

California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

BALT USA, LLC Recalls Prestige Coil System

Recall Date	Product Description	Recalling Firm	Recall Reason
6/08/25	Prestige Coil System REFs/UDI-DI codes: PRES0153CXPPLT 00810068567311 PRES1045CPKPLT 00810068567663 PRES1245CPKPLT 00810068567694 PRES1445CPKPLT 00810068567724 PRES0103CXPPLT 00810068567304 PRES2512CXPPLT 00810068567397 PRES0258CXPPLT 00810068567380 PRES0212CXPPLT 00810068567373 PRES0204CXPPLT 00810068567342 PRES0206CXPPLT 00810068567359 PRES0208CXPPLT 00810068567366 PRES3520CXPPLT 00810068567441 PRES3530CXPPLT 00810068567458 PRES0310CXPPLT 00810068567403 PRES0320CXPPLT 00810068567410 PRES0420CPKPLT	BALT USA, LLC	Due to radiopaque (RO) marker was not visible during angiography and it was determined that the RO marker was not manufactured to specification.

00810068567489 PRES0517CPKPLT 00810068567519 PRES0540CPKPLT 00810068568028 PRES0620CPKPLT 00810068567557 PRES0635CPKPLT 00810068567564 PRES0650CPKPLT 00810068567571 PRES0720CPKPLT 00810068567588 PRES0735CPKPLT 00810068567595 PRES0750CPKPLT 00810068567601 PRES0830CPKPLT 00810068567618 PRES0845CPKPLT 00810068567625 PRES0153HXPPL 00818053027147 PRES0204HXPPL 00818053029943 PRES0204CXPPL 00818053027321 PRES0208HXPPL 00818053029981 PRES0315HXPPL 00818053027178 PRES0307CXPPL 00818053027376 PRES0420HPKPL 00818053027185 PRES0440HPKPL 00810068567830 PRES0520HPKPL 00818053027192 PRES0540HPKPL 00810068567847 PRES0650HPKPL 00810068567854 PRES0720HPKPL 00818053027215 PRES0750HPKPL 00810068567861 PRES0830HPKPL		
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	00818053027222 The Prestige Coil System consists of an implantable embolization coil comprised of a platinum-tungsten alloy attached to a proximal stainless steel hypotube and distal body coil delivery pusher with a radiopaque distal positioning marker and a proximal fluorosafe marker. The Optima Coil delivery pusher is 185cm in length. It is designed for use with the XCEL Detachment Controller. The XCEL Detachment Controller comes pre-loaded with batteries and is a sterile, handheld, single patient-use device which should not be reused, re-sterilized, opened or tampered with. The Optima Coil achieves detachment by an internal heater element, which is powered by the XCEL Detachment Controller. The Optima Coil System and XCEL Detachment Controller(s) are sold separately.		
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Recall Class	Product Identification	Distribution	Affected Dates
II	Product Description/Product Catalog Number/UDI-DI/Lot Numbers: PRES0153CXPPLT Prestige 1.5mm x 3cm (Ver T) Prestige Plus Complex Xtra Pk PRES0153CXPPLT 00810068567311 F230800442 PRES0153CXPPLT Prestige 1.5mm x 3cm (Ver T) Prestige Plus Complex Xtra Pk PRES0153CXPPLT 00810068567311 F230800505 PRES0153CXPPLT Prestige 1.5mm x 3cm (Ver T) Prestige	268 in California	May 2025 and prior.

