Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Elin Andersson - ELIAND	2021-12-03 - 08:58
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Approved:	DD	Diana Tieger - DIATIE	2021-12-06 - 21:05
Released:	QA	Elin Andersson - ELIAND	2021-12-09 - 09:32

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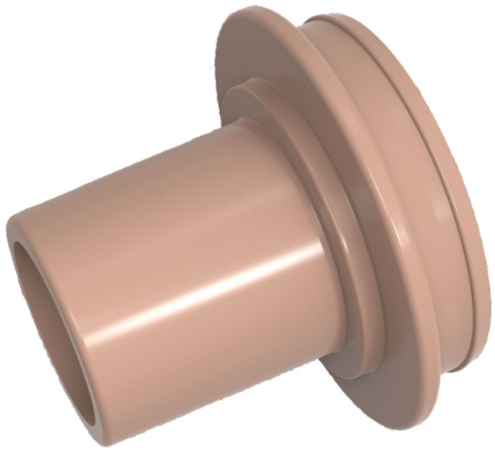
Product Information

Provox® Life™ BasePlate Adaptor



Product description:

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

Document No: 10000045282 Edition: 01 Release date: 2021-12-09

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Product Information

Document ID:	*PF018-02-TechInfo*	**Edition:**	*01*

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.

Contraindications: *Shall not be used for mechanical ventilation.*

CE Mark: *Yes. Devices are 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.*

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.*

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Product Information

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

Product Information

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 LaryButton	*7331791-LTU-0-000-0005-3P*
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	

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Sara Dahl - X-SARDAH	2021-11-08 - 10:28
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Released:	QA	Sara Dahl - X-SARDAH	2021-11-10 - 15:17

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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.

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Product Information

Document ID: PF086-01-TechInfo **Edition:** 16

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 device shall not be used by patients with reduced mental or physical cognitive ability. Patients who are unable to attach or remove the device themselves, or without sufficient knowledge how to use the device, or the cognitive ability to understand the risks connected to the use, should not use the device.
The device shall not be used by patients with a low tidal volume, as the added dead space may cause CO_2 (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)
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-Polyethylene 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-Polyethylene 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.

Document No: 10000033114 Edition: 16 Release date: 2021-11-10

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
Provox Life LaryButton	7331791-LTU-0-000-0005-3P

Document No: 10000033114 Edition: 16 Release date: 2021-11-10

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Approved:	DD	Diana Tieger - DIATIE	2021-01-27 - 08:01
Released:	DD	Peter Sundsten - PETSUN	2021-02-04 - 09:08

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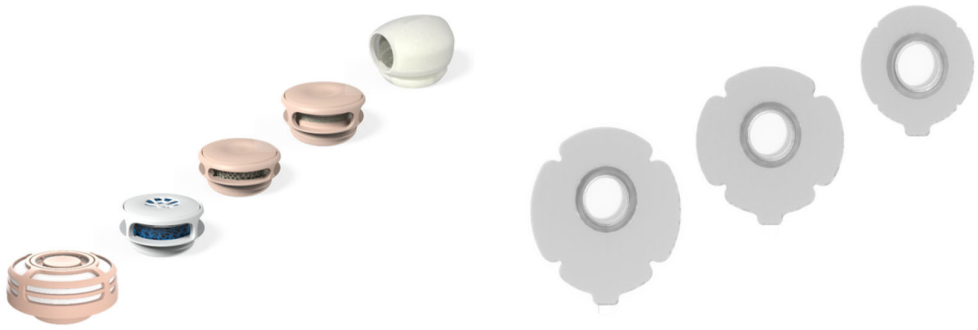
Product Information

Provox® Life™ Sample Packs



Product description:

The Provox Life Sample Packs is a combination of Provox Life HMEs and Provox Life Adhesives.

Provox Life HME:
Provox Life HMEs are heat and moisture exchangers. HMEs are single use devices used for pulmonary rehabilitation and facilitation of speech.

Provox Life Adhesive:
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 Adhesive 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: PF086-02-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 HMEs are single use heat- and moisture exchangers for patients breathing through a tracheostoma.

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: Male and female of any age.
HME: Not intended for patients with mechanical ventilation.
Not intended for patients with a low tidal volume.
Intended usage: Single use, over-the-counter device.
Intended part of the body/type of tissue applied to or interacted with:
Adhesive: The device is a peristomal adhesive with skin contact.
HME: The product is placed in front of the tracheostoma to condition respiratory air. The tissue contact is Indirect via inhaled air.
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. The device can be used in any location and situation except during radiation therapy. Sensitive Adhesive can be used during and after radiotherapy depending on clinical suitability.

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.
HME: 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: HME: 58705 (Tracheostoma protective filter)
Adhesive: 62175 (Stomal appliance skin-adherent patch, non-sterile).

Sterilization: Non-sterile.

