

Technical Info / Material Data Sheet

Document ID: PF064-01-TechInfo	Edition: 05
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REF Number	1502
Product Name	Stoma Oil
Models:	1 model
Classification: (MDD 93/42/EEC)	IIb (2.1 rule 5)
CE Mark:	Yes
GMDN code:	57897 (Tracheostomy tube lubricant)
Produced by:	Atos Medical AB Kraftgatan 8 P.O. Box 183 242 22 Hörby Sweden
Intended Use:	The stoma-oil is intended to be used to moisten the cannula to make the insertion into the stoma easier. It is also intended to lubricate the inner cannula of plastic tracheal cannulas before insertion into the outer cannula.
Description:	The Stoma Oil is make of 100% Coconut oil and comes in a 100 mL bottle.
Sterilization:	Non-sterile.
Raw material:	Caprylic/Capric Acid Triglyceride (MCT).
Latex information	Not manufactured with natural rubber latex.
Biological origin:	The device is not manufactured with any materials derived from human or animal source.
Handling and storage:	Keep dry and away from sunlight. Temperature limit 2-42°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:	Glass bottle, 100 ml, packed in low density polyethylene (LDPE) bubble bag. One Instructions for Use Stoma Oil is included.

Reviewed by:


 Vice President QA&RA

 2016-02-18

 Date

Approved by:


 Vice President Design & Development

 2016-02-22

 Date

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	DD	Pontus Eklund - X-PONEKL	2020-04-21 - 14:00
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Approved:	DD	Fredrik Calais - FRECAL	2020-04-21 - 16:16
Released:	DD	Jon Berg - JONBER	2020-05-28 - 15:07

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Released

Product Information

Freevent® TubeBrush

**Product description:**

The Freevent TubeBrush is used for cleaning of tracheostomy tubes ex situ.

The Freevent TubeBrush is packed 10 pieces in a plastic bag.

It is available in five different models with outer diameter - 6 mm, 8 mm, 10 mm, 12 mm or 14 mm.

Product Information

Document ID:	PF082-01-TechInfo	Edition:	02
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:	The Freevent TubeBrush is used for cleaning of tracheostomy tubes ex situ.		
CE Mark:	Yes, the devices are CE marked.		
GMDN code:	34883 (Airway device, cleaning brush, noninvasive).		
Sterilization:	Non-sterile.		
Raw material:	ABS, Stainless Steel, PBT and Cotton.		
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 brushes in each package except for Freevent TubeBrush set (1210) which includes 3 brushes (8, 10 and 12 mm) in each package.		

Devices under Basic UDI-DI: 7331791-GEN-A-000-0001-E9

REF	Name	UDI-DI
1205	Freevent TubeBrush Sz 6	7331791014833
1206	Freevent TubeBrush Sz 8	7331791014840
1207	Freevent TubeBrush Sz 10	7331791014857
1208	Freevent TubeBrush Sz 12	7331791014864
1209	Freevent TubeBrush Sz 14	7331791014871
1210	Freevent TubeBrush Set 1x8, 1x10, 1x12mm	7331791014888

Atos Medical AB Compatible products:

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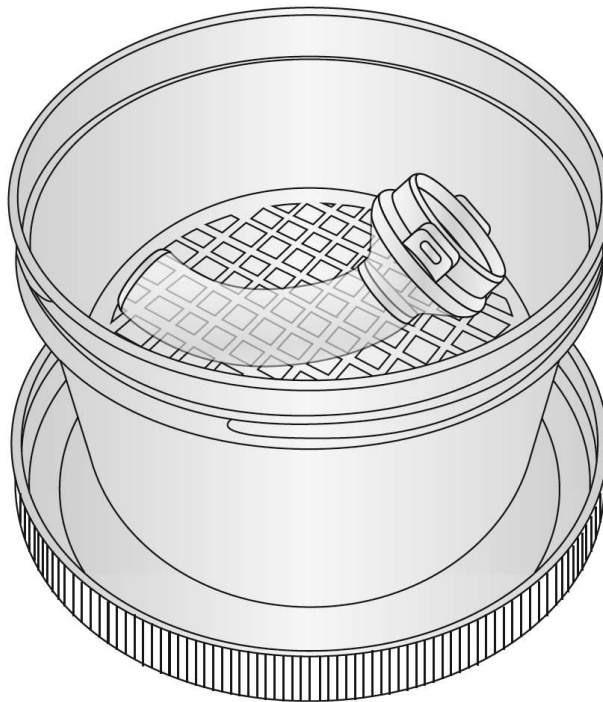
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Product Information

