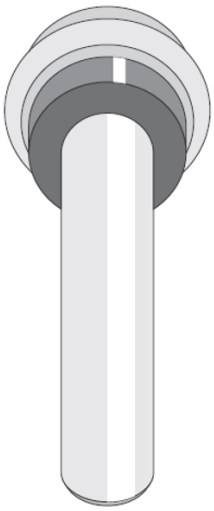
Provox LaryTube



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.

Product Information

Document ID:	PF011-01-TechInfo	**Edition:**	2.0

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

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

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:	3 years after manufacturing.
Packaging:	**Provox LaryTube (standard)** is packed in a plastic bag of polyethylene. 5 pcs of Provox XtraFlow HME are packed in a plastic bag of polyethylene. The products and instructions for use for Provox LaryTube and Provox XtraHME are packed in a cardboard box. **Provox LaryTube (fenestrated)** is packed in a plastic bag of polyethylene. 5 pcs of Provox XtraFlow HME are packed in a plastic bag of polyethylene. 1 Provox Brush is packed in a plastic bag of polyethylene. The products and instructions for use for Provox LaryTube and Provox XtraHME and Provox Brush are packed in a cardboard box. **Provox LaryTube (with ring)** is packed in a plastic bag of polyethylene. 5 pcs of Provox XtraFlow HME are packed in a plastic bag of polyethylene. The products and instructions for use for Provox LaryTube and Provox XtraHME are packed in a cardboard box.

Product Information

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

REF	Name	UDI-DI
7601	Provox LaryTube 8/27	07331791002076
7602	Provox LaryTube 8/36	07331791002090
7603	Provox LaryTube 8/55	07331791002113
7605	Provox LaryTube 9/27	07331791002137
7606	Provox LaryTube 9/36	07331791002151
7607	Provox LaryTube 9/55	07331791002175
7609	Provox LaryTube 10/27	07331791002199
7610	Provox LaryTube 10/36	07331791002212
7611	Provox LaryTube 10/55	07331791002236
7613	Provox LaryTube 12/27	07331791002250
7614	Provox LaryTube 12/36	07331791002274
7615	Provox LaryTube 12/55	07331791002298
7624	Provox LaryTube 8/36 with Ring	07331791002311
7625	Provox LaryTube 8/55 with Ring	07331791002335
7626	Provox LaryTube 9/36 with Ring	07331791002359
7627	Provox LaryTube 9/55 with Ring	07331791002373
7628	Provox LaryTube 10/36 with Ring	07331791002397
7629	Provox LaryTube 10/55 with Ring	07331791002410
7630	Provox LaryTube 12/36 with Ring	07331791002434
7631	Provox LaryTube 12/55 with Ring	07331791002458
7637	Provox LaryTube 8/36, Fenestrated	07331791002472
7638	Provox LaryTube 8/55, Fenestrated	07331791002496
7640	Provox LaryTube 9/36, Fenestrated	07331791002519
7641	Provox LaryTube 9/55, Fenestrated	07331791002533
7643	Provox LaryTube 10/36, Fenestrated	07331791002557
7644	Provox LaryTube 10/55, Fenestrated	07331791002571
7646	Provox LaryTube 12/36, Fenestrated	07331791002595
7647	Provox LaryTube 12/55, Fenestrated	07331791002618

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

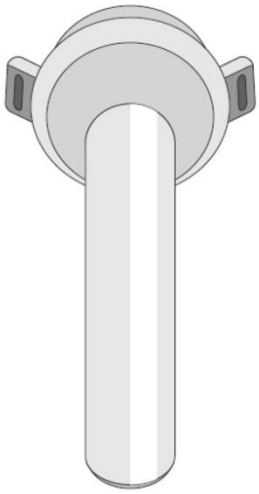
Task: Approval Task Verdict: Approve	ABDALM Abdallah Almashharawi, Sustaining Engineer (abdallah.almashharawi-atosmedical@coloplast.com) Issuer 23-Oct-2023 10:05:09 GMT+0000

