# PREVENA™
INCISION MANAGEMENT SYSTEM

# U.S. SPECIFICATION SHEET

| | Item | Product Description | | | Specifications |
|---|---|---|---|---|---|
| Therapy Units | PREVENA™ 125 Therapy Unit | FDA Class II Medical Device<br>• Negative Pressure Options: Pre-set, continuous NPWT at -125mmHg<br>• Disposable, single patient use<br>• 3 AA batteries pre-installed | | | Weight:<br>0.4lbs (0.20kg)<br>Dimensions:<br>Approx. 13.6 x 7.5 x 3cm |
| | PREVENA PLUS™ 125 Therapy Unit | FDA Class II Medical Device<br>• Negative Pressure Options: Pre-set, continuous NPWT at -125mmHg<br>• Disposable, single patient use<br>• Rechargeable battery | | | Weight with empty canister:<br>0.7lbs (0.32kg)<br>Dimensions:<br>Approx 16 x 9 x 3cm |
| Dressings | • Contain a skin friendly wicking interface layer that includes 0.019% ionic silver and polyurethane foam bolster, specially designed for application to the surgical area<br>• Silver (0.019%) in the interface layer is not intended to treat infection, but to reduce bacterial colonization in the fabric | PEEL & PLACE™ Dressing - 20cm | Polyurethane foam bolster | | 25.4 x 6.4 x 1.8cm |
| | | | Polyurethane drape | | 35.6 x 20.3cm |
| | | | Connecting tube (integrated with dressing) | | Dressing tube length: 112cm |
| | | | Appropriate incision length | | Maximum 20cm (8 inches) |
| | | PEEL & PLACE™ Dressing - 13cm | Polyurethane foam bolster | | 15.2 x 6.4 x 1.8cm |
| | | | Polyurethane drape | | 22.8 x 13.3cm |
| | | | Connecting tube (integrated with dressing) | | Dressing tube length: 112cm |
| | | | Appropriate incision length | | Maximum 13cm (5 inches) |
| | | PEEL & PLACE™ Dressing - 35cm | Polyurethane foam bolster | | 37.8 x 6.4 x 1.8cm |
| | | | Polyurethane drape | | 47.5 x 13.5cm |
| | | | Dressing tube (integrated with dressing) | | Dressing tube length: 112cm |
| | | | Appropriate incision length | | Maximum 35cm (17 inches) |
| | | PREVENA™ CUSTOMIZABLE™ Dressing with SENSAT.R.A.C.™ Technology | Polyurethane foam bolster with integrated hydrocolloid strips | | 90 x 9.8 x 1.8cm |
| | | | Hydrocolloid strips (2) | | 2 x 24cm each |
| | | | V.A.C.® Drape (4) | | 30.5 x 26cm each |
| | | | SENSAT.R.A.C.™ Pad | | Tube length: 91cm |
| | | | Appropriate incision length | | Recommended 90cm (34.5 inches) or less |
| Canisters | PREVENA™ 45ml Canister | • 45ml canister with connecting tubing<br>• Single use, sterile, disposable | | Canister | 7.2 x 6.9 x 3cm |
| | | | | Canister tube | Canister tube length: 20.2cm |
| | PREVENA PLUS™ 150ml Canister | • 150ml canister with connecting tubing<br>• Single use, sterile, disposable | | Canister | 15.5 x 9 x 2.5cm |
| | | | | PREVENA PLUS™ Connector | Tube length: 45cm |
| Connectors | PREVENA™ Therapy V.A.C.® Connector | Required for connection of PREVENA™ Incision Dressings to approved V.A.C.® Therapy Units | | Dimensions: | 2.7 x 1.5 x 1.2cm |
| | | | | Weight: | 1.6 grams |
| | PREVENA™ Y-Connector | Connects two PREVENA™ Incision Dressings to a single approved V.A.C.® Therapy Unit | | Dimensions: | 3.8 x 1.5 x 2.6cm |
| | | | | Weight: | 2.6 grams |

## Environmental Conditions

### PREVENA™ PEEL & PLACE™ Incision Management System

| | |
|---|---|
| **Storage Temperature Range:** | -4°F (-20°C) to 140°F (60°C) |
| **Operating Temperature Range:** | 41°F (5°C) to 104°F (40°C) |
| **Altitude Range for Optimum Performance:** | -1253 to 9878 feet (-381.9m to 3010m) |
| **Relative Humidity Range:** | 15-95%, non-condensing |

### PREVENA PLUS™ Incision Management System

| | |
|---|---|
| **Storage Temperature Range:** | 0°F (-18°C) to 140°F (60°C) |
| **Operating Temperature Range:** | 41°F (5°C) to 104°F (40°C) |
| **Altitude Range for Optimum Performance:** | -1,253 to 9,878 feet (-381.9m to 3010m) |
| **Relative Humidity Range:** | 15-93%, non-condensing |

## Electrical Specifications (PREVENA™ 125 Therapy Unit)

**Battery Powered using primary (non-rechargeable) 3 AA Lithium-ion batteries**
**IEC Classification:**

- Medical Equipment
- Electrical Safety: Internally powered
- EMC: Class B for hospital use
- Type BF Applied Part according to IEC 60601-1:2005 (3rd Ed)
- IP24: Protection against solid objects greater than 12.5mm and against liquid water falling for short periods of time
- Suitable for home use

| Contains **Latex** | Contains **DEHP** (Di(2-ethylhexyl)phthalate) | Contains **Mercury** | Contains **Haz Mat** | Contains **Thimerosal** | **Radiopaque** |
|---|---|---|---|---|---|
| NO | NO | NO | NO | NO | NO |

## Electrical Specifications (PREVENA PLUS™ 125 Therapy Unit)

**A rechargeable Lithium-ion battery pack with AC Mains disconnection IEC Classification: Medical Equipment**

- Electrical Safety: Class II
- EMC: The PREVENA PLUS™ 125 Therapy Unit conforms to the intent of the 2004/108/EC EMC Directive; however, all medical equipment may produce electromagnetic interference or be susceptible to electromagnetic interference.
- Type BF Applied Part according to IEC 60601-1:2005 (3rd Ed)
- IP22: Protection against solid objects greater than 12.5mm and against liquid water falling for short periods of time
- Suitable for home use

| Contains **Latex** | Contains **DEHP** (Di(2-ethylhexyl)phthalate) | Contains **Mercury** | Contains **Haz Mat** | Contains **Thimerosal** | **Radiopaque** |
|---|---|---|---|---|---|
| NO | YES, SENSAT.R.A.C.™ Pad | NO | NO | NO | NO |

For more information, visit **acelity.com** or call **800-275-4524**

Follow local institutional protocols for infection control and waste disposal procedures. Local protocols should be based on the applicable local government environmental regulations.

**NOTE: Specific indications, contraindications, warnings, precautions and safety information exist for the PREVENA™ Incision Management System. Please consult the PREVENA™ Incision Management System Clinician Guide Instructions for Use prior to application. Rx only.**


LIT#29-A-333 • DSL#16-1242.US (08/17)

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