Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	DD	Mårten Cervin - SEHRBCNM	2020-11-02 - 15:47
Reviewed:	QA	John Wennborg - JOHWEN	2020-11-03 - 08:16
Approved:	DD	Diana Tieger - DIATIE	2020-11-03 - 08:29
Released:	DD	Mårten Cervin - SEHRBCNM	2020-11-04 - 15:04

This document has been electronically signed by the persons above.

Product Information

Product® Group

Product description:

Provox Silicone Glue is a liquid glue used for increased adhesion of the Provox Adhesive. The glue cures via air contact. Long-term use may cause skin irritation.

Document No: 10000030279 Edition: 12 Release date: 2020-11-04

Atos Medical AB
Kraftgatan 8, P.O Box 183
SE-242 22 Hörby, Sweden
Tel: +46 (0) 415 198 00
Web Site: www.atosmedical.com
E-mail: info@atosmedical.com
Org.nr 556268-7607
VAT no. SE556268760701

Product Information

Document ID:	PF013-01-TechInfo	**Edition:**	12
Manufacturer:	Atos Medical AB Kraftgatan 8, P.O. Box 183, SE-242 22 Hörby, Sweden		
Classification: (EU) 2017/745	Class I, Rule 1		
Intended Use:	To reinforce attachment of Provox Adhesive base plates to intact skin around the tracheostoma.		
CE Mark:	Yes, the devices are CE marked.		
GMDN code:	58978 (Synthetic-polymer liquid barrier dressing, nonsterile)		
Sterilization:	Non-sterile		
Raw material:	Silicone in solvent. MSDS: DOW CORNING™ MG-2401 Silicone Adhesive		
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.		
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:	2 years after manufacturing.		
Packaging:	The glue is bottled in a glass bottle. The bottle is packed in a cardboard box.		

Product Information

Devices under Basic UDI-DI: 7331791-GEN-A-000-0003-EF

REF	Name	UDI-DI
7720	Provox Silicone Glue	07331791002984
7720-18	Provox Silicone Glue	07331791014789

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox StabiliBase	7331791-ADH-0-000-0000-CQ
Provox XtraBase	7331791-ADH-0-000-0000-CQ
Provox Skin Barrier	7331791-ADH-A-000-0004-UL
Provox Adhesive Remover	7331791-ADH-A-000-0005-UP
Provox Cleaning Towel	7331791-ADH-A-000-0003-UH
Provox StabiliBase OptiDerm	7331791-ADH-0-000-0000-CQ
Provox Adhesive Strip	7331791-ADH-A-000-0002-UE
Provox Life Standard	7331791-ADH-0-000-0001-CT
Provox Life Sensitive	7331791-ADH-0-000-0001-CT
Provox Life Stability	7331791-ADH-0-000-0001-CT
Provox Flexiderm	7331791-ADH-0-000-0000-CQ
Provox Optiderm	7331791-ADH-0-000-0000-CQ

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Carolina Johansson - SEHRBJNC	2023-03-29 - 09:50
Reviewed:	QA	Abdallah Almashharawi - ABDALM	2023-03-29 - 09:59
Approved:	QA	Elin Andersson - ELIAND	2023-04-04 - 08:30
Released:	QA	Carolina Johansson - SEHRBJNC	2023-04-17 - 12:56

This document has been electronically signed by the persons above.

Atos
atosmedical.com

Product Information

Provox® BasePlate Adaptor

Product description:

The Provox BasePlate Adaptor ("adaptor") is an accessory product for rehabilitation after total laryngectomy. It allows attaching medical devices, (HME), with ISO 15mm standard connector to a tracheostoma by fitting it into a Provox Adhesive base plate, Provox LaryButton or Provox LaryTube. A typical example would be to attach an HME with built-in oxygen adapter (TrachPhone).

Provox BasePlate Adaptor facilitates the use of TrachPhone together with Provox Adhesives or Provox LaryTube.

Document No: 10000037228 Edition: 09 Release date: 2023-04-17

Atos Medical AB
Kraftgatan 8
SE-242 35 Hörby, Sweden
Tel: +46 (0) 415 198 00
Web Site: www.atosmedical.com
E-mail: info@atosmedical.com
Org.nr 556268-7607
VAT no. SE556268760701

Product Information

Document ID:	PF018-01-TechInfo	**Edition:**	09

Manufacturer:
Atos Medical AB
Kraftgatan 8
SE-242 35 Hörby,Sweden

Classification: (EU) 2017/745 Class I (Rule 1)

Intended Use: Provox BasePlate Adaptor is an accessory that allows attaching medical device, e.g. an HME, with an ISO 15 mm standard connector to a Provox attachment

Use specifications:

Intended medical indication:
Accessory product for patients after total laryngectomy

Intended patient population:
Male and female
Typical average age: N/A.
Cognitive ability, by a clinician judged as sufficient
Manual dexterity: Unconscious patients must be constantly monitored.
Not intended for patients with mechanical ventilation.

Intended usage:
Single patient use.

Intended part of the body/type of tissue applied to or interacted with:
Neck, (tracheostoma).

Intended user profile:
Patient, clinician, trained nurse.

Intended conditions of use:
Home use (normal daily environment without any hygienic or environmental restrictions regarding temperature, moisture etc.).
Hospital use.
Frequency of use: Continuous use.
Replacement rate: Shall be changed after used for a maximum of 3 months.