Freevent® Tracheal Tube Cleansing Jar



N.B. the tube is not included in the product

Product description:

The Freevent Tracheal Tube Cleansing Jar is intended for cleaning of all types of tracheal tubes with Freevent Tracheal Tube Detergent Powder

Product Information

Document ID:	PF084-02-TechInfo	Edition:	03
Manufacturer:	Atos Medical AB Kraftgatan 8, P.O. Box 183, SE-242 22 Hörby, Sweden		
Classification: (EU) 2017/745	Class I (1.1 rule 1)		
Intended Use:	The Freevent Tracheal Tube Cleansing Jar is intended for cleaning of all types of tracheal tubes with Freevent Tracheal Tube Detergent Powder		
CE Mark:	Yes, the devices are CE marked.		
GMDN code:	62628 (Artificial airway washing/disinfection jar)		
Sterilization:	Non-sterile		
Raw material:	Polypropylene		
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:	5 years after manufacturing.		
Packaging:	Single package		

Product Information

Devices under Basic UDI-DI: 7331791-TTU-A-000-0001-WK

REF	Name	UDI-DI
1602	Freeevent Tracheal Tube Cleansing Jar	07331791006111

Atos Medical AB Compatible products:

Range	BASIC UDI-DI
Freeevent Tracheal Tube Detergent Powder	7331791-TTU-A-000-0002-WN

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Document No: 10000031086 Edition: 03 Release date: 2020-05-28

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Product Information

Provox® Tracheofix



Product description:

The Provox Tracheofix is a single use foam protector intended to absorb secretions and to provide protection and aesthetic coverage of the tracheostoma.

A patient-worn device in the form of a self-adhesive patch designed to protect a tracheostoma orifice against harmful external influences and to absorb secretions; it may also act as a tracheal air filter. It is typically made of porous textile, foam or synthetic fabric materials; it is not intended to be used as a shower shield. This is a single-use device

3 models: 38*63 mm, 55*60 mm and 70*70 mm.

Product Information

Document ID: PF090-01-TechInfo **Edition:** 03

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

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

Intended Use: The Provox Tracheofix is a single use foam protector intended to absorb secretions and to provide protection and aesthetic coverage of the tracheostoma.

CE Mark: Yes, the devices are CE marked.

GMDN code: 63378 (Tracheostoma protector, single-use)

Sterilization: Non-sterile product

REF	Raw material
1427, 1428, 1435	Elastic polyurethane foam Polyethylene film with acrylate
1429H, 1430H, 1432H, 1433H, 1434H	Polyurethane foam Polyethylene film with acrylate

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: 5 years after manufacturing.

Packaging: 10 products in Mini-grip bag (PE, 120*170 mm, 50 µm) with packing slip.

Product Information

Devices under Basic UDI-DI: 7331791-COM-0-000-0003-58

REF	Name	UDI-DI
1427	Provox Tracheofix 1 strip ivory 55x60	07331791012440
1428	Provox Tracheofix 1 strip ivory 70x70	07331791012457
1435	Provox Tracheofix 2 strips ivory 70x70	07331791012464
1429H	Provox Tracheofix 1 strip beige 55x60	07331791006760
1430H	Provox Tracheofix 1 strip beige 70x70	07331791006777
1432H	Provox Tracheofix 2 strips beige 55x60	07331791006791
1433H	Provox Tracheofix 2 strips beige 70x70	07331791006807
1434H	Provox Tracheofix 1 strip beige 38x63	07331791005985



1 strip ivory



2 strips ivory



1 strip beige



2 strips beige

Atos Medical AB Compatible products:

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Product Information

Freevent® Clothing Stoma Cover

**Product description:**

The Freevent Clothing Cover is a reusable clothing cover that provides protection and coverage of the tracheostoma.

The Clothing cover works as a cosmetic cover for the tracheostoma.

