



California Medical Device Recall Information



Recall Name

Codman Neuro Recalls TRUFILL n-BCA Liquid Embolic System Due to Incorrect Instructions for Use

Recall Date	Product Description	Recalling Firm	Recall Reason
10/11/13	<p>TRUFILL n-Butyl Cyanoacrylate (n-BCA) Liquid Embolic System</p> <p><i>Contains n-Butyl Cyanoacrylate (n-BCA), TRUFILL Ethiodized Oil, and TRUFILL Tantalum Powder.</i></p>	Codman Neuro Raynham, MA	<p><i>The product's Instructions For Use (IFU) contains an incorrect statement describing a suggested mixing ratio for use in certain treatment conditions.</i></p> <p><i>The use of the incorrectly mixed product can result in the liquid mixture solidifying too slowly in the intended areas, and unintended embolization or reflux into arteries and pulmonary vessels.</i></p>
Recall Class	Product Identification	Distribution	Affected Dates
I	<p>All lots:</p> <p>Product Code: 631400 Two 1 gram tubes n-BCA</p> <p>Product Code: 631500 One 1 gram tube n-BCA</p>	CA, nationwide	<p>Manufactured between February 25, 2010 and October 31, 2013.</p> <p>Distributed from February 2010 through October 2013.</p>

FOR ADDITIONAL INFORMATION, PLEASE VISIT:

<http://www.fda.gov/Safety/Recalls/ucm382496.htm>