California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Merit Medical Systems, Inc. EsophyX Z+ and with SerosaFuse Implantable Fasteners

Recall Date	Product Description	Recalling Firm	Recall Reason
04/21/2025	Merit Medical, REF: R2007, EsophyX Z+, (1) Fastener Delivery Device, SterileEO, RxOnly Merit Medical , REF: R2275, EsophyX Z+ with SerosaFuse Implantable Fasteners, (1) Fastener Delivery Device, (2) 7.5mm Cartridges, STERILEEO, RxOnly	Merit Medical Systems, Inc.	Update to IFU to provide additional information related to risk with device over-rotation and multiple deployment of fasteners.

Recall Class	Product Identification	Distribution	Affected Dates
II	All Lots UDI: 00810275011089 All Lots UDI: 00810275014011	805 units in California	March and prior

For additional information, please visit: FDA Website (R2007) and FDA Website (R2275).