Class 2 Recall
TiMagna Fx WasherTiVersaFXII
Femoral Fixation System S/C Plates

See Related Information[21]

Date Classified	November 01, 2013
Recall Number	Z-0129-2014
Product	Ti-Magna Fx Washer Ti-Versa-FX®II Femoral Fixation System S/C Plates The compression tube/plates of this trauma system are used with Ti-Versa-Fx® II Femoral Fixation System lag screws for the internal fixation of proximal femoral and supracondylar fractures. The Ti-Magna Fx System is an osteosynthesis item for orthopedic use in open internal fixation of fractures of the femoral neck, condyle, or tibia, etc. The washer prevents the screw head from being buried in the bone.
Code Information	00365888 00366414 60004449 60146383 60186345 60197210 60208698 60282431 60389889 60405108 60407931 60869220 61080693 61327948 61375455 61754656 61923922 60004450 60208699 60276711 60282432 60869221 61080694 61391007 60024174 61080695 61328382 61375457 61421602 24416600 60084846 60154683 60186372 60197211 60199098 60266079 60266080 60279692 60373565 60405109 60407932 60415506 60428806 60586953 60725599 61041311 61261269 61287734 61309831 61391008 61698392 61732770 61933545 60024175 60146386 60186373 60197212 60208702 61041313 61375459 61505519 61895287 62020570 60390423 60407933 60855531 60855535 60855536 60855537 61261270 23318000 23349600 60065066 60088732 60118716 60126399 60137449 60150012 60160727 60252568 60282398 60321685 60341615 60373346 60407903 60415261 60463630 60582482 60629012 60665668 60665669 60676030 60830532 60926411 60982760 61041155 61041156 61052948 61079688 61088994 61228687 61426136 61559639 61599273 61683731 61732260 61765106 61804102 61829985 61853628 61885960 61926992 61992671 62058073 62152073 62157809
Recalling Firm/ Manufacturer	Zimmer, Inc. 345 E Main St Warsaw, Indiana 46580-2746
Manufacturer Reason for Recall	Zimmer recently conducted a review of historic packaging validations completed. Based on this review, it was determined that a subset of product packaged at a single Zimmer facility required testing to ensure that previously packaged product from this facility met the established requirements for sterile barrier integrity. The number of samples required for packaging testing, to provide statisti
Action	The firm, Zimmer Inc., sent a letter entitled "Voluntary Recall of Ti-VFxII Condylar Tube Plates and Ti-Washers" dated September 12, 2013 to its customer. The letter described the product, problem and action to be taken. The customer was instructed to immediately discontinue use of the listed products. A Sales representatives from Zimmer K.K. or agencies will be in contact with you. Zimmer Inc. is planning to resume product manufacturing upon the completion of package validation review. Zimmer K.K. will contact you when a detailed schedule has been determined. If you have any questions, contact Zimmer K.K. Safety Office (9:00 to 17:00; closed weekends and public holidays) TEL: 0120-015-180.
Quantity in Commerce	2,632 devices
Distribution	International distribution: Japan only.

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10. /scripts/cdrh/cfdocs/cfRES/res.cfm
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15. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm