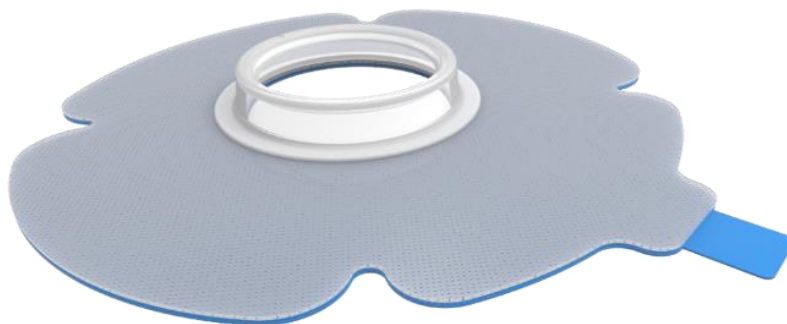


Provox Life Comfort Adhesive



Product description:

Provox Life Provox Life Comfort Adhesive is a single use adhesive that provides attachment for Provox Life HMEs and accessories after total laryngectomy. The adhesive is designed to be suitable for post-operative laryngectomy patients and everyday use for patients with sensitive skin.

Document ID:	PF124-01-TechInfo	Edition:	1.0
Manufacturer:	Atos Medical AB Kraftgatan 8 SE-242 35 Hörby, Sweden		
Classification: (EU) 2017/745	Class I (Rule 1)		
Intended Use:	Provox Life Comfort Adhesive is a single use adhesive that provides attachment for Provox Life HMEs and accessories after total laryngectomy.		
Use specifications:	<p>Intended medical indication Facilitation of pulmonary rehabilitation after total laryngectomy. The product is intended for adults.</p> <p>Intended patient population Adult patients from 18+ years. Cognitive ability, by a clinician judged as sufficient. Manual dexterity, by a clinician judged as sufficient.</p> <p>Intended usage Single use, over-the-counter.</p> <p>Intended part of the body/type of tissue applied to or interacted with The device will be in contact with intact skin around the neck stoma.</p> <p>Intended user profile Healthcare professionals, patients and lay caregivers.</p> <p>Intended conditions of use Environment: Home use/Outpatient clinic use/Hospital use. Frequency of use: Continuous use. Replacement rate: Max usage of 24 hours. Replacement is performed by the patient, clinician or caregiver.</p>		
Operating principle	<p>Provox Life Comfort Adhesive is a single use adhesive that provides attachment for Provox Life HMEs and accessories after a total laryngectomy by adhering to the skin around the neck stoma.</p> <p>Designed to be suitable for post-operative laryngectomy patients and for daily use by individuals with sensitive skin.</p> <p>Clean the skin around the stoma before application. To apply an adhesive, take one plastic bag with adhesive out of the cardboard box, open the plastic bag and take out the adhesive. Remove the liner from the adhesive and place the adhesive on the skin around the laryngectomy stoma. Attach compatible Provox Life HME or applicable accessory to the adaptor on the adhesive.</p> <p>The adhesive shall be changed at least every 24 hours or earlier if clinically indicated (e.g. soiled or loose).</p>		

Product Information

Contraindications:	Patients without the physical, cognitive, or mental ability required to attach, remove or operate the devices themselves, should not use the devices independently and should only use them if they are under sufficient supervision of a clinician or a trained caregiver. If not, this may lead to restricted breathing and/or suffocation.
CE Mark:	Yes. Device is CE-marked.
GMDN code:	62175 (Stomal appliance skin-adherent patch, non-sterile).
Sterilization:	Non-sterile.
Raw material:	Provox Life Comfort Adhesive consists of a silicone adhesive gel (direct contact with the patient) with top layer consisting of a polyethylene carrier, acrylic adhesive and polyurethane carrier. The adapter material is ethylene butyl acrylate copolymer (indirect contact with the patient). The liner is made from low-density polyethylene (indirect contact with the patient).
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.
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:	1 year and 11 months after manufacturing.
Packaging:	<p>Each adhesive is packed individually in a polyethylene plastic bag. The adhesives bags are packed in a cardboard box with one Provox Life Comfort Adhesive IFU.</p> <p>Available in Oval shape in two packaging sizes:</p> <ul style="list-style-type: none">• Provox Life Adhesive Comfort Oval (30 pcs)• Provox Life Comfort Experience Oval (5 pcs)

Devices under Basic UDI-DI: 7331791-ADH-0-000-0003-CZ

REF	Name	UDI-DI
8403	Provox Life Adhesive Comfort Oval	07331791181221
8094	Provox Life Comfort Experience Oval	07331791181269

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox Life HME	7331791-HME-0-000-0001-XC
Provox Life Oxygen	7331791-HME-A-000-0009-FP
Provox Life Shower	7331791-ADH-A-000-0001-UB
Provox Life BasePlate Adapter	7331791-HME-A-000-0005-FB
Provox Life LaryTube with Ring	7331791-LTU-0-000-0004-3L
Provox Life LaryTube fenestrated with ring	7331791-LTU-0-000-0004-3L
Provox Cleaning Towel 10-p	7331791-ADH-A-000-0003-UH

Document Approvals
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Task: Approval Task Verdict: Approve	SOFIE.CEDERLUND Sofie Cederlund, Design Control Specialist (sofie.cederlund-atosmedical@coloplast.com) Issuer 20-Nov-2025 08:40:29 GMT+0000
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