Class 2 Recall
Centurion Sterile 84 Rubber Bands

See Related Information[21]

Date Posted	December 06, 2013
Recall Status[1]	Open
Recall Number	Z-0464-2014
Product	Centurion Sterile # 84 Rubber Bands Reorder EB84, Caution: This product contains natural rubber latex which may cause allergic reactions. LATEX FREE , CAUTION: FEDERAL IAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN Single Use Only bands items together and podiatry office uses bands as tourniquet on toe during in grown toenail procedure
Code Information	EB84, Lot 2013041801 Expriation 2018/03
Recalling Firm/ Manufacturer	Centurion Medical Products Corporation 301 Catrell Dr Howell, Michigan 48843-1703
For Additional Information Contact	Matthew K. Price, 517-546-5400
Manufacturer Reason for Recall	Package labeling indicates both "latex free" and "contains natural rubber latex" . The rubber bands do contain natural rubber latex. This could cause a significant risk to users with latex allergies.
FDA Determined Cause [2]	MISBRANDING: Labeling False and Misleading
Action	Centurion sent a Urgent Recall Notification letter via Certified Mail October 31, 2013, return receipt to all affected customers. The affected Centurion Medical Products Corporation sales representatives were notified via email on October 28, 2013. Customers were instructed to destroy all implicated product and complete the accountability record included with the notice and fax to 517-546-3356. Customers were asked to forward a copy of the notice if product was further distributed. Additional notices will be mailed to non-responsive customers via Certified Mail Return Receipt, and will be documented in the recall file. For further questions please call (517) 546-5400.
Quantity in Commerce	500 lots
Distribution	US Distribution including the states of GA, LA and NY.

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[22]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

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