



California Medical Device Recall Information



Recall Name

DePuy Synthes Recalls Craniomaxillofacial (CMF) Distraction System Due to Potential for Post-Operative Device Reversal

Recall Date	Product Description	Recalling Firm	Recall Reason
04/16/14	Craniomaxillofacial (CMF) Distraction System (AB Distractor Bodies and BC Distractor Bodies)	Synthes (USA) West Chester, PA	<i>The AB and BC Distractor Bodies used in the Craniomaxillofacial Distraction System may reverse post-operatively.</i> <i>Should this occur, the patient may need prolonged distraction therapy or revision surgery.</i>
Recall Class	Product Identification	Distribution	Affected Dates
I	Refer to the letter below for affected part and lot numbers: <u>Customer Notification Letter</u>	Nationwide	Manufacturing Dates: April 20, 2009 through April 15, 2011 Distribution Dates: November 3, 2009 to April 14, 2014

FOR ADDITIONAL INFORMATION, PLEASE VISIT:

<http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm411589.htm>