Raw material: Provox Life HME:
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)

Provox Life Adhesive:
Provox Life Standard Adhesive consist of an acrylic adhesive tape with a polyethylene carrier and an ethylene and butyl acrylate copolymer adapter. Provox Life Sensitive Adhesive consist of a hydrocolloid adhesive

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Product Information

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 for 7475-7476.
Excursions permitted between 2°C - 30°C for 7467-7474.

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:

HME:	Maximum 36 months after manufacturing.
Adhesives:	Maximum 18 months after manufacturing.

Packaging: HME: The HMEs are single packed 10 pieces(5 pcs for protect) in a LD-Polyethylen blister sealed with a high barrier polyester-based lidding film.
Adhesive: Each adhesive is packed individually in a polyethylene plastic bag (Provox Life Night Adhesive is packed in an aluminum foil bag).

7467-7469:
1 blister of Provox Life Home HME, 1 blister of Provox Life GO HME, 10 pcs of Provox Life Standard Adhesive Round/Oval/Plus, 10 pcs Provox Life Sensitive Adhesive Round/Oval/Plus and 2 IFU packed in cardboard box.
7470-7472:
1 blister of Provox Life Home HME, 1 blister of Provox Life GO HME, 10 pcs of Provox Life Sensitive Adhesive Round/Oval/Plus and 2 IFU packed in cardboard box.
7473:
1 blister of Provox Life Home HME, 1 blister of Provox Life GO HME, 10 pcs of Provox Life Stability Adhesive and 2 IFU packed in cardboard box
7474:
1 blister of Provox Life Night HME, 10 pcs of Provox Life Night Adhesive and 2 IFU packed in cardboard box.
7475-7476:
1 blister of Provox Life Protect HME/Energy HME and IFU packed in cardboard box.

Document No: 10000045225 Edition: 00 Release date: 2021-02-04

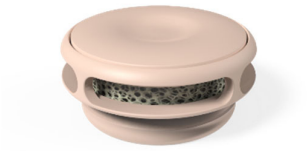
Product Information

Devices under Basic UDI-DI: 7331791-KIT-0-000-0003-HV

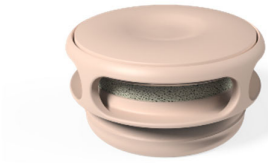
REF	Name	UDI-DI
7467	Provox Life Sample Pack Standard Round	07331791015199
7468	Provox Life Sample Pack Standard Oval	07331791015205
7469	Provox Life Sample Pack Standard Plus	07331791015212
7470	Provox Life Sample Pack Sensitive Round	07331791015229
7471	Provox Life Sample Pack Sensitive Oval	07331791015236
7472	Provox Life Sample Pack Sensitive Plus	07331791015243
7473	Provox Life Sample Pack Stability	07331791015250
7474	Provox Life Sample Pack Night	07331791015267

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

REF	Name	UDI-DI
7475	Provox Life Sample Pack Protect HME	07331791015274
7476	Provox Life Sample Pack Energy HME	07331791015281

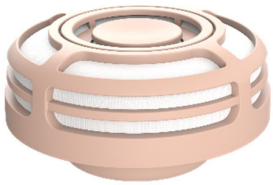


Go



Home

Energy



Protect

Night

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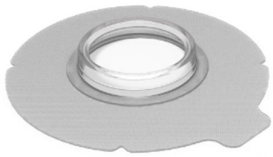
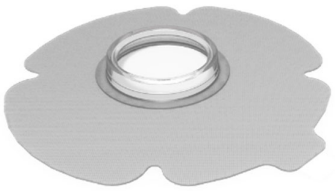
Product Information

 Standard Adhesive Round	 Sensitive Adhesive Round
 Standard Adhesive Oval	 Sensitive Adhesive Oval
 Life Standard Adhesive Plus	 Sensitive Adhesive Plus
 Night Adhesive	 Stability Adhesive

Atos Medical AB compatible products:

Range	BASIC UDI-DI
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
Provox Life LaryTube	7331791-LTU-0-000-0004-3L
Provox Life LaryTube Fenestrated	7331791-LTU-0-000-0004-3L

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Approved:	DD	Diana Tieger - DIATIE	2021-11-08 - 21:10
Released:	QA	Sara Dahl - X-SARDAH	2021-11-10 - 15:17

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Product Information

Provox® Life™ Experience Packs

Go

Home

Energy

Protect

Night

Standard Adhesive Round

Sensitive Adhesive Round

Night Adhesive

Standard Adhesive Oval

Sensitive Adhesive Oval

Stability Adhesive

Standard Adhesive Plus

Sensitive Adhesive Plus

Document No: 10000047272 Edition: 03 Release date: 2021-11-10

Released

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Product Information

Product description:

The Provox Life Experience Packs are a combination of Provox Life HMEs and Provox Life Adhesives.

Provox Life HME:
Provox Life HMEs are heat and moisture exchangers. HMEs are single use devices used for pulmonary rehabilitation and facilitation of speech.

