Class 2 Recall
Medtronic Intersept Tubing Packs

See Related Information[21]

Date Classified	December 28, 2012
Recall Number	Z-0618-2013
Product	Medtronic Intersept Custom Tubing Pack with or without coating (Carmeda BioActive Surfact, Carmeda BioActive Surfact and Trillium Biosurface,or Balance Biosurface) with the following Model numbers: 0E27R16, 1A30R6, 2493R24, 2493R25, 5D56R5, 5Z93R4, 5Z93R5, 7E64R2, 7J53R2, 7M13R1, 7M14R1, 7N16R, 7P25R1, 7P93R1, 7Q11R1, BB7L63R2, BB7N26R, CB5174R11, CB175R13, CB5Q03R6, CB5Q03R7, CB6C53R6, CB7C15R2, CB7C59R2, CB7C60R2, CB7C74R2, CB7D91R5, CB7E35R2, CB7E38R1, CB7G21R4, CB7L48R1, CB7L72R1, CB7P82R1, HY6U96R2, HY6Y52R2, HY7E87R1, SS7J91R3, SSCB7L48R, SSTL7G78R1,TL5S33R7, TL6VTTR1, TL7B51R1, TL7G20R3, TL7G78R3, TL7R87R1. Sterilized Using Ethylene Oxide, Nonpyrogenic, Assembled in Mexico, Manufacturer Medtronic, Inc, Minneapolis, Mn 55432 Product is used by perfusionists as part of the extracorporeal circuit during cardiopulmonary bypass procedures, and is configured specifically as designated by each customer.
Code Information	Pack Model Pack Lot 0E27R16- 11239917 11252800 11264666; 1A30R6- 12132577 12219267; 2493R24- 11187015 11199707 11224309 11227205 11556735; 2493R25- 11646941 11713200 11745242 11813334 11852673 11886412 11990393 12033630 12114699 12178107 12191642 12450856; 5D56R5- 11298229 11357085 11465358 11541270 11601193 11654853 11702415 11745232 11766305 11822320 11838721 11852677 11930380 12024708 12166379 12292156; 5Z93R4- 11713132 11736880 11749958 11766283 11808651 11860604 11878689 11911068 11948473 5Z93R5- 12236493; 12411746 7E64R2- 11933798; 7J53R2- 12172725; 7M13R1- 12168157; 7M14R1- 12349772; 7N16R- 12349786; 7P25R1- 12327801 12449801 12457250; 7P93R1- 12349795 12374420; 7Q11R1- 12344028 12456303; BB7L63R2- 12408737; BB7N26R- 12312571; CB5174R11- 11293051 11315344 11334856 11489271 11745162 11886341 11977682 12019852 12062713 12098852 12139621 12146752 12258941 12277502 12326468 12421465 206110946; CB5175R13- 11292866 11334859 11432873 11442937 12182778 12411655; CB5Q03R6- 11713162 11766245 11787583 11923139 11934952; CB5Q03R7- 12114626; CB6C53R6- 12423767; CB7C15R2- 12411647; CB7C59R2- 11731501; 11813316 11838743 11869767 11908794 11982413 12019907 12146796 12151706 12201727 12292133 12423702; CB7C60R2- 11687047 11724030 11843434 11878672; CB7C74R2- 11895167; CB7D91R5- 11961280 12130493 12146882 12191604 12277455 12411687 12423760; CB7E35R2- 11839101; CB7E38R1- 11843886 11885844 11990360 12105025 12133083 12159400; CB7G21R4- 12032413 12033728 12040524 12083359 12360622; CB7L48R1- 12301694; CB7L72R1- 12155258; CB7P82R1- 12440601; HY6U96R2- 206133995; HY6Y52R2- 11826276; HY7E87R1- 11830948 11898103 11923498 12323794 12435409; SS7J91R3- 12175428; SSCB7L48R- 12120109; SSTL7G78R1 -11986264; TL5S33R7- 12093478; 12139612 12172589 12315375; TL6V77R1- 11217931 11260111; TL7B51R1- 11559097 11622968 11664762 11687063 11712834; TL7G20R3- 12258680 12271138 12360554 TL7G78R3- 12067309; TL7R87R1- 206114578 206145379
Recalling Firm/ Manufacturer	Medtronic Inc. Cardiac Rhythm Disease Management 8200 Coral Sea St NE Saint Paul, Minnesota 55112-4391
Manufacturer Reason for Recall	Medtronic is initiating an Urgent Medical Device Customer Notification. We have confirmed that certain Medtronic Intersept Tubing Packs contain packaging trays that are susceptible to damage that can compromise product sterility.
Action	Medtronic sent a "Urgent Medical Device Customer Notification" letter dated November 19, 2012, to all affected customers. The letter identified the product the problem and the action needed to be taken by the customer. Customers were instructed to immediately identify and quarantine all affected product and to return affected product, but if they have concerns about replacement than they recommend to inspect and return any damaged product.. For further questions please contact your local Medtronic sales representative or Lifeline Technical Services at 1-877-526-7890. Outside the US, please call 1+763-526-7890. We apologize for any inconveniences this issue may have caused you or your institution.
Quantity in Commerce	1552
Distribution	Worldwide Distribution--USA (nationwide) including the states of AZ, CA, CT, FL, GA, IL IA, MD, MA, MI, MS, NJ, NY, OH, OK, SC, TN, TX and WI. and the countries of CANADA and MALAYSIA.

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