Class 2 Recall Monodek

See Related Information[21]

Date Posted	April 25, 2014
Recall Status[1]	Open
Recall Number	Z-1509-2014
Recall Event ID	67972[22]
Premarket Notification 510(K) Number	K030212[23]
Product Classification	Suture, Surgical, Absorbable, Polydioxanone[24] - **Product Code** NEW[25]
Product	Monodek Violet Synthetic Absorbable Surgical Sutures, MF 0 TC43/HR26 48
Code Information	Product Code: 833-137, Batch: 02H1103434, 02H1200349, and 02K1201354.
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	Product does not meet minimum knot tensile strength requirements.
FDA Determined Cause [2]	OTHER/UNDETERMINED: Under Investigation by the firm
Action	Consignees were notified by an Urgent Medical Device Recall Notification letter, dated 3/11/2014. The letter identified the affected product and the reason for recall. Customers were instructed to immediately discontinue use of and quarantine any affected product in stock. The affected product is to be returned; and the Recall Acknowledgement Form should be completed and faxed to the number provided regardless of whether customers have affected product in stock. Questions should be directed to a local sales rep or Customer Service at 1-866-246-6990.
Quantity in Commerce	3,072 ea.
Distribution	Worldwide Distribution -- USA, including the state of MA, and the country of Germany
Total Product Life Cycle	TPLC Device Report[26]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[27]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

510(K) Database	510(K)s with Product Code = NEW and Original Applicant = GENZYME BIOSURGERY[28]

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1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php

Class 2 Device Recall Sutures, Nonabsorbable, Silk, Sterile

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Class 2 Recall
Sutures, Nonabsorbable, Silk, Sterile

See Related Information[21]

Date Posted	March 26, 2014
Recall Status[1]	Open
Recall Number	Z-1296-2014
Recall Event ID	67733[22]
Premarket Notification 510(K) Number	K021019[23]
Product Classification	Suture, Nonabsorbable, Synthetic, Polyethylene[24] - **Product Code** GAT[25]
Product	Sutures, Non-absorbable, Silk, Sterile, Rx only, Product Usage: Natural non-absorbable silk surgical suture is a non-absorbable, sterile, flexible multifilament thread composed of an organic protein called fibroin. This protein is derived from the domesticated species Bombyx mori (B. mori) of the family Bombycidae. Natural non-absorbable silk surgical suture is indicated for use in soft tissue approximation. Natural non-absorbable silk surgical suture meets the United States Pharmacopeia (U.S.P.) monograph requirements for Non-absorbable Surgical Suture (class I). Natural non-absorbable silk surgical suture may be braided or twisted; it may be provided uncoated or coated; and it may be undyed or dyed with an FDA listed color additive.
Code Information	Product Code: X-6371M5, Lot numbers: 02E0801603
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 products are being recalled because they did not meet minimum needle attachment strength requirements.
FDA Determined Cause [2]	OTHER/UNDETERMINED: Under Investigation by the firm
Action	Teleflex sent an Urgent Medical Device Recall Notification letter dated March 11, 2014 to all affected customers. The letter identified the affected product, problem and actions to be taken. Customers were instructed to return all affected product to Teleflex Medical per the instructions provided in the letter. Customers were asked to complete the enclosed Recall Acknowledgment Form and fax it 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	Total 32,271 ea.
Distribution	Worldwide Distribution - U.S. Nationwide and the countries of Canada, Germany, and Ireland
Total Product Life Cycle	TPLC Device Report[26]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[27]

Class 2 Device Recall Sutures, Nonabsorbable, Steel, Monofilament and Multifilament, Sterile

Class 2 Recall
Sutures, Nonabsorbable, Steel, Monofilament and Multifilament, Sterile

See Related Information[21]