Task: Final Approval Verdict: Approve	ELIAND Elin Andersson, Associate Design Control & Usability Specialist (elin.andersson-atosmedical@coloplast.com) Technical / Specialist 24-Oct-2023 09:29:44 GMT+0000

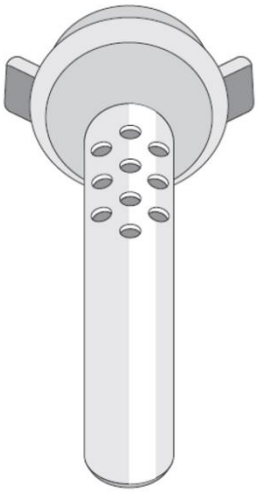
Product Information

Provox® LaryTube™

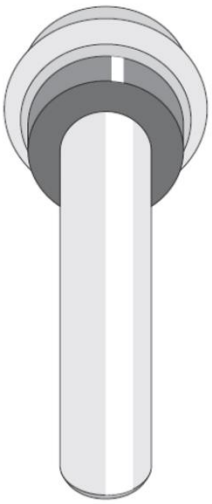
Provox LaryTube



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.

Product Information

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

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

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

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.

Product Information

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

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

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Carolina Johansson - SEHRBJNC	2022-04-12 - 14:46
Reviewed:	QA	Karolina Nilsson - KARNIL	2022-04-12 - 15:48
Approved:	DD	Diana Tieger - DIATIE	2022-04-14 - 08:06
Released:	QA	Carolina Johansson - SEHRBJNC	2022-05-19 - 15:07

This document has been electronically signed by the persons above.

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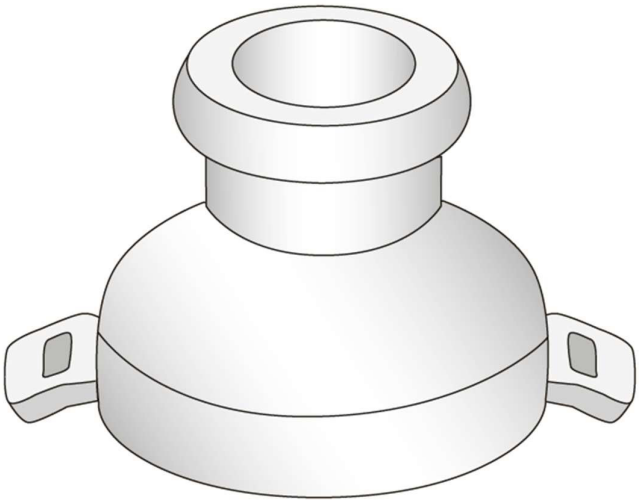
Product Information

Provox® LaryButton™



Product description:

Provox LaryButton is delivered single packed, non-sterile, ready for use. The goal is to create a self-retaining, comfortable and airtight fit between the Provox LaryButton and the tracheostoma.

Document No: 10000050656 Edition: 06 Release date: 2022-05-19

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Atos
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Product Information

Document ID:	PF031-01-TechInfo	**Edition:**	06

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

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

Intended Use: The Provox LaryButton is a self-retaining holder for devices in the Provox HME System intended for vocal and pulmonary rehabilitation after total laryngectomy.
For patients with a shrinking tracheostomas it is also used to maintain the tracheostoma for beathing.
The Provox LaryButton 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.
Not intended for patients with mechanical ventilation.
Not intended for patients with a low tidal volume.
Intended usage
Provox LaryButton is a single patient use device prescribed by a clinician.
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 usage for 6 months. Replacement is performed by the patient, clinician or caregiver.

Contraindications: Provox LaryButton is not intended to be used by patients that are under any form of mechanical ventilation or have damaged tracheostoma tissue.

CE Mark: Yes. Devices are CE-marked.