Product Information

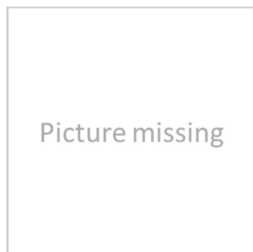
Document ID:	PF091-01-TechInfo	Edition:	02								
Manufacturer:	Atos Medical AB Kraftgatan 8, P.O. Box 183, SE-242 22 Hörby, Sweden										
Classification: (EU) 2017/745	Class I (1.1 rule 1)										
Intended Use:	The Freevent Clothing Cover is a reusable clothing cover that provides protection and coverage of the tracheostoma.										
CE Mark:	Yes, the devices are CE marked.										
GMDN code:	31065 (Tracheostoma protector, reusable)										
Sterilization:	Non-Sterile										
Raw material:	<table border="1"> <thead> <tr> <th>REF</th> <th>Raw material</th> </tr> </thead> <tbody> <tr> <td>1400, 14001, 140011, 1401, 14011, 14012, 1402, 14022, 14023, 1403, 14033, 14034</td> <td>Polyester, Cotton and Polyamide.</td> </tr> <tr> <td>1413RSR1, 1413RSR2, 1413RSR3, 1413RSR4, 1413RSR6, 1413RSR7, 1413RSR8, 1413RSR9, 1413RSR11, 1413RSR15, 1414RS1, 1414RS2, 1414RS3, 1414RS4, 1414RS5, 1414RS6</td> <td>Polyester, Cotton, Elastan and Polyamide.</td> </tr> <tr> <td>1410A15BP, 1410A21BP, 1410A3BP, 1410A4BP, 1410A5BP, 1410A7BP, 1410A15TG, 1410A1TG, 1410A3TG, 1410A4TG, 1410A5TG, 1410A9TG</td> <td>Polyester, Cotton, Polyamide and Polyurethane</td> </tr> </tbody> </table>			REF	Raw material	1400, 14001, 140011, 1401, 14011, 14012, 1402, 14022, 14023, 1403, 14033, 14034	Polyester, Cotton and Polyamide.	1413RSR1, 1413RSR2, 1413RSR3, 1413RSR4, 1413RSR6, 1413RSR7, 1413RSR8, 1413RSR9, 1413RSR11, 1413RSR15, 1414RS1, 1414RS2, 1414RS3, 1414RS4, 1414RS5, 1414RS6	Polyester, Cotton, Elastan and Polyamide.	1410A15BP, 1410A21BP, 1410A3BP, 1410A4BP, 1410A5BP, 1410A7BP, 1410A15TG, 1410A1TG, 1410A3TG, 1410A4TG, 1410A5TG, 1410A9TG	Polyester, Cotton, Polyamide and Polyurethane
REF	Raw material										
1400, 14001, 140011, 1401, 14011, 14012, 1402, 14022, 14023, 1403, 14033, 14034	Polyester, Cotton and Polyamide.										
1413RSR1, 1413RSR2, 1413RSR3, 1413RSR4, 1413RSR6, 1413RSR7, 1413RSR8, 1413RSR9, 1413RSR11, 1413RSR15, 1414RS1, 1414RS2, 1414RS3, 1414RS4, 1414RS5, 1414RS6	Polyester, Cotton, Elastan and Polyamide.										
1410A15BP, 1410A21BP, 1410A3BP, 1410A4BP, 1410A5BP, 1410A7BP, 1410A15TG, 1410A1TG, 1410A3TG, 1410A4TG, 1410A5TG, 1410A9TG	Polyester, Cotton, Polyamide and Polyurethane										
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:	5 years after manufacturing.										
Packaging:	Single-pack in Mini-grip bag (120x170 or 160x220) with packing slip.										

