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## Class 2 Device Recall Sengstaken Tube and SengstakenBlakemore Tube

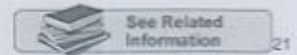


510(k)<sup>7</sup> Registration & Listing<sup>8</sup> Adverse Events<sup>9</sup> Recalls<sup>10</sup> PMA<sup>11</sup> Classification<sup>12</sup> Standards<sup>13</sup> Inspections<sup>14</sup>  
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### Class 2 Recall Sengstaken Tube and SengstakenBlakemore Tube



<b>Date Posted</b>	April 24, 2014
<b>Recall Status<sup>1</sup></b>	Open
<b>Recall Number</b>	Z-1506-2014
<b>Recall Event ID</b>	<u>67648</u> <sup>22</sup>
<b>Premarket Notification 510(K) Numbers</b>	<u>K973892</u> <sup>23</sup> <u>K981203</u> <sup>24</sup>
<b>Product Classification</b>	Tubes, Gastrointestinal (And Accessories) <sup>25</sup> - <b>Product Code</b> KNT <sup>26</sup>
<b>Product</b>	Sengstaken Tube and Sengstaken-Blakemore Tube. Teleflex product codes 204800, 204802, and 204803, a gastrointestinal tube and accessories, consisting of flexible or semi-rigid tubing used for instilling fluids into, withdrawing fluids from, splinting, or suppressing bleeding of the alimentary tract.
<b>Code Information</b>	Lots 10251, 10201, 10301, 10401, 10481, 10381, 11041, 11321, 12151, 12231, 1226, 11201, 12311, 123821, 12474, 13151, 13191, 13211, 13261, 13381
<b>Recalling Firm/ Manufacturer</b>	Teleflex Medical 4024 Stirrup Creek Dr Durham, North Carolina 27703-9000
<b>For Additional Information Contact</b>	Michael T. Taggart 919-433-4816
<b>Manufacturer Reason for Recall</b>	Sterility of the product cannot be guaranteed.
<b>Action</b>	Letters were issued on 3/4/2014 to consignees asking them to immediately discontinue use and quarantine any products with the recalled catalog numbers. Distributors were also asked to conduct a sub-recall. The recall letters included a Recall Acknowledgment Form which was to be faxed back to Teleflex.
<b>Quantity in Commerce</b>	117,801 ea.
<b>Distribution</b>	Worldwide Distribution-USA (nationwide) including the states of AL, AK, AR, CA, CO, FL, GA, ID, IL, IA, KY, LA, MD, MA, MI, MN, MS, MO, NE, NH, NJ, NM, NY, NC, OH, PA, SC, TN, TX, UT, VT, VA, WA, WV, and WI, and the countries of Algeria, Andorra, Armenia, Argentina, Austria, Australia, Azerbaijan, Belarus, Bermuda, Bahamas, Boliva, Brazil, Canada, Chile, China, Costa Rica, Cyprus, Czechoslovakia, Germany Guatemala, Denmark, Estonia, Egypt, Finland, France, Great Britain, Georgia, Guadeloupe, Greece, Guyana, Curacao, Hungary, Israel, India, Italy, Jordan, Japan, Kuwait, Kazakhstan, Luxembourg, Latvia, Libya, Madagascar, Macedonia, Martinique, Malta, Mauritius, Mexico, Nicaragua, Nigeria, Netherlands, Norway, Oman, Peru, French Polynesia, Poland, Portugal, San Marino, Singapore, Spain, Suriname, San Salvador, Thailand, Tunisia, Turkey, Uruguay, Uzbekistan, Wallis & Futuna Islands, Zambia.
<b>Total Product Life Cycle</b>	<u>TPLC Device Report</u> <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>