Medtronic

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Urgent Medical Device Recall
Endurant™ / Endurant II ™ 23mm and 25mm Bifurcated Stent Graft Systems

03 March 2017

Dear Risk Manager or Health Care Professional,

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

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, or other Medtronic product or implantable devices.

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 Urgent Medical Device Recall to further mitigate this risk through removal of the unused affected subset of devices.

Through 27 January 2017, Medtronic has received 20 complaints 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 three (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 observation and should continue to be monitored in accordance with your standard practice.

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

- 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.

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- Return unused products from the attached model and serial number list that are in your inventory to Medtronic by contacting your **Medtronic APV Sales Representative** or **Customer Service** at **1-800-854-3570 (#4)** and referencing this communication to initiate a return and credit of unused product. Your Medtronic sales representative can assist you in the return of this product as necessary.
- Complete the attached Customer Confirmation Certificate and email it to dl.sgreg@medtronic.com or fax it to Medtronic at +65 6776 6355.

Medtronic will notify all applicable regulatory agencies, as required, regarding this product recall.

Please share this notification with others in your organization as appropriate, and contact your Medtronic Sales Representative with any questions related to this product recall.

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

Yours Sincerely,

[redacted]

Business Manager

Enclosure:
Appendix A: Affected Endurant / Endurant II Model Numbers
Appendix B: Customer Acknowledgement Response Form

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Appendix A: Affected Endurant / Endurant II Model Numbers

Note: Serial numbers as indicated in the enclosed document are affected.

ETBF2313C124E
ETBF2313C145E
ETBF2313C166E
ETBF2316C124E
ETBF2316C145E
ETBF2316C166E
ETBF2513C124E
ETBF2513C145E
ETBF2513C166E
ETBF2516C124E
ETBF2516C145E
ETBF2516C166E

ENBF2313C120EE
ENBF2313C145EE
ENBF2313C170EE
ENBF2316C120EE
ENBF2316C145EE
ENBF2316C170EE
ENBF2513C145EE
ENBF2513C170EE
ENBF2516C145EE
ENBF2516C170EE
ETBF2313C124EE
ETBF2313C145EE
ETBF2313C166EE
ETBF2316C124EE
ETBF2316C145EE
ETBF2316C166EE
ETBF2513C124EE
ETBF2513C145EE
ETBF2513C166EE
ETBF2516C124EE
ETBF2516C145EE
ETBF2516C166EE

ETBF2313C124EJ
ETBF2313C145EJ
ETBF2313C166EJ
ETBF2316C124EJ
ETBF2316C145EJ
ETBF2316C166EJ
ETBF2513C124EJ
ETBF2513C145EJ
ETBF2513C166EJ
ETBF2516C124EJ
ETBF2516C145EJ
ETBF2516C166EJ

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.

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Appendix B: Customer Confirmation Certificate

Urgent Medical Device Recall

Endurant™ / Endurant II™ 23mm and 25mm
Bifurcated Stent Graft Systems
Specific Models and Serial Numbers on Customer Detail Report

February 2017

Account Number:
Account Name
Address
City, State, Zip
Sales Representative: *Rep Name*
Representative Phone: *Rep phone number*

For completion by Medtronic Customers Only – Please complete all fields below

By signing this form I confirm that I have read and understand the Urgent Medical Device Recall Letter from Medtronic regarding a subpopulation of Endurant / Endurant II 23mm and 25mm Bifurcated Stent Graft Systems and I have taken one of the following actions:

1. **I have returned all unused Endurant / Endurant II 23mm and / or 25mm Bifurcated Stent Graft Systems from the enclosed model /serial number list that were located in my inventory to Medtronic per the instructions below.** *Please note product affected by this issue is limited to the affected models and serials listed on the Customer Detail Report provided.*

–OR–

2. **I confirm that all of the Endurant / Endurant II 23mm and/or 25mm Bifurcated Stent Graft Systems from the affected model /serial number list were either used or unable to be located in my inventory.**

Customer Name (Print): _____

Customer Title (Print): _____

Customer Signature and Stamp: _____ Date: _____

Telephone: _____

Return Instructions:

- Immediately quarantine and remove all products that remain in your inventory.
- Contact your **Medtronic APV Sales Representative** or **Customer Service** at **1-800-854-3570 (#4)** to assist with the return and credit of affected product.
- Complete this provided Customer Confirmation Certificate and email to dl.sgreg@medtronic.com or fax it to Medtronic at +65 6776 6355 attention of Customer Focused Quality.