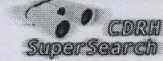


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Medical & Radiation Emitting Device Recalls

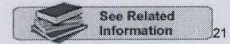


510(k)⁷|Registration & Listing⁸|Adverse Events⁹|Recalls¹⁰|PMA¹¹|Classification¹²|Standards¹³|Inspections¹⁴
CFR Title 21¹⁵|Radiation-Emitting Products¹⁶|X-Ray Assembler¹⁷|Medsun Reports¹⁸|CLIA¹⁹|TPLC²⁰

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**Class 2 Recall
CareFusion Gravity Set**



Date Classified	September 26, 2013
Recall Number	Z-2281-2013
Product	CareFusion Gravity Set, Model #44000-07 The CareFusion Gravity Sets are used to administer fluid and medication through a needle or catheter inserted into the patient's artery or vein. The CareFusion Gravity Set is comprised of components commonly found on intravascular administration sets and extension sets. It includes a check valve, injection ports, 4-way stopcock, anti-siphon valve, roller clamp and tubing.
Code Information	Lot Numbers: 12086930, 12106215, 13016408, 13016834, 13025446, and 13025672.
Recalling Firm/ Manufacturer	CareFusion 303, Inc. 10020 Pacific Mesa Blvd San Diego, California 92121-4386
Manufacturer Reason for Recall	CareFusion is recalling the Gravity Set (Model 44000-07) because of an incorrect expiration date. The affected lot numbers of the Gravity Set are labeled with a 5 year expiration instead of three (3) years.
Action	CareFusion sent an Urgent Medical Device Recall Notification letter dated August 30, 2013, to all affected customers to inform them that CareFusion is recalling the Gravity Set, Model 44000-07, Lot Numbers 12086930, 12106215, 13016408, 13016834, 13025446 and 13025672 as a result of an incorrect expiration date. The letter informs the customers of the problem identified, issues, potential risk, and the immediate actions to be taken. Customers are instructed to complete the customer response form and return the form to CareFusion. Customers are instructed to return recalled products directly to distributors. A distributor letter will also be sent to distributors on August 30, 2013, to inform them of the problems identified and the actions to be taken. Distributors are instructed to contact the Customer Support Team, return customer response form, and if they have questions then they are instructed to contact the CareFusion Support Center at 1-800-562-6018. For questions regarding this recall call 858-617-4000.
Quantity in Commerce	2,850 units
Distribution	IL

Links on this page:

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2. <http://www.addthis.com/bookmark.php>
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4. <http://www.fda.gov/MedicalDevices/default.htm>
5. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm>
6. </scripts/cdrh/devicesatfda/index.cfm>
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11. </scripts/cdrh/cfdocs/cfPMA/pma.cfm>
12. </scripts/cdrh/cfdocs/cfPCD/classification.cfm>
13. </scripts/cdrh/cfdocs/cfStandards/search.cfm>
14. </scripts/cdrh/cfdocs/cfTPLC/inspect.cfm>
15. </scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm>
16. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
17. </scripts/cdrh/cfdocs/cfAssem/assembler.cfm>
18. </scripts/cdrh/cfdocs/Medsun/searchReportText.cfm>
19. </scripts/cdrh/cfdocs/cfClia/Search.cfm>
20. </scripts/cdrh/cfdocs/cfTPLC/tplc.cfm>
21. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/relateditems.cfm?page_title=medical%20device%20recalls&item1_text=medical%20device%20recalls%20&item1_url=www.fda.gov/medicaldevices/safety/recalls/correctionsremovals/listofrecalls/default.htm&item2_text=fda%20enforcement%20report%20index&item2_url=www.fda.gov/safety/recalls/enforcementreports/default.htm