Contraindications: Shall not be used for mechanical ventilation

CE Mark: Yes. Device is CE-marked

GMDN code: 58705 (Tracheostoma protective filter)

Sterilization: Non-sterile

Raw material: Polyether ether ketone (PEEK)

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: 5 years after manufacturing.

Packaging: Provox BasePlate Adaptor is separately packed in a plastic bag of Low Density Polypropylene.
The products and instructions for use are packed in a cardboard box.

Devices under Basic UDI-DI: 7331791-HME-A-000-0003-F5

REF	Name	UDI-DI
7263	Provox BasePlate Adaptor	7331791001697

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox LaryTube	7331791-LTU-0-000-0002-3E
Provox LaryButton	7331791-LTU-0-000-0000-38
Provox StabiliBase Provox XtraBase Provox StabiliBase OptiDerm Provox Flexiderm Provox Optiderm	7331791-ADH-0-000-0000-CQ
TrachPhone	7331791-HME-0-000-0006-XT
Freevent DualCare	7331791-HME-0-000-0005-XQ
Freevent XtraCare	7331791-HME-0-000-0004-XM

Document No: 10000037228 Edition: 09 Release date: 2023-04-17

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Adel Khwatmi - ADEKHW	2022-11-24 - 11:26
Reviewed:	QA	Abdallah Almashharawi - ABDALM	2022-11-24 - 11:27
Approved:	QA	Elin Andersson - ELIAND	2022-11-28 - 12:55
Released:	QA	Abdallah Almashharawi - ABDALM	2022-12-14 - 10:07

This document has been electronically signed by the persons above.

Atos
atosmedical.com

Product Information

Provox® ShowerAid

Product description:

The Provox ShowerAid is used to temporarily replace the HME during showering. The ShowerAid can be placed in all Provox appliance holders.

Document No: 10000031509 Edition: 14 Release date: 2022-12-14

Atos Medical AB
Kraftgatan 8
SE-242 35 Hörby, Sweden
Tel: +46 (0) 415 198 00
Web Site: www.atosmedical.com
E-mail: info@atosmedical.com
Org.nr 556268-7607
VAT no. SE556268760701

Document Number: XV-0542485 Status: Effective Version: 1.0
Name: PF020-01-TECHINFO Provox ShowerAid

Product Information

Document ID:	PF020-01-TechInfo	**Edition:**	14

Manufacturer:
Atos Medical AB
Kraftgatan 8
SE-242 35 Hörby,Sweden

Classification: (EU) 2017/745
Class I, Rule 1

Intended Use:
The Provox ShowerAid is used to temporarily replace the HME during showering. The ShowerAid can be placed in all Provox appliance holders.

Use specifications:

Intended medical indication:
Laryngectomized patients breathing through a tracheostoma.

Intended patient population:
Male and female.
Typical average age for a laryngectomy is 65 years.
Cognitive ability, by a clinician judged as sufficient.
Manual dexterity, by a clinician judged as sufficient.

Intended usage:
Single patient use.

Intended part of the body/type of tissue applied to or interacted with:
Skin.

Intended user profile:
Patient.

Intended conditions of use:
Home use (normal daily environment without any hygienic or environmental restrictions regarding temperature, moisture etc.).

Contraindications:
There are no contraindications for Provox ShowerAid.

CE Mark:
Yes. Devices are CE-marked.

GMDN code:
62047 (Tracheostoma shower shield)

Sterilization:
Non-sterile

Raw material:
Polypropylene (PP) with blue masterbatch.

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.

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

Product Information

Expiration date: 5 years after manufacturing.

Packaging: The Shower Aid is packed in a OPET/PE plastic bag that is packed together with instructions for use in a cardboard box also including one piece of Provox FlexiDerm Oval.

Devices under Basic UDI-DI: 7331791-ADH-A-000-0000-U8

REF	Name	UDI-DI
7260	Provox ShowerAid	7331791001680
7260-18	Provox ShowerAid	7331791014796

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox StabiliBase	7331791-ADH-0-000-0000-CQ
Provox XtraBase	7331791-ADH-0-000-0000-CQ
Provox StabiliBase OptiDerm	7331791-ADH-0-000-0000-CQ
Provox Flexiderm	7331791-ADH-0-000-0000-CQ
Provox Optiderm	7331791-ADH-0-000-0000-CQ
Provox LaryTube	7331791-LTU-0-000-0002-3E
Provox LaryButton	7331791-LTU-0-000-0000-38

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Carolina Johansson - SEHRBJNC	2023-06-26 - 08:07
Reviewed:	QA	Niki Svensson - NIKSVE	2023-06-26 - 08:48
Approved:	DD	Elin Andersson - ELIAND	2023-06-26 - 13:22

This document has been electronically signed by the persons above.

Atos
atosmedical.com

Product Information

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.

Atos Medical AB
Kraftgatan 8
SE-242 35 Hörby, Sweden
Tel: +46 (0) 415 198 00
Web Site: www.atosmedical.com
E-mail: info@atosmedical.com
Org.nr 556268-7607
VAT no. SE556268760701

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:

Intended medical indication
Product for rehabilitation for patients breathing through a tracheostoma.
Intended patient population
Intended for laryngectomized patients of any age breathing through a tracheostoma.
Intended usage
Single use.
Intended part of the body/type of tissue applied to or interacted with
The device is attached to the skin around the tracheostoma.
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.
Intended conditions of use
Environment: Primarily home use (normal daily environment without any hygienic or environmental restrictions regarding temperature, moisture etc.). Secondarily 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).

