

California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

MEDLINE INDUSTRIES, LP - Northfield Recalls Electrophysiology Catheter Models

Recall Date	Product Description	Recalling Firm	Recall Reason
8/28/25	Medline ReNewal Reprocessed St. Jude Medical Response and Supreme Diagnostic Electrophysiology Catheter Models 401150RH, 401206RH, 401207RH, 401210RH, 401211RH, 401212RH, 401222RH, 401223RH, 401226RH, 401227RH, 401228RH, 401260RH, 401261RH, 401271RH, 401305RH, 401306RH, 401309RH, 401310RH, 401311RH, 401312RH, 401317RH, 401353RH, 401357RH, 401381RH, 401392RH, 401399RH, 401400RH, 401425RH, 401430RH, 401433RH, 401434RH, 401435RH, 401436RH, 401438RH, 401441RH, 401442RH, 401445RH, 401443RH, 401444RH, 401448RH, 401449RH, 401450RH, 401451RH, 401453RH, 401466RH, 401468RH, 401474RH, 401475RH, 401859RH, 401860RH, 401863RH, 401864RH, 401865RH, 401876RH, 401877RH, 401878RH, 401890RH, 401891RH, 401892RH, 401893RH, 401966RH, 401967RH, 401979RH, 401994RH, 401996RH, 402004RH, 402008RH, 402009RH, 402010RH, 402011RH, 402012RH	MEDLINE INDUSTRIES, LP - Northfield	Specific lots of reprocessed electrophysiology catheters may contain small residual particulates.

Recall Class	Product Identification	Distribution	Affected Dates
I	1) 401211RH, UDI-DI:	398 units Nationwide	July 2025 and

