Avelle™ Negative Pressure Wound Therapy System

I. INTRODUCTION

1. The Avelle™ NPWT Dressing should not be used on patients who are sensitive to, or have had an allergic reaction to, any of the components of the system. The NPWT pump and accessories should not be used if damaged. See Section 9 for instructions on how to handle NPWT Dressing if inadvertently exposed to bodily fluids.

2. The Avelle™ NPWT System is intended for use in the home by the patient or carer in cases where it is assessed that they have the physical and mental ability to use it safely and effectively. The Avelle™ NPWT System should be used under the direct supervision of a Health Care Professional, trained in the application of NPWT devices.

3. The pump is a Class I, Type A medical device and is not intended for use in a hospital, post-acute and health care environment.

II. PATIENT SELECTION

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### Electrical Shock
- **Degree of Protection Against**:
  - Maximum vacuum: 144 mmHg
  - 80 mmHg

### Continuous Mode of Operation
- **Lifespan (pump unit)**: once

### Dimensions (maximum)
- 72 mm x 78 mm x 25 mm / 3 in. x 3 in. x 1 in.

### Medical Systems (PEMS)
- **Programmable Electronic Sterility**
- **Storage/Transport**: -25 to +70°C (-13 - 158°F), 90% RH.

### Guidance and Manufacturer’s Declaration – Electromagnetic Immunity

<table>
<thead>
<tr>
<th>IMMUNITY test</th>
<th>IEC 60061 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment – guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electronic discharge (ESD) IEC 61000-4-2</td>
<td>≥ 8 kV contact, 15 kV air</td>
<td>≥ 8 kV contact, 15 kV air</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Electric field transient/burst IEC 61000-4-4</td>
<td>≥ 3 kV for power supply lines</td>
<td>≥ 1 kV for input/output lines</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Surge IEC 61000-4-5</td>
<td>≥ 1 kV (level 1)</td>
<td>KVP</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Voltage dip, short interruptions and voltage variations on power supply input lines IEC 61000-4-11</td>
<td>≤ 5% U0 (≤ 5% of U0) for 5 cycles</td>
<td>≤ 40% U0 (≤ 40% of U0) for 5 cycles</td>
<td>Not Applicable</td>
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</tbody>
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### Portable RF communications equipment should be used no closer than 30 cm (12 in.) to the Avelle™ NPWT Pump unit.

### 10. ELECTROMAGNETIC COMPATIBILITY

- **No specific guidance or information on electromagnetic immunity and emissions is needed.**
- **Consult ConvaTec** or visit us online at www.convatec.com.

### 11. CAUTIONS

- These instructions for use are not intended as a guarantee or warranty. They are only intended as a guide. For medical questions, please consult a physician.

### 12. DEFINITION OF SYMBOLS

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<thead>
<tr>
<th>Symbol</th>
<th>Definition</th>
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<tbody>
<tr>
<td>DOT</td>
<td>Federal (U.S.A.) law restricts this device to display a DOT symbol.</td>
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<tr>
<td>CE</td>
<td>Conformité Européenne (Conform with EU Directives).</td>
</tr>
<tr>
<td>CML</td>
<td>Conformité Médicale Légale (Conform with Medical Legislation).</td>
</tr>
<tr>
<td>IEC</td>
<td>International Electro-technical Committee.</td>
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<tr>
<td>ISO</td>
<td>International Organization for Standardization.</td>
</tr>
<tr>
<td>EN</td>
<td>European Norm.</td>
</tr>
<tr>
<td>CAD</td>
<td>Canadian Standards Association.</td>
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<tr>
<td>C22.2</td>
<td>Canadian Standards Association.</td>
</tr>
<tr>
<td>ANSI</td>
<td>American National Standards Institute.</td>
</tr>
<tr>
<td>AAMI</td>
<td>American Association of Medical Instrumentation.</td>
</tr>
<tr>
<td>NRTL</td>
<td>National Recognized Testing Laboratory.</td>
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<td>UL</td>
<td>Underwriters Laboratories.</td>
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