Product Information

Devices under Basic UDI-DI: 7331791-TEX-0-000-0000-WK

REF	Name	UDI-DI
1400	Clothing cover White 3ply Velcro closure	07331791006142
1401	Clothing cover White 4ply Velcro closure	07331791006173
1402	Clothing cover White 8ply Velcro closure	07331791012624
1403	Clothing cover White 12ply Velcro closure	07331791006258
14001	Clothing cover Beige 3ply Velcro closure	07331791006159
14011	Clothing cover Blue 4ply Velcro closure	07331791006180
14012	Clothing cover Beige 4ply Velcro closure	07331791006197
14022	Clothing cover Beige 8ply Velcro closure	07331791006227
14023	Clothing cover Blue 8ply Velcro closure	07331791006234
14033	Clothing cover Beige 12ply Velcro closure	07331791006265
14034	Clothing cover Blue 12ply Velcro closure	07331791006272
140011	Clothing cover blue 3ply Velcro closure	07331791012617
1410A1TG	Clothing scarf, blue with white dots TG	07331791007071
1410A3BP	Clothing scarf, white cotton/polyester	07331791007101
1410A3TG	Clothing scarf, white trevira-georgette	07331791007095
1410A4BP	Clothing scarf, black cotton/polyester	07331791007125
1410A4TG	Clothing scarf, black trevira-georgette	07331791007118
1410A5BP	Clothing scarf, vine red cotton/polyester	07331791007149
1410A5TG	Clothing scarf, vine red trevira-george	07331791007132
1410A7BP	Clothing scarf, beige cotton/polyester	07331791007170
1410A9TG	Clothing scarf speckled black'n white TG	07331791007194
1410A15BP	Clothing scarf, dark blue cotton/polyester	07331791007231
1410A15TG	Clothing scarf, dark blue trevira-george	07331791007224
1410A21BP	Clothing scarf, grey cotton/polyester	07331791007262
1413RSR1	Clothing round neck T-shirt w zip lock white	07331791006449
1413RSR2	Clothing round neck T-shirt w zip lock beige	07331791006470
1413RSR3	Clothing round neck T-shirt w zip lock yellow	07331791012686
1413RSR4	Clothing round neck T-shirt w zip lock light blue	07331791006487
1413RSR6	Clothing round neck T-shirt w zip lock red	07331791006494
1413RSR7	Clothing round neck T-shirt w zip lock d.green	07331791012693
1413RSR8	Clothing round neck T-shirt w zip lock blue	07331791006500
1413RSR9	Clothing round neck T-shirt w zip lock black	07331791006517
1413RSR11	Clothing round neck T-shirt w zip grey	07331791006456
1413RSR15	Clothing round neck T-shirt w zip lock d.brown	07331791012679
1414RS1	Clothing round neck T-shirt form white	07331791006524
1414RS2	Clothing round neck T-shirt form beige	07331791012709
1414RS3	Clothing round neck T-shirt form light blue	07331791006531
1414RS4	Clothing round neck T-shirt form green	07331791012716
1414RS5	Clothing round neck T-shirt form blue	07331791006548
1414RS6	Clothing round neck T-shirt form black	07331791006555

Product Information



Clothing cover - Velcro closure



Clothing scarf



Clothing round neck T-shirt w zip lock



Clothing round neck T-shirt form

Atos Medical AB Compatible products:

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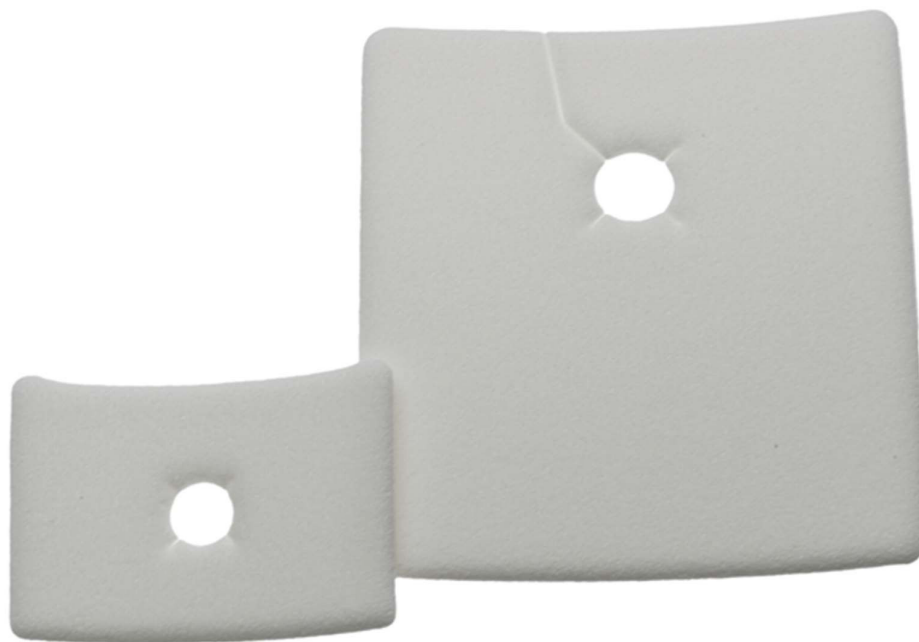
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Issued:	DD	Pontus Eklund - X-PONEKL	2020-04-23 - 10:26
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Released:	DD	Pontus Eklund - X-PONEKL	2020-11-23 - 09:01

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Released

Product Information

Freevent® Pads



Product description:

The Freevent Pads are single use tracheostomy pads that provide protection between the tracheal cannula and the skin and absorb secretions.

