Quality Management System

Technical Info / Material Data Sheet

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REF Number 7601, 7602, 7603, 7605, 7606, 7607, 7609, 7610, 7611, 7613, 7614, 7615, 7624, 7625, 7626, 7627, 7628, 7629, 7630, 7631, 7637, 7638, 7640, 7641, 7643, 7644, 7646, 7647

Product Name Provox LaryTube

Models: Provox Larytube are available in 3 models (Standard, Fenestrated and with ring), 4 sizes (8, 9, 10 and 12) and 3 lengths (27, 36 and 55 mm).

LaryTube (Size/Length)	Standard	Fenestrated	with Ring
LaryTube 8/27	7601	-	-
LaryTube 8/36	7602	7637	7624
LaryTube 8/55	7603	7638	7625
LaryTube 9/27	7605	-	-
LaryTube 9/36	7606	7640	7626
LaryTube 9/55	7607	7641	7627
LaryTube 10/27	7609	-	-
LaryTube 10/36	7610	7643	7628
LaryTube 10/55	7611	7644	7629
LaryTube 12/27	7613	-	-
LaryTube 12/36	7614	7646	7630
LaryTube 12/55	7615	7647	7631

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

CE Mark: Yes

GMDN code: 38792 (Basic tracheostomy tube, reusable)

EAN code:

REF	Description	EAN code
7601	LaryTube 8/27	7331791002076
7602	LaryTube 8/36	7331791002090
7603	LaryTube 8/55	7331791002113
7605	LaryTube 9/27	7331791002137
7606	LaryTube 9/36	7331791002151
7607	LaryTube 9/55	7331791002175
7609	LaryTube 10/27	7331791002199
7610	LaryTube 10/36	7331791002212

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7611	LaryTube 10/55	7331791002236
7613	LaryTube 12/27	7331791002250
7614	LaryTube 12/36	7331791002274
7615	LaryTube 12/55	7331791002298
7637	LaryTube 8/36, Fenestrated	7331791002472
7638	LaryTube 8/55, Fenestrated	7331791002496
7640	LaryTube 9/36, Fenestrated	7331791002519
7641	LaryTube 9/55, Fenestrated	7331791002533
7643	LaryTube 10/36, Fenestrated	7331791002557
7644	LaryTube 10/55, Fenestrated	7331791002571
7646	LaryTube 12/36, Fenestrated	7331791002595
7647	LaryTube 12/55, Fenestrated	7331791002618
7624	LaryTube 8/36, with Ring	7331791002311
7625	LaryTube 8/55, with Ring	7331791002335
7626	LaryTube 9/36, with Ring	7331791002359
7627	LaryTube 9/55, with Ring	7331791002373
7628	LaryTube 10/36, with Ring	7331791002397
7629	LaryTube 10/55, with Ring	7331791002410
7630	LaryTube 12/36, with Ring	7331791002434
7631	LaryTube 12/55, with Ring	7331791002458

Produced by: Atos Medical AB
Kraftgatan 8
P.O. Box 183
242 22 Hörby
Sweden

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.

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 also 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. The holes are punched by using the Provox Fenestration Punch according to the Instructions for Use accompanying the Provox Fenestration Punch.
Standard versions – made for use with or without a voice prosthesis.
Can be attached with a Provox TubeHolder or Provox LaryClips.
Fenestrated versions – For voice prosthesis users.
Can be attached with a Provox TubeHolder or Provox LaryClips.
Ring versions – made for use with or without a voice prosthesis.
Can only be attached with a Provox Adhesive.

Sterilization: Non-sterile

Raw material: LaryTube: Silicone. Ring: Silicone with blue masterbatch
HME Cassette: Polypropylene (PP), Polyoxymethylene (POM), Polyuretane (PUR) with calcium chloride (CaCl2), Silicone oil
Provox Brush: Stainless steel, Polyamide (PA), Polypropylene (PP) with blue

	masterbatch.
Latex information:	Not manufactured with natural rubber latex
Biological origin:	The device is not manufactured with any materials derived from human or animal source.
Handling and storage:	Keep dry and away from sunlight. Temperature limit 2 - 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:	The Provox LaryTube (standard) is packed with 5 pcs of Provox XtraFlow HME and instructions for use for LaryTube and Provox Xtra HME in a cardboard box. The Provox LaryTube (fenestrated) is packed with 5 pcs of Provox XtraFlow HME, 1 Provox Brush and instructions for use for Provox LaryTube, Provox Brush and Provox HME in a cardboard box. The Provox LaryTube (with ring) is packed with 5 pcs of Provox XtraFlow HME and instructions for use for Provox LaryTube and Provox Xtra HME in a cardboard box.

