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Issued:	DD	Diana Tieger - DIATIE	2020-12-07 - 09:41
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Approved:	DD	Mikael Melefors - SEHRBSGM	2020-12-07 - 10:14
Released:	DD	Diana Tieger - DIATIE	2020-12-09 - 07:43

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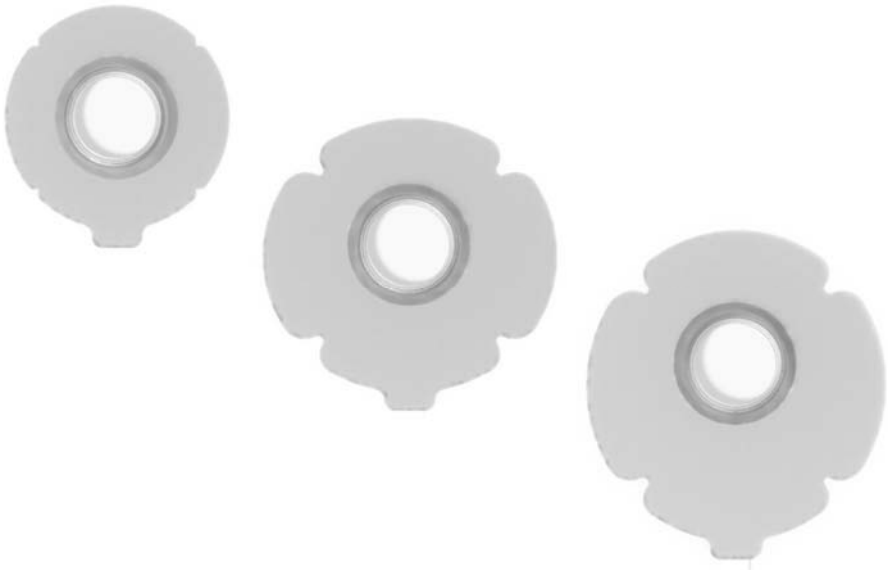
Document No: 10000046234 Edition: 08 Release date: 2020-12-09

Product Information

Provox® Life Adhesive



Product description:

Provox Life Adhesives are designed to be used together with Provox Life HMEs and accessories. Provox Life Standard Adhesive, Provox Life Sensitive Adhesive and Provox Life Stability Adhesive are flexible adhesives suitable for flat to moderately deep stomas. Provox Life Sensitive Adhesives and Provox Life Night Adhesive have an adhesive material with permanent skin contact that is hypoallergenic and suitable for sensitive skin.

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Product Information

Document ID:	PF101-01-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: Provox Life Adhesives are single use adhesives that provide attachment for Provox Life HMEs and accessories after total laryngectomy

Use specifications:
Intended medical indication: Facilitation of pulmonary rehabilitation after total laryngectomy.
Intended patient population: Any age and condition
Intended usage: Single use, over-the-counter device.
Intended part of the body/type of tissue applied to or interacted with: The device is a peristomal adhesive with skin contact.
Intended user profile: Patient, clinician, trained nurse, caregiver. Cognitive ability, by a clinician judged as sufficient. Manual dexterity, by a clinician judged as sufficient.
Intended conditions of use: The device will be used in hospitals, clinics and (mainly) in the patient´s normal environment. Daily usage with replacement as needed.

Contraindications: The product shall not be used by patients with a decreased level of consciousness, patients with reduced mobility of the arms and/or hands, or patients who are unable to remove the device themselves.

CE Mark: Yes, the devices are CE marked.

GMDN code: 62175 (Stomal appliance skin-adherent patch, non-sterile).

Sterilization: Non-Sterile

Raw material: Provox Life Standard Adhesives consist of an acrylic adhesive tape with a polyethylene carrier and an ethylene and butyl acrylate copolymer adapter.

Provox Life Sensitive Adhesives consist of a hydrocolloid adhesive tape with an ethyl methyl acetate carrier (EMA) and butyl acrylate copolymer adapter.

Provox Life Night Adhesive consists of a hydrogel adhesive tape with a polyurethane carrier and a thermoplastic elastomer adapter.

Provox Life Stability Adhesive consists of an acrylic adhesive with a polyethylene carrier and a thermoplastic elastomer adapter.

