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| Issued: | DD | Pontus Eklund - X-PONEKL | 2020-04-21 - 14:00 |
| Reviewed: | DD | Jon Berg - JONBER | 2020-04-21 - 15:56 |
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| Released: | DD | Jon Berg - JONBER | 2020-05-28 - 15:07 |

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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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| Justification: | Function: | Electronic signature justification: | Signed: Date (yyyy-mm-dd) - Time (hh:mm): |
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| Issued: | DD | Pontus Eklund - X-PONEKL | 2020-04-20 - 13:49 |
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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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| Justification: | Function: | Electronic signature justification: | Signed: Date (yyyy-mm-dd) - Time (hh:mm): |
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| Issued: | DD | Pontus Eklund - X-PONEKL | 2020-04-21 - 14:27 |
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| Released: | DD | Jon Berg - JONBER | 2020-05-28 - 15:09 |

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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 a cosmetic cover for the tracheostoma.

Product Information

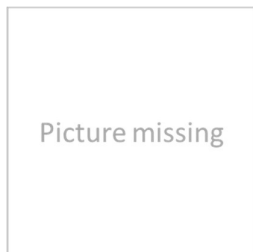
| Document ID: | PF091-01-TechInfo | Edition: | 02 | | | | | | | | |
|--|--|-----------------|----|-----|--------------|---|----------------------------------|--|---|---|---|
| Manufacturer: | Atos Medical AB Kraftgatan 8, P.O. Box 183, SE-242 22 Hörby, Sweden | | | | | | | | | | |
| Classification: (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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Document No: 10000035711 Edition: 02 Release date: 2020-05-28

Released

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 65x70 is a foam dressing that provides a protection between the tracheostomy tube and the skin. It is intended for patients with small secretion.

Document ID: PF093-01-TechInfo **Edition:** 2.0

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

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

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. Devices are CE-marked.

GMDN code: 15624 (Tracheostomy tube dressing)

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.

Product Information

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 |
|-------------------------|---|
| 142700-D, 142700-PED | 15 products are single packed in plastic bags made of polyethylene and then packed together with instructions for use in a cardboard box. |
| 142800 | 30 products are single packed in plastic bags made of polyethylene and then packed together with instructions for use in a cardboard box. |
| 1431 | 10 products are packed in a Mini-grip plastic bag made of polyethylene together with instructions for use. |

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 65x70 | 07331791006784 |



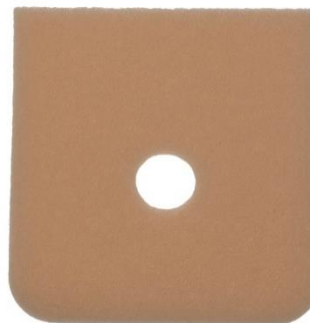
Freeevent Dressing Pad slit 90x100



Freeevent Dressing Pad slit 65x70 PED



Freeevent Dressing Pad 65x45



Freeevent Dressing Foam 65x70

Atos Medical AB compatible products:

None

Document Approvals
Approved Date: 2023-12-01

| | |
|--|--|
| Task: Approval Task Verdict: Approve | SEHRBJNC Carolina Johansson, Sustaining Engineer (carolina.johansson-atosmedical@coloplast.com) Quality 28-Nov-2023 14:13:25 GMT+0000 |
| Task: Approval Task Verdict: Approve | SEHRBHNU Ulrika Svensson, Quality Assurance Specialist (ulrika.svensson-atosmedical@coloplast.com) Issuer 28-Nov-2023 16:43:27 GMT+0000 |
| Task: Final Approval Verdict: Approve | KARNIL Karolina Nilsson, Head of Regulatory Affairs (karolina.nilsson-atosmedical@coloplast.com) Regulatory 01-Dec-2023 07:31:11 GMT+0000 |

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

This document has been electronically signed by the persons above.

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

Document No: 10000034769 Edition: 04 Release date: 2020-05-28

Released

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 | Freevent Neckband, one-piece , small | 07331791012914 |
| 1652 | Freevent Neckband, two-piece, small | 07331791012921 |
| 1661 | Freevent Neckband, one-piece, large | 07331791012938 |
| 1662 | Freevent Neckband, two-piece, large | 07331791012945 |
| 1751 | Freevent Neckband, one-piece, small | 07331791013607 |
| 1752 | Freevent Neckband, two-piece, small | 07331791013621 |
| 1761 | Freevent Neckband, one-piece, large | 07331791013614 |
| 1762 | Freevent Neckband, two-piece, large | 07331791013638 |



Freevent Neckband, one-piece



Freevent 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 |

Released

Product Information

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|----------------|-----------|-------------------------------------|---|
| Issued: | QA | Alexandra Holmberg - ALEHOL | 2021-10-15 - 14:20 |
| Reviewed: | QA | John Wennborg - JOHWEN | 2021-10-18 - 17:47 |
| Approved: | DD | Fredrik Calais - FRECAL | 2021-10-19 - 10:20 |
| Released: | QA | Alexandra Holmberg - ALEHOL | 2021-11-01 - 11:14 |

This document has been electronically signed by the persons above.



Product description:

The Freevent 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.

