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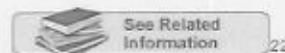
## Class 2 Device Recall ENDOTAK RELIANCE SG



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Class 2 Recall  
ENDOTAK RELIANCE SG

<b>Date Posted</b>	August 05, 2014
<b>Recall Status<sup>1</sup></b>	Open
<b>Recall Number</b>	Z-2147-2014
<b>Recall Event ID</b>	<u>68700<sup>23</sup></u>
<b>Premarket Approval PMA Number</b>	<u>P910073/S115<sup>24</sup></u>
<b>Product Classification</b>	<u>Implantable Cardioverter Defibrillator (Non-Crt)<sup>25</sup> - Product Code LWS<sup>26</sup></u>
<b>Product</b>	Boston Scientific ENDOTAK RELIANCE® SG, transvenous defibrillation lead, Models 0180 & 0292, Sterile EO. Product Usage: The ENDOTAK RELIANCE leads provide pacing and rate-sensing and deliver cardioversion and defibrillation shocks for automatic implantable cardioverter defibrillator (AICD) systems.
<b>Code Information</b>	Model 0180 s/n 310735 & 310892. Model 0292 s/n 130450, & 309339.
<b>Recalling Firm/ Manufacturer</b>	Boston Scientific CRM Corp 4100 Hamline Ave N Saint Paul, Minnesota 55112-5700
<b>For Additional Information Contact</b>	Local Sales Representative 800-227-3422
<b>Manufacturer Reason for Recall</b>	A review of manufacturing test records for Boston Scientific ENDOTAK RELIANCE implantable leads revealed a suspected test data recording error. Specifically, some test results were recorded as "failed" without any other indication of failure. There are no reported injuries from the devices.
<b>FDA Determined Cause<sup>2</sup></b>	PRODUCTION CONTROLS: Software Manufacturing/Software Deployment
<b>Action</b>	Sales representatives hand delivered a Boston Scientific "Medical Device Retrieval" Letter dated June 19, 2014 or June 20, 2014 when they were retrieving the devices from the hospital shelves. The letter was addressed to Hospital Administrator. The letter described the problem, product being recalled and the retrieval of the device by Boston scientific sales representative. For further questions they can contact their local sales representative or Boston Scientific International Technical Services. Physicians were contacted via telephone starting on July 6, 2014. A Boston Scientific letter dated July 8, 2014 followed the telephone conversation. For further information physicians can contact their local Boston Scientific representative or Technical Services at 1-800-227-3422.
<b>Quantity in Commerce</b>	21
<b>Distribution</b>	Worldwide Distribution -US (nationwide) in the states of OH, MN and country of France
<b>Total Product Life Cycle</b>	<u>TPLC Device Report<sup>27</sup></u>

<sup>1</sup> For details about termination of a recall see [Code of Federal Regulations \(CFR\) Title 21 §7.55<sup>28</sup>](#)

<sup>2</sup> Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.