IRISH MEDICINES BOARD

Notice Information: Medical Devices - Recall 15 October 2007

Part 1. Product Information

a)	Title:	Recall of Medtronic Sprint Fidelis Defibrillation Leads
b)	Product Name/Type:	Medtronic Sprint Fidelis Defibrillation Leads
c)	Reference:	V3710
d)	Manufacturer/Supplier:	Medtronic Inc.

Part 2. Problem/Issue

a)	Problem/Issue:	The Irish Medicines Board (IMB) today confirmed that Medtronic Inc. has voluntarily suspended worldwide distribution of the Sprint Fidelis family of defibrillation leads and is recalling any unused leads because of the potential for lead fractures. The vast majority of Sprint Fidelis leads should continue to function normally; however, where a lead actually breaks, or 'fractures', this may result in an audible alert or may cause inappropriate shocks and / or loss of device function. The IMB are advising any patients who believe they may have a Sprint Fidelis lead to contact their cardiologists and seek medical advice. Following consultation with an independent group of experts, Medtronic Inc. are currently recommending that patients do not require automatic replacement of Sprint Fidelis leads, as the risks of removal or insertion of another lead exceed the small risk to patients of a lead fracture. Medtronic Inc. has been in contact with cardiologists to inform them of the issue and provide them with follow up recommendations. Medtronic Inc. recommends against the further implantation of Sprint Fidelis Leads (models: 6930, 6931, 6948, 6949). It is important to note that the Sprint Fidelis leads are not used with standard pacemaker devices but are used only with more specialist Implantable Cardioverter Defibrillators (ICDs) and Cardiac Resynchronization Therapy – Defibrillators (CRT-Ds) devices. Medtronic Inc. has informed the IMB that since October 2004 approximately 1178 Sprint Fidelis leads have been implanted in patients in 14 centres in Ireland. The IMB are advising any patients who believe they may have a Sprint Fidelis lead to contact their cardiologists and seek medical advice. Medtronic Inc. is continuing to investigate the root cause of the lead fractures. The IMB will continue to be in close communication with the manufacturer to ensure that this recall is conducted efficiently in Ireland. Recall of Medtronic Sprint Fidelis Defibrillation Leads

Part 3. Enquiries

a)	All enquiries should be made to:	Siobhan Molloy Telephone: 01-6760168 Weber Shandwick FCC or 086-8175066

Part 4. Keywords

a)	Keywords:	Recall, Medtronic Sprint Fidelis Defibrillation Leads