Medtronic

Urgent Field Safety Notice

Endurant™ / Endurant II ™ 23mm and 25mm Bifurcated Stent Graft Systems

Recall of specific Model and Serial Numbers

March 2017

Medtronic reference: FA758

Dear Risk Manager or Healthcare Professional:

Medtronic is initiating a voluntary recall for a subset of Endurant/ Endurant II Bifurcated Stent Graft Systems of specific models (see Appendix A) and serial numbers.

This specific subset of stent grafts has greater susceptibility to fabric permeability variations that may be associated with endoleaks observed during the initial implant procedure. At the time of implant procedure this permeability variation may cause the physician to categorize a Type IV endoleak (which typically self-resolves over time) as an acute Type III Fabric endoleak because the leak may appear to be focal or a localized leak as opposed to a diffused leak (blush). The misclassification as an acute Type III Fabric endoleak may lead to unnecessary secondary interventions.

The permeability variation is limited to a subset of 23mm and 25 mm devices that were manufactured with specific lots of graft material. This recall does not affect any other models or serial numbers of the Endurant/Endurant II Bifurcated Stent Graft Systems.

Although the incremental risk associated with the affected subset of Endurant/ Endurant II Bifurcated Stent Graft Systems is low, there remains a potential for unnecessary secondary interventions being performed to treat a perceived acute Type III endoleak which could actually be a Type IV that self-resolves over time. Medtronic is initiating this recall to mitigate this risk through removal of the unused affected devices.

Medtronic has received 20 complaints between May 2015 and January 2017 related to this reported acuteType III Fabric leak resulting in additional interventions at the time of the procedure. There have been two (2) reports of adverse events. One patient death was reported to have occurred 3 weeks post-procedure, but it is inconclusive if the death was related to the secondary procedure.

There are no actions required for patients already implanted, as the potential for endoleak misclassification due to permeability variation occurs acutely at implant. Patients who have been implanted with an Endurant /Endurant II 23mm or 25mm Bifurcated Stent Graft System affected by this recall do not require any additional follow up due to this action and should continue to be monitored in accordance with your standard practice.

Our records indicate that your facility has received one or more potentially affected Endurant /Endurant II 23mm and / or 25mm Bifurcated Stent Graft System(s) from the identified subset. As a result, Medtronic is asking that you take the following actions:

1. Identify and quarantine unused Endurant /Endurant II 23mm and 25mm Bifurcated Stent Graft System from the identified subset of models and serial numbers that are in your inventory.

2. Return all affected products in your inventory to Medtronic. Your Medtronic Representative can assist you in the return and replacement of this product as necessary.

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

Please share this notification with others in your organization as appropriate or to any organization where the potentially affected product may have been transferred. In case of any questions related to this Urgent Field Safety Notice contact your Medtronic Representative at <XXXX>.

We appreciate your cooperation and apologise for the inconvenience this may cause you; please be assured that patient safety and product quality remain our primary concern.

Sincerely,

Please Note: A website link has been created to be able to look up the serial number of any unused Endurant /Endurant II 23mm and 25mm Bifurcated Stent Graft System from the identified subset of models and serial numbers that are in your inventory .

- Note the Serial Number of any unused Endurant /Endurant II 23mm and 25mm Bifurcated Stent Graft System in your inventory.
- Go to www.Medtronic.com > Healthcare Professionals > Products > Product Performance & Advisories > Endurant Permeability (http://www.medtronic.com/us-en/healthcare-professionals/products/product-performance/endurant-permeability.html)
- Input your Serial Number as found on your unused product
- If your Serial Number is shown to be NOT AFFECTED, no further action is necessary for this device.
- If your Serial Number is shown as AFFECTED, quarantine this device and follow the return instructions.

Appendix A: Affected Endurant / Endurant II Model Numbers. Note: Only specific serial numbers are affected, please use the above website to determine whether a serial number is affected or not.

ENBF2313C120EE	ETBF2313C166EE
ENBF2313C145EE	ETBF2316C124EE
ENBF2313C170EE	ETBF2316C145EE
ENBF2316C145EE	ETBF2316C166E
ENBF2316C170EE	ETBF2316C166EE
ENBF2513C145EE	ETBF2513C124EE
ENBF2513C170EE	ETBF2513C145EE
ENBF2516C145EE	ETBF2513C166EE
ENBF2516C170EE	ETBF2516C124EE
ETBF2313C124E	ETBF2516C145E
ETBF2313C124EE	ETBF2516C145EE
ETBF2313C145EE	ETBF2516C166E
ETBF2313C166E	ETBF2516C166EE