GMDN code: 14093 (Tracheostoma button)

Sterilization: Non-sterile

Raw material: Silicone

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.

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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 LaryButton 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-0-000-0000-38

REF	Name	UDI-DI
7671	Provox LaryButton 12/8	07331791002694
7672	Provox LaryButton 14/8	07331791002700
7673	Provox LaryButton 16/8	07331791002717
7674	Provox LaryButton 18/8	07331791002724
7685	Provox LaryButton 12/18	07331791002731
7686	Provox LaryButton 14/18	07331791002748
7687	Provox LaryButton 16/18	07331791002755
7688	Provox LaryButton 18/18	07331791002762

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox BasePlate Adaptor	7331791-HME-A-000-0003-F5
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

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

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

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Document Number: XV-0543464 Status: Effective Version: 1.0
Name: PF032-01-Techinfo

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. 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.

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atosmedical.com

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.

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

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	DD	Pontus Eklund - X-PONEKL	2020-04-20 - 13:35
Reviewed:	DD	Jon Berg - JONBER	2020-04-20 - 14:57
Approved:	DD	Fredrik Calais - FRECAL	2020-04-20 - 16:59
Released:	DD	Pontus Eklund - X-PONEKL	2020-10-28 - 16:35

This document has been electronically signed by the persons above.

Atos
atosmedical.com

Product Information

Provox® TubeBrush

Product description:

The Provox TubeBrush is used for cleaning of the Provox LaryTube and Provox LaryButton ex situ. The Provox TubeBrush is packed 6 pieces in a plastic bag. It is available in two different models with outer diameter 8 mm or 12 mm.

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Org.nr 556268-7607
VAT no. SE556268760701

Document Number: VV-0543145 Status: Effective Version: 1.0
Name: PF052-01-TECHINFO Provox TubeBrush

Atos
atosmedical.com

Product Information

Document ID:	PF052-01-TechInfo	**Edition:**	09
Manufacturer:	Atos Medical AB Kraftgatan 8, P.O. Box 183, SE-242 22 Hörby, Sweden		
Classification: (EU) 2017/745	Class I, Rule 1		
Intended Use:	The Provox TubeBrush is used for cleaning of the Provox LaryTube and Provox LaryButton ex situ.		
CE Mark:	Yes, the devices are CE marked.		
GMDN code:	34883 (Airway device, cleaning brush, noninvasive).		
Sterilization:	Non-Sterile		
Raw material:	ABS, Stainless Steel, PBT and Cotton.		
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.		
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:	3 years after manufacturing.		
Packaging:	6 pieces Provox TubeBrush are packed in a tamperproof plastic bag together with Instructions for Use.		

Product Information

Devices under Basic UDI-DI: 7331791-GEN-A-000-0001-E9

REF	Name	UDI-DI
7660	Provox TubeBrush 8 mm	7331791002656
7661	Provox TubeBrush 12 mm	7331791002663

Atos Medical AB Compatible products:

Range	BASIC UDI-DI
Provox LaryTube	7331791-LTU-0-000-0002-3E
Provox LaryButton	7331791-LTU-0-000-0000-38
Provox LaryButton Sizer Kit	7331791-LTU-0-000-0001-3B

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Released:	QA	Sara Dahl - X-SARDAH	2021-12-10 - 09:53

This document has been electronically signed by the persons above.

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Product Information

Provox® TubeHolder

Product description:

The Provox TubeHolder has been developed for use with the Provox LaryTube and Provox LaryButton. The integrated clip connectors allow for optimal fit to the wings of the Provox LaryTube and LaryButton, which reduces the physical stress on the soft silicone material.

Document No: 1000038378 Edition: 07 Release date: 2021-12-10

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Document Number: VV-0543442 Status: Effective Version: 1.0
Name: PF053-01-TECHINFO Provox TubeHolder

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Product Information

Document ID:	PF053-01-TechInfo	**Edition:**	07

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

Classification: (EU) 2017/745
Class I (Rule 1)

Intended Use:
The Provox TubeHolder is used for extra support for Provox LaryButton and Provox LaryTube. It goes around the neck of the user and the ends are attached to the "ears" of the LaryTube/LaryButton. The Tubeholder is adjustable in length using a Velcro® connection and allows the user to cut the band to suitable length.

