Internal Defibrillation Handles and Electrodes

NOTE: These internal handle and electrode sterilization guidelines supersede all others for these accessories.

WARNING: Failure to follow the guidelines or use of the accessory beyond the limits stated may result in damage that limits the device performance or sterilization effectiveness.

CAUTION:
• Use one sterilization method for the life of the product. Using different sterilization methods on the same accessory may damage the accessory and limit the effectiveness of the additional sterilization cycles.
• The useful life of internal defibrillation handles and electrodes is affected by the number of sterilization cycles rather than by the age of the handles and electrodes.
• Take great care to protect each electrode during transport, use, cleaning, and sterilization, to prevent damage to electrode surfaces. Prevent electrodes from bumping one another, or other equipment. Handle electrodes individually, not as a group. Wrap each electrode individually for sterilization.

The following paragraphs provide current handling, cleaning, and sterilization guidelines for internal defibrillation handles and electrodes (paddles). Please keep this guideline document with your LIFEPAK defibrillator operating instructions manual and in your sterilization department. The accessories covered by this guideline are:
• Internal handles with discharge control (PN 3010901 and PN 805249)
• Internal electrodes (PN 805355)

During Surgical Set-up:
• Examine handles, cables, and connectors for damage or signs of wear (such as loose cable connections, damaged pins, exposed wires, or cable connector corrosion).
• Before connecting the handles to a defibrillator, press the shock button on the handle to check for actuation. An audible click should be heard from the shock button.
• Examine the electrodes for scratched, pitted, or chipped surfaces, and for bubbled, scratched, or chipped epoxy coating. If any of these conditions are found, or if an audible click is not heard from the shock button during the actuation check, remove the affected component from use immediately.

After Each Use and Prior to Sterilizing:
• Remove electrode(s) from handle(s).
• Manually wipe or rinse electrodes, handles, cables, and connectors with Enzol® or chemically equivalent mild enzymatic detergent using a damp sponge or towel. A brush may be used on the handle, including its cable and connector. Do not use a brush on the electrodes. Do not immerse or soak (except for the removable internal electrodes).
• Rinse all parts thoroughly with deionized water.
• Dry thoroughly.
• Individually protect electrodes before and after cleaning and sterilization to prevent damage to electrode surfaces.
• Examine handles, cables, and connector for damage or signs of wear (that is, loose cable connections, damaged pins, exposed wires, and cable connector corrosion).
• Examine electrodes for scratched, pitted, or chipped surfaces and bubbled, scratched, or chipped epoxy coating. If any of these conditions are found, remove the affected component from use immediately.
• Internal handles must be positioned in the sterilizer to allow recessed electrode socket (lumen) area to drain.
• Coil cables loosely away from handles during sterilization. Damage may occur if cables have tight bends or are wrapped around the handles.

Testing:
Perform 20 J defibrillation test using a defibrillator analyzer no less than quarterly or after ten sterilization cycles, whichever comes first.
Physio-Control internal handles and electrodes are capable of withstanding the following sterilization methods and cycles.

<table>
<thead>
<tr>
<th>Sterilization Method</th>
<th>LIFEPAK 12/ LIFEPAK 20 Internal Handles</th>
<th>LIFEPAK 9 Internal Handles</th>
<th>Internal Electrodes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevacuum Steam (wrapped)</td>
<td>25 cycles</td>
<td>25 cycles</td>
<td>10 cycles**</td>
</tr>
<tr>
<td>Prevacuum Steam (wrapped)</td>
<td>25 cycles</td>
<td>25 cycles</td>
<td>1 cycle*</td>
</tr>
<tr>
<td>STERRAD 100S (wrapped)</td>
<td>100 cycles</td>
<td>100 cycles</td>
<td>1 cycle**</td>
</tr>
</tbody>
</table>

* When used with either monophasic or biphasic defibrillators.
** When used only with biphasic defibrillators.

**Prevacuum Steam Sterilization (Wrapped in two layers of KIMGUARD® KC600 or equivalent polypropylene wrap)**

Physio-Control has tested and approved the internal defibrillation handles and electrodes listed above using the following prevacuum steam sterilization settings:

- **Prevacuum (Wrapped)**
- Sterilization Temperature: 132°-135°C (270°-275°F)
- Preconditioning Pulses: 4 pulses
- Prevacuum: 254 mmHg (10.0 inHg) minimum
- Sterilization Exposure Time: 4 minutes
- Dry Time: Up to 30 minutes

**STERRAD® 100S Hydrogen Peroxide Gas Plasma Sterilization**

Physio-Control has tested and approved the internal defibrillation handles and electrodes listed above for peroxide gas plasma sterilization (STERRAD 100S System), in two layers of KIMGUARD KC600 or equivalent polypropylene wrap.

**General Precautions**

- These sterilization parameters are valid only with equipment properly maintained and calibrated.
- Sterilization cycle times and efficacy vary depending on equipment, wrapping, and load configuration.

The instructions provided above have been validated by the medical device manufacturer as being CAPABLE of preparing a medical device for re-use. It remains the responsibility of the processor to ensure that the processing as actually performed using equipment, materials and personnel in the processing facility achieve the desired result. This requires validation and routine monitoring of the process. Likewise any deviation by the processor from the instructions provided should be properly evaluated for the effectiveness and potential adverse consequences.