Product Technical Data Sheet

Product Name: SteriTec Integraph Integrator

Product Type: Chemical Integrator

Reorder Number: CI 101

Description: The SteriTec Integraph provides an integrated response to steam sterilization at 132°-134° C for pre-vacuum sterilizers operating for 3 minutes or longer. The Integraph integrator gives a visible confirmation of the attainment of sterilization conditions at the location within the sterilizer chamber.

Performance Characteristics:
The Integraph has three different timing indicator inks printed on each indicator. The user can determine:
1. If only the first indicator bar turns green, the integrator has been subjected an insufficient steam sterilization process.
2. If the first and second bars turn green, sterilization conditions were met.
3. If the first two bars turn green as well as the short bar steam sterilization conditions occurred for an extended period.

Color Change: Purple to Green.

Critical Parameters: (in a standard hospital steam pre-vacuum sterilizer)

<table>
<thead>
<tr>
<th></th>
<th>134°C</th>
<th>132°C</th>
<th>121°C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Check Mark</td>
<td>1 min. (-10/+0 sec.)</td>
<td>1.5 min. (-15/+0 sec.)</td>
<td>5 min. (-45/+0 sec.)</td>
</tr>
<tr>
<td>Long Bar</td>
<td>3 min (-30/+0 sec.)</td>
<td>3.5 min. (-30/+0 sec.)</td>
<td>12 min. (-2/+0 min.)</td>
</tr>
<tr>
<td>Short Bar</td>
<td>10 min (-1.5/+0 min.)</td>
<td>11 min. (-100/+0 sec.)</td>
<td>35 min. (-5.5/+0 min.)</td>
</tr>
</tbody>
</table>

Stated Value: (as determined in a steam resistometer)

<table>
<thead>
<tr>
<th></th>
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<th>121°C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Check Mark</td>
<td>3 min. (-18/+0 sec.)</td>
<td>4 min. (-45/+0 sec.)</td>
<td>6.5 min. (-2.1/+0 min.)</td>
</tr>
<tr>
<td>Long Bar</td>
<td>5 min. (-23/+0 sec.)</td>
<td>7 min. (-.9/+0 min.)</td>
<td>16 min. (-2.4/+0 min.)</td>
</tr>
<tr>
<td>Short Bar</td>
<td>13 min. (-1/+0 min.)</td>
<td>17 min. (-2.1/+0 min.)</td>
<td>36 min. (-5.4/+0 min.)</td>
</tr>
</tbody>
</table>

Indicator Stability: Before and After Sterilization: Excellent

Physical Characteristics:
Lamination: Top and Bottom
Dimensions: 3" L X .75" W
Indicator Substrate Material: Blotter Paper
Quantity / Bag: 250
Bags / Case: 20
Selling Unit: Case

Environmental Limitations:
Storage: 32° - 104° F (0° – 40° C) at 10-60% humidity. Indicator strips are packaged in tamper evident moisture barrier foil bags. After removing indicators for use, reseal ziplock to protect remaining indicators from exposure to high humidity environmental conditions.

Shelf Life: 3 years from date of manufacture

FDA 510(k) Release to Market Date: May 8, 1997, K960441

Standard Classification:
AAMI ST60, Class 5
ISO 11140-1: 2005, Class 5