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

Released

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

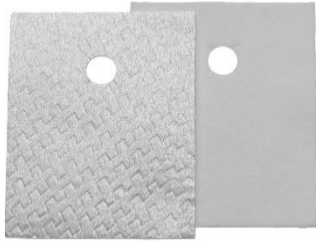
Devices under Basic UDI-DI: 7331791-COM-0-000-0001-52

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

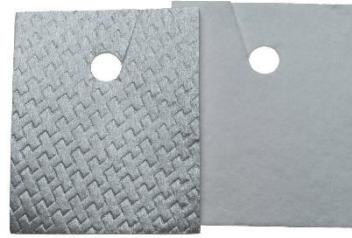


Freevent Dressing slt

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

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

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Product Information



Freeevent Dressing Combi BG slit



Freeevent Dressing Combi BG slit



Freeevent Dressing Dbl



Freeevent Dressing Dbl slit



Freeevent Dressing Dbl AL



Freeevent Dressing Dbl AL slit

Atos Medical AB Compatible products:

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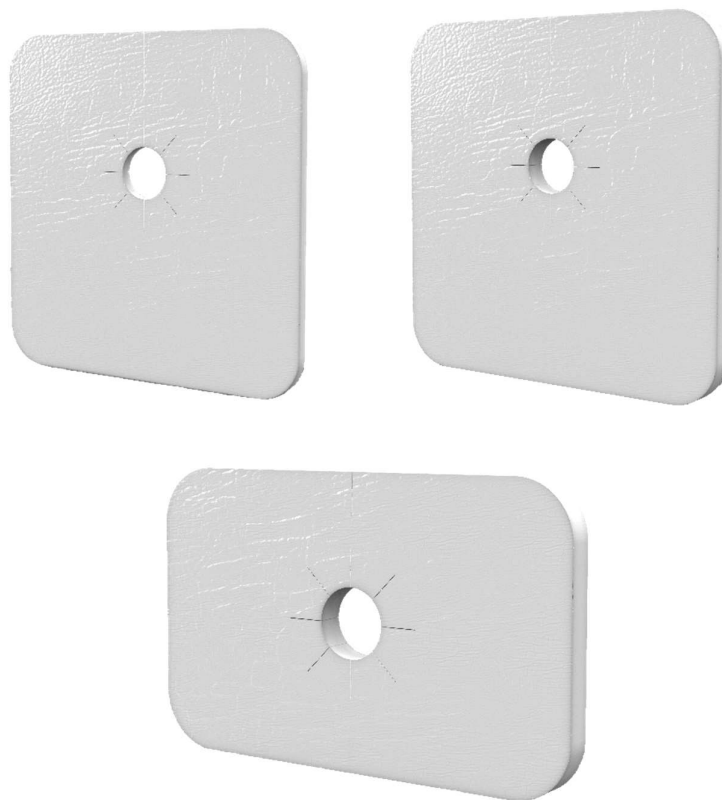
Document No: 10000034908 Edition: 05 Release date: 2021-11-01

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| Justification: | Function: | Electronic signature justification: | Signed: Date (yyyy-mm-dd) - Time (hh:mm): |
|----------------|-----------|-------------------------------------|---|
| Issued: | QA | Niki Svensson - NIKSVE | 2022-11-29 - 11:10 |
| Reviewed: | QA | Sofia Thomasson - SOFTHO | 2022-11-29 - 11:23 |
| Approved: | QA | Elin Andersson - ELIAND | 2022-11-29 - 13:41 |
| Released: | QA | Niki Svensson - NIKSVE | 2023-04-13 - 13:06 |

This document has been electronically signed by the persons above.

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 Dressings Softfoam comes in three different sizes with a perforated slit and standard white.

Product Information

| | | |
|--|--|--------------------|
| Document ID: | PF095-02-TechInfo | Edition: 07 |
| Manufacturer: | Atos Medical AB Kraftgatan 8 SE-242 35 Hörby, Sweden | |
| Classification: (MDD 93/42/EEC) | Class Is (1.4 rule 4) | |
| Intended Use: | 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. | |
| Use specifications: | <p>Intended medical indication Patients using a tracheostomy tube.</p> <p>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.</p> <p>Intended usage Single use, Over-the-counter.</p> <p>Intended part of the body/type of tissue applied to or interacted with: Skin around the tracheostoma.</p> <p>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.</p> <p>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. The products are sterilized.</p> | |
| Contraindications: | There are no known contraindications | |
| CE Mark: | Yes. Devices are CE-marked. | |
| GMDN code: | 15624 (Tracheostomy tube dressing, sterile) | |
| Sterilization: | Freevent Dressing Softfoam is gamma sterilized. | |
| Raw material: | Polyurethane foam and Polyurethane film | |



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 8034 and 8035 is individually packed in a paper-polyethylene pouch (12 x 14 cm). 20 pouches are packed in one card-board box with matte film (12.5 x 11.5 x 14.5 cm) together with instructions for use.

REF 8036 is individually packed in a paper-polyethylene pouch (12 x 14 cm). 20 pouches are packed in one card-board box with matte film (12.5 x 7.5 x 14.5 cm) together with instructions for use.

Document No: 10000040640 Edition: 07 Release date: 2023-04-13

Released

Product Information

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

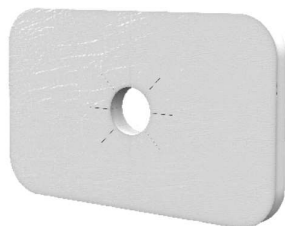
| REF | Name | UDI-DI |
|------|-----------------------------------|----------------|
| 8034 | Freevent Dressing Softfoam L | 07331791014086 |
| 8035 | Freevent Dressing Softfoam S | 07331791014093 |
| 8036 | Freevent Dressing Softfoam Slim L | 07331791014109 |



Freevent Dressing SoftFoam Slim L
(80 x 80 x 2,5 mm)



Freevent Dressing SoftFoam L
(80 x 80 x 5 mm)



Freevent Dressing SoftFoam S
(80 x 50 x 5 mm)

Atos Medical AB compatible products:

| Range | BASIC UDI-DI |
|-------|--------------|
| N/A | N/A |

Document No: 10000040640 Edition: 07 Release date: 2023-04-13

Released