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 (2-30°C for Provox Life Night Adhesive and Provox Life Sensitive Adhesives).

Document No: 10000046234 Edition: 08 Release date: 2020-12-09
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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: REFs 7460-7464 and 7466: 18 months after manufacturing.
REF 8263: 14 months after manufacturing.
REF 8261: 3 years after manufacturing.

Packaging: Each adhesive is packed individually in a polyethylene plastic bag (Provox Life Night Adhesive is packed in an aluminum foil bag).
The adhesives are packed 30 pcs in a cardboard box:

- Provox Life Standard Adhesive Round
- Provox Life Standard Adhesive Oval
- Provox Life Standard Adhesive Plus
- Provox Life Sensitive Adhesive Round
- Provox Life Sensitive Adhesive Oval
- Provox Life Sensitive Adhesive Plus

The adhesives are packed 15 pcs in a cardboard box:

- Provox Life Stability Adhesive
- Provox Life Night Adhesive

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Product Information

Devices under Basic UDI-DI: 7331791-ADH-0-000-0001-CT

REF	Name	UDI-DI
7460	Provox Life Standard Adhesive Round	07331791014420
7461	Provox Life Standard Adhesive Oval	07331791014437
7462	Provox Life Standard Adhesive Plus	07331791014444
7463	Provox Life Sensitive Adhesive Round	07331791014451
7464	Provox Life Sensitive Adhesive Oval	07331791014468
7466	Provox Life Sensitive Adhesive Plus	07331791014482
8261	Provox Life Night Adhesive	07331791014505
8263	Provox Life Stability Adhesive	07331791014499

Standard Adhesive Round

Sensitive Adhesive Round

Standard Adhesive Oval

Sensitive Adhesive Oval

Life Standard Adhesive Plus

Sensitive Adhesive Plus

Night Adhesive

Stability Adhesive

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Document No: 10000046234 Edition: 08 Release date: 2020-12-09

Product Information

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox Life HME	7331791-HME-0-000-0001-XC
Provox Life Shower	7331791-ADH-A-000-0001-UB
Provox Life BasePlate Adapter	7331791-HME-A-000-0005-FB
Provox Silicone Glue	7331791-GEN-A-000-0003-EF
Provox Cleaning Towel 10-p	7331791-ADH-A-000-0003-UH
Provox Adhesive Remover (50 pcs)	7331791-ADH-A-000-0005-UP
Provox Skin Barrier (50 pcs)	7331791-ADH-A-000-0004-UL
Provox Life LaryTube with Ring	7331791-LTU-0-000-0004-3L
Provox Life LaryTube Fenestrated with Ring	7331791-LTU-0-000-0004-3L

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Approved:	DD	Diana Tieger - DIATIE	2020-10-19 - 12:29
Released:	DD	Peter Sundsten - PETSUN	2020-11-12 - 09:26

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Document No: 10000045282 Edition: 00 Release date: 2020-11-12

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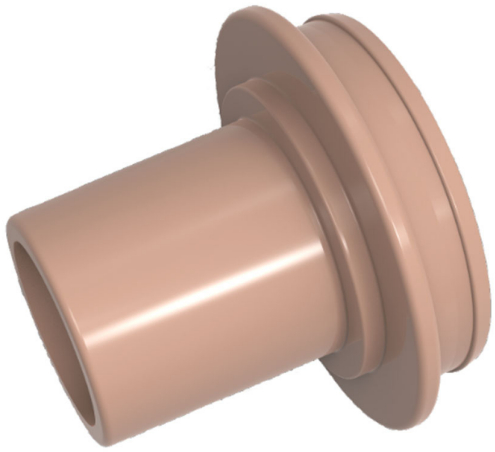
Product Information

Provox® Life™ BasePlate Adaptor



Product description:

Provox Life BasePlate Adaptor is an accessory that allows attaching and detaching medical device, e.g. an HME, with an ISO 15 mm standard connector to a Provox Life attachment. The adaptor shall be cleaned between use.

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Product Information

Document ID:	PF018-02-TechInfo	**Edition:**	00

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

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

Intended Use:
Provox Life BasePlate Adaptor is an accessory that allows attaching medical device, e.g. an HME, with an ISO 15 mm standard connector to a Provox Life attachment.