Provox Life Adhesive:
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 Adhesive and Provox Life Night Adhesive have an adhesive material with permanent skin contact that is hypoallergenic and suitable for sensitive skin.

Document ID:	PF086-03-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 HMEs are single use heat- and moisture exchangers for patients breathing through a tracheostoma. 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:* Male and female of any age. HME: Not intended for patients with mechanical ventilation. Not intended for patients with a low tidal volume. *Intended usage:* Single use, over-the-counter device. *Intended part of the body/type of tissue applied to or interacted with:* Adhesive: The device is a peristomal adhesive with skin contact. HME: The product is placed in front of the tracheostoma to condition respiratory air. The tissue contact is Indirect via inhaled air. *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. The device can be used in any location and situation except during radiation therapy. Sensitive Adhesive can be used during and after radiotherapy depending on clinical suitability.*		

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Product Information

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.
HME: 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. Devices are CE-marked.

GMDN code: HME: 58705 (Tracheostoma protective filter)
Adhesive: 62175 (Stomal appliance skin-adherent patch, non-sterile).

Sterilization: Non-sterile.

Raw material: Provox Life HME:
Housing & Lid: Polypropylene (PP) with polyethylene (PE) master batch
Housing (only 8262 and no Lid): Polydimethylsiloxane (Silicone)
Foam: Polyurethane (PUR) with calcium chloride (CaCl2)
Filter (only used in ref. 8313): Acrylic, Polypropylene (PP)
Provox Life Adhesive:
Provox Life Standard Adhesive consist of an acrylic adhesive tape with a polyethylene carrier and an ethylene and butyl acrylate copolymer adapter. Provox Life Sensitive Adhesive 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 for 8065-8067, 8071-8074.
Excursions permitted between 2°C - 30°C for 8060-8064, 8068-8070 and 8075.

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:

HME:	Maximum 36 months after manufacturing.
Adhesives:	Maximum 36 months after manufacturing

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Product Information

Packaging:

HME: The HMEs are single packed 5 pieces(10 pcs of Night HME in 8072) in a LD-Polyethylene blister sealed with a high barrier polyester-based lidding film.
Adhesive: Each adhesive is packed individually in a polyethylene plastic bag (Provox Life Night Adhesive is packed in an aluminum foil bag).

8060-8063:
1 blister of Provox Life Home HME, 1 blister of Provox Life GO HME, 1 blister of Provox Life Night HME, 5 pcs of Provox Life Standard Adhesive Round/Oval/Plus, 5 pcs Provox Life Sensitive Adhesive Round/Oval/Plus and 2 IFU packed in cardboard box.
8064:
1 blister of Provox Life Home HME, 1 blister of Provox Life GO HME, 5 pcs of Provox Life Stability Adhesive and 2 IFU packed in cardboard box.
8065-8067:
5 pcs of Provox Life Standard Adhesive Round/Oval/Plus and 1 IFU packed in cardboard box.
8068-8070:
5 pcs of Provox Life Sensitive Adhesive Round/Oval/Plus and 1 IFU packed in cardboard box.
8071:
5 pcs of Provox Life Stability Adhesive and 1 IFU packed in cardboard box.
8072-8074,8264-8265:
1 blister of Provox Life Night/Energy/Protect/Home/Go HME and IFU packed in cardboard box.
8075:
5 pcs of Provox Life Night Adhesive and 1 IFU packed in cardboard box.

Devices under Basic UDI-DI: 7331791-KIT-0-000-0005-J3

REF	Name	UDI-DI
8060	Provox Life Day & Night Experience Round	07331791015601
8061	Provox Life Day & Night Experience Oval	07331791015618
8062	Provox Life Day & Night Experience Plus	07331791015625
8063	Provox Life Day & Night EXP Sensitive	07331791015632
8064	Provox Life Day & Night EXP Stability	07331791015649

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

REF	Name	UDI-DI
8065	Provox Life Standard Experience Round	07331791015656
8066	Provox Life Standard Experience Oval	07331791015663
8067	Provox Life Standard Experience Plus	07331791015670
8068	Provox Life Sensitive Experience Round	07331791015687
8069	Provox Life Sensitive Experience Oval	07331791015694
8070	Provox Life Sensitive Experience Plus	07331791015700
8071	Provox Life Stability Experience	07331791015717
8075	Provox Life Night Adhesive Experience	07331791015755

Document No: 10000047272 Edition: 03 Release date: 2021-11-10

Product Information

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

REF	Name	UDI-DI
8072	Provox Life Night HME Experience	07331791015724
8073	Provox Life Energy HME Experience	07331791015731
8074	Provox Life Protect HME Experience	07331791015748
8264	Provox Life Home HME Experience	07331791016103
8265	Provox Life Go HME Experience	07331791016110

Atos Medical AB compatible products:

Range	BASIC UDI-DI
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
Provox Life LaryTube	7331791-LTU-0-000-0004-3L
Provox Life LaryTube Fenestrated	7331791-LTU-0-000-0004-3L
Provox Life LaryButton	7331791-LTU-0-000-0005-3P

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Released:	QA	Elin Andersson - ELIAND	2021-12-09 - 09:32

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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.

