A. Indications for Use

JEM Series Endotracheal Tube Changers provide a simple, rapid technique for changing endotracheal and orotracheal tubes with specific inside diameters. JEM Series Endotracheal Tube Changers are intended for single patient use.

B. Warnings

WARNING:

Sterilization and High Level Disinfection Procedures

STERIS V-PRO® Low Temperature Sterilization Systems:

Package in VIS-U-ALL Low Temperature Sterilization Tyvek® Pouches and sterilize in the Flexible Cycle of the following V-PRO Low Temperature Sterilization Systems: V-PRO® max, V-PRO® max2, V-PRO® 60, V-PRO® 12.

High Level Disinfection Pasteurization:

Pasteurize at 160°F - 170°F (71°C - 77°C) for no less than 30 minutes.

Chemical Disinfectants:

Disinfect according to validated parameters. Follow the chemical manufacturer’s recommendation for temperature and soak time. Chemical disinfection must be followed by a sterile rinse and device must be allowed to thoroughly dry before use.

C. Sterilization and High Level Disinfection Procedures

JEM Series Endotracheal Tube Changers MUST be sterilized or disinfected before use.

JEM Series Endotracheal Tube Changers are Single Patient Use devices.

Note:

Steam Autoclave, Gas Plasma, Sterrad, and Gamma Radiation are NOT recommended processing methods.

Sterilization Ethylene Oxide:

Sterilize in ethylene oxide at 129°F (54°C) for 60 minutes. Sterilized tubes must be aerated within the chamber for no less than 12 hours to dissipate any residual gas.

STERIS V-PRO® Low Temperature Sterilization Systems:

Package in VIS-U-ALL Low Temperature Sterilization Tyvek® Pouches and sterilize in the Flexible Cycle of the following V-PRO Low Temperature Sterilization Systems: V-PRO® max, V-PRO® max2, V-PRO® 60, V-PRO® 12.

High Level Disinfection Pasteurization:

Pasteurize at 160°F - 170°F (71°C - 77°C) for no less than 30 minutes.

Chemical Disinfectants:

Disinfect according to validated parameters. Follow the chemical manufacturer’s recommendation for temperature and soak time. Chemical disinfection must be followed by a sterile rinse and device must be allowed to thoroughly dry before use.

D. Product Specifications

<table>
<thead>
<tr>
<th>Model #</th>
<th>JEM Series</th>
<th>Material</th>
<th>High Density Polyethylene</th>
</tr>
</thead>
<tbody>
<tr>
<td>JEM 325</td>
<td>2.5mm I.D.</td>
<td>15&quot;</td>
<td></td>
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<tr>
<td>JEM 330</td>
<td>3.0mm I.D.</td>
<td>16.5&quot;</td>
<td></td>
</tr>
<tr>
<td>JEM 340</td>
<td>4.0mm I.D.</td>
<td>19.5&quot;</td>
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</tr>
<tr>
<td>JEM 350</td>
<td>5.0mm I.D.</td>
<td>23&quot;</td>
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<tr>
<td>JEM 355</td>
<td>5.5mm I.D.</td>
<td>25&quot;</td>
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<tr>
<td>JEM 360</td>
<td>6.0mm I.D.</td>
<td>26&quot;</td>
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<tr>
<td>JEM 365</td>
<td>6.5mm I.D.</td>
<td>26.5&quot;</td>
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<tr>
<td>JEM 370</td>
<td>7.0mm I.D.</td>
<td>27.5&quot;</td>
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</tr>
<tr>
<td>JEM 400</td>
<td>7.5mm I.D.</td>
<td>29&quot;</td>
<td></td>
</tr>
<tr>
<td>JEM 401</td>
<td>Package of 1 each of all 9 sizes</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
How to Use a JEM Endotracheal Tube Changer

Changing an ORIGINAL LENGTH, UNSHORTENED endotracheal tube:

- (If the Endotracheal Tube has been shortened, see steps 4a - 4d)

4. Carefully insert JEM Endotracheal Tube Changer into EXISTING endotracheal tube until the PROXIMAL MARK on the inserted end of the changer is even with the PROXIMAL END (not adapter) of the endotracheal tube (Example 1, Figures 1 & 2).

5. Determine the GUIDE MARK at the lip or nostril (Figure 1, Figure 2). During the tube exchange process, this marked position must be maintained as closely as possible. Special care must be taken to prevent further advancement of thechanger into the patient.

6. Deflate EXISTING endotracheal tube cuff.

7. While stabilizing the JEM Endotracheal Tube Changer, remove the EXISTING endotracheal tube over the Changer (Figure 3).

8. While continuing to stabilize the JEM Endotracheal Tube Changer, pass the NEW endotracheal tube over the JEM Endotracheal Tube Changer (Figure 4) until the PROXIMAL END of the endotracheal tube is aligned with the PROXIMAL MARK, or the CORRECTED PROXIMAL MARK if Corrective Allowance has been made for a shortened tube on the Changer. Ensure that the Changer is in the original position, based upon the GUIDE MARK at the lip or nostril, prior to setting final depth of endotracheal tube (Figure 5).

CAUTION: Advancing a JEM Endotracheal Tube Changer without a proper corrective allowance into an endotracheal tube that has been shortened will cause the JEM Endotracheal Tube Changer to protrude beyond the bevel, potentially causing tracheal and/or endotracheal mucosal trauma.

4a. A Corrective Allowance must be determined before insertion of the JEM Endotracheal Tube Changer for proper GUIDE MARK alignment. The Corrective Allowance is equal to the length of the cut-off portion of the endotracheal tube. This can be determined by:

1) Measuring the length of the cut-off portion of the endotracheal tube, if available.

2) Relying on an ACCURATE written record of the length of the cut-off portion of the endotracheal tube.

3) Comparing an IDENTICAL endotracheal tube to the visible portion of the SHORTENED/CUT-OFF tube and determining the difference in length.

4b. Starting at the PROXIMAL MARK on the inserted end of the JEM Endotracheal Tube Changer, add amount of CUT-OFF length in the direction of GUIDE MARKS (i.e. 3cm). The closest GUIDE MARK is the CORRECTED PROXIMAL MARK. If cut-off length is between GUIDE MARKS, round up to the next GUIDE MARK (i.e. Area between GUIDE MARK 2 and 3 becomes 3).

4c. Carefully insert JEM Endotracheal Tube Changer into EXISTING endotracheal tube, aligning CORRECTED PROXIMAL MARK with the PROXIMAL END (not adapter) of existing endotracheal tube (Example 2).