Use specifications:
Intended medical indication:
Accessory product for patients after total laryngectomy.
Intended patient population:
Male and female
Typical average age: N/A.
Cognitive ability, by a clinician judged as sufficient
Manual dexterity: Unconscious patients must be constantly monitored.
Not intended for patients with mechanical ventilation.
Intended usage:
Single patient use.
Intended part of the body/type of tissue applied to or interacted with:
Neck, (tracheostoma).
Intended user profile:
Patient, clinician, trained nurse.
Intended conditions of use:
Home use (normal daily environment without any hygienic or environmental restrictions regarding temperature, moisture etc.). Hospital use.
Frequency of use: Continuous use.
Replacement rate: Shall be changed after used for a maximum of 3 months.

Contraindications:
Shall not be used for mechanical ventilation.

CE Mark:
Yes, CE marked.

GMDN code:
58705 (Tracheostoma protective filter)

Sterilization:
Non-sterile

Raw material:
Polyether ether ketone (PEEK)

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.

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Document No: 10000045282 Edition: 00 Release date: 2020-11-12

Product Information

Hazardous components: 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.

Expiration date: 5 years after manufacturing.

Packaging: Provox Life BasePlate Adaptor is separately packed in a plastic bag and together with instructions for use in a cardboard box.

Devices under Basic UDI-DI: 7331791-HME-A-000-0005-FB

REF	Name	UDI-DI
8057	Provox Life BasePlate Adaptor	07331791015342

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox Life LaryTube	7331791-LTU-0-000-0004-3L
Provox Life Standard Adhesive	7331791-ADH-0-000-0001-CT
Provox Life Sensitive Adhesive	
Provox Life Night Adhesive	
Provox Life Stability Adhesive	
TrachPhone	7331791-HME-0-000-0006-XT
Freevent DualCare	7331791-HME-0-000-0005-XQ
Freevent XtraCare	7331791-HME-0-000-0004-XM
Freevent XtraCare Mini	

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Issued:	DD	Diana Tieger - DIATIE	2020-12-08 - 14:44
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Approved:	DD	Mikael Melefors - SEHRBSGM	2020-12-08 - 18:49
Released:	DD	Diana Tieger - DIATIE	2020-12-10 - 09:58

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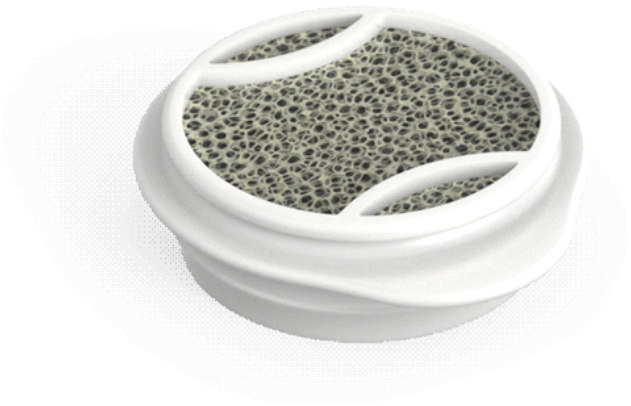
Released
Document No: 10000040528 Edition: 03 Release date: 2020-12-10

Product Information

Provox® Life™ FreeHands HME



Product description:

Provox Life FreeHands HME is a heat- and moisture exchanger facilitating pulmonary rehabilitation by humidifying the inhaled air, which helps to keep the lungs healthy.

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Product Information

Document ID:	PF099-01-TechInfo	**Edition:**	03

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

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

Intended Use: Provox Life FreeHands HME is a single use heat- and moisture exchanger intended for spontaneously breathing laryngectomized patients, utilizing a voice prosthesis and in combination with a Provox speaking valve or a DigiTop.

Use specifications:
Intended medical indication:
Product for rehabilitation after total laryngectomy.
Intended patient population:
Male and female 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:
Single use.
Intended part of the body/type of tissue applied to or interacted with:
The product is placed in front of the tracheostoma to condition respiratory air. The tissue contact is indirect via inhaled air.
Intended user profile:
The product is supposed to be handled by the patient but is also handled by physicians, trained nurses, SLPs.
Intended conditions of use environment:
Home use (normal daily environment without any hygienic or environmental restrictions regarding temperature, moisture etc.).
Outpatient clinic use. Hospital use.
Frequency of use: Continuous use.
Replacement rate: Max usage for 24 hours. Replacement is performed by the patient.
Not for use during sleep unless in combination with a HME DigiTop.