	10197344043736(each), 10197344043736(case), Lot Number: EP250106; 2) 401222RH, UDI-DI: 10197344043712(each), 10197344043712(case), Lot Number: EP241118; 3) 401222RH, UDI-DI: 10197344043712(each), 10197344043712(case), Lot Number: EP250106; 4) 401223RH, UDI-DI: 10197344043705(each), 10197344043705(case), Lot Number: EP250106; 5) 401226RH, UDI-DI: 10197344043699(each), 10197344043699(case), Lot Number: EP241118; 6) 401226RH, UDI-DI: 10197344043699(each), 10197344043699(case), Lot Number: EP250106; 7) 401227RH, UDI-DI: 10197344043682(each), 10197344043682(case), Lot Number: EP250106; 8) 401260RH, UDI-DI: 10197344043668(each), 10197344043668(case), Lot Number: EP241118; 9) 401260RH, UDI-DI: 10197344043668(each), 10197344043668(case), Lot Number: EP250106; 10) 401261RH, UDI-DI: 10197344043651(each), 10197344043651(case), Lot Number: EP250106; 11) 401305RH, UDI-DI: 10197344043637(each), 10197344043637(case), Lot Number: EP250106; 12) 401309RH, UDI-DI: 10197344043613(each), 10197344043613(case), Lot Number: EP250106; 13) 401353RH, UDI-DI:		prior.
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10197344043569(each), 10197344043569(case), Lot Number: EP241118; 14) 401353RH, UDI-DI: 10197344043569(each), 10197344043569(case), Lot Number: EP250106; 15) 401381RH, UDI-DI: 10197344043545(each), 10197344043545(case), Lot Number: EP241118; 16) 401381RH, UDI-DI: 10197344043545(each), 10197344043545(case), Lot Number: EP250106; 17) 401399RH, UDI-DI: 10197344043521(each), 10197344043521(case), Lot Number: EP241118; 18) 401399RH, UDI-DI: 10197344043521(each), 10197344043521(case), Lot Number: EP250106; 19) 401430RH, UDI-DI: 10197344043491(each), 10197344043491(case), Lot Number: EP241118; 20) 401430RH, UDI-DI: 10197344043491(each), 10197344043491(case), Lot Number: EP250106; 21) 401433RH, UDI-DI: 10197344043484(each), 10197344043484(case), Lot Number: EP241118; 22) 401434RH, UDI-DI: 10197344043477(each), 10197344043477(case), Lot Number: EP241118; 23) 401435RH, UDI-DI: 10197344043460(each), 10197344043460(case), Lot Number: EP241118; 24) 401436RH, UDI-DI: 10197344043453(each), 10197344043453(case), Lot Number: EP250106; 25) 401441RH, UDI-DI:		
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10197344043439(each), 10197344043439(case), Lot Number: EP241118; 26) 401441RH, UDI-DI: 10197344043439(each), 10197344043439(case), Lot Number: EP250106; 27) 401442RH, UDI-DI: 10197344044245(each), 10197344044245(case), Lot Number: EP241118; 28) 401442RH, UDI-DI: 10197344044245(each), 10197344044245(case), Lot Number: EP250106; 29) 401443RH, UDI-DI: 10197344044252(each), 10197344044252(case), Lot Number: EP241118; 30) 401443RH, UDI-DI: 10197344044252(each), 10197344044252(case), Lot Number: EP250106; 31) 401444RH, UDI-DI: 10197344044269(each), 10197344044269(case), Lot Number: EP241118; 32) 401444RH, UDI-DI: 10197344044269(each), 10197344044269(case), Lot Number: EP250106; 33) 401448RH, UDI-DI: 10197344044283(each), 10197344044283(case), Lot Number: EP250106; 34) 401449RH, UDI-DI: 10197344044290(each), 10197344044290(case), Lot Number: EP241118; 35) 401449RH, UDI-DI: 10197344044290(each), 10197344044290(case), Lot Number: EP250106; 36) 401450RH, UDI-DI: 10197344044306(each), 10197344044306(case), Lot Number: EP241118; 37) 401450RH, UDI-DI:		
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10197344044306(each), 10197344044306(case), Lot Number: EP250106; 38) 401451RH, UDI-DI: 10197344044313(each), 10197344044313(case), Lot Number: EP241118; 39) 401451RH, UDI-DI: 10197344044313(each), 10197344044313(case), Lot Number: EP250106; 40) 401453RH, UDI-DI: 10197344044320(each), 10197344044320(case), Lot Number: EP250106; 41) 401474RH, UDI-DI: 10197344044351(each), 10197344044351(case), Lot Number: EP241118; 42) 401474RH, UDI-DI: 10197344044351(each), 10197344044351(case), Lot Number: EP250106; 43) 401860RH, UDI-DI: 10197344044382(each), 10197344044382(case), Lot Number: EP241118; 44) 401860RH, UDI-DI: 10197344044382(each), 10197344044382(case), Lot Number: EP250106; 45) 401863RH, UDI-DI: 10197344044399(each), 10197344044399(case), Lot Number: EP241118; 46) 401863RH, UDI-DI: 10197344044399(each), 10197344044399(case), Lot Number: EP250106; 47) 401864RH, UDI-DI: 10197344044405(each), 10197344044405(case), Lot Number: EP241118; 48) 401864RH, UDI-DI: 10197344044405(each), 10197344044405(case), Lot Number: EP250106; 49) 401877RH, UDI-DI:		
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10197344044436(each), 10197344044436(case), Lot Number: EP241118; 50) 401878RH, UDI-DI: 10197344044443(each), 10197344044443(case), Lot Number: EP241118; 51) 401890RH, UDI-DI: 10197344044450(each), 10197344044450(case), Lot Number: EP241118; 52) 401890RH, UDI-DI: 10197344044450(each), 10197344044450(case), Lot Number: EP250106; 53) 401891RH, UDI-DI: 10197344044467(each), 10197344044467(case), Lot Number: EP241118; 54) 401966RH, UDI-DI: 10197344044498(each), 10197344044498(case), Lot Number: EP250106; 55) 402004RH, UDI-DI: 10197344044566(each), 10197344044566(case), Lot Number: EP241118; 56) 402004RH, UDI-DI: 10197344044566(each), 10197344044566(case), Lot Number: EP250106; 57) 402008RH, UDI-DI: 10197344044573(each), 10197344044573(case), Lot Number: EP241118; 58) 402010RH, UDI-DI: 10197344044597(each), 10197344044597(case), Lot Number: EP241118; 59) 402010RH, UDI-DI: 10197344044597(each), 10197344044597(case), Lot Number: EP250106; 60) 402012RH, UDI-DI: 10197344043835(each), 10197344043835(case), Lot Number: EP241118; 61) 402012RH, UDI-DI:		
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	10197344043835(each), 10197344043835(case), Lot Number: EP250106		
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For additional information, please visit the [FDA Website](#).