REF: 142700-D,142700-PED,142800: The Freevent Dressing Pads provides protection between the tracheostoma and the tracheostomy tube. The PU-foam material absorbs secretions from the tracheostoma. The Freevent Pad is intended to be used as a cushion between canula and skin and also for patients with strong secretion.

REF: 1431

The Freevent Dressing Foam 70x70 is a foam dressing that provides a protection between the tracheostomy tube and the skin. It is intended for patients with small secretion.

Product Information

Document ID:	PF093-01-TechInfo	Edition:	01
Manufacturer:	Atos Medical AB Kraftgatan 8, P.O. Box 183, SE-242 22 Hörby, Sweden		
Classification: (EU) 2017/745	Class I (1.1 rule 1)		
Intended Use:	The Freevent Pads are single use tracheostomy pads that provide protection between the tracheal cannula and the skin and absorb secretions.		
CE Mark:	Yes, the devices are CE marked.		
GMDN code:	63324 (Tracheostomy tube dressing, non-sterile)		
Sterilization:	Non-sterile		
Raw material:	REF 142700-D,142700-PED,142800: Polyether Polyurethane foam REF 1431: Polyurethane foam		
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:	5 years after manufacturing.		

REF	Packaging
142700-D, 142700-PED	15 products single packed (PE, 120*120 mm, 50 µm) in paper box. Instructions for use attached
142800	30 products single packed (PE, 70*10 mm, 50 µm) in paper box. Instructions for use attached
1431	10 products in Mini-grip bag (PE, 120*170 mm, 50 µm) with packing slip. Instructions for use attached.

Product Information

Devices under Basic UDI-DI: 7331791-COM-0-000-0001-52

REF	Name	UDI-DI
142700-D	Freeevent Dressing Pad slit 90x100	07331791012587
142700-PED	Freeevent Dressing Pad slit 65x70 PED	07331791012594
142800	Freeevent Dressing Pad 65x45	07331791012570
1431	Freeevent Dressing Foam 70x70	07331791006784



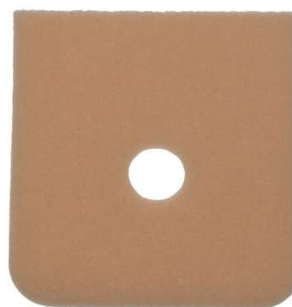
Freeevent Dressing Pad slit 90x100



Freeevent Dressing Pad slit 65x70 PED



Freeevent Dressing Pad 65x45



Freeevent Dressing Foam 70x70

Atos Medical AB Compatible products:

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Document No: 10000034907 Edition: 02 Release date: 2020-11-23

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Released:	DD	Jon Berg - JONBER	2020-05-28 - 15:08

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Product Information

Freevent® Neckband

**Product description:**

The Freevent Neckbands are tube/button holders for patients breathing through a tracheostoma. Two-piece variants connect with hook-and-loop whereas one-piece variants connect with twill ties.

Adult and Child sizes

Product Information

Document ID:	PF094-01-TechInfo	Edition:	04
Manufacturer:	Atos Medical AB Kraftgatan 8, P.O. Box 183, SE-242 22 Hörby, Sweden		
Classification: (EU) 2017/745	Class I (1.1 rule 1)		
Intended Use:	The Freevent Neckbands are used for holding a tube/button in place by wearing it around the neck and connecting the ends of the neckband to the tube/button.		
CE Mark:	Yes, the devices are CE marked.		
GMDN code:	63438 (Tracheostomy tube neck holder, single use)		
Sterilization:	Non-sterile		
Raw material:	Nylon, cotton and polyester polyurethane foam.		
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:	5 years after manufacturing.		
Packaging:	REF 1651, 1661, 1652 and 1662: 10 pcs in a box, each neckband individually packed in a polybag (polyethylene) REF 1751, 1761, 1752 and 1762: 100 pcs in a box, each neckband individually packed in a polybag (polyethylene)		

