

Safety Communication

رسالة سلامة

Stop the distribution and sale of the HeartWare Ventricular Assist Device (HVAD)TM System

Device/ Product Description:	HeartWare Ventricular Assist Device (HVAD) System
Manufacturer:	Medtronic
Problem:	A growing body of observational clinical comparisons demonstrate a higher frequency of neurological adverse events and mortality with the HVAD TM System as compared to other commercially available durable left ventricular assist devices (LVAD).
Recommendation /Actions:	<ul style="list-style-type: none"> • Make sure that this document is reached to the end-users. • Stop new implants of the Medtronic HVADTM System. • Continue normal use of peripherals and contact Medtronic for replacement of peripheral components (for example: Controllers, batteries AC/DC Adapters, Carrying Case). • Physicians continue following best clinical practices and manage patients implanted with HVADTM pump according to the recommendations in the Instructions for Use (IFU). • Contact the authorized representative for replacement & required corrective action. <p>For more information please click here and here.</p> <p>If you think you had a problem with your device or a device your patient uses, please report the problem to SFDA through: NCMDR Vigilance system (19999) unified call center</p>

Devices/Products photo:		
Authorized Representative Details	AR name:	Medtronic Saudi Arabia
	Assigned Contact Person:	Nahar Alsurayi
	Mobile/Phone:	0503226812
	Email:	nahar.s.alsurayi@medtronic.com