Contraindications: The products are not intended to be used by patients unable to remove or operate the device, unless the patient is under constant supervision of a clinician or a trained caregiver. For example, patients who are unable to move their arms, patients with decreased levels of consciousness, or patients with diseases that put them at risk for unpredictable periodic loss of consciousness.
The product shall not be used by patients with a low tidal volume, as the added dead space may cause CO2 (Carbon dioxide) retention.

CE Mark: Yes, CE marked.

GMDN code: 58705 (Tracheostoma protective filter)

Sterilization: Non-Sterile

Raw material: Provox Life FreeHands HME is composed of an injection molded polypropylene Housing, assembled with a polyurethane foam (which is impregnated with calcium chloride).

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Document No: 10000040528 Edition: 03 Release date: 2020-12-10

Product Information

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: 20 months after manufacturing.

Packaging: The HMEs are single packed 10 pieces in a LD-Polyethylen blister sealed with a high barrier polyester-based lidding film. 3 blisters (30 cassettes) are then packed in a cardboard box together with a paper IFU.

Devices under Basic UDI-DI: 7331791-HME-0-000-0008-XZ

REF	Name	UDI-DI
7440	Provox Life FreeHands HME	07331791014895

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox FreeHands FlexiVoice	7331791-HME-0-000-0007-XW
Provox Life Adhesives	7331791-ADH-0-000-0001-CT
Provox Life LaryTubes	7331791-LTU-0-000-0004-3L

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Approved:	DD	Diana Tieger - DIATIE	2020-10-07 - 20:22
Released:	DD	Peter Sundsten - PETSUN	2020-10-22 - 10:13

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Released
Document No: 10000033114 Edition: 14 Release date: 2020-10-22

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Product Information

Provox® Life™ HME

Product description:

Provox Life™ HMEs are single-use devices for pulmonary rehabilitation. They come in different levels of humidification, breathing resistance and filtration that makes them suitable for different situations.
The different Provox Life™ HMEs are:
Home: when taking it easy, **Go:** when you are out and about, **Energy:** when physically active, **Protect:** when you need protection from bacteria, virus, dust and pollen, **Night:** when sleeping.

Document No: 10000033114 Edition: 14 Release date: 2020-10-22

Released

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Product Information

Document ID: PF086-01-TechInfo **Edition:** 14

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

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

Intended Use: Provox Life HMEs are single use heat- and moisture exchangers for patients breathing through a tracheostoma.

Use specifications:
Intended medical indication:
Product for rehabilitation for patients breathing through a tracheostoma.
Intended patient population:
Male and female 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:
Single use, Over-the-counter.
Intended part of the body/type of tissue applied to or interacted with:
The product is placed in front of the tracheostoma to condition respiratory air. The tissue contact is Indirect via inhaled air.
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:
Home use (normal daily environment without any hygienic or environmental restrictions regarding temperature, moisture etc.).
Outpatient clinic use. Hospital use.
Frequency of use:
Continuous use.
Replacement rate:
Max usage for 24 hours. Replacement is performed by the patient, clinician or caregiver.

Contraindications: The product shall not be used by patients with a decreased level of consciousness, patients with reduced mobility of the arms and/or hands, or patients who are unable to remove the device themselves.
The product shall not be used by patients with a low tidal volume, as the added dead space may cause CO2 (Carbon dioxide) retention.

CE Mark: Yes, the devices are CE marked.

GMDN code: 58705 (Tracheostoma protective filter)

Sterilization: Non-sterile

Raw material: Housing & Lid: Polypropylene (PP) with polyethylene (PE) master batch
Housing (only 8262 and no Lid): Polydimethylsiloxane (Silicone) with white master batch
Foam: Polyurethane (PUR) with calcium chloride (CaCl2)
Filter (only used in ref. 8313): Acrylic, Polypropylene (PP)

Latex information: Not manufactured with natural rubber latex

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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: 8310, 8311, 8312, 8262:
The HMEs are single packed 10 pieces in a LD-Polyethylen blister sealed with a high barrier polyester-based lidding film. 3 blisters (total of 30 HMEs) are then packed together with an IFU in a cardboard box.