Product Information

Devices under Basic UDI-DI: 7331791-GEN-A-000-0000-E6

REF	Name	UDI-DI
1651	Freeevent Neckband, one-piece , small	07331791012914
1652	Freeevent Neckband, two-piece, small	07331791012921
1661	Freeevent Neckband, one-piece, large	07331791012938
1662	Freeevent Neckband, two-piece, large	07331791012945
1751	Freeevent Neckband, one-piece, small	07331791013607
1752	Freeevent Neckband, two-piece, small	07331791013621
1761	Freeevent Neckband, one-piece, large	07331791013614
1762	Freeevent Neckband, two-piece, large	07331791013638



Freeevent Neckband, one-piece



Freeevent Neckband, two-piece

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 LaryButton Sizer Kit	7331791-LTU-0-000-0001-3B

Product Information

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Approved:	DD	Fredrik Calais - FRECAL	2021-10-19 - 10:20
Released:	QA	Alexandra Holmberg - ALEHOL	2021-11-01 - 11:14

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Product description:

The Freeevent Dressings are single use tracheal dressings that provide protection between the tracheal cannula and the skin and absorb secretions.

REF	Models
1425, 14251, 14251-PED, 1425932, 1425933, 18008-001	The Tracheostomy dressing, AL coated provides protection between the tracheostoma and the tracheostomy tube. The fleece material absorbs secretions from the tracheostoma. The aluminum metallized side prevents sticking to the skin.
142510, 142512, 142512-PED, 142514, 142516	The Tracheostomy dressing double provides protection between the tracheostoma and the tracheostomy tube. The fleece material absorbs secretions from the tracheostoma. The Tracheostomy dressing double is intended for patients with strong secretion.

Product Information

14255, 14255H, 14253, 14253H, 14253H-PED, 14253-PED, 14257, 14259, 14259H	The Tracheostomy dressing combi provides protection between the tracheostoma and the tracheostomy tube. The fleece material absorbs secretions from the tracheostoma. The front side is covered by a washable polyurethane film that prevents soaking of the underlying fleece layers.
142511, 142513, 142515	The Tracheostomy dressing double, AL coated provides protection between the tracheostoma and the tracheostomy tube. The fleece material absorbs secretions from the tracheostoma. The aluminum metallized side prevents sticking to the skin. The Tracheostomy dressing double, AL coated is intended for patients with strong secretion.
14250, 14250-PED, 1425921, 1425923	The Tracheostoma dressing provides protection between the tracheostoma and the tracheostoma tube and prevents adhesion to skin. The fleece material absorbs secretions from the tracheostoma.
14254, 14256, 14258, 14256H	The Tracheostomy dressing combi, AL coated provides protection between the tracheostoma and the tracheostomy tube. The fleece material absorbs secretions from the tracheostoma. The aluminum metallized side prevents sticking to the skin. The front side is covered by a washable polyurethane film that prevents soaking the underlying fleece layers.

Document ID: PFPF095-01-TechInfo **Edition:** 05

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

Classification: (EU) 2017/745 Class I (1.4 rule 4)

Intended Use: The Freevent Dressings are single use tracheal dressings that provide protection between the tracheal cannula and the skin and absorb secretions.

Product Information

Use specifications:

- Intended medical indication: Patients using a tracheostomy tube.
- Intended patient population: Adult and pediatric patients using a tracheostomy tube. Intended to be used by medical personnel or patients with sufficient cognitive ability and manual dexterity who are judged as able to manage the device independently by a clinician.
- Intended usage: Single use.
- Intended part of the body/type of tissue applied to or interacted with: Skin around tracheostoma.
- Intended user profile: Medical personnel or patients with sufficient cognitive ability and manual dexterity who are judged as able to manage the device independently by a clinician.
- Intended conditions of use: Freevent Dressings are for single use and for daily continuous use. Intended for use at home (indoor and outdoor), care facilities and hospitals, during rest, sleep and exercising under normal daily environment without any hygienic or environmental restrictions regarding temperature, moisture etc.
- Frequency of use: Continuous use, can be used during night.

Contraindications: None

CE Mark: Yes, the devices are CE marked.