Contraindications:
None

CE Mark:
Yes. Devices are CE-marked.

GMDN code:
62175 (Stomal appliance skin-adherent patch)

Sterilization:
Non-sterile

Raw material:
FlexiDerm: Ethylene-butyl acrylate (EBA), Polyethylene (PE), Acrylic adhesive.
XtraBase: Ethylene-butyl acrylate (EBA), Polyethylene (PE), Acrylic adhesive.
OptiDerm: Ethylene-butyl acrylate (EBA), Hydrocolloid, Polyethylene (PE), Acrylic adhesive.

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.

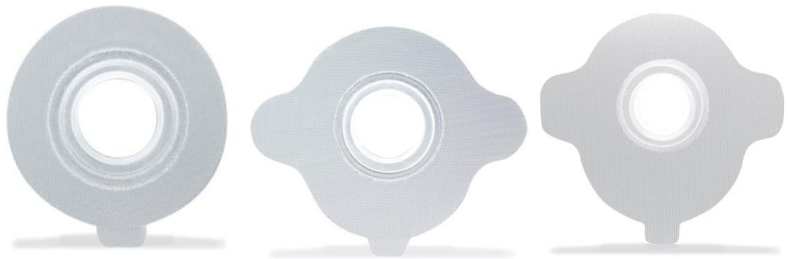
Devices under Basic UDI-DI: 7331791-ADH-0-000-0000-CQ

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

Atos
atosmedical.com

Product Information

Provox Adhesive FlexiDerm Round/oval/Plus



Provox Adhesive OptiDerm Round/Oval/Plus

Provox XtraBase Adhesive

Atos
atosmedical.com

Product Information

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

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Sara Dahl - X-SARDAH	2021-12-06 - 11:41
Reviewed:	QA	John Wennborg - JOHWEN	2021-12-07 - 10:01
Approved:	DD	Diana Tieger - DIATIE	2021-12-07 - 10:36
Released:	QA	Sara Dahl - X-SARDAH	2021-12-10 - 09:52

This document has been electronically signed by the persons above.

Atos
atosmedical.com

Product Information

Provox® HME Cassette Adaptor

Product description:

The Provox HME Cassette Adaptor is intended to facilitate a connection between Provox HME Cassette and on the market available tracheal cannulas with ISO-cone (15mm).

For laryngectomies who need a cannula initially or for a longer period of time. Enables immediate start of pulmonary rehabilitation with HME.

Document No: 10000038341 Edition: 10 Release date: 2021-12-10

Atos Medical AB
Kraftgatan 8
SE-242 35 Hörby, Sweden
Tel: +46 (0) 415 198 00
Web Site: www.atosmedical.com
E-mail: info@atosmedical.com
Org.nr 556268-7607
VAT no. SE556268760701

Document Number: VV-0543435 Status: Effective Version: 1.0
Name: PF038-01-TECHINFO HME Cassette Adaptor

Atos
atosmedical.com

Product Information

Document ID:	PF038-01-TechInfo	**Edition:**	10

Manufacturer:
Atos Medical AB
Kraftgatan 8
SE-242 35 Hörby, Sweden

Classification: (EU) 2017/745 Class I (1.1 Rule 1)

Intended Use: The Provox HME Cassette Adaptor is intended to facilitate a connection between Provox HME Cassettes and on the market available tracheal cannulas with ISO-cone (15mm).

Use specifications:

Intended medical indication:
For patients breathing through a tracheostoma who use a device with a 15 mm connector. To enable the use of a different diameter HME for pulmonary rehabilitation.

Intended patient population:
Male and female patients breathing through a tracheostoma.
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.

Intended usage:
Used together with an HME. Intended for attachment on cannulas with 15 mm ISO connection. Continuous use.
Intended part of the body/type of tissue applied to or interacted with:
Indirect contact with tissue/bone/dentin via inhaled air.

Intended user profile:
Patient (continuous use and replacement), clinician, trained nurse (primary fitting).

Intended conditions of use:
Home use (normal daily environment without any hygienic or environmental restrictions regarding temperature, moisture etc.). Hospital use.
Frequency of use: Continuous use.
Replacement rate: Replaced after maximum usage for 6 months or sooner if damaged.

Contraindications: N/A

CE Mark: Yes. Device is CE-marked.

GMDN code: 63623 (Tracheostomy tube adaptor)

Sterilization: Non-sterile

Raw material: Silicone

Latex information: Not manufactured with natural rubber latex

Product Information

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.

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: 5 years after manufacturing.

Packaging: 1 Cassette Adaptor in a plastic bag.
1 IFU

Devices under Basic UDI-DI: 7331791-HME-A-000-0003-F5

REF	Name	UDI-DI
7246	Provox HME Cassette Adaptor	7331791001543

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox Xtra HME	7331791-HME-0-000-0000-X9
Provox Micron HME	7331791-HME-0-000-0002-XF
Provox FreeHands HME	7331791-HME-0-000-0003-XJ
Provox ShowerAid	7331791-ADH-A-000-0000-U8

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Carolina Johansson - SEHRBJNC	2022-07-01 - 08:49
Reviewed:	QA	Karolina Nilsson - KARNIL	2022-07-01 - 09:27
Approved:	DD	Diana Tieger - DIATIE	2022-07-04 - 12:49

This document has been electronically signed by the persons above.

