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**Class 2 Device Recall ARROW HANDSOFF Infusion Port Thermodilution Catheter**

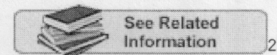


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**Class 2 Device Recall ARROW HANDSOFF Infusion Port Thermodilution Catheter**



<b>Date Initiated by Firm</b>	September 02, 2016
<b>Create Date</b>	November 02, 2016
<b>Recall Status<sup>1</sup></b>	Open <sup>3</sup> , Classified
<b>Recall Number</b>	Z-0331-2017
<b>Recall Event ID</b>	<a href="#">75372</a> <sup>23</sup>
<b>510(K)Number</b>	<a href="#">K895268</a> <sup>24</sup>
<b>Product Classification</b>	Catheter, intravascular, diagnostic <sup>25</sup> - <b>Product Code DQO</b> <sup>26</sup>
<b>Product</b>	HANDS-OFF Infusion Port Thermodilution Catheter consists of the Arrow IPTD thermodilution catheter enclosed in a contamination shield (Arrow Cath-Gard) with integral flushing/balloon test chamber, enabling the practitioner to prepare, test, and insert the catheter without exposing it to external contamination.
<b>Code Information</b>	Lot # 16F15C0114, 16F15D0003, 16F15A0072, 16F15F0031, 16F15F0090, 16F15H0037, 16F16B0001, 16F16B0014, 16F16C0056, 16F16C0079, 16F16C0109, 16F16E0004, 16F16E0030
<b>Recalling Firm/ Manufacturer</b>	Arrow International Inc 2400 Bernville Rd Reading PA 19605-9607
<b>For Additional Information Contact</b>	610-378-0131
<b>Manufacturer Reason for Recall</b>	Labeling inconsistency
<b>FDA Determined Cause<sup>2</sup></b>	Labeling mix-ups
<b>Action</b>	Arrow sent an Urgent Medical Device Recall Notification letter dated September 20, 2016, to all affected customers via FedEx 2-day air. The letter identified the problem and provided instructions to immediately discontinue use and quarantine any products with the associated lot numbers indicated in the letter. If product was found, customers were asked to complete the Recall Acknowledgement Form and a Customer Service Rep will issue a Return Goods Authorization (RGA) Number for the product's return. Disposition of recalled product will be scrapped. For further questions, please call (610) 378-0131
<b>Quantity in Commerce</b>	330 units in US and 1,031 units OUS
<b>Distribution</b>	Nationwide distribution
<b>Total Product Life Cycle</b>	<a href="#">TPLC Device Report</a> <sup>27</sup>

<sup>1</sup> A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated.