



CALIFORNIA DEVICE RECALL INFORMATION SHEET

Medtronic Vascular Recalls Endurant Series Stent for Spindle Detachment

Recall Date	Product Description	Recalling Firm	Recall Reason
10/15/2021	Endurant Stent Graft System REF/Description: ENTF2525C70EE STENT GRAFT ENTF2525C70EE ENDURANT TUBE	Medtronic Vascular, Inc. Santa Rosa, California	During stent graft deployment, the spindle may detach from the distal end of the spindle hypotube
10/15/2021	Endurant II Stent Graft System REF/Description: ETBF2513C145EE STENT GRAFT ETBF2513C145EE ENDUR II BIF ETBF2820C166EE STENT GRAFT ETBF2820C166EE ENDUR II BIF ETCF2828C49EE STENT GRAFT ETCF2828C49EE ENDUR II CUFF ETCF2828C49EE STENT GRAFT ETUF2514C102EE ENDUR II AUI ETUF2514C102EE STENT GRAFT ETBF2313C124EE ENDUR II BIF ETBF2513C145EESTENT GRAFT ETBF2513C145EE ENDUR II BIF ETBF2513C145EE STENT GRAFT ETBF2513C145EE ENDUR II BIF ETBF2516C166EE STENT GRAFT ETBF2516C166EE ENDUR II BIF ETBF2516C166EE STENT GRAFT ETBF2516C166EE ENDUR II BIF ETBF2813C166EE STENT GRAFT ETBF2813C166EE	Medtronic Vascular, Inc. Santa Rosa, California	Spindle Detachment

	<p> ENDUR II BIF ETBF2816C166EE STENT GRAFT ETBF2816C166EE ENDUR II BIF ETBF2516C145EE STENT GRAFT ETBF2516C145EE ENDUR II BIF ETUF2514C102E STENT GRAFT ETUF2514C102E ENDUR II AUI ETTF2828C70EE STENT GRAFT ETTF2828C70EE ENDUR II TUBE ETTF2828C70EE STENT GRAFT ETCF2525C49E ENDUR II AOEXT ETCF2828C49E STENT GRAFT ETCF2828C49E ENDUR II AOEXT ETCF2828C49E STENT GRAFT ETUF2814C102E ENDUR II AUI ETUF2814C102E STENT GRAFT ETUF2814C102E ENDUR II AUI ETTF2525C70EE STENT GRAFT ETTF2525C70EE ENDUR II TUBE ETTF2525C70EE STENT GRAFT ETBF2313C166EE ENDUR II BIF ETBF2513C124EESTENT GRAFT ETBF2513C124EE ENDUR II BIF ET </p>		
<p>10/15/2021</p>	<p> Endurant IIs Stent Graft System REF/Description: ESBF2814- C103EE STENT GRAFT ESBF2814C103EE ENDUR IIS BIF ESBF2314C103E Stent Graft ESBF2314C103E Endur IIs BIF ESBF2314C103E Stent Graft ESBF2514C103EE ENDUR IIS BIF ESBF2814C103EE STENT GRAFT ESBF2814C103EE ENDUR IIS BIF ESBF2814C103EE STENT GRAFT ESBF2314C103EE ENDUR IIS BIF ESBF2314C103EE STENT GRAFT ESBF231 </p>	<p> Medtronic Vascular, Inc. Santa Rosa, California </p>	<p>Spindle Detachment</p>

Recall Class	Product Identification	Distribution	Affected Dates
II	Endurant Stent Graft System Serial Numbers: V30624638 - V30624639	2 Devices Nationwide including California	October 2021 and prior
II	Endurant II Stent Graft System Serial Numbers: V30584649 - V30627699	511 Devices Nationwide including California	October 2021 and prior
II	Endurant IIs Stent Graft System Serial Numbers: V30609409 - V30628657	419 Devices nationwide including California	October 2021 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE [FDA WEBSITE](#)

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