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Quality Management System

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Product Name Provox® LaryTube

Models: Provox Larytube are available in 3 models (Standard, Fenestrated and with Ring), 4 sizes (8, 9, 10 and 12) and 3 lengths (27, 36 and 55 mm).

LaryTube (Size/Length)	Standard	Fenestrated	with Ring
LaryTube 8/27	7601FR	-	-
LaryTube 8/36	7602FR	7637FR	7624FR
LaryTube 8/55	7603FR	7638FR	7625FR
LaryTube 9/27	7605FR	-	-
LaryTube 9/36	7606FR	7640FR	7626FR
LaryTube 9/55	7607FR	7641FR	7627FR
LaryTube 10/27	7609FR	-	-
LaryTube 10/36	7610FR	7643FR	7628FR
LaryTube 10/55	7611FR	7644FR	7629FR
LaryTube 12/27	7613FR	-	-
LaryTube 12/36	7614FR	7646FR	7630FR
LaryTube 12/55	7615FR	7647FR	7631FR

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

CE Mark: Yes

GMDN code: 38792 (Basic tracheostomy tube, reusable)

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Released

Technical Info / Material Data Sheet

EAN code:

REF	Description	EAN code
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

Produced by:

Atos Medical AB
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P.O. Box 183
242 22 Hörby
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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..

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 also to provide attachment for

Document No: 10000037867 Edition: 08 Release date: 2020-07-02

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. The holes are punched by using the Provox Fenestration Punch according to the Instructions for Use accompanying the Provox Fenestration Punch.
Standard versions – made for use with or without a voice prosthesis.
Can be attached with a Provox TubeHolder or Provox LaryClips.
Fenestrated versions – For voice prosthesis users.
Can be attached with a Provox TubeHolder or Provox LaryClips.
Ring versions – made for use with or without a voice prosthesis.

Sterilization:	Non-sterile
Raw material:	LaryTube: Silicone Ring: Silicone with blue masterbatch
Latex information:	Not manufactured with natural rubber latex
Biological origin:	The device is not manufactured with any materials derived from human or animal source.
Handling and storage:	Keep dry and away from sunlight. Temperature limit 2 - 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:	The Provox LaryTube is packed in a plastic bag together with instructions for use in a cardboard box.

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Technical Info / Material Data Sheet

Document ID: PF031-01-TechInfo	Edition: 04

REF Number	7671-7674 and 7685-7688
Product Name	Provox LaryButton
Models:	2 different lengts, 8 and 18mm and 4 different diameters per length.
Classification: (MDD 93/42/EEC)	IIb (2.1 Rule5)
CE Mark:	Yes
GMDN code:	14093 (Tracheostoma button)
Produced by:	Atos Medical AB Kraftgatan 8 242 22 Hörby Sweden
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 breathing. The Provox LaryButton is intended for single patient use.
Description:	Provox LaryButton is delivered single packed, non-sterile, ready for use. Provox LaryButton. The goal is to create a self-retaining, comfortable and airtight fit between the Provox LaryButton and the tracheostoma.
Sterilisation:	Non-sterile
Raw material:	Silicone
Latex information	Not made with natural rubber latex
Biological origin:	The device does not contain any materials derived from human or animal source.
Handling and storage:	Standard 22°C ± 20°C, 45% rH ± 35% rH, not direct sunlight.
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:	LaryButton is single packed in a plastic bag and then in a cardboard box together with a manual.

Reviewed by:

Vice President Quality Assurance

2015-03-25

Date

Approved by:

Vice President Design & Development

2015-03-25

Date

Document No: 10000018374 Edition: 04 Release date: 2015-03-27

Quality Management System

Technical Info / Material Data Sheet

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REF Number 7690

Product Name Provox LaryButton Sizer Kit

Models: 1 model

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

CE Mark: Yes

GMDN code: 14093 (Tracheostomy button)

EAN code:

REF	Description	EAN code
7690	Provox LaryButton Sizer Kit	7331791002779

Produced by:
Atos Medical AB
Kraftgatan 8
P.O. Box 183
242 22 Hörby
Sweden

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. 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.

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
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 any materials derived from human or animal source.
Handling and storage:	Standard 22° C ± 20° C, 45% rH ± 35% rH, not direct sunlight
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 together with one IFU for the product, one IFU for Provox LaryButton and one IFU for cleaning and sterilization.

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Edition: 03
Document No: 1000038474

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Released:	DD	Pontus Eklund - X-PONEKL	2020-10-28 - 16:39

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Atos
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Product Information

Provox® Fenestration Punch

Product description:

The Fenestration Punch is used for making small fenestrations in a Provox LaryTube at desired locations.

The Fenestration Punch is made of polypropylene, stainless steel and silicone and is used for making small fenestrations in a Provox LaryTube. This is done when the Provox LaryTube is intended to be used in combination with a voice prosthesis.

