Class 2 Device Recall CAPIO, Monodeck

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See Related Information[21]

Date Posted	May 01, 2014
Recall Status[1]	Open
Recall Number	Z-1534-2014
Recall Event ID	67973[22]
Product	CAPIO, Monodeck, Violet Monofilament Polydioxanone Suture, 1 x 48 inches (122cm) Absorbable Surgical Suture, Rx Only, Teleflex Medical. Product Usage: Monodek sutures are absorbable sutures prepared from the polyester, ply (p-dioxanone). The empirical molecular formula of the polymer is (C4H6O3). Monodek is indicated for use in all types of soft tissue approximation, including used in pediatric cardiovascular tissue where growth is expected to occur and ophthalmic surgery. Monodek suture is not indicated in adult cardiovascular tissue, microsurgery and neural tissue. Monodek sutures meet USP except for oversized diameter. Monodek sutures meet EP specifications for diameter. These sutures are particularly useful where the combination of an absorbable suture and extended wound support (up to 6 weeks) is desirable.
Code Information	Product Code: 833-137, Lot numbers: 02A0901938, 02B0901537, 02H1001025, 02H1001026, 02H1001027, 02C1102979, 02C1102983, 02D1300294, 02D1301164, 02C1302078, 02D1302468.
Recalling Firm/ Manufacturer	Teleflex Medical 2917 Weck Dr. Research Triangle Park, North Carolina 27709
For Additional Information Contact	Michael T. Taggart 919-433-4940
Manufacturer Reason for Recall	The product did not meet minimum and/or average minimum Teleflex resorption strength requirements.
Action	Teleflex Medical sent an Urgent Medical Device Recall Notification dated March 11, 2014. The letter identified the affected product, problem and actions to be taken. Custmers were instructed to return all affected product to Teleflex Medical per the instructions on the Urgent Recall Notice. Customers were asked to complete the enclosed Recall Acknowledgement Form and fax to 1-866-804-9881, Attn: Customer Service. For questions contact your local sales representative or Customer Service at 1-866-246-6990.
Quantity in Commerce	7,380 ea (total)
Distribution	Worldwide Distribution - US Nationwide in the states of CA, CO, GA, LA, IL, MA, MI, MN, MO, NC, and in the countries of Ireland and Singapore.

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[23]

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