

Urgent Field Safety Notice **Endurant™ II/IIIs Stent Graft System** Radiopaque (RO) Marker Bond Detachment Recall

June 2021

Medtronic reference: FA982

Dear Risk Manager or Healthcare Professionals,

On 08-JUN-2021, Medtronic initiated a verbal Urgent Field Safety Notice requesting you quarantine a specific subset of non-implanted Endurant II/IIIs Stent Graft Systems. This notice is a follow-up to that action. Medtronic has identified that this specific subset (see appendix 1) of Endurant II/IIIs Stent Graft Systems may have a higher potential of RO marker bond detachment during stent graft deployment. There are no other model numbers or serial numbers of Medtronic devices in scope of this notification.

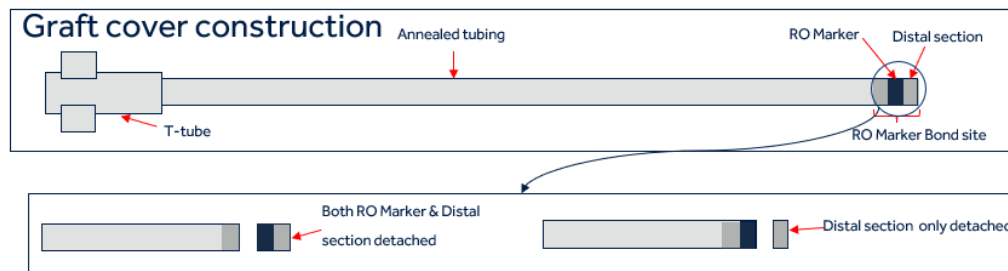


Figure 1: Shows a schematic of the Delivery System Graft Cover construction and RO Marker Bond detachments observed

The potential hazardous situation related to the RO marker bond detachment would occur during stent graft deployment. As the stent graft is being deployed, the RO marker bond may detach and constrain the suprarenal stent, leading to partial deployment of the stent graft and the inability to remove the delivery system. Conversion to open repair may be required to remove the delivery system and partially deployed stent graft from the patient. To mitigate patient safety risk, Medtronic is taking action to retrieve this specific subset of unused devices.

As of 09-JUN-2021, Medtronic has received two (2) product complaints related to RO marker bond detachment in this subset of devices. In each of the two cases, the patient was converted to open repair and died during the open procedure.

Since the RO marker bond detachment occurs during stent graft deployment and impacts the delivery system, there are no additional actions required for patients where the Endurant II/IIIs Stent Graft Systems was successfully deployed during a procedure.

Customer Instructions:

Medtronic requests that you take the following actions:

- Return all unused affected devices to Medtronic. Your local Medtronic Representative can assist you in the return and replacement of this product as necessary.
- Please forward this notice to all those who need to be aware within your organization.

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 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 / BU Manager

Appendix 1: Impacted Serial Numbers

CFN	Product Description	Serial Number
ESBF3214C103E	Endurant IIs Bifur	V29780759, V29780771, V29780773
ESBF3614C103EE	Endurant IIs Bifur	V29781932, V29781933, V29781934, V29781935, V29781936, V29781937, V29781938, V29781939, V29781940, V29781941, V29781942, V29781943, V29781944, V29781945, V29781946, V29781947, V29781948, V29781951
ETBF3216C166EE	Endurant II Bifur	V29778214, V29778215
ETCF3636C49EE	Endurant II Cuff	V29775024, V29775025, V29775026, V29775027
ETUF3214C102EE	Endurant II AUI	V29775791, V29775792, V29775793, V29775794, V29775795
ETUF3614C102E	Endurant II AUI	V29781882, V29781883, V29781886, V29781887, V29781889, V29781890, V29781891