



[FDA Home](#)<sup>3</sup> [Medical Devices](#)<sup>4</sup> [Databases](#)<sup>5</sup>

**Class 2 Device Recall 9.6F Plastic Dignity MidSized CT port w/PreAttached Silicone Catheter**

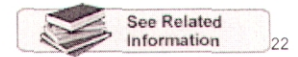


[510\(k\)](#)<sup>6</sup> | [DeNovo](#)<sup>8</sup> | [Registration & Listing](#)<sup>7</sup> | [Adverse Events](#)<sup>10</sup> | [Recalls](#)<sup>11</sup> | [PMA](#)<sup>12</sup> | [HDE](#)<sup>13</sup> | [Classification](#)<sup>14</sup> | [Standards](#)<sup>15</sup> | [CFR Title 21](#)<sup>16</sup> | [Radiation-Emitting Products](#)<sup>17</sup> | [X-Ray Assembler](#)<sup>18</sup> | [Medsun Reports](#)<sup>19</sup> | [CLIA](#)<sup>20</sup> | [TPLC](#)<sup>21</sup>

[New Search](#)

[Back to Search Results](#)

**Class 2 Device Recall 9.6F Plastic Dignity MidSized CT port w/PreAttached Silicone Catheter**



<b>Date Initiated by Firm</b>	February 23, 2017
<b>Date Posted</b>	March 08, 2017
<b>Recall Status<sup>1</sup></b>	Open <sup>3</sup> , Classified
<b>Recall Number</b>	Z-1536-2017
<b>Recall Event ID</b>	<u>76625</u> <sup>23</sup>
<b>510(K)Number</b>	<u>K132177</u> <sup>24</sup>
<b>Product Classification</b>	Port & catheter, implanted, subcutaneous, intravascular <sup>25</sup> - <b>Product Code</b> LJT <sup>26</sup>
<b>Product</b>	9.6F Plastic Dignity Mid-Sized CT Port w/Pre-Attached Silicone Catheter The CT Power Injectable Implantable Infusion Ports are indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples. When used with a power injectable needle, the Power Injectable Implantable Infusion Port device is indicated for power injection of contrast media
<b>Code Information</b>	MRCTI96801 Lot# MHWQ060 S2 , UDI# 884908031232
<b>Recalling Firm/Manufacturer</b>	Medical Components, Inc dba MedComp 1499 Delp Dr Harleysville PA 19438-2936
<b>For Additional Information Contact</b>	Susan M. Smith 215-256-4201
<b>Manufacturer Reason for Recall</b>	The 9.6F port kits were packaged with the incorrect valved peelable introducer. The label states the kit contains a 10F valved peelable introducer. The kit is packaged with a 9F valved peelable introducer. The port lumen will not fit through the introducer during the insertion procedure.
<b>FDA Determined Cause<sup>2</sup></b>	Unknown/Undetermined by firm
<b>Action</b>	Medcomp mailed a Customer Notification letter dated February 23, 2017, to all affected customers to inform them of the issue. Customers were asked to examine their inventory and return all unused product. Distributors were also asked to locate the end user/facility of where the affected product was sold and communicate the recall to them. Customers were instructed to contact their customer service representative for a Returned Goods Authorization (RGA) number if necessary at 215-256-4201. Customers were also instructed to complete and return page 2 of the letter by fax to 215-256-9191. For questions regarding this recall call 215-256-4201.
<b>Quantity in Commerce</b>	71 units
<b>Distribution</b>	Worldwide Distribution to PR and Panama
<b>Total Product Life Cycle</b>	TPLC Device Report <sup>27</sup>