Atos
atosmedical.com

Product Information

Provox® StabiliBase

Product description:

Provox StabiliBase is designed to ensure an airtight attachment for the Provox HME system components. The Provox StabiliBase consists of an adhesive tape with a peel-off liner and a plastic adapter where components of the HME system can be connected. The firm base with vertical stabilizing bars provides support to the tracheostoma during speech.
The design of the StabiliBase adapter can be especially suitable for deep tracheostomas. The peel-off liner is divided into three sections to facilitate application to the skin

Atos Medical AB
Kraftgatan 8
SE-242 35 Hörby, Sweden
Tel: +46 (0) 415 198 00
Web Site: www.atosmedical.com
E-mail: info@atosmedical.com
Org.nr 556268-7607
VAT no. SE556268760701

Atos
atosmedical.com

Product Information

Document ID:	PF066-01-TechInfo	**Edition:**	07

Manufacturer:
Atos Medical AB
Kraftgatan 8
SE-242 35 Hörby,Sweden

Classification: (EU) 2017/745 Class I, Rule 1

Intended Use: [The Provox StabiliBase adhesive is a single use device intended for laryngectomized patients breathing through a tracheostoma. The device is attached to the skin around the tracheostoma in order to provide attachment of components of the Provox HME System.

Use specifications:

Intended medical indication:
Product for rehabilitation for patients breathing through a tracheostoma.

Intended patient population:
Patients of any age.
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 is attached to the skin around the tracheostoma.

Intended user profile:
The product is supposed to be handled by the patient but is also handled by physicians, trained nurses, SLPs, clinicians and caregivers.

Intended conditions of use:
Environment: Primarily home use (normal daily environment without any hygienic or environmental restrictions regarding temperature, moisture etc.).
Secondarily 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). Replacement is performed by the patient, clinician or caregiver.

Contraindications: None

CE Mark: Yes. Devices are CE-marked.

GMDN code: 62175 (Stomal appliance skin-adherent patch)

Sterilization: Non sterile

Raw material: Polyethylene (PE), Ethylene-buthylacrylate (EBA), Siliconized Polypropylene (PP), Acrylic adhesive

Latex information: Not manufactured with natural rubber latex

Product Information

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.

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:

7289,7289-18:
15 adhesives are separately packed in a plastic bag of Ecobar. The products and instructions for use are packed in a cardboard box.

7299:
3 adhesives are separately packed in a plastic bag of Ecobar. 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
7289	Provox StabiliBase (15 pcs)	07331791008016
7289-18	Provox StabiliBase(15pcs)	07331791014680
7299	Provox StabiliBase (3 pcs)	07331791008023

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

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Elin Andersson - ELIAND	2021-09-30 - 08:30
Reviewed:	QA	Elin Algotson - ELIALG	2021-09-30 - 08:53
Approved:	DD	Diana Tieger - DIATIE	2021-09-30 - 20:50
Released:	QA	Elin Andersson - ELIAND	2021-11-09 - 10:09

This document has been electronically signed by the persons above.

Atos
atosmedical.com

Product Information

Provox® StabiliBase™ OptiDerm™

Product description:

The Provox StabiliBase OptiDerm is a peristomal adhesive that is designed to ensure an airtight attachment for the Provox HME system components. It consists of an adhesive part, a three part peel-off liner and an adapter where components of the HME system can be connected.

Document No: 10000043060 Edition: 06 Release date: 2021-11-09

Atos Medical AB | SE-242 35 Hörby, Sweden | Web Site: www.atosmedical.com | Org.nr 556268-7607
Kraftgatan 8 | Tel: +46 (0) 415 198 00 | E-mail: info@atosmedical.com | VAT no. SE556268760701

Atos
atosmedical.com

Product Information

Document ID:	*PF071-01-TechInfo*	**Edition:**	*06*

Manufacturer: *Atos Medical AB*
Kraftgatan 8
SE-242 35 Hörby, Sweden

Classification: (EU) 2017/745 *Class I, Rule 1*

Intended Use: *Provox StabiliBase OptiDerm adhesive is a single use device intended for laryngectomized patients breathing through a tracheostoma. The device is attached to the skin around the tracheostoma in order to provide attachment of components of the Provox HME System.*

Use specifications:

Intended medical indication
Product for rehabilitation for patients breathing through a tracheostoma.

Intended patient population
Intended for laryngectomized patients of any age breathing through a tracheostoma.

Intended usage
The device is attached to the skin around the tracheostoma in order to provide connections for components of the Provox HME system.

Intended part of the body/type of tissue applied to or interacted with:
The device is attached to the skin around the tracheostoma.

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.

Intended conditions of use
Environment: Primarily home use (normal daily environment without any hygienic or environmental restrictions regarding temperature, moisture etc.). Secondarily outpatient clinic use.
Not intended for use during radiotherapy.
Frequency of use: Continuous use.
Replacement rate: Daily usage with replacement as needed.

