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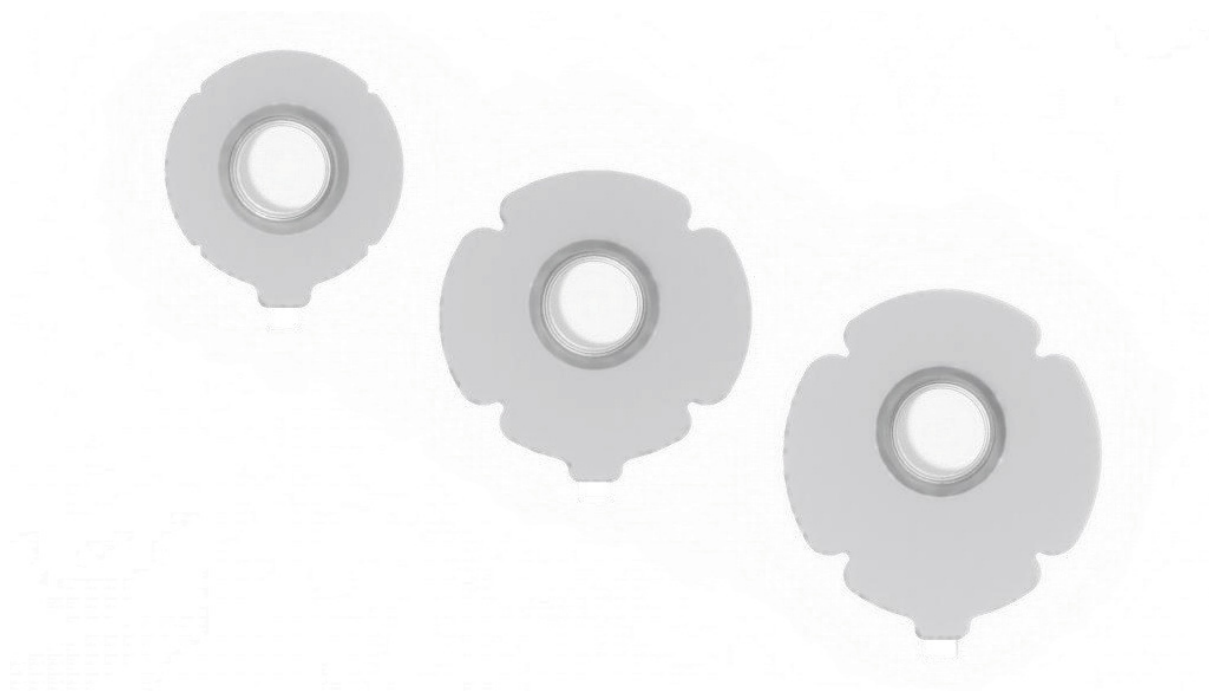
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Released

Document No: 10000046234 Edition: 11 Release date: 2022-08-24

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:	11
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 devices should only be used in accordance with the Instructions for Use. 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.		
CE Mark:	Yes. 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.		

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 (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:	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

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

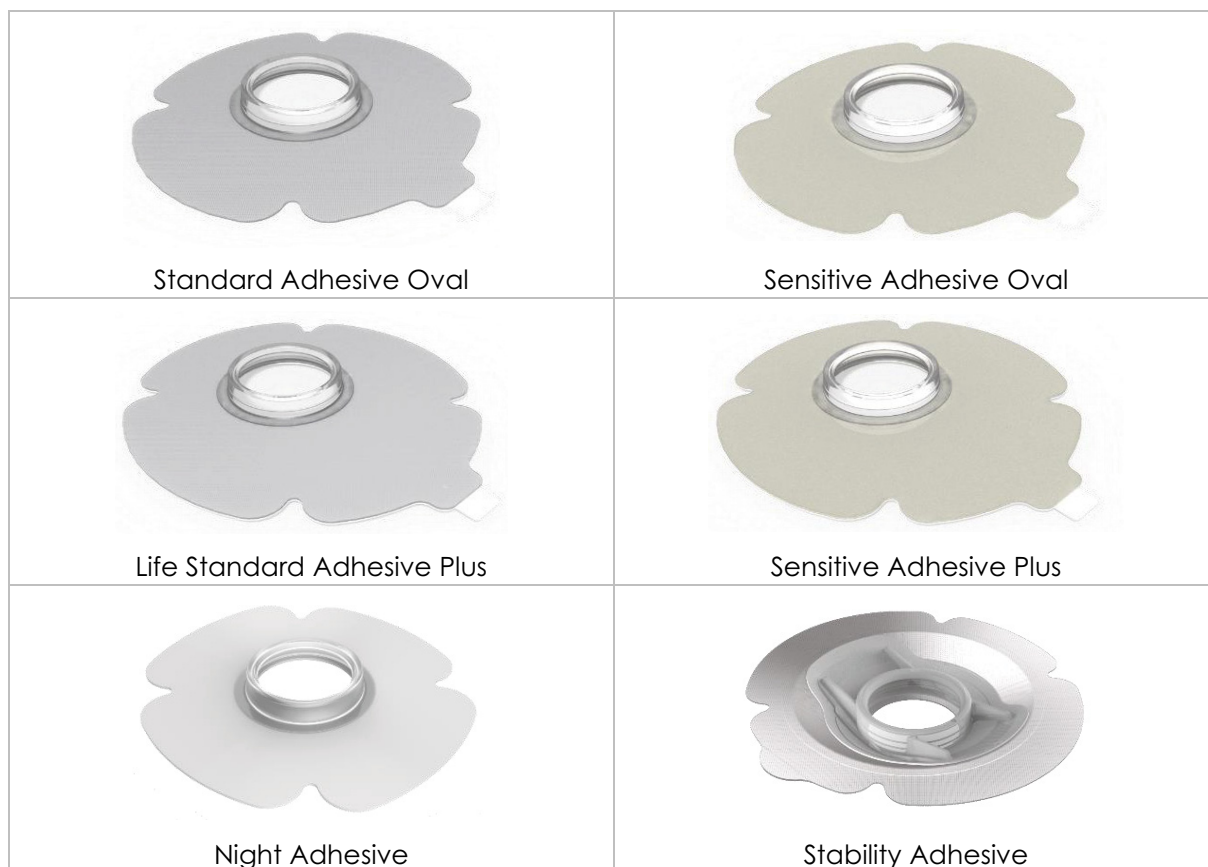


Standard Adhesive Round



Sensitive Adhesive Round

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
Provox Adhesive Strip	7331791-ADH-A-000-0002-UE