**Class 2 Recall**

**Deknalok**

**Date Posted:** May 01, 2014  
**Recall Status:** Open  
**Recall Number:** Z-1535-2014  
**Recall Event ID:** A27972  
**Product:** Deknalok, 1 x 17.73 cm. Violet Braided Poliglycolic Acid Coated 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 coating and suture are noncollagenous and nonantigenic. The suture is available dyed (ivory) or undyed. Bondek Plus synthetic absorbable suture meets all requirements 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 # 02F08012590 and Product Code: BP1000V2L, Lot numbers: 02C01003535 & 02F1000711.

**Recalling Firm/Manufacturer:** Teledex Medical  
2817 Weck Dr.  
Research Triangle Park, North Carolina 27709

**For Additional Information Contact:** Michael T. Taggart  
019-433-4940

**Manufacturer Reason for Recall:** The product did not meet minimum and/or average minimum Teledex resorption strength requirements.

**Action:** Teledex Medical sent an Urgent Medical Device Recall Notification dated March 11, 2014. The letter identified the affected product, problem and actions to be taken. Customers were instructed to return all affected product to Teledex Medical per the instructions on the Urgent Recall Notice. Customers were asked to complete the enclosed Recall Acknowledgment Form and fax to: 1-866-904-9891, Attn: Customer Service. For questions contact your local sales representative or Customer Service at 1-866-246-6990.

**Quantity in Commerce:** 7,330 ca (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.

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1 For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §5.55

Links on this page:
3. [http://www.fda.gov/default.htm](http://www.fda.gov/default.htm)

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