Document No: 10000033112 Edition: 08 Release date: 2021-12-09

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Product Information

Document ID:	*PF088-01-TechInfo*	**Edition:**	*08*

Manufacturer: *Atos Medical AB*
Kraftgatan 8
SE-242 35 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.*

Use specifications: *Intended medical indication:*
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.
Intended usage:
Single patient use.
Intended part of the body/type of tissue applied to or interacted with:
Indirect contact through inhaled air, brief skin contact when attaching the device.
Intended user profile:
Patient, clinician and other caregivers.
Intended conditions of use:
Normal daily environment without any hygienic or environmental restrictions regarding temperature, moisture etc.

Contraindications: *No known contraindications*

CE Mark: *Yes. 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: *3 years after manufacturing.*

Packaging: *Provox Life Shower is single packed in a LD-Polyethylen blister sealed with*

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Product Information

a high barrier polyester-based lidding film. It is then packed together with instructions for use in a cardboard box.

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*
Provox Life LaryTube	*7331791-LTU-0-000-0004-3L*
Provox Life LaryButton	*7331791-LTU-0-000-0005-3P*

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Issued:	QA	Carolina Johansson - SEHRBJNC	2022-01-17 - 08:30
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Approved:	DD	Diana Tieger - DIATIE	2022-01-17 - 09:29
Released:	QA	Carolina Johansson - SEHRBJNC	2022-01-17 - 09:34

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Product Information

Provox® Life™ LP Kit

Product description:

Provox Laryngectomy Kits provide all-in-one packaging for immediate post-operative 24/7 pulmonary rehabilitation and the option for ready-to-use surgical placement. The kits feature Provox Heat and Moisture Exchangers (HMEs) – approved for 24-hour use.

Document No: 10000046910 Edition: 04 Release date: 2022-01-17

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Product Information

Document ID:	PF089-01-TechInfo	**Edition:**	04

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

Classification: (EU) 2017/745
Procedure pack listed in EUDAMED.

Intended Use:
See information provided with the individual devices included in the kit.

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/multiple use by Single patient.
Prescription device. To be provided by clinician.
Intended part of the body/type of tissue applied to or interacted with:
See information provided with the individual devices included in the kit.
Intended user profile:
The product is intended 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 living environment without any specific environmental restrictions regarding temperature, moisture etc.).
Outpatient clinic use. Hospital use.
Frequency of use: See information provided with the individual devices included in the kit.
Replacement rate: See information provided with the individual devices included in the kit.

Contraindications:
See information provided with the individual devices included in the kit.

CE Mark:
LP Kit is not CE marked. Medical devices included in LP Kit are CE marked individually.

GMDN code:
See individual Product Information.

Sterilization:
Non-sterile

Raw material:
See individual 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.

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Product Information

Hazardous components: None

Expiration date: 3 years after manufacturing. The included device with the shortest shelf life upon packing of each lot, will determine the shelf life.

Packaging: These products are packed in a box and contain marketing materials and a mix of the following final products (configuration dependent).
Provox Life LaryTube
Provox Life Home HME
Provox Life Night HME
Freevent Neckband two-piece L
Provox TubeBrush
Provox Life Shower
Provox SolaTone Plus
Provox TruTone Plus

Devices under Basic UDI-DI: 7331791-KIT-0-000-0004-HY

REF	Name	UDI-DI
6130	Provox Life LP Kit 1 - LT 8/36, 8/55	7331791015373
6131	Provox Life LP Kit 2 - LT 9/36, 9/55	7331791015380
6132	Provox Life LP Kit 3 - LT 10/36,10/55	7331791015397
6133	Provox Life LP Kit 4 - LT 12/36,12/55	7331791015403
6134	Provox Life LP Kit 5 - LT 8/36, 8/55	7331791015410
6135	Provox Life LP Kit 6 - LT 9/36, 9/55	7331791015427
6136	Provox Life LP Kit 7 - LT 10/36,10/55	7331791015434
6137	Provox Life LP Kit 8 - LT 12/36,12/55	7331791015441
6138	Provox Life LP Kit 9 - LT 8/36, 8/55	7331791015458
6139	Provox Life LP Kit 10 - LT 9/36, 9/55	7331791015465
6140	Provox Life LP Kit 11- LT 10/36,10/55	7331791015472
6141	Provox Life LP Kit 12 - LT 12/36,12/55	7331791015489
6142	Provox Life LP Kit 13 - LT 9/55	7331791015496
6143	Provox Life LP Kit 14 - LT 10/55	7331791016165
6144	Provox Life LP Kit 15 - LT 10/55-2H	7331791016134
6145	Provox Life LP Kit 16 - LT 10/55-2HSTP	7331791016141
6146	Provox Life LP Kit 17 - LT 10/55-2HTTP	7331791016158

Atos Medical AB compatible products:
See information provided with the individual devices included in the kit.

