



# Product Comparison Sheet: HCT Tamper Evident Syringe Cap

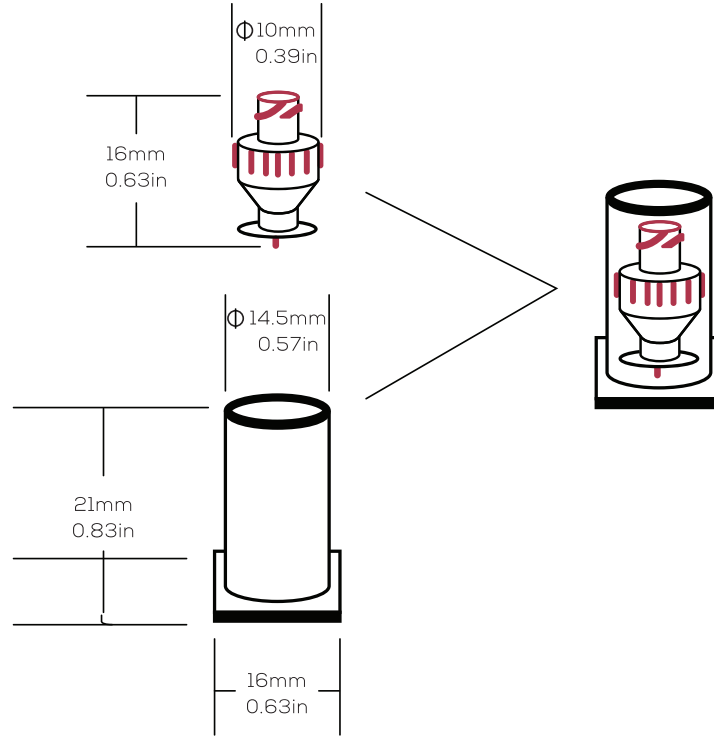
Criteria	Subject Device	Comparable Device	Comparable Device	Conclusion
<b>Device Name</b>	HCT Tamper Evident Syringe Cap	IMI Tamper Evident Syringe Cap	BBraun Tamper Evident Syringe Cap	Same
<b>Packaging Configuration</b>	10 Caps per Tray	10 Caps per Tray	10 Caps per Tray	Same
<b>Labeling</b>	Instructions on how to open syringe cap trays and attach to syringes.	Instructions on how to open syringe cap trays and attach to syringes,	Instructions on how to open syringe cap trays and attach to syringes,	Same
<b>Sterility</b>	Sterile EO (10 <sup>-6</sup> )	Sterile EO (10 <sup>-6</sup> )	Sterile EO (10 <sup>-6</sup> )	Same
<b>Number of Uses</b>	Single Use, Rx only	Single Use, Rx only	Single Use, Rx only	Same
<b>Cap Material</b>	Polypropylene Inner Cap	Polypropylene Inner Cap	Polypropylene Inner Cap	Same
<b>Tamper Evident Design Feature</b>	Cap Separation Upon Opening	Cap Separation Upon Opening	Cap Separation Upon Opening	Same



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<b>Manufacturer:</b>	Yangzhou WEIDELI Trade Co., Ltd..		
<b>Description:</b>	Tamper Evident Cap (with female, luer lock fitting)		
<b>HCT Part Number(s):</b>	HCT10R (Red) HCT10W (White) HCT10B (Blue) HCT10K (Black)	HCT100R-5B (Red) HCT100W-5B (White) HCT100B-5B (Blue) HCT100K-5B (Black)	HCT500R-5B (Red) HCT500W-5B (White) HCT500B-5B (Blue) HCT500K-5B (Black)
<b>Unit of Measure:</b>	500 Units per Case	1000 Units per Case	1000 Units per Case
<b>Packaging Configuration:</b>	<b>Sterile Primary Packaging:</b> 10 Units per Tray  <b>Secondary Primary Packaging:</b> 50 Trays per Box	<b>Sterile Primary Packaging:</b> 10 Trays per Bag  <b>Secondary Primary Packaging:</b> 10 Bags per Box	<b>Sterile Primary Packaging:</b> 500 Units per Bag  <b>Secondary Primary Packaging:</b> 2 Bags per Box
<b>Sterilization:</b>	Ethylene Oxide (EO)		
<b>Biocompatibility:</b>	Biocompatibility testing has been conducted on materials used in the manufacturing of this device.		
<b>Endotoxin:</b>	Manufacturing lots of the device are routinely monitored for Bacterial Endotoxins.		
<b>DEHP:</b>	This product is made from materials that do not contain Di(2-ethylhexyl)phthalate (DEHP)		
<b>Latex Statement:</b>	This product does not contain natural rubber latex.		
<b>Physical and Chemical Properties:</b>	The physical and chemical properties of the plastic used manufacturing of this product have been tested.		
<b>BSE/TSE Statement:</b>			
<b>Materials:</b>	<b>Item(s)</b> Inside Luer Lock Cap Clear Outer Shell  Cover Tray	<b>Material(s) Used</b> Polypropylene (PP) Polyac MABS  Tyvek Polyethylene Terephthalate Glycol (PETG)	
<b>510(k) Number:</b>	K121803		
<b>European Conformity:</b>			
<b>Additional Notes:</b>			

### Specifications of the HCT Tamper Evident Syringe Cap



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