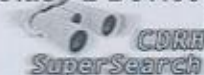


FDA Home³ Medical Devices⁴ Databases⁵

Class 2 Device Recall Deknalok

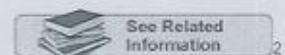


510(k)⁷ Registration & Listing⁸ Adverse Events⁹ Recalls¹⁰ PMA¹¹ Classification¹² Standards¹³ Inspections¹⁴
CFR Title 21¹⁵ Radiation-Emitting Products¹⁶ X-Ray Assembler¹⁷ Medsun Reports¹⁸ CLIA¹⁹ TPLC²⁰

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Class 2 Recall Deknalok



| | |
|---|---|
| Date Posted | May 01, 2014 |
| Recall Status¹ | Open |
| Recall Number | Z-1535-2014 |
| Recall Event ID | <u>67973</u> ²² |
| Product | Dekna-lok, 1 x 17.78 cm, Violet Braided Polyglycolic 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 (violet) 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 # 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. Customers 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 §7.55²³

Links on this page:

1. <http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdomain>
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