Document No: 10000046910 Edition: 04 Release date: 2022-01-17

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Released:	QA	Elin Andersson - ELIAND	2022-03-21 - 15:47

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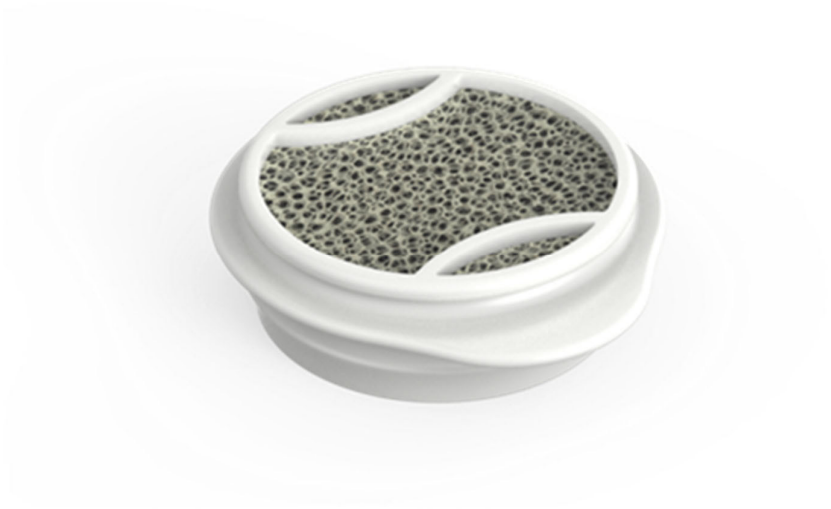
Product Information

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:** 04

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.

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
Single use.
Intended part of the body/type of tissue applied to or interacted with
The device will contact intact skin and mucosal membrane and as external communicating device the contact mode with tissue is indirect via 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
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 24 hours. Replacement is performed by the patient, clinician or caregiver.

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. Devices are 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).

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:	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.

Product Information

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

REF	Name	UDI-DI
7440	Provox Life FreeHands HME	07731791014895

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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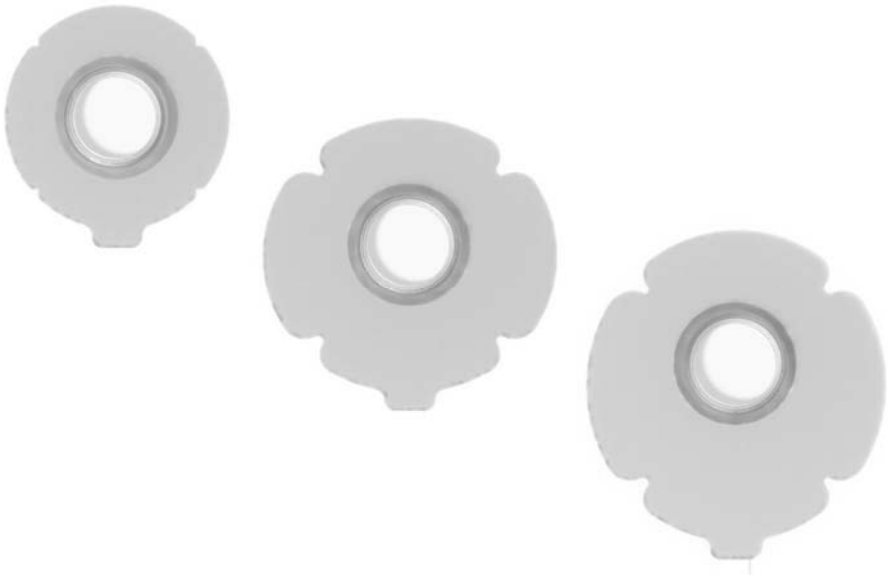
Product Information

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.

Document No: 10000046234 Edition: 10 Release date: 2021-04-16

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Product Information

Document ID:	PF101-01-TechInfo	**Edition:**	10

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. The majority of the users are elderly.
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. The device can be used in any location and situation.

Contraindications: The device shall not be used by patients with reduced mental or physical cognitive ability. Patients who are unable to attach or remove the device themselves, or without sufficient knowledge how to use the device, or the cognitive ability to understand the risks connected to the use, should not use the device.

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.

Product Information

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).

