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**Class 2 Device Recall Tearaway Introducer**

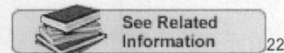


6 510(k)|DeNovo<sup>8</sup> | Registration & Listing<sup>9</sup> | Adverse Events<sup>10</sup> | Recalls<sup>11</sup>|PMA<sup>12</sup>|HDE<sup>13</sup>|Classification<sup>14</sup>|Standards<sup>15</sup>  
 CFR Title 21<sup>16</sup>|Radiation-Emitting Products<sup>17</sup>|X-Ray Assembler<sup>18</sup>|Medsun Reports<sup>19</sup>|CLIA<sup>20</sup>|TPLC<sup>21</sup>

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**Class 2 Device Recall Tearaway Introducer**



<b>Recall Date</b>	June 07, 2016
<b>Recall Status<sup>1</sup></b>	Open
<b>Recall Number</b>	Z-1924-2016
<b>Recall Event ID</b>	<a href="#">74176<sup>23</sup></a>
<b>510(K)Number</b>	<a href="#">K130687<sup>24</sup></a>
<b>Product Classification</b>	<a href="#">Introducer, catheter<sup>25</sup></a> - <a href="#">Product Code DYB<sup>26</sup></a>
<b>Product</b>	Tearaway Introducer, Model # VS203, VS303, 510 K # 130687, packaged individually in a pouch, 5 pouches per carton, lot # MBZ140, MBZL450, MBZV930 MBZZ490  Product Usage: The 2F and 3F Vascu-Sheath Tearaway Introducer is intended for percutaneous venous access by modified Seldinger Technique in neonates, infants and children.
<b>Code Information</b>	Catalog Numbers/Lot Numbers/Exp. Date/UDI Number: VS203 Lot # MBZX140 exp. date 01/18/2021 UDI# 884908105209 VS303 Lot # MBZL450 exp. date 11/14/2020 UDI# 884908105216 VS303 Lot # MBZV930 exp. date 11/01/2021 UDI# 884908105216 VS303 Lot # MBZZ490 exp. date 01/28/2021 UDI# 884908105216
<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>	This recall has been initiated due to the product labeled with the incorrect expiration date.
<b>FDA Determined Cause<sup>2</sup></b>	Labeling mix-ups
<b>Action</b>	MedComp sent a Product Recall letter dated May 5, 2016 to customers. The letter identified the affected product, problem and actions to be taken. Customers were instructed to evaluate their inventory and quarantine for the return of all un-used affected product. They were asked to contact Customer Service for a Return Goods Authorization (RGA) number at 215-256-9191.
<b>Quantity in Commerce</b>	VS203 Lot# MBZX140 (100 units); VS303 Lot # MBZL450 (60 units); VS303 Lot # MBZV930 (65 units); VS303 Lot # MBZZ490 (33 units).
<b>Distribution</b>	US Distributed to: FL, TX, NC
<b>Total Product Life Cycle</b>	TPLC Device Report <sup>27</sup>

<sup>1</sup> For details about termination of a recall see [Code of Federal Regulations \(CFR\) Title 21 §7.55<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.