Date Posted	March 26, 2014
Recall Status[1]	Open
Recall Number	Z-1295-2014
Recall Event ID	67733[22]
Premarket Notification 510(K) Number	K021019[23]
Product Classification	Suture, Nonabsorbable, Synthetic, Polyethylene[24] - **Product Code** GAT[25]
Product	Sutures, Non-absorbable, Steel, Monofilament and Multifilament, Sterile, Rx only, Product Usage: A smooth or threaded metallic bone fixation fastener is a device intended to be implanted that consists of a stiff wire segment or rod made of alloys, such as cobalt-chromium-molybdenum and stainless steel, and that may be smooth on the outside, fully or partially threaded, straight or Ushaped; and may be either blunt pointed, sharp pointed, or have a formed, slotted head on the end. It may be used for fixation of bone fractures, for bone reconstructions, as a guide pin for insertion of other implants, or it may be implanted through the skin so that a pulling force (traction) may be applied to the skeletal system.
Code Information	Product Code: X-4981M4, Lot number: 02J0800451
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 products are being recalled because they did not meet minimum needle attachment strength requirements.
FDA Determined Cause [2]	OTHER/UNDETERMINED: Under Investigation by the firm
Action	Teleflex sent an Urgent Medical Device Recall Notification letter dated March 11, 2014 to all affected customers. The letter identified the affected product, problem and actions to be taken. Customers were instructed to return all affected product to Teleflex Medical per the instructions provided in the letter. Customers were asked to complete the enclosed Recall Acknowledgment Form and fax it 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	Total 32,271 ea.
Distribution	Worldwide Distribution - U.S. Nationwide and the countries of Canada, Germany, and Ireland
Total Product Life Cycle	TPLC Device Report[26]

Class 2 Device Recall Sutures, Absorbable, Synthetic, Polyglycolic Acid.

New Search

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Class 2 Recall
Sutures, Absorbable, Synthetic, Polyglycolic Acid.

See Related Information[21]

Date Posted	March 26, 2014
Recall Status[1]	Open
Recall Number	Z-1294-2014
Recall Event ID	67733[22]
Premarket Notification 510(K) Number	K021019[23]
Product Classification	Suture, Nonabsorbable, Synthetic, Polyethylene[24] - **Product Code** GAT[25]
Product	Sutures, Absorbable, Synthetic, Polyglycolic Acid, Sterile, Rx only, Product Usage: Non-absorbable polypropylene surgical suture is a monofilament, Non-absorbable, sterile, flexible thread prepared from long-chain polyolefin polymer known as polypropylene and is indicated for use in soft tissue approximation.
Code Information	Product Code: BON100, Lot numbers: 02H1302839, 02J1101705, 02D1101137, and 02F1103013.
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 products are being recalled because they did not meet minimum needle attachment strength requirements.
FDA Determined Cause [2]	OTHER/UNDETERMINED: Under Investigation by the firm
Action	Teleflex sent an Urgent Medical Device Recall Notification letter dated March 11, 2014 to all affected customers. The letter identified the affected product, problem and actions to be taken. Customers were instructed to return all affected product to Teleflex Medical per the instructions provided in the letter. Customers were asked to complete the enclosed Recall Acknowledgment Form and fax it 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	Total 32,271 ea.
Distribution	Worldwide Distribution - U.S. Nationwide and the countries of Canada, Germany, and Ireland
Total Product Life Cycle	TPLC Device Report[26]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[27]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

510(K) Database	510(K)s with Product Code = GAT and Original Applicant = GENZYME CORP.[28]

Links on this page:

Class 2 Device Recall Suture, nonabsorbable, synthetic, polyethylene

New Search

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Class 2 Recall
Suture, nonabsorbable, synthetic, polyethylene

See Related Information[21]

Date Posted	March 26, 2014
Recall Status[1]	Open
Recall Number	Z-1293-2014
Recall Event ID	67733[22]
Premarket Notification 510(K) Number	K021019[23]
Product Classification	Suture, Nonabsorbable, Synthetic, Polyethylene[24] - **Product Code** GAT[25]
Product	Sutures, Non-absorbable, Synthetic, Polypropylene, Sterile, Rx only, Product Usage: Non-absorbable polypropylene surgical suture is a monofilament, Non-absorbable, sterile, flexible thread prepared from long-chain polyolefin polymer known as polypropylene and is indicated for use in soft tissue approximation.
Code Information	Product Code: 833-123, Lot numbers: 02A0902858, 02D0900775, 02G1003092, 02H1100535, 02H1100536, & 02K1102309; Product Code: 833-124, Lot numbers: 02A1200503, 02B1101450 & 02C0903400; Product Code: 02D0900010, 02D0900103, 02D1003285, 02D1003286 & 02F1302321; Product Code: 02G1000045, 02G1300348, 02G1301122, 02H1100494, & 02L0803407; Product Code: 02L1100009, 02M1002289, 02M1101933 & 02F1302322; 833-213, Lot number: 02H1100687; Product Code: D-5007K, Lot numbers: 02B1002310, 02C1103731, 02F1100069 & 02H1102294; Product Code: D-5007M4A, Lot number: 02M0902844; Product Code: D-5007M4K, Lot numbers: 02C1002252, & 02F1100124; Product Code: D-7016M4K, Lot number: 02G1301749; Product Code: D-7070K, Lot numbers: 02A1103450 & 02B1002276; Product Code: D-7070M4K, Lot numbers: 02C1103707, 02F1301100, 02G1100876 & 02G1301739; Product Code: D-7076M1K, Lot number: 02H1103237; Product Code: D-7076M4K, Lot numbers: 02F1101036, 02J1301343, and 02K0900010: Product Code: D-7375K, Lot number: 02A1201015; Product Code: D-793M4K, Lot number: 02L1002488; Product Code: ED-6072, Lot numbers: 02C1002218, 02E1002342 & 02J0902517; Product Code: ED-6276, Lot number: 02F0902457; Product Code: ED-6896, Lot numbers: 02A0902278, 02B0900089, 02B0901762, 02C0900661, 02C1002207, 02D0900634, 02D1100186, 02E0901921, 02E0902608, 02E1301581, 02H1300608, 02J0900501, 02K0901590, 02K0902406, 02L0900676, 02M0901869, & 02G1301755; Product Code: ED-853, Lot numbers: 02G1002594, 02B0902976, 02D0902457 & 02M0901348 and Product Code: EP4049N, Lot number: 02A1003137.
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 products are being recalled because they did not meet minimum needle attachment strength requirements.
FDA Determined Cause [2]	OTHER/UNDETERMINED: Under Investigation by the firm
Action	Teleflex sent an Urgent Medical Device Recall Notification letter dated March 11, 2014 to all affected customers. The letter identified the affected product, problem and actions to be

