Class 2 Device Recall Deknalok[6]

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Class 2 Recall Deknalok

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Date Posted	May 01, 2014
Recall Status[1]	Open
Recall Number	Z-1535-2014
Recall Event ID	67973[22]
Product	Dekna-lok, 1 x 17.78 cm, Violet Braided Polyglycolic Acid Coasted Suture, Synthetic Absorbable Surgical Suture USP, Rx Only, Sterile. Product Usage: Bondek Plus sutures are braided synthetic absorbable sterile surgical suture composed of a homopolymer of glycolic acid. Bondek plus is provided coated. The substances contained in the coasting and suture are noncollagenous and nonantigenic. The suture is available dyed (violet) or undyed. Bondek Plus synthetic absorbable suture meets all re1uirements established by the United States Pharmacopeia (USP) for absorbable surgical suture and the European Pharmacopeia for Sterile Synthetic absorbable braided sutures. Bondek Plus is indicated for use in general soft tissue approximation and/or ligation, including in ophthalmic procedures, but not for use in cardiovascular and neurological procedures.
Code Information	Product Code: 200101-01, Lot # 02F0801290 and Product Code: BP1000V2L, Lot numbers: 02C1003535 & 02F1000711.
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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