

California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Micro Therapeutics, Inc. Medtronic Pipeline Vantage Embolization Device with Shield Technology

Recall Date	Product Description	Recalling Firm	Recall Reason
03/05/2025	Medtronic Pipeline Vantage Embolization Device with Shield Technology REF: PED3-021-350-16, PED3-021-250-14, PED3-021-350-20, PED3-021-250-20, PED3-021-300-16, PED3-021-300-20, PED3-021-275-12, PED3-021-275-16, PED3-021-325-12, PED3-021-325-14, PED3-021-325-16, PED3-021-325-20, PED3-021-250-12, PED3-021-300-14, PED3-021-250-16, PED3-021-300-12, PED3-021-275-14, PED3-021-350-14, PED3-021-350-25, PED3-021-350-12, PED3-021-250-10, PED3-021-275-20, PED3-021-350-18, PED3-021-325-18, PED3-021-275-18, PED3-021-250-18, PED3-021-300-18; and Instructions for Use, Part: M056989CDOC2 Medtronic Pipeline Vantage Embolization Device with Shield Technology REF: PED3-027-350-12, PED3-027-350-14, PED3-027-350-16,	Micro Therapeutics, Inc.	Use of embolization device with diameters greater-than-or-equal-to 4mm may lead to incomplete wall apposition and/or braid deformation (fish-mouthing/braid narrowing/braid collapse) noted during procedure and post-procedure, typically noted at 6-12 month imaging follow-up, potentially can lead to thrombosis and/or serious adverse events. Higher risk in females less-than-or-equal-to 45 years of age

	PED3-027-350-20, PED3-027-350-25, PED3-027-400-12, PED3-027-400-14, PED3-027-400-16, PED3-027-400-18, PED3-027-400-20, PED3-027-400-25, PED3-027-400-30, PED3-027-450-12, PED3-027-450-14, PED3-027-450-16, PED3-027-450-18, PED3-027-450-20, PED3-027-450-25, PED3-027-450-30, PED3-027-450-40, PED3-027-500-14, PED3-027-500-16, PED3-027-500-18, PED3-027-500-20, PED3-027-500-25, PED3-027-500-30, PED3-027-500-40, PED3-027-550-16, PED3-027-550-18, PED3-027-550-20, PED3-027-550-30, PED3-027-550-40, PED3-027-550-50, PED3-027-600-16, PED3-027-600-18, PED3-027-600-20, PED3-027-600-30, PED3-027-600-40, PED3-027-600-50		
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Recall Class	Product Identification	Distribution	Affected Dates
	REF: PED3-021-350-16 UDI-DI: 00847536030701, 00847536035195, 00847536036529 Lot: B317460 - B807494 REF: PED3-021-250-14 UDI-DI: 00847536030411, 00847536034907, 00847536036239 Lot: B317936 - B801770 REF: PED3-021-350-20 UDI-DI: 00847536030725, 00847536035218, 00847536036543 Lot: B319436 - B792630	7,820 units nationwide	January and prior