Use specifications:
Intended medical indication:
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 use.
Intended part of the body/type of tissue applied to or interacted with:
The device will contact intact skin on the neck.
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 environments without any environmental restrictions regarding temperature, moisture etc.). Hospital use.
Frequency of use: Continuous use.

Contraindications:
None.

CE Mark:
Yes. Devices are CE-marked.

GMDN code:
63438 (Tracheostomy tube neck holder, single-use)

Sterilization:
Non-Sterile

Raw material:
Tricot textile, Polyurethane (PUR) foam, Polyamide (PA).

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.

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.

Product Information

Hazardous components: None.

Expiration date: 5 years after manufacturing.

Packaging: Single packed together with IFU in a plastic bag.

Devices under Basic UDI-DI: 7331791-GEN-A-000-0000-E6

REF	Name	UDI-DI
7668	Provox TubeHolder	07331791002670

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox LaryTube	7331791-LTU-0-000-0002-3E
Provox LaryButton	7331791-LTU-0-000-0000-38
Provox LaryButton Sizer Kit	7331791-LTU-0-000-0001-3B
Provox Life LaryTube	7331791-LTU-0-000-0004-3L
Provox Life LaryButton	7331791-LTU-0-000-0005-3P

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Released:	QA	Abdallah Almashharawi - ABDALM	2022-07-29 - 09:09

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Product Information

Provox® LaryClip™

Product description:

The Provox LaryClip consists of a square adhesive base and a hook-and-loop clip that allows for optimal fit to the wings of the Provox LaryButton and LaryTube. When the adhesive Base is attached to the skin at both sides of the stoma and is eventually removed due to loss of its stickiness, the Clip part can be removed and re-attached as needed.

Document No: 1000038379 Edition: 08 Release date: 2022-07-29

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Product Information

Document ID:	PF061-01-TechInfo	**Edition:**	08

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

Classification: (EU) 2017/745
Class I (1.1, Rule 1)

Intended Use:
The Provox LaryClip is used for extra support for LaryButton and LaryTube. The product consists of two parts, one that is attached to the patients' skin on each side of the stoma and the other part is attached to the LaryButton or the LaryTube. The two parts are then connected by Velcro.

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 use, Over-the-counter

Intended part of the body/type of tissue applied to or interacted with:
The device will contact intact skin (neck).

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 is performed by the patient, clinician or caregiver.

Contraindications:
There are no known contraindications.

CE Mark:
Yes. Devices are CE-marked.

GMDN code:
35752 (Tracheostomy tube neck holder, reusable)

Sterilization:
Non-sterile

Raw material:
LaryClip Base: Polyethylene (PE), Acrylic Adhesive, velcro
LaryClip: Knitted fabric, Polyamide (PA)

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.

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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: 3 years after manufacturing.

Packaging: One package consists of 8 pcs of LaryClip and 40 pcs of LaryClip Base. They are packed together with instruction for use in a cardboard box.

Devices under Basic UDI-DI: 7331791-LTU-A-000-0001-JT

REF	Name	UDI-DI
7669	Provox LaryClip	07331791002687

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox LaryTube	7331791-LTU-0-000-0002-3E
Provox LaryButton	7331791-LTU-0-000-0000-38
Provox LaryButton Sizer Kit	7331791-LTU-0-000-0001-3B
Provox Vega Plug 17	7331791-VPS-A-000-0004-RU
Provox Vega Plug 20	7331791-VPS-A-000-0004-RU
Provox Vega Plug 22.5	7331791-VPS-A-000-0004-RU

