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Medical Device / Equipment RECALL

Date Issued : 7 April 2008 **Ref:MDB/R/2008/001**

IMMEDIATE ACTION	√
ACTION	
UPDATE	
INFORMATION REQUEST	

PRODUCT	**Implantable Cardioverter Defibrillator (ICD) lead. Sprint Fidelis manufactured by Medtronic**, Model numbers: 6930, 6931, 6948 and 6949.
CLASS	Not Mentioned By The Manufacturer
USE	Implantable Defibrillator
SOURCE OF MEDICAL DEVICE RECALL / ALERT	MHRA website, date issued: 19th October 2007
RECALLING FIRM	Medtronic International Ltd.
REASON FOR RECALL	ICD lead recall due to risk of inappropriate patient shocks, loss of defibrillation therapy and/or loss of pacing output, caused by fracture of the lead conductor. The MHRA has received 23 reports of lead conductor fracture for the above models (6930, 6931, 6948 and 6949), among approximately 6900 leads distributed in the United Kingdom. This includes one ongoing investigation of a fatality which may have been a consequence of lead fracture. Fractures typically occur at two main sites on the lead: one at the ring electrode affecting the anode conductor; the second near the anchoring sleeve tiedown affecting the cathode conductor and occasionally the high voltage conductor. In the UK, incident reports have included:

	• delivering a number of inappropriate shocks • oversensing caused by noise on the lead • an increase in the pace/sense or shock lead impedance. Medtronic has informed the MHRA that it is suspending distribution of all models of the Sprint Fidelis lead and is recalling all un-implanted stock. The company communicated this to all its customers in its 'Urgent Medical Device Information' issued on 15 October 2007. This provides important programming advice to help increase the chance of early detection of lead fracture, and reduce the risk of inappropriate therapy. However, **it is important to note that all ICD leads, not only Medtronic's Sprint Fidelis models, are associated with a small risk of conductor fracture once implanted**, and **the steps identified in Medtronic's notice would not necessarily identify fractures in all cases.**
SCENARIO IN MALAYSIA	No details available at this moment.
ACTION	If the device is available, clinician should:- Follow up all patients as soon as practicable, ideally within eight weeks. − Review the following parameters which can indicate lead fracture: □ number of inappropriate shocks □ oversensing and noise on the RV Lead □ an increase in the lead impedance □ an increase in the noise sensing on the noise integrity counter. − Consider provocative testing (eg shoulder/arm movements, and deep respiration by the patient), which may help confirm a suspected lead fracture, although this diagnostic method should not be relied upon alone. − Programme the patient's ICD where appropriate to the following parameters as outlined in Medtronic's 'Urgent Medical Device Information': **To reduce inappropriate shocks due to oversensing**: • Program VF detection for initial number of intervals to detect (NID) to nominal settings (18/24) or longer at clinical discretion and redetect NID to nominal settings of

	(12/16). • Where clinically appropriate increase the number of intervals to detect in the VT zones. **To increase the chance of detection of lead fracture** • Turn ON patient alert pacing, RV and SVC defibrillation impedance. • To optimise effectiveness of the lead impedance alert: − Review V pacing lead performance trend to determine typical chronic impedance value for the patient (typical values for Fidelis leads should be 350-1,000 ohms). − Programme lead impedance alert threshold for RV pacing to 1,000 ohms if the typical chronic impedance for the patient is ≤ 700 ohms, or − Programme lead impedance alert threshold for RV pacing to 1,500 ohms if the typical chronic impedance for the patient is > 700 ohms. − Programme lead impedance alert threshold for RV defibrillation and SVC defibrillation to 100 ohms
RECOMMENDATION	To all users and healthcare providers having the abovementioned device used in their premises. Users of the abovementioned device should contact the distributors of this device (if available) and inform the Medical Devices Bureau, Ministry of Health providing the following information:- a. Name of healthcare centre/hospital/clinic b. Contact person and contact number c. Numbers of units available
CONTACT/ENQUIRIES	Medtronic International Ltd.-Malaysia Branch F-39-7 CREST, 3 Two Square No. 2, Jalan 19/1 46300 Petaling Jaya Selangor Darul Ehsan Tel:- 03-79534800
REFERENCES	https://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON2032785