Class 2 Device Recall Sengstaken Tube and SengstakenBlakemore Tube

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Class 2 Recall
Sengstaken Tube and
SengstakenBlakemore Tube

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Date Posted	April 24, 2014
Recall Status[1]	Open
Recall Number	Z-1506-2014
Recall Event ID	67648[22]
Premarket Notification 510(K) Numbers	K973892[23] K981203[24]
Product Classification	Tubes, Gastrointestinal (And Accessories)[25] - **Product Code** KNT[26]
Product	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.
Code Information	Lots 10251, 10201, 10301, 10401, 10481, 10381, 11041, 11321, 12151, 12231, 1226, 11201, 12311, 123821, 12474, 13151, 13191, 13211, 13261, 13381
Recalling Firm/ Manufacturer	Teleflex Medical 4024 Stirrup Creek Dr Durham, North Carolina 27703-9000
For Additional Information Contact	Michael T. Taggart 919-433-4816
Manufacturer Reason for Recall	Sterility of the product cannot be guaranteed.
Action	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.
Quantity in Commerce	117,801 ea.
Distribution	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.
Total Product Life Cycle	TPLC Device Report[27]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[28]