<table>
<tr><td>Manufacturer</td><td colspan="4">International Medical Industries, Inc.</td></tr>
<tr><td>Description</td><td colspan="4">Tamper Evident Caps for Oral Dispensers (Non-Sterile)</td></tr>
<tr><td rowspan="6">IMI Part Number(s)</td><td>Part Number</td><td colspan="2">Device Color (Bottom)</td><td>Compatible Dispenser</td></tr>
<tr><td>57-70</td><td colspan="2">Red</td><td>Baxter</td></tr>
<tr><td>57-70-100</td><td colspan="2">Red</td><td>Baxter</td></tr>
<tr><td>57-73</td><td colspan="2">Yellow</td><td>BD</td></tr>
<tr><td>57-73-100</td><td colspan="2">Yellow</td><td>BD</td></tr>
<tr><td>57-74</td><td colspan="2">White</td><td>Comar</td></tr>
<tr><td>Unit of Measure, as provided</td><td colspan="2">1,000 Units per Box</td><td colspan="2">-100 Configurations have 100 Units per Box</td></tr>
<tr><td rowspan="2">Packaging Configuration</td><td>Sterile Primary Packaging</td><td>Secondary Packaging</td><td>Sterile Primary Packaging</td><td>Secondary Packaging</td></tr>
<tr><td>100 Units per Bag</td><td>10 Bags per Box</td><td>100 Units per Bag</td><td>1 Bag per Box</td></tr>
<tr><td>Sterilization</td><td colspan="4">Not Applicable. This product is non-sterile.</td></tr>
<tr><td>Shelf Life - Expiration</td><td colspan="4">Not Applicable.</td></tr>
<tr><td>Biocompatibility</td><td colspan="4">Biocompatibility testing has been conducted on product materials and colorant combinations per the ISO 10993-1 Biological Evaluation of Medical Devices standard.</td></tr>
<tr><td>Endotoxin</td><td colspan="4">Not Applicable. This product is non-sterile.</td></tr>
<tr><td>Conflict Minerals</td><td colspan="4">IMI products contain no conflict minerals.</td></tr>
<tr><td>DEHP / BPA</td><td colspan="4">This product is made from materials that do not contain Di(2-ethylhexyl) phthalate (DEHP) or Bisphenol A (BPA).</td></tr>
<tr><td>Latex Statement</td><td colspan="4">This product is not made with natural rubber latex.</td></tr>
<tr><td>BSE/TSE Statement</td><td colspan="4">All International Medical Industries products are manufactured completely from synthetic or manufactured materials and do not contain any raw materials produced from, or substances derived from animal origin. Moreover, our products are not derived from specific-risk materials as defined in European Commission Decision 97/534/EC.
The manufacturing process does not use any ingredient of animal origin nor do our products come in contact with animal products during the manufacturing and packaging process. IMI has established environmental, In Process Cross Contamination Controls, and procedures that meet the requirements of ISO 13485 and Title 21 of the Code of Federal Regulations, Part 820 to prevent product contamination. Air and Product bio burden testing is performed at a specified frequency and trended to detect potential problems and to assure a “state of control” is being maintained.
As such, products manufactured by IMI are free from the conditions that could introduce Transmissible Spongiform Encephalopathy (TSE) and Bovine Spongiform Encephalopathy (BSE).</td></tr>
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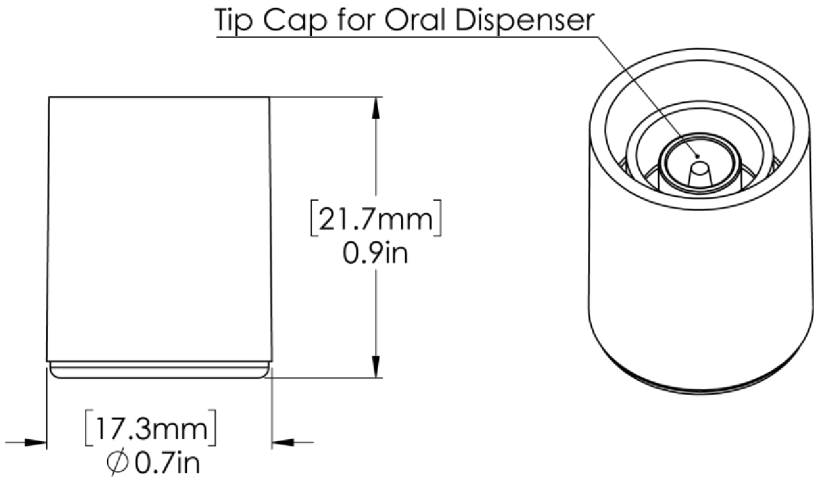
<tr><td rowspan="5">Materials</td><td>Item(s)</td><td>Material(s) Used</td><td>Packaging Material(s) Used</td></tr>
<tr><td>Tip Cap (57-70, 57-74, 57-75)</td><td>ABS</td><td rowspan="4">Polyethylene zip lock bag</td></tr>
<tr><td>Tip Cap (57-73)</td><td>Polypropylene</td></tr>
<tr><td>Sleeve</td><td>Polystyrene</td></tr>
<tr><td>Bottom Cap</td><td>Polystyrene</td></tr>
<tr><td rowspan="2">Storage & Shipping Conditions</td><td colspan="2">Device</td><td>Packaging</td></tr>
<tr><td colspan="2">No temperature or humidity special requirements, no light or moisture sensitivity.</td><td>No temperature or humidity special requirements, light sensitivity and corrugated packaging must be kept dry.</td></tr>
<tr><td>510(K) Number</td><td colspan="3">Exempt</td></tr>
<tr><td>European Conformity</td><td colspan="3">Product is CE Marked
CE</td></tr>
<tr><td colspan="4">Technical Drawing Shown Below</td></tr>
<tr><td colspan="4"> 

Tamper Evident Caps for Oral Syringes</td></tr>
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