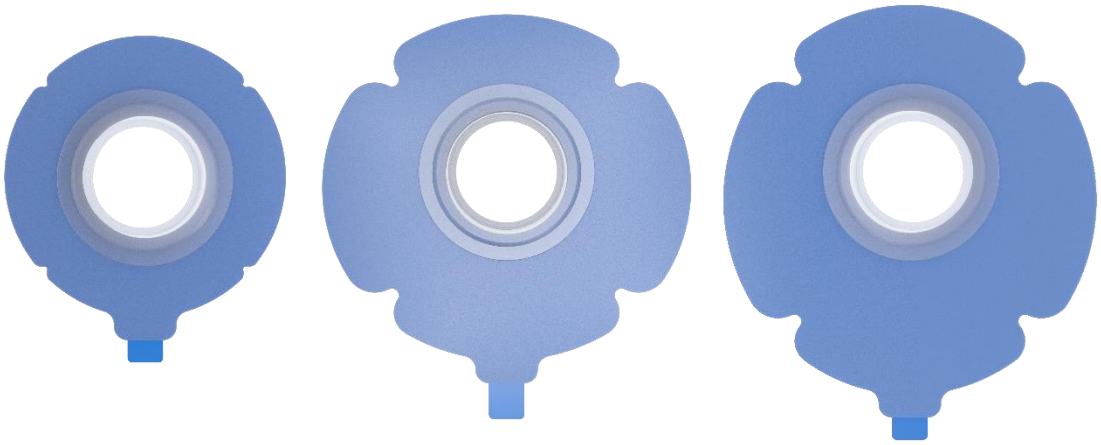
Product Information

Provox Comfort Adhesive



Product description:

Provox Comfort Adhesive is a single use adhesive that provides attachment for Provox 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.

Product Information

Manufacturer:	Atos Medical AB Kraftgatan 8 SE-242 35 Hörby, Sweden
Classification: (EU) 2017/745	Class I (Rule 1)
Intended Use:	Provox Comfort Adhesive is a single use adhesive that provides attachment for Provox HMEs and accessories after total laryngectomy.
Use specifications:	**Intended medical indication** Facilitation of pulmonary rehabilitation after total laryngectomy. The product is intended for adults. **Intended patient population** Adult patients from 18+ years. Cognitive ability, by a clinician judged as sufficient. Manual dexterity, by a clinician judged as sufficient. **Intended usage** Single use, over-the-counter **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. **Intended user profile** Healthcare professionals, patients and lay caregivers **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.
Operating principles	Provox Comfort Adhesive is a single use adhesive that provides attachment for Provox HMEs and accessories after a total laryngectomy by adhering to the skin around the neck stoma. Designed to be suitable for post-operative laryngectomy patients and for daily use by individuals with sensitive skin. 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 HME or applicable accessory to the adaptor on the adhesive. The adhesive shall be changed at least every 24 hours or earlier if clinically indicated (e.g. soiled or loose). The product shall be used in accordance with the Instructions for Use (IFU).

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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. Devices are CE-marked.

EMDN code: R060280 - HUMIDIFICATION SYSTEMS – ACCESSORIES.

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

Sterilization: Non-sterile.

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: 3 years after manufacturing.

Packaging: Each adhesive is packed individually in a polyethylene plastic bag. The adhesive bags are packed in a cardboard box with one Provox Comfort Adhesive IFU.

Available in the following variants and packaging sizes:

- Provox Comfort Adhesive Round (30 pcs)
- Provox Comfort Adhesive Oval (30 pcs)
- Provox Comfort Adhesive Plus (30 pcs)
- Provox Comfort Adhesive Experience Round (5 pcs)
- Provox Comfort Adhesive Experience Oval (5 pcs)

Raw material:

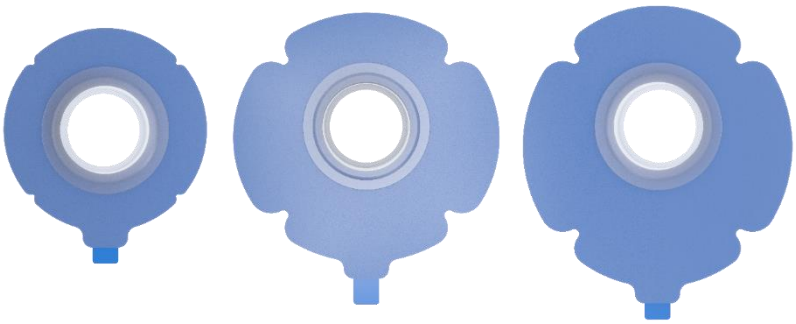
Part name	Material (Generic chemical name)	End-user contact
Adhesive (bottom layer)	Silicone gel adhesive	Direct contact
Adhesive (top layer)	Polyethylene carrier, Acrylic adhesive & Polyurethane carrier	Indirect contact
Adaptor	Ethylene butyl acrylate copolymer	Indirect contact
Liner	Low-density polyethylene	Indirect contact
Primary packaging, Plastic bag	Polyethylene	No contact

Product Information

Devices under Basic UDI-DI: 7331791-ADH-0-000-0004-D4

REF	Name	UDI-DI
8406	Provox Comfort Adhesive Round	07331791181948
8407	Provox Comfort Adhesive Oval	07331791181979
8408	Provox Comfort Adhesive Plus	07331791182006
8411	Provox Comfort Adhesive Experience Round	07331791182037
8412	Provox Comfort Adhesive Experience Oval	07331791182051

Provox Comfort Adhesive Round/oval/Plus



Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox XtraFlow HME	7331791-HME-0-000-0000-X9
Provox XtraMoist HME	7331791-HME-0-000-0000-X9
Provox ShowerAid	7331791-ADH-A-000-0000-U8
Provox Skin Barrier	7331791-ADH-A-000-0004-UL
Provox Micron HME	7331791-HME-0-000-0002-XF
Provox BasePlate Adaptor	7331791-HME-A-000-0003-F5
Provox Cleaning Towel	7331791-ADH-A-000-0003-UH
Provox LaryTube with Ring	7331791-LTU-0-000-0002-3E
Provox FreeHands HME Cassette	7331791-HME-0-000-0003-XJ

Document Approvals

Approved Date: 2026-11-12

Task: Approval Task Verdict: Approve	SOFIE.CEDERLUND Sofie Cederlund, Design Control Specialist (sofie.cederlund-atosmedical@coloplast.com) Issuer 10-Nov-2026 13:29:23 GMT+0000

Task: Final Approval Verdict: Approve	HIND.ABUTALEB Hind Palm, Regulatory Affairs Specialist (hind.abutaleb-atosmedical@coloplast.com) Regulatory 12-Nov-2026 10:11:43 GMT+0000