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Product Information

Document ID:	PF037-01-TechInfo	**Edition:**	06
Manufacturer:	Atos Medical AB Kraftgatan 8, P.O. Box 183, SE-242 22 Hörby, Sweden		
Classification: (EU) 2017/745	Class I (1.1 Rule 1)		
Intended Use:	The Fenestration Punch is used for making small fenestrations in a Provox LaryTube at desired locations.		
CE Mark:	Yes, the devices are CE marked.		
GMDN code:	38792 (Basic tracheostomy tube, reusable)		
Sterilization:	Non-sterile		
Raw material:	Stainless Steel, Plastic, 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.		
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:	The Fenestration Punch is single-packed in a plastic bag		

Product Information

Devices under Basic UDI-DI: 7331791-LTU-A-000-0000-JQ

REF	Name	UDI-DI
7654	Provox FenestrationPunch	07331791002632

Atos Medical AB Compatible products:

Range	BASIC UDI-DI
Provox LaryTube	7331791-LTU-0-000-0002-3E

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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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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.

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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:	DD	Jon Berg - JONBER	2021-05-26 - 17:08

This document has been electronically signed by the persons above.

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.

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Product Information

Document ID:	PF061-01-TechInfo	**Edition:**	07

Manufacturer: Atos Medical AB
Kraftgatan 8, P.O. Box 183,
SE-242 22 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.

CE Mark: Yes, the 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.

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.

Product Information

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

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Quality Management System

Technical Info / Material Data Sheet

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REF Number 7648

Product Name Provox® LaryTube™ Sizer Kit

Models: 1 model

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

CE Mark: Yes

GMDN code: 38792 (Basic tracheostomy tube, reusable)

EAN code:

REF	Description	EAN code
7648	Provox LaryTube Sizer Kit	7331791005329

Produced by:
Atos Medical AB
Kraftgatan 8
P.O. Box 183
242 22 Hörby
Sweden

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 clinician 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 correct size(s) have been determined, a new LaryTube(s) shall be prescribed to the patient for actuall use.

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 "insructions for cleaning and sterilization".

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Technical Info / Material Data Sheet

Sterilization:	Delivered unsterile, steam sterilizable.
Raw material:	LaryTubes Ref 7601, 7637-38, 7340-41, 7643-44 and 7647: Silicone Outer and inner boxes: Polypropylene
Latex information:	Not made with natural rubber latex
Biological origin:	The device is not manufactured with any materials derived from human or animal source.
Handling and storage:	Standard 22° C ± 20° C, 45% rH ± 35% rH, not direct sunlight
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

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Edition: 04
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Released:	QA	Sara Dahl - X-SARDAH	2021-12-10 - 09:51

This document has been electronically signed by the persons above.

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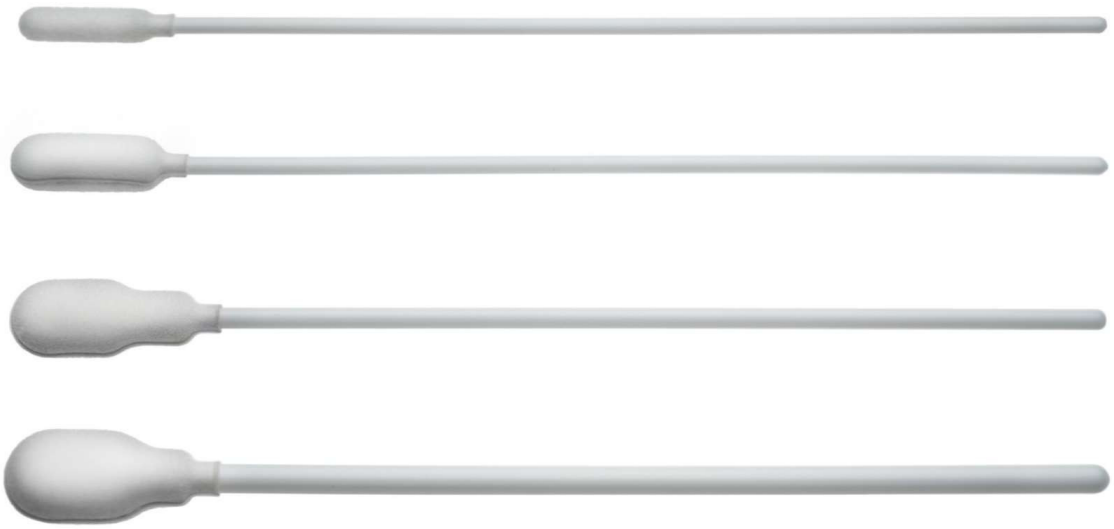
Product Information

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

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