Class 2 Device Recall Suture, nonabsorbable, synthetic, polyethylene.

Class 2 Recall
Suture, nonabsorbable, synthetic, polyethylene.

See Related Information[21]

Date Posted	March 26, 2014
Recall Status[1]	Open
Recall Number	Z-1292-2014
Recall Event ID	67733[22]
Premarket Notification 510(K) Number	K021019[23]
Product Classification	Suture, Nonabsorbable, Synthetic, Polyethylene[24] - **Product Code** GAT[25]
Product	Sutures, Non-absorbable, Synthetic, Polyethylene, Sterile, Rx only, Product Usage: Non-absorbable poly(ethylene terephthalate) surgical suture is a multifilament, non-absorbable, sterile, flexible thread prepared from fibers of high molecular weight, long-chain, linear polyesters having recurrent aromatic rings as an integral component and is indicated for use in soft tissue approximation.
Code Information	Product Code: 0100019-507, Lot number: 02F1301128; Product Code: 6-511, Lot number: 02M0800561; Product Code: 6-559, Lot number: 02A0800005; Product Code: 69-403, Lot number: 02H0802530; Product Code: 7-5008M4, Lot number: 02C0900466; Product Code: 7-518, Lot number: 02E1302561; Product Code: 7-565, Lot number: 02B1100185; Product Code: 7-655A, Lot numbers: 02C0901963 & 02M0800836; Product Code: 7-740, Lot number: 02L1000536; Product Code: 833-114, Lot numbers: 02A1202112, 02C0903374 & 02D1202794; Product Code: 02F0902697, 02K1100404, 02L1202369 & 02M0802509; Product Code: E13-6351, Lot number: 02F0902446; Product Code: E13-6354, Lot number: 02F0902439; Product Code: E13-6399, Lot number: 02F0902436; Product Code: E6-545, Lot number: 02F0902443; Product Code: E7-4578, ot number: 02D0901672; Product Code: H5300, Lot number: 1450153E13; Product Code: RN6-5106M5, Lot number: 02F1003837; Product Code: RN7-536M5, Lot number: 02A0801205; Product Code: TEV100, Lot number: 02G1101500; Product Code: V-2599, Lot number: 02F0802055; Product Code: X-5424, Lot number: 02B0900765; Product Code: X6-692W, Lot number: 02C0803135; Product Code: X7-655M6A, Lot number: 02A0900806, 02A0902742, 02C0900446 & 02H1003233 and Product Code: XF7-7011, Lot numbers: 02A0901594.
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 products are being recalled because they did not meet minimum needle attachment strength requirements.
FDA Determined Cause [2]	OTHER/UNDETERMINED: Under Investigation by the firm
Action	Teleflex sent an Urgent Medical Device Recall Notification letter dated March 11, 2014 to all affected customers. The letter identified the affected product, problem and actions to be taken. Customers were instructed to return all affected product to Teleflex Medical per the instructions provided in the letter. Customers were asked to complete the enclosed Recall Acknowledgment Form and fax it to 1-866-804-9881, Attn: Customer Service. For questions contact your local sales representative or Customer Service at 1-866-246-6990.