8313:
The HMEs are single packed 5 pieces in a LD-Polyethylen blister sealed with a high barrier polyester-based lidding film. 3 blister (total of 15 HMEs) are then packed together with an IFU in a cardboard box.

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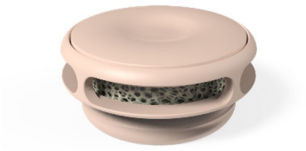
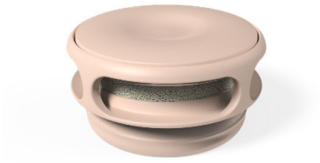
Product Information

Devices under Basic UDI-DI: 7331791-HME-0-000-0001-XC

REF	Name	UDI-DI
8310	Provox Life Go HME	07331791011399
8311	Provox Life Home HME	07331791011405
8312	Provox Life Energy HME	07331791013744
8313	Provox Life Protect HME	07331791013751
8262	Provox Life Night HME	07331791014512

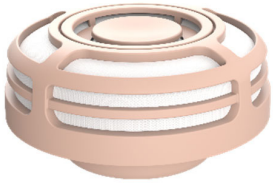


Go



Home

Energy



Protect

Night

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox Life Adhesive	7331791-ADH-0-000-0001-CT
Provox Life LaryTube	7331791-LTU-0-000-0004-3L

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Issued:	DD	Christian Engelhardt - CHRENG	2020-04-30 - 09:19
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Approved:	DD	Daniel Åberg - DANABE	2020-05-04 - 15:09
Released:	DD	Christian Engelhardt - CHRENG	2020-08-21 - 14:54

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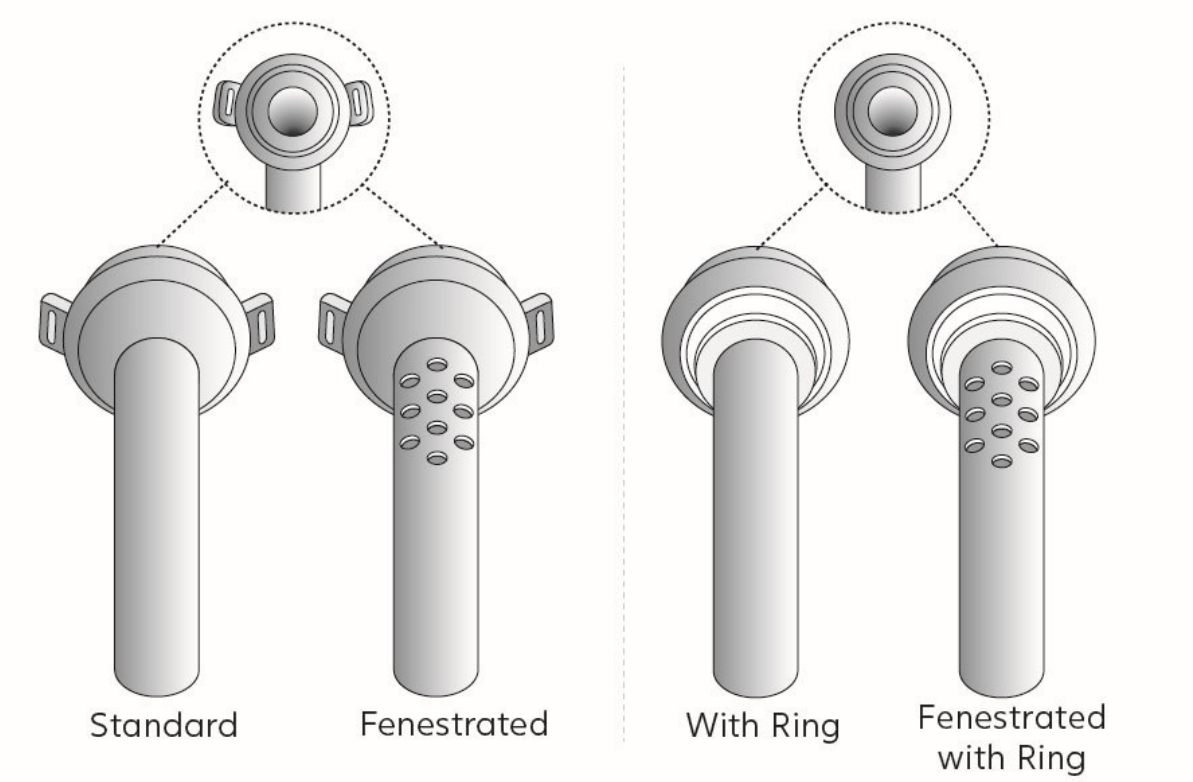
Product Information

