Manufacturer	International Medical Industries, Inc.			
Description	Tamper Evident Cap (with female, luer lock fitting)			
IMI Part Number(s)	57-24-CE (Red)		57-24-100 (Red)	
	57-25-CE (Blue)		57-25-100 (Blue)	
	57-26-CE (White)		57-26-100 (White)	
Unit of Measure, as provided	1,000 Units per Box		100 Units per Box	
Packaging Configuration	**Sterile Primary Packaging**	**Secondary Packaging**	**Sterile Primary Packaging**	**Secondary Packaging**
	10 Units per Tray	100 Trays per Box	10 Units per Tray	10 Trays per Box
Sterilization	Ethylene Oxide (EO) to 10^{-6} SAL per ISO 11135			
Shelf Life - Expiration	As marked on the device, typically 3 years (36 months)			
Biocompatibility	Biocompatibility testing has been conducted on product materials and colorant combinations per the ISO 10993-1 Biological Evaluation of Medical Devices standard.			
Endotoxin	Manufacturing lots of the device are routinely monitored for Bacterial Endotoxins.			
Conflict Minerals	IMI products contain no conflict minerals.			
DEHP / BPA	This product is made from materials that do not contain Di(2-ethylhexyl) phthalate (DEHP) or Bisphenol A (BPA).			
Latex Statement	This product is not made with natural rubber latex.			
BSE/TSE Statement	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).			

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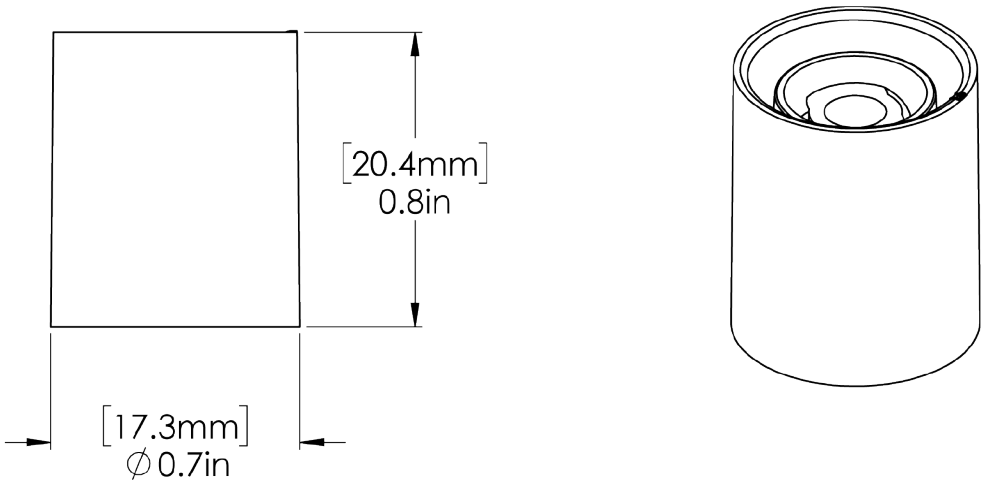
<table>
<tr><td rowspan="4">Materials</td><td>Item(s)</td><td>Material(s) Used</td><td>Packaging Material(s) Used</td></tr>
<tr><td>LL Cap</td><td>Polypropylene</td><td rowspan="3">Polypropylene Tray and Tyvek</td></tr>
<tr><td>TEC Sleeve</td><td>Polystyrene</td></tr>
<tr><td>TEC Bottom Cap</td><td>Polystyrene</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 – _Tyvek® is not recommended for constant UV exposure, corrugated packaging must be kept dry.</td></tr>
<tr><td>510(K) Number</td><td colspan="3">K861276</td></tr>
<tr><td>European Conformity</td><td colspan="3">Product is CE Marked
CE
1639</td></tr>
<tr><td colspan="4">Technical Drawing Shown Below</td></tr>
<tr><td colspan="4"> 

57-24 Tamper Evident Cap (with female, luer lock fitting)</td></tr>
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