



# California Medical Device Recall Information



## Recall Name

**Iradimed Corporation Recalls MRidium 3860+ Infusion Systems  
Equipped with MRidium 1145 Dose Error Reduction System Drug Library Kit  
Due to Incorrect Recommend Infusion Rate Value**

Recall Date	Product Description	Recalling Firm	Recall Reason
7/01/13	MRidium 3860+ Infusion Systems with MRidium 1145 Dose Error Reduction System (DERS) Drug Library Kit	<b>Iradimed Corp.</b> Winter Park, FL	<i>Potential for an incorrect recommended value for the pump infusion rate during initial infusion setup.</i>
Recall Class	Product Identification	Distribution	Affected Dates
I	Suspect <b>Part 1145 Lot Numbers</b> Recalled:  4501,4510, 4538, 4587, 4596, 4675, 4690, 4705, 4738, 4748, 4960, 4970, 5001, 5065, 5104, 6164, 5221, 5240, 5349, 5361, 5517, 5737, 5764, 5881, 6006, 6151, 6170, 6180, 6252, 6470, 6583, 6806, 6881, 6984, and 7213.	CA, nationwide	Distributed from October 6, 2011 through June 28, 2013

FOR ADDITIONAL INFORMATION, PLEASE VISIT:

<http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm364659.htm>