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: 3 years after manufacturing.
REF 8263: 3 years 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

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

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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Released:	QA	Sara Dahl - X-SARDAH	2021-02-17 - 13:53

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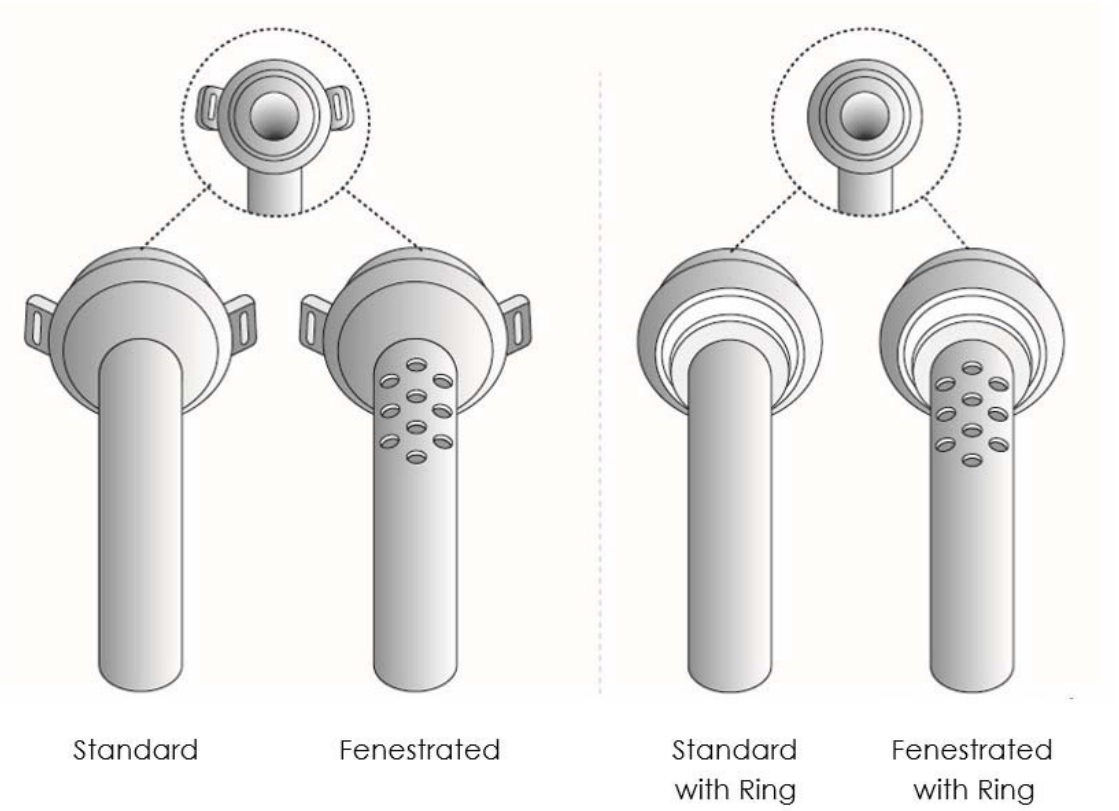
Product Information

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.

Standard with 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.

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Document No: 10000041195 Edition: 04 Release date: 2021-02-17

Product Information

Document ID:	PF106-01-TechInfo	**Edition:**	04

Manufacturer:
Atos Medical AB
Kraftgatan 8
SE-242 35 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.

Use specifications:

Intended medical indication:
The Provox Life LaryTube is a holder for devices for pulmonary and vocal rehabilitation (HMEs and Automatic Speaking Valves (Provox FreeHands)) for patients breathing through a tracheostoma. The device is used together with Provox Life System (Provox Life Adhesives, Provox Life HMEs and Provox Life Shower).

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

Intended usage; How is the device intended to be used:
Provox Life LaryTube is a single patient use device prescribed by a clinician. The availability of this product without prescription outside the United States may vary from country to country.

Intended part of the body/type of tissue applied to or interacted with:
Tracheostoma.

Intended user profile:
Patient, clinician, nurse or other caretaker.

Intended conditions of use:
Primarily home use (normal day and night environment without any hygienic or environmental restrictions regarding temperature, moisture etc.). Secondary outpatient clinic use and at hospital.
Frequency of use: Continuous use.

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

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 materials derived from human or animal source.

Product Information

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

Waste handling and disposal: Waste handling and disposal should be carried out in agreement with medical practice and applicable national laws and legislations. Used product may be a potential biohazard.

Hazardous components: None

Expiration date: 5 years after manufacturing.

Packaging: Provox® Life LaryTube is single packed in a LD-Polyethylene 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.