Contraindications: *None*

CE Mark: *Yes, the devices are CE marked.*

GMDN code: *62175 (Stomal appliance skin-adherent patch)*

Sterilization: *Non-Sterile*

Raw material: *Adhesive: Hydrocolloid, Polyethylene (PE)*
Liner: Polypropylene (PP), siliconized
Adapter: Ethylene-Butylacrylate (EBA)

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.*

Atos
atosmedical.com

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:	*The adhesives are separately packed in a plastic bag and with 15 or 3 adhesives in each box. Each box contains Instructions For Use (IFU).*

Product Information

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

REF	Name	UDI-DI
7318	*Provox StabiliBase OptiDerm (15pc)*	*07331791009037*
7328	*Provox StabiliBase OptiDerm (3pcs)*	*07331791009044*

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox Xtra HME	*7331791-HME-0-000-0000-X9*
Provox Silicone Glue	*7331791-GEN-A-000-0003-EF*
Provox Micron HME	*7331791-HME-0-000-0002-XF*
Provox FreeHands HME	*7331791-HME-0-000-0003-XJ*
Provox LaryTube	*7331791-LTU-0-000-0004-3L*
Provox Adhesive Remover	*7331791-ADH-A-000-0005-UP*
Provox Skin Barrier	*7331791-ADH-A-000-0004-UL*
Provox Cleaning Towel	*7331791-ADH-A-000-0003-UH*
Provox Shower Aid	*7331791-ADH-A-000-0000-U8*
Provox Adhesive Strip	*7331791-ADH-A-000-0002-UE*
Provox BasePlate Adaptor	*7331791-HME-A-000-0003-F5*

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Peter Sundsten - X-PETSUN	2020-04-21 - 10:11
Reviewed:	DD	Jon Berg - JONBER	2020-04-21 - 10:53
Approved:	DD	Fredrik Calais - FRECAL	2020-04-21 - 16:10
Released:	QA	Peter Sundsten - X-PETSUN	2020-06-16 - 09:58

This document has been electronically signed by the persons above.

Product Information

Provox® Skin Barrier

Product description:

Provox Skin Barrier contains a sting free solvent that is wiped on skin providing a barrier between Provox adhesive and the skin.

Document No: 10000038383 Edition: 04 Release date: 2020-06-16

Atos Medical AB
Kraftgatan 8, P.O Box 183
SE-242 22 Hörby, Sweden
Tel: +46 (0) 415 198 00
Web Site: www.atosmedical.com
E-mail: info@atosmedical.com
Org.nr 556268-7607
VAT no. SE556268760701

Product Information

Document ID:	PF076-01-TechInfo	**Edition:**	04

Manufacturer: Atos Medical AB
Kraftgatan 8, P.O. Box 183,
SE-242 22 Hörby, Sweden

Classification: (EU) 2017/745 Class I, Rule 1

Intended Use: Provox Skin Barrier is a single use wipe for laryngectomized patients that forms a barrier between Provox Adhesive and the skin.

CE Mark: Yes, the devices are CE marked.

GMDN code: 58978 (Synthetic-polymer liquid barrier dressing, non-sterile)

Sterilization: Non-sterile

Raw material: Cloth: Polyester and Viscous fabric
Solution: Hexamethyldisiloxane, Isopropyl-myristate and Trimethylsiloxysilicate.

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.

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: Please read the instruction for use or consult the Material Safety Data Sheet (MSDS) before handling for safe use, physical and health hazard information. The MSDS is not included with the product packaging, but can be obtained by contacting Atos Medical AB.

Expiration date: 3 years after manufacturing.

Packaging: 1 wipe in a bag and 50 bags in one box.

Product Information

Devices under Basic UDI-DI: 7331791-ADH-A-000-0001-UB

REF	Name	UDI-DI
8011	Provox Skin Barrier (50 pcs)	07331791009228
8011-18	Provox Skin Barrier	07331791014765

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox StabiliBase	7331791-ADH-0-000-0000-CQ
Provox Adhesive Flexiderm	7331791-ADH-0-000-0000-CQ
Provox Adhesive Optiderm	7331791-ADH-0-000-0000-CQ
Provox XtraBase Adhesive	7331791-ADH-0-000-0000-CQ
Provox Adhesive Remover	7331791-ADH-A-000-0001-UB
Provox Cleaning Towel	7331791-ADH-A-000-0001-UB
Provox Silicone Glue	7331791-GEN-A-000-0003-EF
Provox Life Standard Adhesives	7331791-ADH-0-000-0001-CT
Provox Life Sensitive Adhesives	7331791-ADH-0-000-0001-CT
Provox Life Stability Adhesive	7331791-ADH-0-000-0001-CT

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Peter Sundsten - X-PETSUN	2020-04-21 - 10:16
Reviewed:	DD	Jon Berg - JONBER	2020-04-21 - 10:53
Approved:	DD	Fredrik Calais - FRECAL	2020-04-21 - 16:10
Released:	QA	Peter Sundsten - X-PETSUN	2020-06-16 - 09:57

This document has been electronically signed by the persons above.

Product Information

Provox® Adhesive Remover

Product description:

Provox Adhesive Remover contains a sting free solvent that helps laryngectomized patients remove Provox Adhesives and Provox Silicone Glue.

