

Urgent Field Safety Notice

Endurant™ II/IIIs 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/IIIs 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/IIIs 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/IIIs 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.

Sincerely,

[Local / OU manager](#)

Table 1: Impacted Serial Numbers - Denmark

Model	Serial Number
ESBF2314C103EE	V30533175, V30538930, V30628738, V30677830
ESBF2514C103EE	V30526643, V30535067, V30536201, V30575406, V30640858, V30645700, V30646351
ESBF2814C103EE	V30535151, V30535152, V30535153, V30538948, V30539120, V30559790, V30564443, V30564574, V30589874, V30589882, V30640907, V30640908, V30646370, V30666552, V30666590, V30666615
ESBF3214C103EE	V30546323, V30592179, V30609442, V30609443
ESBF3614C103EE	V30642457, V30670070
ETBF2316C166EE	V30601083
ETBF2516C166EE	V30642091
ETBF2813C145EE	V30601123
ETBF2813C166EE	V30641502
ETBF2816C124EE	V30667845
ETBF2816C166EE	V30525977, V30574813, V30574815, V30598272, V30608638, V30641542, V30641543, V30676409, V30676410
ETBF2820C166EE	V30590306
ETBF3216C166EE	V30547516, V30609569, V30609577, V30620591, V30620592, V30620593, V30620595, V30627902, V30627903
ETBF3220C145EE	V30585721
ETBF3220C166EE	V30540615
ETBF3620C166EE	V30575964, V30667993
ETCF2525C49EE	V30554121
ETCF2828C49EE	V30554176
ETCF3232C49EE	V30542982
ETCF3636C49EE	V30628758
ETTF2525C70EE	V30672947
ETTF3636C70EE	V30673025
ETUF2314C102EE	V30628798, V30645672, V30664736
ETUF2514C102EE	V30554266, V30641293
ETUF2814C102EE	V30664762
ETUF3614C102EE	V30620058