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This document has been electronically signed by the persons above.

Provox® Adhesives



Product description:

Provox Adhesives are designed to ensure an airtight attachment for the Provox HME system components. The adhesives have an adhesive part, a peel-off liner and an adapter where components of the HME system can be connected.

FlexiDerm is a very flexible material and has the strongest adhesive properties. It is a sticky, yet soft and flexible adhesive. The FlexiDerm adhesives are Provox FlexiDerm Round/Oval/Plus and Provox **XtraBase** with a concave shaped base.

The hydrocolloid **OptiDerm** is made of a hypoallergenic adhesive material that forms a gel in contact with water. The OptiDerm adhesives are Provox OptiDerm Round/Oval/Plus.

Product Information

Document ID:	PF025-01-TechInfo	Edition:	16
Manufacturer:	Atos Medical AB Kraftgatan 8 SE-242 35 Hörby, Sweden		
Classification: (EU) 2017/745	Class I, Rule 1		
Intended Use:	The Provox Adhesives are single use devices intended for laryngectomized patients breathing through a tracheostoma. The devices are attached to the skin around the tracheostoma in order to provide attachment of components of the Provox HME System.		
Use specifications:	<p>Intended medical indication Product for rehabilitation for patients breathing through a tracheostoma.</p> <p>Intended patient population Intended for laryngectomized patients of any age breathing through a tracheostoma.</p> <p>Intended usage Single use.</p> <p>Intended part of the body/type of tissue applied to or interacted with The device is attached to the skin around the tracheostoma.</p> <p>Intended user profile Gender: Female and male Cognitive ability: By a clinician judged as sufficient. Manual dexterity: By a clinician judged as sufficient. If not, the operating principle may be performed by someone else than the patient.</p> <p>Intended conditions of use Environment: Primarily home use (normal daily environment without any hygienic or environmental restrictions regarding temperature, moisture etc.). Secondly outpatient clinic use. Not intended for use during radiotherapy. Frequency of use: Continuous use. Replacement rate: Approximately every 1-4 days (May stay on as long as it provides an airtight seal).</p>		
Contraindications:	None		
CE Mark:	Yes. Devices are CE-marked.		
GMDN code:	62175 (Stomal appliance skin-adherent patch)		
Sterilization:	Non-sterile		
Raw material:	<p>FlexiDerm: Ethylene-butyl acrylate (EBA), Polyethylene (PE), Acrylic adhesive.</p> <p>XtraBase: Ethylene-butyl acrylate (EBA), Polyethylene (PE), Acrylic adhesive.</p> <p>OptiDerm: Ethylene-butyl acrylate (EBA), Hydrocolloid, Polyethylene (PE), Acrylic adhesive.</p>		
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.		

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: 3 years after manufacturing.

Packaging: **Provox Adhesive FlexiDerm** are separately packed in a plastic bag of OPET/PE. The products and instructions for use are packed in a cardboard box.

Provox Adhesive OptiDerm are separately packed in a plastic bag of OPET/PE. The products and instructions for use are packed in a cardboard box.

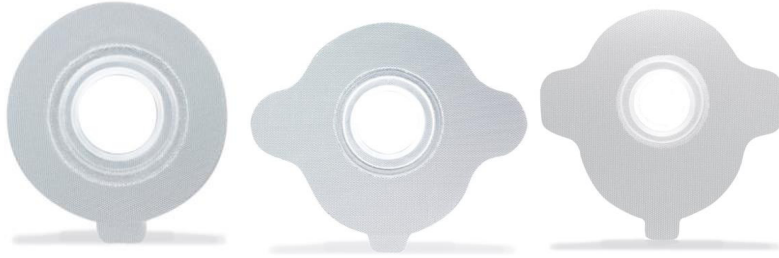
Provox Adhesive XtraBase is separately packed in a plastic bag of polyethylene. The products and instructions for use are packed in a cardboard box.

Devices under Basic UDI-DI: 7331791-ADH-0-000-0000-CQ

REF	Name	UDI-DI
7253	Provox Adhesive FlexiDerm Round	07331791001611
7254	Provox Adhesive FlexiDerm Oval	07331791001628
7255	Provox Adhesive OptiDerm Round	07331791001635
7256	Provox Adhesive OptiDerm Oval	07331791001642
7253ES	Provox Adhesive FlexiDerm Round	07331791011351
7254ES	Provox Adhesive FlexiDerm Oval	07331791011368
7254JP	Provox Adhesive FlexiDerm Oval (15pcs)	07331791015328
7256JP	Provox Adhesive OptiDerm Oval (15pcs)	07331791015335
7331	Provox Adhesive FlexiDerm Plus	07331791008160
7332	Provox Adhesive OptiDerm Plus	07331791008177
8234	Provox FlexiDerm Round (3pcs)	07331791010309
8235	Provox FlexiDerm Oval (3pcs)	07331791010316
8236	Provox OptiDerm Round (3pcs)	07331791010323
8237	Provox OptiDerm Oval (3pcs)	07331791010330
8238	Provox FlexiDerm Plus (3pcs)	07331791010347
8239	Provox OptiDerm Plus (3pcs)	07331791010354
7253-18	Provox Adhesive FlexiDerm Round	07331791014574
7254-18	Provox Adhesive FlexiDerm Oval	07331791014581
7255-18	Provox Adhesive OptiDerm Round	07331791014628
7256-18	Provox Adhesive OptiDerm Oval	07331791014635
7331-18	Provox Adhesive FlexiDerm Plus	07331791014567
7332-18	Provox Adhesive OptiDerm Plus	07331791014642
7265	Provox XtraBase Adhesive	07331791001703
8233	Provox XtraBase (3pcs)	07331791010293
7265-18	Provox XtraBase Adhesive	07331791014727

Product Information

Provox Adhesive FlexiDerm Round/oval/Plus



Provox Adhesive OptiDerm Round/Oval/Plus



Provox XtraBase Adhesive



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 Silicone Glue	7331791-GEN-A-000-0003-EF
Provox Adhesive Remover	7331791-ADH-A-000-0005-UP
Provox Skin Barrier	7331791-ADH-A-000-0004-UL
Provox Adhesive Strip	7331791-ADH-A-000-0002-UE
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 Lary Tube with Ring	7331791-LTU-0-000-0002-3E
Provox FreeHands HME Cassette	7331791-HME-0-000-0003-XJ