



## **Urgent Field Safety Notice**

### **Medtronic HeartWare™ HVAD™ Pump Implant Kit**

RETRIEVAL OF One (1) NON-IMPLANTED DEVICE

June 2021

Medtronic reference: FA983

Dear Healthcare Provider,

During the week of 24 May 2021, Medtronic retrieved one (1) HeartWare™ HVAD™ Pump Implant Kit from your facility (on consignment) for engineering evaluation. See below for the device identification.

Model Number	Product Description	Serial Number
MCS1705PU	HVAD™ Pump Implant Kit	HW42843

This device may be useful in supporting our on-going investigation into pumps that delay or fail to restart. The pump does not have the issue identified in the pump failure to restart population (reference the December 2020 Urgent Field Safety Notice Communication). It is expected to perform normally. However, the internal pump housing and impeller measurements suggest it may be useful in our continued investigation and engineering testing.

This letter serves as a notification for your records regarding the retrieval of the non-implanted product identified above. Please share this notice with those who need to be aware within your organization.

The Competent Authority of your country has been notified of this action.

Sincerely,

Country/BU manager