California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Medtronic Neurosurgery Exacta External Drainage and Monitoring System

Recall Date	Product Description	Recalling Firm	Recall Reason
12/19/2024	Exacta External Drainage and Monitoring System: 27581 KIT 27581 EXACTA W/EDM VCATH 35CM 27636 EDM 27636 EXACTA W/BRAIDED CORD LOCK 27666 EDM 27666 EXCTA W GLUE STPCK GR PT LN 27732 EDM 27732 EXACTA W/NDL-LS INJ. ST W/CAP 27785 EDMS 27785 EXACTA 50ML BC NDLESS INJ 27795 EDMS 27795 EXACTA 100ML CATH 27861 EDMS 27861 EXACTA 50ML ANTIRFLUX GRNPL 46700 SYSTEM 46700 EXACTA DISP. DRAINAGE 46705 SYSTEM 46705 EXACTA DRAINAGE 100ML The Exacta external drainage and monitoring system (EDMS) is a system for externally draining and monitoring cerebrospinal fluid (CSF) and monitoring intracranial pressure (ICP).	Medtronic Neurosurgery	Due to complaints received reporting cracks and/or leaks of the stopcocks associated with the external drainage and monitoring system (EDMS).

Recall Class	Product Identification	Distribution	Affected Dates
I	27581 KIT 27581 EXACTA W/EDM VCATH 35CM UDI-DI/GTIN code: 00763000333478 Lot Numbers: 219434737 - 228957823 27636 EDM 27636 EXACTA W/BRAIDED CORD LOCK UDI-DI/GTIN code: 00763000333492 Lot Numbers: 219390373 - 228783458 27666 EDM 27666 EXCTA W GLUE STPCK GR PT LN UDI-DI/GTIN code: 00763000333515 Lot Numbers: 219390375 - 229189950 27732 EDM 27732 EXACTA W/NDL-LS INJ. ST W/CAP UDI-DI/GTIN code: 00763000333560 Lot Numbers: 219888964 - 228501266 27785 EDMS 27785 EXACTA 50ML BC NDLESS INJ UDI-DI/GTIN code: 00763000333607 Lot Numbers: 219390374 - 229010916 27795 EDMS 27795 EXACTA 100ML CATH UDI-DI/GTIN code: 00763000333614 Lot Numbers: 219694828 - 221922072 27861 EDMS 27861 EXACTA 50ML ANTIRFLUX GRNPL UDI-DI/GTIN code:	258,367 units nationwide	November and prior

	00763000333645 Lot Numbers: 221687760 - 227906187 46700 SYSTEM 46700 EXACTA DISP. DRAINAGE UDI-DI/GTIN code: 00763000333690 Lot Numbers: 219317961 - 229190409 46705 SYSTEM 46705 EXACTA DRAINAGE 100ML UDI-DI/GTIN code: 00763000333706 Lot Numbers: 219390372 - 228123262		

For additional information, please visit the FDA Website.