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**Class 2 Device Recall Access Tray**

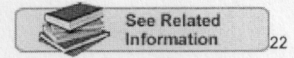


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**Class 2 Device Recall Access Tray**



<b>Date Initiated by Firm</b>	January 11, 2017
<b>Create Date</b>	February 22, 2017
<b>Recall Status<sup>1</sup></b>	Open <sup>3</sup> , Classified
<b>Recall Number</b>	Z-1228-2017
<b>Recall Event ID</b>	<u>76237</u> <sup>23</sup>
<b>510(K)Number</b>	<u>K930129</u> <sup>24</sup>
<b>Product Classification</b>	<u>Catheter, intravascular, therapeutic, long-term greater than 30 days</u> <sup>25</sup> - <b>Product Code</b> <u>LJS</u> <sup>26</sup>
<b>Product</b>	Vascular catheter introduction kit The PICC is indicated for short or long term peripheral access to the central Venous system for intravenous therapy, blood sampling, infusion and power injection of contrast media.
<b>Code Information</b>	Material # , ASK-01663-MST, ASK-04001-DU4, ASK-04001-DU5, PI-01351-LS, PI-01351-LS5, PI-01351-SS, PI-01552-LS, PI-01552-LS5, PI-01552-SS, PL-05041, PL-05041, PL-05052, PR-05041, PR-05041, PR-05041-T, PR-05042, ASK-01663-MST, ASK-04001-DU4, ASK-04001-DU5, PI-01351-LS, PI-01351-LS5, PI-01351-SS, PI-01351-SS, PI-01451-LS, PI-01451-LS5, PI-01451-SS, PI-01451-SS, PI-0-1552-LS
<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>	There have been complaints for peel away sheaths flaring
<b>FDA Determined Cause<sup>2</sup></b>	Device Design
<b>Action</b>	Arrow International mailed an Urgent Medical Device Advisory Notification letter to affected customers on 01/13/2017 to inform them of the issue. Customers with questions were instructed to contact their local sales representative or Customer Service at 1-866-246-6990.
<b>Quantity in Commerce</b>	215,703 units
<b>Distribution</b>	Nationwide Distribution
<b>Total Product Life Cycle</b>	<u>TPLC Device Report</u> <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. Learn more about [medical device recalls](#)<sup>28</sup>.

<sup>2</sup> Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.