

# Medtronic

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## Urgent Field Safety Notice

### Endurant™ and Endurant™ II/IIIs Stent Graft System (18 Fr)

#### Recall

October 2021

Medtronic reference: FA1207

Dear Healthcare Professional,

Medtronic is issuing a voluntary recall of a specific subset of **unused** 18 Fr Endurant™ and Endurant™ II/IIIs Stent Graft Systems that may be susceptible to a delivery system component failure. Devices built with specific batches of spindle-hypotube subassemblies have the potential for the spindle to detach from the hypotube. Detachment of the spindle may interfere with or prevent release of the suprarenal stent potentially resulting in partial deployment of the stent graft and inability to remove the delivery system. This could lead to surgical conversion for open repair to remove the delivery system and partially deployed stent graft from the patient.

As of 12<sup>th</sup> October 2021, Medtronic has received **one (1)** product complaint regarding spindle detachment that caused difficulty in deploying the suprarenal stent of the stent graft. The physician in this case was able to eventually deploy the stent graft without additional intervention, remove the delivery system, and the procedure was successfully completed without any harm to the patient.

Medtronic is taking action to retrieve this specific subset of unused Endurant and Endurant II/IIIs Stent Graft Systems as indicated in Attachment 1. There are no increased risks to patients who have an Endurant and Endurant II/IIIs stent graft previously implanted. Since the spindle detachment can only occur during the deployment of the stent graft, there are no additional actions required for patients where the Endurant and Endurant II/IIIs Stent Graft Systems were successfully deployed during the procedure.

**Customer Instructions:**

Medtronic requests that you take the following actions:

- 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 organisation or to any organisation where the potentially affected devices have been transferred.

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 to this matter, and we sincerely apologise for any inconvenience this may cause. If you have any questions regarding this communication, please contact your Medtronic Field Representative at 01 511 1400.

Sincerely,



Bethany Moxon

Associate Regulatory Affairs Specialist - UK and Ireland

## Attachment 1: Impacted Serial Numbers:

Model number	Serial Number
ESBF2314C103EE	V30628737, V30628587, V30628588, V30625917, V30628580, V30628738, V30628586, V30628750, V30628744, V30628754, V30628584, V30628585, V30628743, V30628748, V30628583, V30628576, V30628577, V30628578, V30628579, V30628581, V30628582, V30628742, V30628751, V30628752, V30628753, V30628746, V30628739, V30628740, V30628741, V30628745, V30628747, V30625918, V30625921, V30625915, V30625916
ESBF2514C103EE	V30619120
ESBF2814C103EE	V30609415, V30618965, V30625943, V30625957, V30618989, V30618969, V30618982, V30625942, V30625948, V30625954, V30609421, V30618973, V30625935, V30625950, V30625947, V30629772, V30629773, V30618964, V30629766, V30629771, V30618971, V30625963, V30625962, V30619161, V30629767, V30629768, V30629770, V30625949, V30618988, V30625936, V30619159, V30629763, V30629765, V30618968, V30618975, V30629760, V30629761, V30629762, V30629764, V30625938, V30625944, V30625951, V30625952, V30625953, V30625958, V30625961, V30618977, V30625941, V30625945, V30625946, V30618972, V30618976, V30618979, V30609409, V30609411, V30609420, V30618963, V30618966, V30618970, V30618974, V30618978, V30618980, V30618984, V30609410, V30609417, V30609423, V30609412, V30618967, V30625985, V30618983
ETBF2313C124EE	V30595456
ETBF2313C145EE	V30628846, V30628845, V30628844
ETBF2313C166EE	V30625997, V30626004, V30629911, V30629913, V30625998, V30629910, V30629912, V30626003, V30617526, V30626001, V30626002
ETBF2316C166EE	V30628859, V30628858, V30628860, V30628857, V30628847
ETBF2513C166EE	V30626007, V30626009, V30626008, V30626005, V30626006
ETBF2513C124EE	V30617798, V30617789
ETBF2513C145EE	V30595516, V30595505, V30628864, V30628866, V30628865, V30628863, V30628862, V30595515, V30595517, V30584649
ETBF2516C124EE	V30625683, V30625679, V30625681, V30625682, V30625678
ETBF2516C145EE	V30625689, V30628893, V30628896, V30628897, V30628891, V30623506, V30623502, V30629230, V30625688, V30603310, V30628894, V30628898, V30628895, V30628892, V30603298, V30603309, V30628883, V30623505, V30623503, V30603315, V30603313, V30603312, V30603311, V30603296
ETBF2516C166EE	V30596585, V30596587, V30596586
ETBF2813C124EE	V30619093, V30619096
ETBF2813C145EE	V30631617, V30631612, V30631619, V30631621, V30631622, V30631614

ETBF2813C166EE	V30596635, V30596639, V30596644, V30596626, V30596641, V30596625, V30596634, V30596640, V30596637
ETBF2816C124EE	V30626016, V30626023, V30626024, V30626019, V30626022, V30626015
ETBF2816C145EE	V30625709, V30625741, V30625735, V30625737, V30625718, V30625715, V30630166, V30623525, V30625720, V30625740, V30630164, V30630165, V30625725, V30625733, V30625739, V30625714, V30625736, V30630163, V30630161, V30630162, V30630160, V30625743, V30625744, V30625712, V30625729, V30625732, V30625734, V30625730, V30630176, V30625724, V30623540, V30623524, V30625723, V30625713, V30625716, V30625717, V30625721, V30623527, V30625711, V30625708, V30623539, V30623523, V30623522
ETBF2816C166EE	V30627691, V30596651, V30626028, V30596650, V30626035, V30627694, V30626031, V30629152, V30627695, V30627696, V30626032, V30629153, V30629154, V30629155, V30626034, V30627693, V30627699, V30629151, V30626030, V30627700, V30627697, V30627698, V30627692, V30626036, V30626029, V30626026, V30626027, V30596645, V30596648, V30596649, V30596655, V30596646
ETBF2820C145EE	V30625775, V30625774, V30625777, V30625776, V30625768
ETBF2820C166EE	V30593594, V30593592, V30593595, V30593591, V30593593, V30593589, V30593590