Document No: 10000038382 Edition: 04 Release date: 2020-06-16

Atos Medical AB
Kraftgatan 8, P.O Box 183
SE-242 22 Hörby, Sweden
Tel: +46 (0) 415 198 00
Web Site: www.atosmedical.com
E-mail: info@atosmedical.com
Org.nr 556268-7607
VAT no. SE556268760701

Document Number: VV-0543445 Status: Effective Version: 1.0
Name: PF076-02-TechInfo

Product Information

Document ID:	PF076-02-TechInfo	**Edition:**	04
Manufacturer:	Atos Medical AB Kraftgatan 8, P.O. Box 183, SE-242 22 Hörby, Sweden		
Classification: (EU) 2017/745	Class I, Rule1		
Intended Use:	Provox Adhesive Remover is a single use wipe to help laryngectomized patients remove Provox Adhesives and Provox Silicone Glue.		
CE Mark:	Yes, the devices are CE marked.		
GMDN code:	60494 (Medical adhesive remover, non-sterile)		
Sterilization:	Non-sterile		
Raw material:	Cloth: Polyester and Viscous fabric Solution: Hexamethyldisiloxane, Isopropyl-myristate.		
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.		
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:	Please read the instruction for use or consult the Material Safety Data Sheet (MSDS) before handling for safe use, physical and health hazard information. The MSDS is not included with the product packaging, but can be obtained by contacting Atos Medical AB.		
Expiration date:	3 years after manufacturing.		
Packaging:	1 wipe in a bag and 50 bags in one box.		

Product Information

Devices under Basic UDI-DI: 7331791-ADH-A-000-0001-UB

REF	Name	UDI-DI
8012	Provox Adhesive Remover (50 pcs)	07331791009235
8012-18	Provox Adhesive Remover	07331791014772

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox StabiliBase	7331791-ADH-0-000-0000-CQ
Provox Adhesive Flexiderm	7331791-ADH-0-000-0000-CQ
Provox Adhesive Optiderm	7331791-ADH-0-000-0000-CQ
Provox XtraBase Adhesive	7331791-ADH-0-000-0000-CQ
Provox Skin Barrier	7331791-ADH-A-000-0001-UB
Provox Cleaning Towel	7331791-ADH-A-000-0001-UB
Provox Silicone Glue	7331791-GEN-A-000-0003-EF
Provox Life Standard Adhesives	7331791-ADH-0-000-0001-CT
Provox Life Sensitive Adhesives	7331791-ADH-0-000-0001-CT
Provox Life Stability	7331791-ADH-0-000-0001-CT

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Carolina Johansson - SEHRBJNC	2021-12-06 - 09:59
Reviewed:	QA	Karolina Nilsson - KARNIL	2021-12-07 - 09:56
Approved:	DD	Diana Tieger - DIATIE	2021-12-07 - 10:35
Released:	QA	Carolina Johansson - SEHRBJNC	2021-12-27 - 14:37

This document has been electronically signed by the persons above.

Atos
atosmedical.com

Product Information

Provox Cleaning Towel

Product description:

Provox Cleaning Towel is alcohol-based and non-perfumed and is available in resealable poaches.

Atos Medical AB
Kraftgatan 8
SE-242 35 Hörby, Sweden
Tel: +46 (0) 415 198 00
Web Site: www.atosmedical.com
E-mail: info@atosmedical.com
Org.nr 556268-7607
VAT no. SE556268760701

Document Number: VV-0544061 Status: Effective Version: 1.0
Name: PF076-03-Techinfo

Product Information

Document ID:	PF076-03-TechInfo	**Edition:**	02

Manufacturer: Atos Medical AB
Kraftgatan 8
SE-242 35 Hörby,Sweden

Classification: (EU) 2017/745 Class I, Rule 1

Intended Use: Provox Cleaning Towel is intended for cleaning around the stoma, it will remove oil from the skin. They are indented to use before application of Provox Adhesives.

Use specifications: N/A

Contraindications: N/A

CE Mark: Yes. Devices are CE-marked.

GMDN code: 46205

Sterilization: Non-sterile

Raw material: Towel: Spunlaced viscose, Polyester
Solution: Chlorhexidine, Ethanol, BTC 2125, deionised water.

MSDS-7244-SE

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.

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: The product contains ethanol (concentrated ethanol is flammable) and chlorhexidine (concentrated chlorhexidine may cause eye damages if in contact with the eyes).

Expiration date: 2 years after manufacturing.

Packaging: 10 towels are packed together in a plastic bag made of polyester/polyethene and PT 12 (white)/PE 70. 20 plastic bags are packed together in every cardboard box

Product Information

Devices under Basic UDI-DI: 7331791-ADH-A-000-0003-UH

REF	Name	UDI-DI
7244*	Provox Cleaning Towel 10-p	07331791001536
7244**	Provox Cleaning Towel 10-p	07331791015762
7244-18	Provox Cleaning Towel	07331791014758

*Contains 20 bags with 10 towels
**Contains 1 bag with 10 towels

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox Luna Adhesive	7331791-ADH-0-000-0000-CQ
Provox StabiliBase	7331791-ADH-0-000-0000-CQ
Provox Adhesive Flexiderm	7331791-ADH-0-000-0000-CQ
Provox Adhesive Optiderm	7331791-ADH-0-000-0000-CQ
Provox XtraBase Adhesive	7331791-ADH-0-000-0000-CQ
Provox Skin Barrier	7331791-ADH-A-000-0004-UL
Provox Adhesive Remover	7331791-ADH-A-000-0005-UP
Provox Silicone Glue	7331791-GEN-A-000-0003-EF
Provox Life Standard Adhesives	7331791-ADH-0-000-0001-CT
Provox Life Sensitive Adhesives	7331791-ADH-0-000-0001-CT
Provox Life Stability Adhesive	7331791-ADH-0-000-0001-CT
Provox Life Night Adhesive	7331791-ADH-0-000-0001-CT

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Abdallah Almashharawi - ABDALM	2022-03-23 - 13:19
Reviewed:	QA	Karolina Nilsson - KARNIL	2022-03-24 - 07:48
Approved:	DD	Diana Tieger - DIATIE	2022-03-24 - 11:27
Released:	QA	Abdallah Almashharawi - ABDALM	2022-08-24 - 10:49

This document has been electronically signed by the persons above.