Provox® Life LaryTube



Product description:

Provox® Life LaryTube is a tube made of medical grade silicone rubber. The purpose of the device is to create a comfortable and airtight fit between Provox® Life LaryTube and the tracheostoma, and also to provide attachment for devices from the Provox® Life HME System and Provox® Life Shower.

Standard model and Ring model can be fenestrated so that air can go through the voice prosthesis for voice prosthesis users. The holes are punched by using Provox® Fenestration Punch according to the Instructions for Use accompanying Provox® Fenestration Punch.

Standard model – made for use with or without a voice prosthesis.

Can be attached with a Provox® TubeHolder or Provox® LaryClips.

Fenestrated model – made for voice prosthesis users.

Can be attached with a Provox® TubeHolder or Provox® LaryClips.

Ring model – made for use with or without a voice prosthesis.

Can only be attached with a Provox® Life Adhesive.

Fenestrated with Ring model – made for voice prosthesis users.

Can only be attached with a Provox® Life Adhesive.

Document No: 10000041195 Edition: 02 Release date: 2020-08-21

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Product Information

Document ID:	PF106-01-TechInfo	**Edition:**	02

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

Classification: (EU) 2017/745
IIb (2.1 Rule 5)(MDD 93/42/EEC)

Intended Use:
Provox® Life LaryTube is a single patient use device intended to provide attachment for Provox® Life HME and accessories after total laryngectomy. For laryngectomized patients with a shrinking tracheostoma it is also used to maintain the tracheostoma for breathing.

CE Mark:
Yes, the devices are CE marked.

GMDN code:
38792 (Basic tracheostomy tube, reusable)

Sterilization:
Non-sterile

Raw material:
Tube: Silicone

Ring for Tube: Silicone with white 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:
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® Life LaryTube is single packed in a LD-Polyethylen blister sealed with a high barrier polyester-based lidding film. It is then packed together with instructions for use for Provox® Life LaryTube in a cardboard box.

Document No: 10000041195 Edition: 02 Release date: 2020-08-21
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Product Information

Devices under Basic UDI-DI: 7331791-LTU-0-000-0004-3L

REF	Name	UDI-DI
7409	Provox® Life LaryTube 8/27	7331791013874
7410	Provox® Life LaryTube 8/36	7331791013881
7411	Provox® Life LaryTube 8/55	7331791013898
7412	Provox® Life LaryTube 9/27	7331791013676
7413	Provox® Life LaryTube 9/36	7331791013683
7414	Provox® Life LaryTube 9/55	7331791013713
7415	Provox® Life LaryTube 10/27	7331791013904
7416	Provox® Life LaryTube 10/36	7331791013911
7417	Provox® Life LaryTube 10/55	7331791013928
7418	Provox® Life LaryTube 12/27	7331791013935
7419	Provox® Life LaryTube 12/36	7331791013942
7420	Provox® Life LaryTube 12/55	7331791013959
7421	Provox® Life LaryTube 8/36 with Ring	7331791013966
7422	Provox® Life LaryTube 8/55 with Ring	7331791013973
7423	Provox® Life LaryTube 9/36 with Ring	7331791013690
7424	Provox® Life LaryTube 9/55 with Ring	7331791013720
7425	Provox® Life LaryTube 10/36 with Ring	7331791013980
7426	Provox® Life LaryTube 10/55 with Ring	7331791013997
7427	Provox® Life LaryTube 12/36 with Ring	7331791014000
7428	Provox® Life LaryTube 12/55 with Ring	7331791014017
7429	Provox® Life LaryTube 8/36, Fenestrated	7331791014024
7430	Provox® Life LaryTube 8/55, Fenestrated	7331791014031
7431	Provox® Life LaryTube 9/36, Fenestrated	7331791013706
7432	Provox® Life LaryTube 9/55, Fenestrated	7331791013737
7433	Provox® Life LaryTube 10/36, Fenestrated	7331791014048
7434	Provox® Life LaryTube 10/55, Fenestrated	7331791014055
7435	Provox® Life LaryTube 12/36, Fenestrated	7331791014062
7436	Provox® Life LaryTube 12/55, Fenestrated	7331791014079
8048	Provox® Life LaryTube 8/36, Fenestrated with Ring	7331791014949
8049	Provox® Life LaryTube 8/55, Fenestrated with Ring	7331791014956
8050	Provox® Life LaryTube 9/36, Fenestrated with Ring	7331791014963
8051	Provox® Life LaryTube 9/55, Fenestrated with Ring	7331791014970
8052	Provox® Life LaryTube 10/36, Fenestrated with Ring	7331791014987
8053	Provox® Life LaryTube 10/55, Fenestrated with Ring	7331791014994
8054	Provox® Life LaryTube 12/36, Fenestrated with Ring	7331791015007
8055	Provox® Life LaryTube 12/55, Fenestrated with Ring	7331791015014

