

Urgent Field Safety Notice

Endurant™ II/II_s 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/II_s 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 II_s 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/II_s 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/II_s 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 Annex A.
- 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,

Annex A: Impacted Serial Numbers in SWITZERLAND

Article number	Serial number
ESBF2314C103EE	V30570477
	V30605914
	V30605930
ESBF2514C103EE	V30536208
	V30564362
	V30595911
	V30640854
	V30662799
ESBF2814C103EE	V30528136
	V30572607
	V30589881
	V30590884
	V30600575
	V30607223
	V30640911
	V30640960
	V30646364
	V30668858
	V30668869
	V30670775
	V30671068
ESBF3214C103EE	V30590913
	V30597750
	V30602505
	V30602522
	V30609454
	V30621945
ESBF3614C103EE	V30602546
	V30608341
	V30642454
ETBF2316C145EE	V30564823
	V30663464
ETBF2316C166EE	V30554366
ETBF2513C166EE	V30557627
ETBF2516C145EE	V30574761
ETBF2516C166EE	V30570311
	V30590257
	V30601098
	V30601099

Article number	Serial number
ETBF2816C145EE	V30557685
	V30566023
	V30590288
ETBF2816C166EE	V30538397
	V30538456
	V30573535
	V30601152
	V30676408
ETBF2820C145EE	V30625776
ETBF3220C166EE	V30644092
ETBF3616C145EE	V30645184
	V30645185
ETBF3616C166EE	V30540644
	V30630206
ETCF2525C49EE	V30625040
ETCF2828C49EE	V30554172
	V30571036
	V30597878
	V30646179
	V30664717
ETCF3232C49EE	V30542978
	V30574421
	V30574425
	V30667730
ETCF3636C49EE	V30543595
	V30547479
	V30573211
	V30631416
	V30675409
ETTF2323C70EE	V30536672
	V30663363
	V30663369
ETTF3232C70EE	V30563114
ETTF3636C70EE	V30627002
	V30627003
ETUF2514C102EE	V30536718
	V30554279
ETUF2814C102EE	V30599384
ETUF3214C102EE	V30547508