Atos
atosmedical.com

Product Information

Provox® Luna™ Adhesive

Product description:

Provox Luna Adhesive consists of an adhesive base, a peel-off liner and a soft connector for Provox Luna HME. Provox Luna Adhesive base is a skin-friendly hydrogel adhesive intended for night-time comfort and skin rest.

Atos Medical AB
Kraftgatan 8
SE-242 35 Hörby, Sweden
Tel: +46 (0) 415 198 00
Web Site: www.atosmedical.com
E-mail: info@atosmedical.com
Org.nr 556268-7607
VAT no. SE556268760701

Atos
atosmedical.com

Product Information

Document ID:	PF077-02-TechInfo	**Edition:**	06

Manufacturer:
Atos Medical AB
Kraftgatan 8
SE-242 35 Hörby,Sweden

Classification: (EU) 2017/745
Class I, Rule 1

Intended Use:
The Provox Luna Adhesive is a skin friendly, single use adhesive that provides attachment for the Provox Luna HME for night time use 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 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.

CE Mark:
Yes. Devices are CE-marked.

GMDN code:
62175 (Stomal appliance skin-adherent patch)

Sterilization:
None-sterile

Raw material:
Adapter: TPE
Carrier: Polyurethane film
Adhesive: Hydrogel, siliconized PET liner

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 - 30°C.

Atos
atosmedical.com

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:	Each adhesive is packed in an aluminum bag and then packed together with an IFU in a cardboard box.

Product Information

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

REF	Name	UDI-DI
8014	Provox Luna Adhesive	07331791009259
8014-18	Provox Luna Adhesive	07331791014741

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox Luna HME	7331791-HME-0-000-0000-X9
Provox Luna ShowerAid	7331791-ADH-A-000-0000-U8
Provox Adhesive Strip	7331791-ADH-A-000-0002-UE
Provox Cleaning Towel	7331791-ADH-A-000-0003-UH

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Carolina Johansson - SEHRBJNC	2022-04-13 - 14:03
Reviewed:	QA	Karolina Nilsson - KARNIL	2022-04-13 - 16:36
Approved:	DD	Diana Tieger - DIATIE	2022-04-14 - 07:59
Released:	QA	Carolina Johansson - SEHRBJNC	2022-05-19 - 15:04

This document has been electronically signed by the persons above.

Atos
atosmedical.com

Product Information

Provox® Luna ShowerAid

Product description:

The Provox Luna ShowerAid is used with the Provox Luna Adhesive while taking a shower to avoid water from entering the stoma.

Document No: 1000030387 Edition: 06 Release date: 2022-05-19

Atos Medical AB
Kraftgatan 8
SE-242 35 Hörby, Sweden
Tel: +46 (0) 415 198 00
Web Site: www.atosmedical.com
E-mail: info@atosmedical.com
Org.nr 556268-7607
VAT no. SE556268760701

Product Information

Document ID:	PF079-01-TechInfo	**Edition:**	06

Manufacturer:
Atos Medical AB
Kraftgatan 8
SE-242 35 Hörby,Sweden

Classification: (EU) 2017/745 Class I, Rule 1.

Intended Use: The Provox Luna ShowerAid is used with the Provox Luna Adhesive while taking a shower to avoid water from entering the stoma. Single patient use.

Use specifications:

Intended medical indication:
Laryngectomized patients breathing through a tracheostoma.
Intended patient population:
Male and female. Typical average age for a laryngectomy is 65 years.
Intended usage:
Single patient use.
Intended part of the body/type of tissue applied to or interacted with:
Indirect contact through inhaled air, brief skin contact when attaching the device.
Intended user profile:
Patient, clinician and other caregivers.
Intended conditions of use:
Normal daily environment without any hygienic or environmental restrictions regarding temperature, moisture etc.

Contraindications: None

CE Mark: Yes. Devices are CE-marked

GMDN code: 62047

Sterilization: Non-sterile

Raw material: Polypropylene (PP) with white masterbatch

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.

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 Luna ShowerAid, 1pc is packed in a plastic bag of polyethylene. The product and instructions for use are packed in a cardboard box.