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Product Information

Compatible products:

Range	BASIC UDI-DI
Provox® Brush	7331791-GEN-A-000-0001-E9
Provox® TubeBrush	7331791-GEN-A-000-0001-E9
Provox® Swab	7331791-GEN-A-000-0001-EC
Provox® Life Standard Adhesive	7331791-ADH-0-000-0001-CT
Provox® Life Standard Adhesive Round	7331791-ADH-0-000-0001-CT
Provox® Life Standard Adhesive Oval	7331791-ADH-0-000-0001-CT
Provox® Life Standard Adhesive Plus	7331791-ADH-0-000-0001-CT
Provox® Life Sensitive Adhesive	7331791-ADH-0-000-0001-CT
Provox® Life Sensitive Adhesive Round	7331791-ADH-0-000-0001-CT
Provox® Life Sensitive Adhesive Oval A	7331791-ADH-0-000-0001-CT
Provox® Life Sensitive Adhesive Oval B	7331791-ADH-0-000-0001-CT
Provox® Life Sensitive Adhesive Plus	7331791-ADH-0-000-0001-CT
Provox® Life Stability Adhesive	7331791-ADH-0-000-0001-CT
Provox® Life Night Adhesive	7331791-ADH-0-000-0001-CT
Provox® Life Go HME	7331791-HME-0-000-0001-XC
Provox® Life Home HME	7331791-HME-0-000-0001-XC
Provox® Life Energy HME	7331791-HME-0-000-0001-XC
Provox® Life Protect HME	7331791-HME-0-000-0001-XC
Provox® Life Night HME	7331791-HME-0-000-0001-XC
Provox® Life Freehands HME	7331791-HME-0-000-0001-XC
Provox® Life Shower	7331791-ADH-A-000-0001-UB
Provox® FenestrationPunch	7331791-LTU-A-000-0000-JQ
Provox® LaryClip	7331791-LTU-A-000-0001-JT
Provox® TubeHolder	7331791-GEN-A-000-0000-E6

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Product Information

Provox® Life™ Shower

Product description:

Provox Life Shower is a single patient use device intended to be placed into a Provox Life attachment to avoid water from entering the tracheostoma during showering.

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Product Information

Document ID:	PF088-01-TechInfo	**Edition:**	06
Manufacturer:	Atos Medical AB Kraftgatan 8, P.O. Box 183, SE-242 22 Hörby, Sweden		
Classification: (EU) 2017/745	Class 1 (1.1 Rule 1)		
Intended Use:	Provox Life Shower is a single patient use device intended to be placed into a Provox Life attachment to avoid water from entering the tracheostoma during showering.		
CE Mark:	Yes, the devices are CE marked.		
GMDN code:	62047 (Tracheostoma shower shield)		
Sterilization:	Non-Sterile		
Raw material:	Polypropylene (PP) with a violet master batch		
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:	Maximum 36 months after manufacturing.		
Packaging:	The Provox Life Shower is packed in a plastic bag and together with instructions for use in a cardboard box.		

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Product Information

Devices under Basic UDI-DI: 7331791-ADH-A-000-0001-UB

REF	Name	UDI-DI
8308	Provox Life Shower	07331791011375

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox Life Adhesive	7331791-ADH-0-000-0001-CT

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