	REF: PED3-021-250-20 UDI-DI: 00847536030442, 00847536034938, 00847536036260 Lot: B321465 - B790055 REF: PED3-021-300-16 UDI-DI: 00847536030541, 00847536035034, 00847536036369 Lot: B321725 - B798864 REF: PED3-021-300-20 UDI-DI: 00847536030565, 00847536035058, 00847536036383 Lot: B322263 - B780044 REF: PED3-021-275-12 UDI-DI: 00847536030466, 00847536034952, 00847536036284 Lot: B323044 - B798851 REF: PED3-021-275-16 UDI-DI: 00847536030480, 00847536034976, 00847536036307 Lot: B323046 - B775168 REF: PED3-021-325-12 UDI-DI: 00847536030602, 00847536035096, 00847536036420 Lot: B324297 - B787017 REF: PED3-021-325-14 UDI-DI: 00847536030619, 00847536035102, 00847536036437 Lot: B324809 - B790478 REF: PED3-021-325-16 UDI-DI: 00847536030626, 00847536035119, 00847536036444 Lot: B324954 - B794192		
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	REF: PED3-021-325-20 UDI-DI: 00847536030640, 00847536035133, 00847536036468 Lot: B325613 - B787131 REF: PED3-021-250-12 UDI-DI: 00847536030404, 00847536034891, 00847536036222 Lot: B326236 - B793905 REF: PED3-021-300-14 UDI-DI: 00847536030534, 00847536035027, 00847536036352 Lot: B327828 - B789256 REF: PED3-021-250-16 UDI-DI 00847536030428, 00847536034914, 00847536036246 Lot: B328095 - B794426 REF: PED3-021-300-12 UDI-DI: 00847536030527, 00847536035010, 00847536036345 Lot: B338969 - B766588 REF: PED3-021-275-14 UDI-DI: 00847536030473, 00847536034969, 00847536036291 Lot: B343142 - B770988 REF: PED3-021-350-14 UDI-DI: 00847536030695, 00847536035188, 00847536036512 Lot: B349031 - B753618 REF: PED3-021-350-25 UDI-DI: 00847536030732, 00847536035225, 00847536036550 Lot: B364361 - B773457		
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	REF: PED3-021-350-12 UDI-DI: 00847536030688, 00847536035171, 00847536036505 Lot: B368529 - B787264 REF: PED3-021-250-10 UDI-DI: 00847536030398, 00847536036215, 00847536034884 Lot: B387475 - B801945 REF: PED3-021-275-20 UDI-DI: 00847536030503, 00847536034990, 00847536036321 Lot: B391792 - B797986 REF: PED3-021-350-18 UDI-DI: 00847536036536 Lot: B798906 REF: PED3-021-325-18 UDI-DI: 00847536036451 Lot: B800239 REF: PED3-021-275-18 UDI-DI: 00847536036314 Lot: B805162 REF: PED3-021-250-18 UDI-DI: 00847536036253 Lot: B805488 REF: PED3-021-300-18 UDI-DI: 00847536036376 Lot: B807417 All unused devices. Product lots including and between B317266 and B817292. REF: PED3-027-350-12 UDI-DI: 00847536035263, 00847536030770 Lot: B409106 - B700548		
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	REF: PED3-027-350-14 UDI-DI: 00847536035287, 00847536030787 Lot: B409234 - B794880 REF: PED3-027-350-16 UDI-DI: 00847536035294, 00847536030794 Lot: B409692 - B809808 REF: PED3-027-350-20 UDI-DI: 00847536035317, 00847536030817 Lot: B410645 - B777630 REF: PED3-027-350-25 UDI-DI: 00847536035324, 00847536030824 Lot: B410718 - B771938 REF: PED3-027-400-12 UDI-DI: 00847536030862, 00847536035362, 00847536036680 Lot: B321585 - B786108 REF: PED3-027-400-14 UDI-DI: 00847536030879, 00847536035379, 00847536036697 Lot: B318079 - B802419 REF: PED3-027-400-16 UDI-DI: 00847536030886, 00847536035386, 00847536036703 Lot: B326193 - B791207 REF: PED3-027-400-18 UDI-DI: 00847536036710 Lot: B795091 REF: PED3-027-400-20 UDI-DI: 00847536030909, 00847536035409, 00847536036727		
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	Lot: B318459 - B811796 REF: PED3-027-400-25 UDI-DI: 00847536030916, 00847536035416, 00847536036734 Lot: B322422 - B786557 REF: PED3-027-400-30 UDI-DI: 00847536030923, 00847536035423, 00847536036741 Lot: B394830 - B798796 REF: PED3-027-450-12 UDI-DI: 00847536030961, 00847536035461, 00847536036789 Lot: B322748 - B794235 REF: PED3-027-450-14 UDI-DI: 00847536030978, 00847536035478, 00847536036796 Lot: B320465 - B814124 REF: PED3-027-450-16 UDI-DI: 00847536030985, 00847536035485, 00847536036802 Lot: B318562 - B803301 REF: PED3-027-450-18 UDI-DI: 00847536036819 Lot: B797308 REF: PED3-027-450-20 UDI-DI: 00847536031005, 00847536035508, 00847536036826 Lot: B325710 - B811668 REF: PED3-027-450-25 UDI-DI: 00847536031012, 00847536035515, 00847536036833 Lot: B319170 - B800797		
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	REF: PED3-027-450-30 UDI-DI: 00847536031029, 00847536035522, 00847536036840 Lot: B396144 - B815818 REF: PED3-027-450-40 UDI-DI: 00847536031043, 00847536035546, 00847536036864 Lot: B353358 - B786518 REF: PED3-027-500-14 UDI-DI: 00847536031067, 00847536035577, 00847536036895 Lot: B353371 - B790520 REF: PED3-027-500-16 UDI-DI: 00847536031074, 00847536035584, 00847536036901 Lot: B320910 - B809811 REF: PED3-027-500-18 UDI-DI: 00847536036918 Lot: B797650 REF: PED3-027-500-20 UDI-DI: 00847536031098, 00847536035607, 00847536036925 Lot: B326325 - B779633 REF: PED3-027-500-25 UDI-DI: 00847536031104, 00847536035614, 00847536036932 Lot: B354639 - B800923 REF: PED3-027-500-30 UDI-DI: 00847536031111, 00847536035621, 00847536036949 Lot: B337320 - B779538		
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	REF: PED3-027-500-40 UDI-DI: 00847536031135, 00847536035645, 00847536036963 Lot: B319346 - B773500 REF: PED3-027-550-16 UDI-DI: 00847536031166, 00847536035683, 00847536037007 Lot: B358321 - B806751 REF: PED3-027-550-18 UDI-DI: 00847536037014 Lot: B803199 REF: PED3-027-550-20 UDI-DI: 00847536035706, 00847536031180, 00847536037021 Lot: B412256 - B808083 REF: PED3-027-550-30 UDI-DI: 00847536031203, 00847536035720, 00847536037045 Lot: B397247 - B783566 REF: PED3-027-550-40 UDI-DI: 00847536031227, 00847536035744, 00847536037069 Lot: B358931 - B780176 REF: PED3-027-550-50 UDI-DI: 00847536031241, 00847536035768, 00847536037083 Lot: B397414 - B785874 REF: PED3-027-600-16 UDI-DI: 00847536031289, 00847536035805, 00847536037120 Lot: B368960 - B801322		
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	REF: PED3-027-600-18 UDI-DI: 00847536037137 Lot: B801452 REF: PED3-027-600-20 UDI-DI: 00847536031302, 00847536035829, 00847536037144 Lot: B317266 - B805791 REF: PED3-027-600-30 UDI-DI: 00847536031326, 00847536035843, 00847536037168 Lot: B339559 - B808813 REF: PED3-027-600-40 UDI-DI: 00847536031340, 00847536035867, 00847536037182 Lot: B320318 - B800873 REF: PED3-027-600-50 UDI-DI: 00847536031364, 00847536035881, 00847536037205 Lot: B327190 - B794845		
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For additional information and product lists, please visit: [FDA Website \(1\)](#) and [FDA Website \(2\)](#).