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Class 2 Device Recall CRN Crono

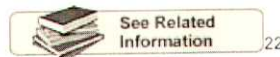


510(k)⁷ | DeNovo⁸ | Registration & Listing⁹ | Adverse Events¹⁰ | Recalls¹¹ | PMA¹² | Classification¹³ | Standards¹⁴
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Class 2 Recall CRN Crono



Date Posted	October 21, 2014
Recall Status¹	Open
Recall Number	Z-0099-2015
Recall Event ID	<u>66541</u> ²³
Product	CRN Crono Syringe CRN20 with 19G x 1 "Steel Needle"
Code Information	Product Code CRN20, lot numbers 14N02, 15E01, 15A02
Recalling Firm/ Manufacturer	Intra Pump Infusion Systems 920 Minters Chapel Rd Ste 200 Grapevine, Texas 76051-1302
Manufacturer Reason for Recall	Product has the potential to have a clear debris on the tip of the needle.
Action	Cane S.p.A. Medical Technology sent an Urgent: Correction and Removal Action Required letter dated October 21, 2013, to all affected customers. The letter identified the product the problem and the action needed to be taken by the customer. Actions to be taken: a. Stop using the 19G x 11/2" 1.10 x 40mm steelneedle included in the CRONO Syringe blister pack. B. Safely discard the 19G x 11/2" 1.10 x 40mm steel needle into a Sharps container. c. Use a TRANSFER DEVICE (e.g., Needleless adapter with female-to-female luer connector) or alternative device to transfer medications into the CRONO syringe. d. For intravenous infusions, we are recommending that a filter also be used during infusions. e. Complete the required 'Acknowledgment and Receipt Form' and fax back to our Distributor; Intra Pump Infusion Systems at 630-845-2768. Contact Information for our US Distributor: INTRA PUMP INFUSION SYSTEMS " Monday through Friday 8:00am to 5:00pm CST, TollFree: 1-866- 211-7867 " Direct: 630-845-7867 " Fax: 630-845-2768 www.Intrapump.com.
Quantity in Commerce	25,440 pieces
Distribution	US Distribution including the states of CA, PA, MA, IL, OH and NY., and Internationally to Canada.

¹ For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55²⁴

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