GMDN code: 15624 (Tracheostomy tube dressing)

Sterilization: Non-sterile

Raw material:

REF	Raw material
1425, 14251, 14251-PED, 18008-001	Polyester, Polypropylene and polyester fibers Viscose fleece
14250, 14250-PED	Viscose, polyester and polyamide fibers, Polyethylene, Polypropylene and polyester fibers Viscose fleece
1425921, 1425923	Viscose, polyester and polyamide fibers, Polyethylene
1425932, 1425933	Polyester, Polypropylene and polyester fibers, Viscose fleece
14253, 14255, 14257, 14259, 14253-PED	Viscos, polyester and polyamide fibers, Polyethylene, Polypropylene and polyester fibers. Thermoplastic elastomeric polymers and additives, Polyester/Cotton
14253H, 14255H, 14256H, 14259H, 14253H-PED	Viscose, polyester and polyamide fibers, Polyethylene, Polypropylene and polyester fibers. Thermoplastic elastomeric polymers and additives, Polyester/Cotton
14254, 14256, 14258	Polyester, Polypropylene and polyester fibers. Thermoplastic elastomeric polymers and additives, Polyester/Cotton
142510, 142512, 142514, 142516, 142512-PED	Viscose, polyester and polyamide fibers, Polyethylene, Polyester/Cotton
142511, 142513, 142515	Viscose, polyester and polyamide fibers, Polyethylene, Polypropylene and polyester fibers Polyester, Polyester/Cotton



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.
- 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:	REF	Packaging
	1425, 14250, 14250-PED 14251, 14251-PED, 142512, 142512-PED, 1425921, 1425932, 18008-001	10 products in Mini-grip bag (Polyethylene, 120*170 mm, 50 µm) with Instructions for Use.
	1425933, 142510, 142514, 142516 14255, 14255H, 14253, 14253H, 14253H-PED, 14253-PED, 14257 142511, 142513, 142515, 14259, 14259H, 1425923, 14254, 14256, 14258, 14256H	10 products in Mini-grip bag (Polyethylene, 160*220 mm, 50 µm) with Instructions for Use.

Document No: 10000034908 Edition: 05 Release date: 2021-11-01

Released

Product Information

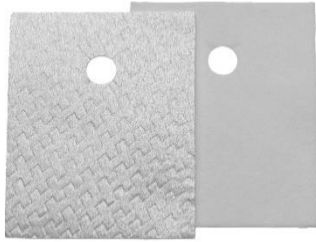
Devices under Basic UDI-DI: 7331791-COM-0-000-0001-52

REF	Name	UDI-DI
1425	Freeevent Dressing AL 80x100	07331791006562
14250	Freeevent Dressing slt 90x100	07331791012488
14251	Freeevent Dressing AL slt 80x100	07331791006579
14253	Freeevent Dressing Combi slt 90x100	07331791006647
14254	Freeevent Dressing Combi AL slt 90x100	07331791006654
14255	Freeevent Dressing Combi 90x100	07331791006661
14256	Freeevent Dressing Combi AL 90x100	07331791006685
14257	Freeevent Dressing Combi slt 90x150	07331791006708
14258	Freeevent Dressing Combi AL slt 90x150	07331791006715
14259	Freeevent Dressing Combi 90x150	07331791012808
142510	Freeevent Dressing Dbl 90x100	07331791006586
142511	Freeevent Dressing Dbl AL 90x100	07331791006593
142512	Freeevent Dressing Dbl slt 90x100	07331791006609
142513	Freeevent Dressing Dbl AL slt 90x100	07331791006616
142514	Freeevent Dressing Dbl 90x150	07331791006623
142515	Freeevent Dressing Dbl AL slt 90x150	07331791012563
142516	Freeevent Dressing Dbl slt 90x150	07331791006630
1425921	Freeevent Trach Dressing slt 90x100	07331791006722
1425923	Freeevent Trach Dressing slt 90x150	07331791006739
1425932	Freeevent Dressing AL slt 90x100	07331791006739
1425933	Freeevent Dressing AL slt 90x150	07331791006753
14250-PED	Freeevent Dressing slt 65x70 PED	07331791012495
142512-PED	Freeevent Dressing Dbl slt 65x70	07331791012556
14251-PED	Freeevent Dressing AL slt 65x70	07331791012471
14253H	Freeevent Dressing Combi BG slt 90x100	07331791012501
14253H-PED	Freeevent Dressing Combi BG slt 65x70	07331791012532
14253-PED	Freeevent Dressing Combi slt 65x70	07331791012549
14255H	Freeevent Dressing Combi BG 90x100	07331791006678
14256H	Freeevent Dressing Combi AL/BG 90x100	07331791006692
14259H	Freeevent Dressing Combi BG slt 90x150	07331791012792
18008-001	Freeevent Dressing AL 65x70 PED	07331791006135