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

REF	Name	UDI-DI
7409	Provox® Life LaryTube 8/27 Standard	7331791013874
7410	Provox® Life LaryTube 8/36 Standard	7331791013881
7411	Provox® Life LaryTube 8/55 Standard	7331791013898
7412	Provox® Life LaryTube 9/27 Standard	7331791013676
7413	Provox® Life LaryTube 9/36 Standard	7331791013683
7414	Provox® Life LaryTube 9/55 Standard	7331791013713
7415	Provox® Life LaryTube 10/27 Standard	7331791013904
7416	Provox® Life LaryTube 10/36 Standard	7331791013911
7417	Provox® Life LaryTube 10/55 Standard	7331791013928
7418	Provox® Life LaryTube 12/27 Standard	7331791013935
7419	Provox® Life LaryTube 12/36 Standard	7331791013942
7420	Provox® Life LaryTube 12/55 Standard	7331791013959
7421	Provox® Life LaryTube 8/36 Standard with Ring	7331791013966
7422	Provox® Life LaryTube 8/55 Standard with Ring	7331791013973
7423	Provox® Life LaryTube 9/36 Standard with Ring	7331791013690
7424	Provox® Life LaryTube 9/55 Standard with Ring	7331791013720
7425	Provox® Life LaryTube 10/36 Standard with Ring	7331791013980
7426	Provox® Life LaryTube 10/55 Standard with Ring	7331791013997
7427	Provox® Life LaryTube 12/36 Standard with Ring	7331791014000
7428	Provox® Life LaryTube 12/55 Standard 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

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Product Information

REF	Name	UDI-DI
8054	Provox® Life LaryTube 12/36 Fenestrated with Ring	7331791015007
8055	Provox® Life LaryTube 12/55 Fenestrated with Ring	7331791015014

Atos Medical AB 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-000-0002-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
Provox® Life BasePlate Adaptor	7331791-HME-A-000-0005-FB

Document No: 10000041195 Edition: 04 Release date: 2021-02-17

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This document has been electronically signed by the persons above.

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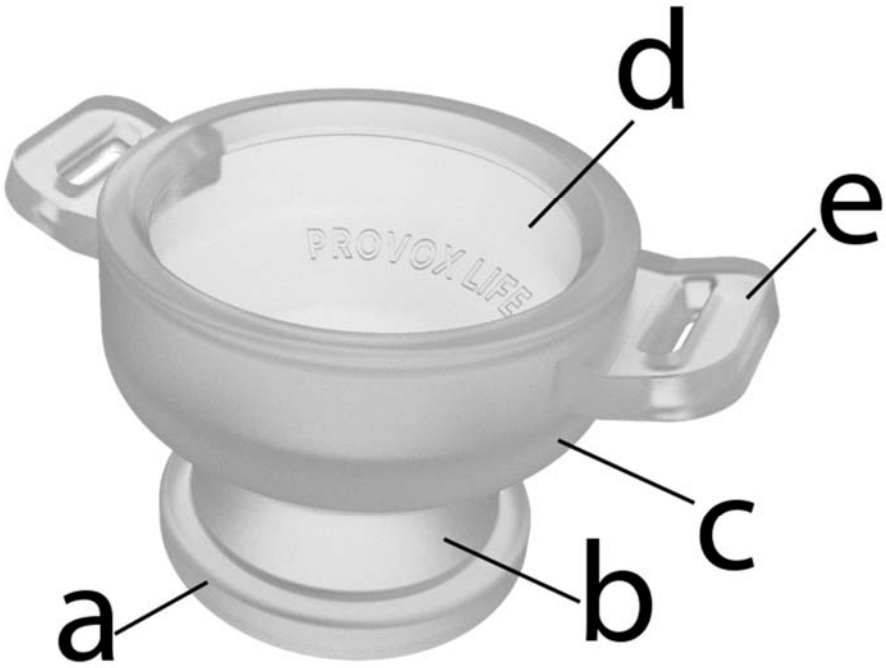
Product Information

Provox® Life™ LaryButton



Product description:

Provox Life™ LaryButton is a self-retaining tracheostoma button made of medical grade silicone rubber. The purpose of the device is to create a comfortable and airtight fit between Provox Life™ LaryButton and the tracheostoma and also to provide attachment for devices from Provox Life™ HME System. The device is delivered single packed, non-sterile and ready to use. The different parts of Provox Life™ LaryButton are:

a) Retention Collar
b) Shaft
c) Shield (conical)
d) HME and Accessory Holder
e) Wings

Document No: 10000043447 Edition: 01 Release date: 2021-05-21

Released

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Product Information

Document ID:	PF116-01-TechInfo	**Edition:**	01

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

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

Intended Use:
Provox Life™ LaryButton is a single patient use self-retaining holder for Provox Life™ HMEs and accessories after total laryngectomy. For patients with a shrinking tracheostomas it is also used to maintain the tracheostoma for breathing.

Use specifications:
Intended medical indication:
Product for rehabilitation for patients breathing through a tracheostoma.
Intended patient population:
For patients breathing through a tracheostoma after total laryngectomy.
Intended usage:
Provox Life™ 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:
Patient, clinician, nurse or other caretaker.
Intended conditions of use (i.e. environment including hygienic requirements, frequency of use, location, mobility):
Primarily home use (normal daily environment without any hygienic or environmental restrictions regarding temperature, moisture etc.).
Secondary, outpatient clinic use and at hospital.

