Medtronic

Urgent Field Safety Notice

Endurant™ and Endurant™ II/IIs Stent Graft System (18 Fr)

Recall

October 2021

Medtronic reference: FA1207

Dear Healthcare Professional,

Medtronic is issuing a voluntary recall of a specific subset of **unused** 18 Fr Endurant™ and Endurant™ II/IIs Stent Graft Systems that may be susceptible to a delivery system component failure. Devices built with specific batches of spindle-hypotube subassemblies have the potential for the spindle to detach from the hypotube. Detachment of the spindle may interfere with or prevent release of the suprarenal stent potentially resulting in partial deployment of the stent graft and inability to remove the delivery system. This could lead to surgical conversion for open repair to remove the delivery system and partially deployed stent graft from the patient.

As of 12-OCT-2021, Medtronic has received **one (1)** product complaint regarding spindle detachment that caused difficulty in deploying the suprarenal stent of the stent graft. The physician in this case was able to eventually deploy the stent graft without additional intervention, remove the delivery system, and the procedure was successfully completed without any harm to the patient.

Medtronic is taking action to retrieve this specific subset of unused Endurant and Endurant II/IIs Stent Graft Systems as indicated in Attachment 1. There are no increased risks to patients who have an Endurant and Endurant II/IIs stent graft previously implanted. Since the spindle detachment can only occur during the deployment of the stent graft, there are no additional actions required for patients where the Endurant and Endurant II/IIs Stent Graft Systems were successfully deployed during the procedure.

Customer Instructions:

Medtronic requests that you take the following actions:

- Return all unused affected devices to Medtronic. Your local Medtronic Field Representative can assist you as necessary in initiating the return and replacement of this product.
- Please forward this notice to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

In alignment with our Mission, Medtronic is committed to patient safety and continues to investigate the cause of this issue. Medtronic has notified the Competent Authority of your country of this action. We appreciate your prompt attention to this matter and we sincerely apologize for any inconvenience this may cause. If you have any questions regarding this communication, please contact your Medtronic Field Representative.

Sincerely,

Local / BU manager

Attachment 1: Impacted Serial Numbers

Model number	Serial Number
ESBF2314C103EE	V30625917, V30628580, V30628738, V30628581, V30628740
ETBF2513C166EE	V30626008
ETBF2516C145EE	V30628896, V30603313
ETBF2816C145EE	V30625743, V30625730
ETBF2816C166EE	V30627698, V30626027, V30596655
ETBF2820C166EE	V30593595, V30593590
ETTF2323C70EE	V30629801
ETTF2525C70EE	V30616799
ETTF2828C70EE	V30623470, V30609560
ETUF2314C102EE	V30628797, V30628798
ETUF2814C102EE	V30619060, V30619059