Freeevent Dressing slt

Product Information



Freeevent Dressing AL



Freeevent Dressing AL slit



Freeevent Dressing Combi



Freeevent Dressing Combi slit



Freeevent Dressing Combi AL



Freeevent Dressing Combi AL slit



Freeevent Dressing Combi AL/BG

Product Information



Freevent Dressing Combi BG slt



Freevent Dressing Combi BG slt



Freevent Dressing Dbl



Freevent Dressing Dbl slt



Freevent Dressing Dbl AL



Freevent Dressing Dbl AL slt

Atos Medical AB Compatible products:

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Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	DD	Daniel Åberg - DANABE	2020-10-02 - 09:09
Reviewed:	QA	Karolina Nilsson - KARNIL	2020-10-02 - 13:23
Approved:	DD	Jon Berg - JONBER	2020-10-05 - 09:46
Released:	DD	Daniel Åberg - DANABE	2020-11-04 - 15:43

This document has been electronically signed by the persons above.

Released

Freevent® Dressing



Product description:

Freevent Dressings are sterile single use dressings that absorb secretion and provide protection for the skin around the tracheostomy tube for patients with a tracheostoma.

Freevent Dressing Softfoam is made of soft polyurethane foam that provides medium to high absorption of secretion.

Freevent Dressing Coated is made of soft viscose that provides low to medium absorption of secretion.

Product	REF and size (width, height, thickness)	Models
Softfoam	8034 = 80 x 80 x 5 mm 8035 = 80 x 50 x 5 mm 8036 = 80 x 80 x 2,5 mm	3 models: Different size and lengths, with a perforated slit and standard white.
Coated	8038 = 80 x 80 x 2 mm 8039 = 80 x 60 x 2 mm	2 models: Different sizes with a permanent slit and standard white.

Product Information

Document ID: PF095-02-TechInfo

Edition: 06

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

Classification: (EU) 2017/745 Class I S (1.4 rule 4)

Intended Use: Freeevent Dressings are sterile single use dressings that absorb secretion and provide protection for the skin around the tracheostomy tube for patients with a tracheostoma.

- Use specifications:**
- Intended medical indication: Patients using a tracheostomy tube.
 - Intended patient population: Adult and pediatric patients using a tracheostomy tube. Intended to be used by medical personnel or patients with sufficient cognitive ability and manual dexterity who are judged as able to manage the device independently by a clinician.
 - Intended usage: Single use.
 - Intended part of the body/type of tissue applied to or interacted with: Skin around the tracheostoma.
 - Intended user profile: Medical personnel or patients with sufficient cognitive ability and manual dexterity who are judged as able by a clinician to manage the device independently.
 - Intended conditions of use: Freeevent Dressings are for single use and for daily continuous use. Intended for use at home (indoor and outdoor), care facilities and hospitals, during rest, sleep and exercising under normal daily environment without any hygienic or environmental restrictions regarding temperature, moisture etc. The products are sterilised.
 - Frequency of use: Continuous use, can be used during the night.

Contraindications: There are no known contraindications

CE Mark: Yes, the devices are CE marked.

GMDN code: 15624 (Tracheostomy tube dressing, sterile)

Sterilization: Freeevent Dressing Softfoam= Gamma sterilized
 Freeevent Dressing Coated= Ethylene oxide gas

Raw material:

REF	Raw material
8034, 8035, 8036	Polyurethane foam Polyurethane film
8038, 8039	Polypropylene film Viscose Polypropylene fabric

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 5°C - 30°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:

REF	Packaging
8034, 8035	1 product in a paper-polyethylene pouch (12 x 14 cm). 20 pouches in 1 card board box with matte film (12,5 x 11,5 x 14,5 cm).
8036, 8038, 8039	1 product in a paper-polyethylene pouch (12 x 14 cm). 20 pouches in 1 card board box with matte film (12,5 x 7,5 x 14,5 cm).

Product Information

Devices under Basic UDI-DI: 7331791-COM-0-0G0-0002-J7

REF	Name	UDI-DI
8034	Freevent Dressing Softfoam L	07331791014086
8035	Freevent Dressing Softfoam S	07331791014093
8036	Freevent Dressing Softfoam Slim L	07331791014109

Devices under Basic UDI-DI: 7331791-COM-0-0E0-0000-GT

REF	Name	UDI-DI
8038	Freevent Dressing Coated L	07331791014116
8039	Freevent Dressing Coated M	07331791014123

Atos Medical AB compatible products:

Range	BASIC UDI-DI
N/A	N/A