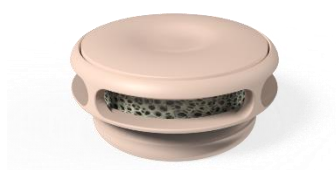


Provox Life Experience Packs



Go



Home



Energy



Protect



Night



Standard Adhesive Round



Sensitive Adhesive Round



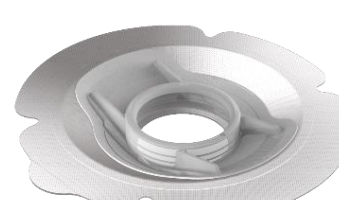
Night Adhesive



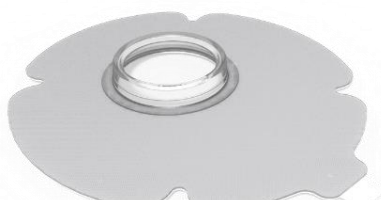
Standard Adhesive Oval



Sensitive Adhesive Oval



Stability Adhesive



Standard Adhesive Plus



Sensitive Adhesive Plus

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:	3.0
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 CO ₂ (Carbon dioxide) retention.		
CE Mark:	Yes. Devices are CE-marked.		
GMDN code:	HME: 58705 (Tracheostoma protective filter) Adhesive: 62175 (Removable ambulatory appliance skin-adherent patch).		
Sterilization:	Non-sterile.		
Raw material:	Provox Life HME: Housing & Lid: Polypropylene (PP) with polyethylene (PE) master batch		

Product Information

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

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 1 IFU packed in a cardboard box.

8064:

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 Stability Adhesive and 1 IFU packed in a cardboard box.

8065-8067:

5 pcs of Provox Life Standard Adhesive Round/Oval/Plus and 1 IFU packed in a cardboard box.

8068-8070:

Product Information

5 pcs of Provox Life Sensitive Adhesive Round/Oval/Plus and 1 IFU packed in a cardboard box.

8071:

5 pcs of Provox Life Stability Adhesive and 1 IFU packed in a cardboard box.

8072-8074,8264-8265:

1 blister of Provox Life Night/Energy/Protect/Home/Go HME and 1 IFU packed in a cardboard box.

8075:

5 pcs of Provox Life Night Adhesive and 1 IFU packed in a 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

Atos 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

Range	BASIC UDI-DI
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

Document Approvals
Approved Date: 2024-07-15

Task: Approval Task Verdict: Approve	DKSIKR Signe Kristensen, Product Support Specialist (dksikr@coloplast.com) Issuer 11-Jul-2024 06:59:48 GMT+0000
Task: Approval Task Verdict: Approve	ABDALM Abdallah Almashharawi, Senior Sustaining Engineer (abdallah.almashharawi-atosmedical@coloplast.com) Quality 11-Jul-2024 07:12:01 GMT+0000
Task: Final Approval Verdict: Approve	KARNIL Karolina Nilsson, Head of Regulatory Affairs (karolina.nilsson-atosmedical@coloplast.com) Regulatory 15-Jul-2024 15:23:47 GMT+0000