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

CE Mark:
Yes, the devices are CE marked.

GMDN code:
14093 (Tracheostoma button)

Sterilization:
Non-Sterile.

Raw material:
Provox Life™ LaryButton consists of transparent medical grade silicone rubber.

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.

Product Information

Packaging: Provox Life™ LaryButton 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™ LaryButton in a cardboard box.

Devices under Basic UDI-DI: 7331791-LTU-0-000-0005-3P

REF	Name	UDI-DI
8040	Provox® Life™ LaryButton 12/8	7331791015304
8041	Provox® Life™ LaryButton 12/18	7331791015106
8042	Provox® Life™ LaryButton 14/8	7331791015113
8043	Provox® Life™ LaryButton 14/18	7331791015120
8044	Provox® Life™ LaryButton 16/8	7331791015137
8045	Provox® Life™ LaryButton 16/18	7331791015144
8046	Provox® Life™ LaryButton 18/8	7331791015151
8047	Provox® Life™ LaryButton 18/18	7331791015168

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox® TubeBrush	7331791-GEN-A-000-0001-E9
Provox® Swab	7331791-GEN-A-000-0002-EC
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-0-000-0008-XZ
Provox® Life™ Shower	7331791-ADH-A-000-0001-UB
Provox® LaryClip	7331791-LTU-A-000-0001-JT
Provox® TubeHolder	7331791-GEN-A-000-0000-E6
Provox® Life™ BasePlate Adaptor	7331791-HME-A-000-0005-FB
Freevent® Neckband	7331791-GEN-A-000-0000-E6
Stoma Sizing Guide	7331791-LTU-A-000-0001-JT

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Approved:	DD	Diana Tieger - DIATIE	2021-10-19 - 13:52
Released:	DD	Daniel Åberg - DANABE	2021-10-21 - 09:07

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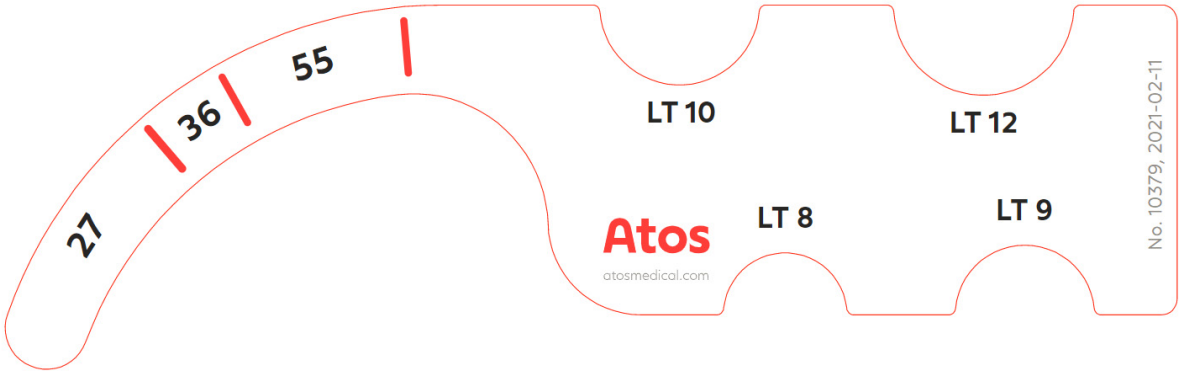
Product Information

Stoma Sizing Guide



Product description:

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

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Product Information

Document ID: PF118-01-TechInfo **Edition:** 01

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

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

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

Use specifications:

Intended medical indication:
Patients breathing through a tracheostoma using LaryTube or LaryButton for pulmonary rehabilitation.
Intended patient population:
For patients breathing through a tracheostoma after total laryngectomy.
Intended usage:
Single use, Prescription only.
Intended part of the body/type of tissue applied to or interacted with:
Tracheostoma. The device will contact intact skin and mucosal membrane.
Intended user profile:
Prescribing clinician and patient.
Intended conditions of use:
Outpatient clinic use. Hospital use.
Frequency of use: Transient, Normally intended for use for less than 60 minutes.
Replacement rate: N/A, Single use only.
Home use (normal daily environment without any hygienical or environmental restrictions).

Contraindications: No known contraindications

CE Mark: Yes. Devices are CE-marked.

GMDN code: 65811 (Tracheostoma sizer)

Sterilization: Non-sterile.

Raw material: Paper laminated with a Polypropylene-film

Latex information: Not manufactured with natural rubber latex

Biological origin: The device is not manufactured with materials derived from human or animal source.

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:	2 years after manufacturing.
Packaging:	5 x 10Pcs of Stoma Sizing Guide in LD-PE plastic bags are packed in a cardboard box.

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Product Information

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

REF	Name	UDI-DI
7135	Stoma Sizing Guide	7331791015366

Atos Medical AB compatible products:

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

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