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

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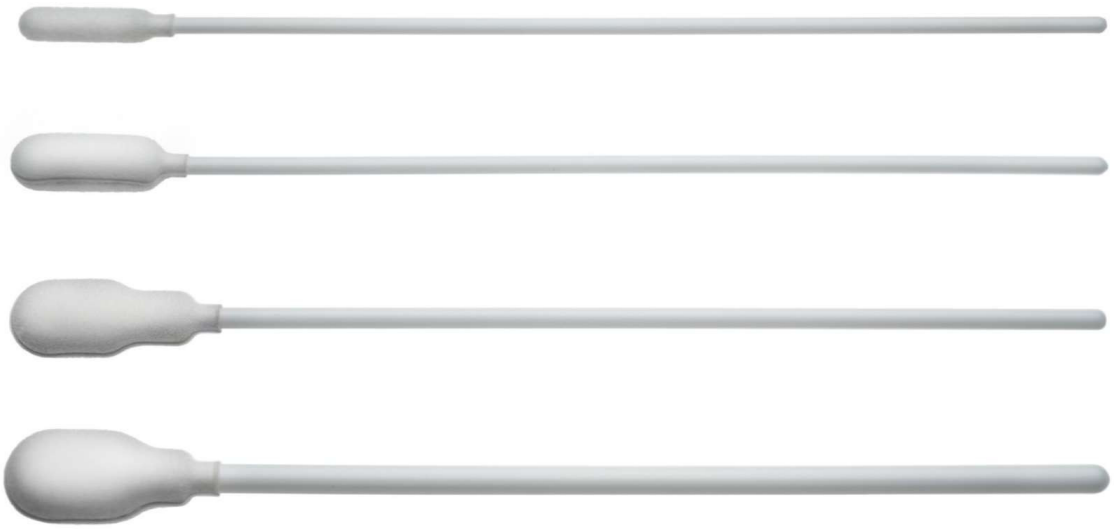
Product Information

Provox® Swab



Product description:

The Provox Swab is a foam attached to a polymer stick handle.

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Product Information

Document ID:	PF085-01-TechInfo	**Edition:**	06

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

Classification: (EU) 2017/745 Class I, Rule 1

Intended Use: Provox Swab is a single use swab for ex-situ cleaning of Provox LaryTube, Provox LaryButton and tracheostomy inner tubes.

Use specifications:
Intended medical indication:
Product for laryngectomized or tracheostomized patients, and/or their caregivers, using Provox LaryTube, Provox LaryButton or double lumen tracheostomy tube, that requires regular cleaning ex-situ.
Intended patient population:
Male and female, laryngectomized or tracheostomized patients.
Intended usage:
Single patient use, swabs should be discarded after use.
Intended part of the body/type of tissue applied to or interacted with:
N/A, cleaning will be performed ex-situ.
Intended user profile:
Patient, clinician, caregiver.
Intended conditions of use:
Normal daily environment without any hygienic or environmental restrictions regarding temperature, moisture etc.

Contraindications: No identified or known contraindications.

CE Mark: Yes. Devices are CE-marked.

GMDN code: 62956 (Airway device cleaning utensil, noninvasive, single-use)

Sterilization: Non-Sterile

Raw material: Polypropylene (stick handle) and Polyurethane, reticulated foam (foam mitt).

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.

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: 3 years after manufacturing.

Product Information

Packaging: 50 pcs per package. Devices are packed in plastic bags made of polyethylene and packed together in a cardboard box with printed instructions for use.
Swab Medium is also available as 10pcs, packed in plastic bags with instructions for use printed on the label.

Devices under Basic UDI-DI: 7331791-GEN-A-000-0002-EC

REF	Name	UDI-DI
8250	Provox Swabs Small	07331791011412
8251	Provox Swab Medium	07331791011429
8252	Provox Swab Large	07331791011436
8258	Provox Swab XtraLarge	07331791012730
8083	Provox Swab Medium 10pcs	07331791016028

Atos Medical AB compatible products:

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