



California Medical Device Recall Information



Recall Name

Medtronic Recalls Deep Brain Stimulation (DBS) Lead Kits and Dystonia Therapy Kits Due to Potential for Lead Damage During Surgery

Recall Date	Product Description	Recalling Firm	Recall Reason
02/08/13	<ul style="list-style-type: none"> DBS Lead Kits Dystonia Therapy Kits 	Medtronic Neuromodulation [a Div. of Medtronic, Inc.] Minneapolis, MN	<i>Reports of leads being damaged when the lead cap was used during implant surgery. Lead replacement may be required or optimal therapy may not be achieved.</i>
Recall Class	Product Identification	Distribution	Affected Dates
I	DBS Lead Kit models: <ul style="list-style-type: none"> 3387 3387S 3389 3389S 3391 3391S Dystonia Therapy Kit models: <ul style="list-style-type: none"> 3317 3319 3337 3339 	CA , nationwide, international	Kits distributed between April 2006 and February 28, 2013.

FOR ADDITIONAL INFORMATION, PLEASE VISIT:

<http://www.fda.gov/Safety/Recalls/ucm350691.htm?source=govdelivery>