Medtronic

Urgent Field Safety Notice

Endurant™ II/IIs Stent Graft System

Recall

January 2022

Medtronic reference: FA1220

Dear Health Care Professional,

The purpose of this letter is to advise you that Medtronic is issuing a voluntary recall of a specific subset of unused Endurant™ II/IIs Stent Graft Systems that may be susceptible to a delivery system component failure. Please note that this is a new recall and not related to any of the prior recalls performed on the Endurant II and Endurant IIs delivery system.

Issue Description:

Devices built with specific batches of taper tip assemblies have the potential for the taper tip to detach from the delivery system. Detachment of the taper tip during the implant procedure may lead to a secondary intervention to attempt to remove the taper tip, either by endovascular retrieval or surgical conversion. There is also potential that the taper tip is intentionally left behind in the patient, at the physician's discretion, if not easily removable.

As of 09-DEC-2021, Medtronic has received five (5) complaints where the taper tip detached from the delivery system during the procedure. In three (3) cases the tip was retrieved successfully: one (1) through surgical conversion and two (2) by snaring. In the remaining two (2) cases the tip was intentionally left behind. No deaths have been reported from the five (5) complaints.

Medtronic is taking action to retrieve a specific subset of unused Endurant II/IIs Stent Graft Systems. Serious injuries and/or deaths could occur due to detachment of the taper tip from the delivery system during the implant procedure. Since the taper tip detachment can only occur during the deployment of the stent graft, there are no increased risks or additional actions required for patients where the Endurant II/IIs Stent Graft System was successfully deployed during the procedure.

Customer Instructions:

Medtronic requests that you take the following actions:

- Immediately identify and quarantine all unused affected devices listed in Table 1.
- 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 organization. Additionally, if any affected devices have been distributed to other organizations, please forward this notice to those entities.

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 and sincerely apologize for any inconvenience this may cause. If you have any questions regarding this communication, please contact your Medtronic Field Representative at <XXXX>.

Sincerely,

Local / OU manager

Medtronic

Table 1: Impacted Serial Numbers < Include on country or account level >

Model	Serial Number