

Safety Updates on Cardiovascular Implants

*Cordis OPTease® Retrievable Vena Cava Filter
St. Jude Medical Fortify™ ST ICD*

ADHERENCE TO INSTRUCTION-FOR-USE (IFU) GUIDELINES IN THE ORIENTATION OF CORDIS OPTease® RETRIEVABLE VENA CAVA FILTER

The OPTease® Retrievable Vena Cava Filter offers a non-permanent implantation option and is indicated for the prevention of pulmonary embolism (PE) via percutaneous placement in the inferior vena cava in patients considered to be at high risk of PE.

Healthcare professionals are urged to adhere to the guidelines in the Cordis OPTease® Retrievable Vena Cava Filter Instruction-for-Use (IFU).

Background

It has been published that following implantation of a vena cava filter, patients may be exposed to long-term complications of deep vein thrombosis, caval thrombosis, caval perforation, and guidewire entrapment.¹ Although such risks can be mitigated with a non-permanent vena cava filter, it remains crucial that these non-permanent implants are placed in accordance to the IFU guidelines to prevent other complications.

From the global post-market safety surveillance conducted by Cordis Corporation ("Cordis"), it has been observed that there is a rising trend where the OPTease® Retrievable Vena Cava Filter was implanted in an orientation opposite to what was specified in the IFU. The OPTease® Retrievable Vena Cava Filter had been placed with the retrieval hook oriented towards the superior vena cava instead of the caudal position, which should be the correct orientation. Further investigation by Cordis found that this was either done inadvertently or intentionally by the implanting physician.

As of April 2013, Cordis has received a total of 16 overseas reports involving the incorrectly orientated filter being implanted in the patient. In addition, four of these reports had complications where the device migrated to the right heart. No deaths had been reported.

Local situation

To date, HSA has not received any local adverse event reports relating to this issue. Johnson & Johnson Medical Singapore had issued a Dear Healthcare Professional Letter* in April 2013 to inform affected physicians of this concern.

Corrective actions and call to reporting

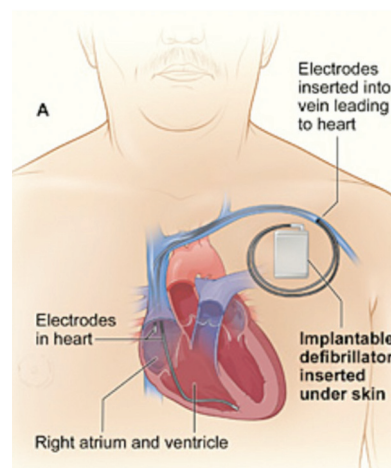
Cordis is in the process of updating the product IFU and supplementing the labelling to further highlight the importance of the correct orientation of the filter and the potential consequences of failing to do so. To ensure the corrective actions taken are effective, complaint rate will be tracked for 6 months upon implementation of the actions. Healthcare professionals are encouraged to report any adverse events related to CORDIS OPTease® Retrievable Vena Cava Filter to the Vigilance Branch.

References

1 *Applied Radiology* 2006; 35(0): 18-23

*A copy of the DHCPL can be found on the MOH Alert database accessible via the professional council websites. All FSCAs were communicated to the affected consignees either through a DHCPL or a Field Safety Notice (FSN).

PRECAUTIONS TO BE TAKEN DURING SOFTWARE UPGRADE OF ST. JUDE MEDICAL FORTIFY™ ST ICD



Source: National Heart, Lung, and Blood Institute; National Institutes of Health; U.S. Department of Health and Human Services.

HSA would like to update healthcare professionals of the potential for St. Jude Medical Fortify™ ST Implantable Cardioverter Defibrillator (ICD) to over-sense and deliver an inappropriate high voltage therapy to the patient.

Fortify™ ST Implantable ICD allows continuous ST segment monitoring and is intended to provide ventricular anti-tachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.

Background

It was noted that when Fortify™ ST Implantable ICD is undergoing a software upgrade, the device will temporarily enter the back-up mode with different parameter settings. These settings may lead to an over-sensing of the patients and result in the device delivering an inappropriate voltage. Given that every patient's cardiovascular physiology differs, patients with intrinsic heart rates higher than 70bpm and large amplitude T-waves are at a greater risk when an inappropriate high voltage therapy is delivered during the software upgrading.

As of April 2013, St. Jude Medical has received 15 overseas complaints involving inappropriate high voltage therapy delivered during the software upgrading for Fortify™ ST Implantable ICD. No deaths, serious injuries or permanent harm to the patients had occurred due to this issue.

Local situation

To date, no complaints relating to this issue has been reported in Singapore. The relevant physicians had been informed of this safety issue by St. Jude Medical via a Dear Healthcare Professional Letter* issued in April 2013.

Corrective action and call to reporting

St. Jude Medical is advising healthcare professionals to ensure the programming of the Tachy Therapy function is disabled prior to initiating the software upgrade. Healthcare professionals are also advised to ensure that Electrocardiography monitoring and back-up external defibrillation equipment are available during the software upgrade process. Healthcare professionals are encouraged to report any adverse events related to ST. JUDE MEDICAL FORTIFY™ ST ICD to the Vigilance Branch.

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