Product Information

Devices under Basic UDI-DI: **7331791-ADH-A-000-0000-U8**

REF	Name	UDI-DI
8016	Provox Luna ShowerAid	07331791009532
8016-18	Provox Luna ShowerAid	07331791014802

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox Luna Adhesive	7331791-ADH-0-000-0000-CQ
Provox Luna Set	7331791-KIT-0-000-0002-HS

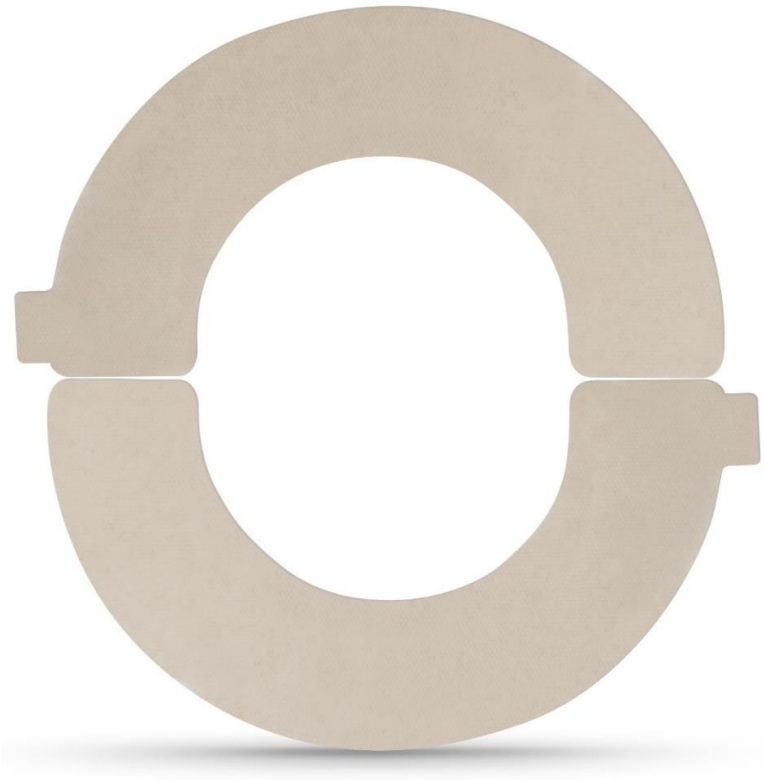
Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Abdallah Almashharawi - ABDALM	2022-03-24 - 14:58
Reviewed:	QA	Karolina Nilsson - KARNIL	2022-03-24 - 15:33
Approved:	DD	Diana Tieger - DIATIE	2022-03-28 - 14:54
Released:	QA	Abdallah Almashharawi - ABDALM	2022-08-24 - 10:49

This document has been electronically signed by the persons above.

Atos
atosmedical.com

Product Information

Provox® Adhesive Strip



Product description:

The Provox Adhesive Strip is developed to be used as a seal for the Provox adhesives, e.g. during showering or when leakage from the adhesive develops.

Document No: 10000030388 Edition: 05 Release date: 2022-08-24

Atos Medical AB
Kraftgatan 8
SE-242 35 Hörby, Sweden
Tel: +46 (0) 415 198 00
Web Site: www.atosmedical.com
E-mail: info@atosmedical.com
Org.nr 556268-7607
VAT no. SE556268760701

Document Number: XV-0542366 Status: Effective Version: 1.0
Name: PF080-01-Techinfo Provox Adhesive Strip

Atos
atosmedical.com

Product Information

Document ID:	PF080-01-TechInfo	**Edition:**	05

Manufacturer: Atos Medical AB
Kraftgatan 8
SE-242 35 Hörby,Sweden

Classification: (EU) 2017/745 Class I, Rule 1

Intended Use: Provox Adhesive Strip is a single use device to seal Provox adhesives, e.g. during showering.

Use specifications:

Intended medical indication: Laryngectomized patients.

Intended patient population: Gender: Male and female. Age: Typical average age for a laryngectomy is ~65 years.

Intended usage: Single use.

Intended part of the body/type of tissue applied to or interacted with: Intact skin.

Intended user profile: Patient, clinician or other caregiver.

Intended conditions of use: Normal daily environment without any hygienic or environmental restrictions regarding temperature, moisture etc.

Contraindications: There are no contraindications for the device.

CE Mark: Yes. Devices are CE-marked.

GMDN code: 62175 (Stomal appliance skin-adherent patch)

Sterilization: Non-sterile.

Raw material: Adhesive: Hydrocolloid, Polyethylene (PE)
Liner: Super calendered glassine paper with siliconized surface
Liner finger lift: Polyethylene (PE)

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.

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: 10 Provox Adhesive Strip in a plastic blister made of A-PET and PP will be packed in one paper box.

Product Information

Devices under Basic UDI-DI: 7331791-ADH-A-000-0002-UE

REF	Name	UDI-DI
8015	Provox Adhesive Strip	07331791009525
8015-18	Provox Adhesive Strip	07331791014819

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox StabiliBase	7331791-ADH-0-000-0000-CQ
Provox XtraBase	7331791-ADH-0-000-0000-CQ
Provox Skin Barrier	7331791-ADH-A-000-0004-UL
Provox Adhesive Remover	7331791-ADH-A-000-0005-UP
Provox Cleaning Towel	7331791-ADH-A-000-0003-UH
Provox StabiliBase OptiDerm	7331791-ADH-0-000-0000-CQ
Provox Life Standard	7331791-ADH-0-000-0001-CT
Provox Life Sensitive	7331791-ADH-0-000-0001-CT
Provox Life Stability	7331791-ADH-0-000-0001-CT
Provox Life Night Adhesive	7331791-ADH-0-000-0001-CT
Provox Luna Adhesive	7331791-ADH-0-000-0000-CQ
Provox Flexiderm	7331791-ADH-0-000-0000-CQ
Provox Optiderm	7331791-ADH-0-000-0000-CQ
Provox Silicone Glue	7331791-GEN-A-000-0003-EF