	Plus Complex Xtra Pk PRES0153CXPPLT 00810068567311 F230800708 PRES0153CXPPLT Prestige 1.5mm x 3cm (Ver T) Prestige Plus Complex Xtra Pk PRES0153CXPPLT 00810068567311 F230800794 PRES1045CPKPLT Prestige 10mm x 45cm (Ver. T) Prestige Plus Complex Pack PRES1045CPKPLT 00810068567663 F230800513 PRES1045CPKPLT Prestige 10mm x 45cm (Ver. T) Prestige Plus Complex Pack PRES1045CPKPLT 00810068567663 F230800544 PRES1245CPKPLT Prestige 12mm x 45cm (Ver. T) Prestige Plus Complex Pack PRES1245CPKPLT 00810068567694 F230800512 PRES1245CPKPLT Prestige 12mm x 45cm (Ver. T) Prestige Plus Complex Pack PRES1245CPKPLT 00810068567694 F230800538 PRES1245CPKPLT Prestige 12mm x 45cm (Ver. T) Prestige Plus Complex Pack PRES1245CPKPLT 00810068567694 F230800790 PRES1445CPKPLT Prestige 14mm x 45cm (Ver. T) Prestige Plus Complex Pack PRES1445CPKPLT 00810068567724 F230800793 PRES0103CXPPLT Prestige 1mm x 3cm (Ver. T) Prestige Plus Complex Xtra Pk PRES0103CXPPLT 00810068567304 F230800574 PRES0103CXPPLT Prestige 1mm x 3cm (Ver. T) Prestige Plus Complex Xtra Pk PRES0103CXPPLT 00810068567304 F230800575		
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	PRES0103CXPPLT Prestige 1mm x 3cm (Ver. T) Prestige Plus Complex Xtra Pk PRES0103CXPPLT 00810068567304 F230800576 PRES0103CXPPLT Prestige 1mm x 3cm (Ver. T) Prestige Plus Complex Xtra Pk PRES0103CXPPLT 00810068567304 F230800947 PRES2512CXPPLT Prestige 2.5mm x 12cm (Ver. T) Prestige Plus Complex Xtra Pk PRES2512CXPPLT 00810068567397 F230800549 PRES2512CXPPLT Prestige 2.5mm x 12cm (Ver. T) Prestige Plus Complex Xtra Pk PRES2512CXPPLT 00810068567397 F230800759 PRES0258CXPPLT Prestige 2.5mm x 8cm (Ver. T) Prestige Plus Complex Xtra Pk PRES0258CXPPLT 00810068567380 F230800833 PRES0212CXPPLT Prestige 2mm x 12cm (Ver. T) Prestige Plus Complex Xtra Pk PRES0212CXPPLT 00810068567373 F230800515 PRES0212CXPPLT Prestige 2mm x 12cm (Ver. T) Prestige Plus Complex Xtra Pk PRES0212CXPPLT 00810068567373 F230800527 PRES0212CXPPLT Prestige 2mm x 12cm (Ver. T) Prestige Plus Complex Xtra Pk PRES0212CXPPLT 00810068567373 F230800578 PRES0212CXPPLT Prestige 2mm x 12cm (Ver. T) Prestige Plus Complex Xtra Pk PRES0212CXPPLT 00810068567373 F230800791 PRES0212CXPPLT Prestige 2mm x 12cm (Ver. T) Prestige Plus Complex Xtra Pk		
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	PRES0212CXPPLT 00810068567373 F230800941 PRES0204CXPPLT Prestige 2mm x 4cm (Ver. T) Prestige Plus Complex Xtra Pk PRES0204CXPPLT 00810068567342 F230800454 PRES0204CXPPLT Prestige 2mm x 4cm (Ver. T) Prestige Plus Complex Xtra Pk PRES0204CXPPLT 00810068567342 F230800546 PRES0204CXPPLT Prestige 2mm x 4cm (Ver. T) Prestige Plus Complex Xtra Pk PRES0204CXPPLT 00810068567342 F230800771 PRES0204CXPPLT Prestige 2mm x 4cm (Ver. T) Prestige Plus Complex Xtra Pk PRES0204CXPPLT 00810068567342 F230800888 PRES0206CXPPLT Prestige 2mm x 6cm (Ver. T) Prestige Plus Complex Xtra Pk PRES0206CXPPLT 00810068567359 F230800479 PRES0206CXPPLT Prestige 2mm x 6cm (Ver. T) Prestige Plus Complex Xtra Pk PRES0206CXPPLT 00810068567359 F230800580 PRES0206CXPPLT Prestige 2mm x 6cm (Ver. T) Prestige Plus Complex Xtra Pk PRES0206CXPPLT 00810068567359 F230800715 PRES0206CXPPLT Prestige 2mm x 6cm (Ver. T) Prestige Plus Complex Xtra Pk PRES0206CXPPLT 00810068567359 F230800938 PRES0206CXPPLT Prestige 2mm x 6cm (Ver. T) Prestige Plus Complex Xtra Pk PRES0206CXPPLT 00810068567359 F241100052 PRES0208CXPPLT Prestige		
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	2mm x 8cm (Ver. T) Prestige Plus Complex Xtra Pk PRES0208CXPPLT 00810068567366 F230800940 PRES0208CXPPLT Prestige 2mm x 8cm (Ver. T) Prestige Plus Complex Xtra Pk PRES0208CXPPLT 00810068567366 F230800949 PRES3520CXPPLT Prestige 3.5mm x 20cm (Ver. T) Prestige Plus Complex Xtra Pk PRES3520CXPPLT 00810068567441 F230800418 PRES3520CXPPLT Prestige 3.5mm x 20cm (Ver. T) Prestige Plus Complex Xtra Pk PRES3520CXPPLT 00810068567441 F230800529 PRES3530CXPPLT Prestige 3.5mm x 30cm (Ver. T) Prestige Plus Complex Xtra Pk PRES3530CXPPLT 00810068567458 F230800482 PRES3530CXPPLT Prestige 3.5mm x 30cm (Ver. T) Prestige Plus Complex Xtra Pk PRES3530CXPPLT 00810068567458 F230800483 PRES3530CXPPLT Prestige 3.5mm x 30cm (Ver. T) Prestige Plus Complex Xtra Pk PRES3530CXPPLT 00810068567458 F230800769 PRES0310CXPPLT Prestige 3mm x 10cm (Ver. T) Prestige Plus Complex Xtra Pk PRES0310CXPPLT 00810068567403 F230800504 PRES0310CXPPLT Prestige 3mm x 10cm (Ver. T) Prestige Plus Complex Xtra Pk PRES0310CXPPLT 00810068567403 F230800763 PRES0320CXPPLT Prestige 3mm x 20cm (Ver. T) Prestige Plus Complex Xtra Pk PRES0320CXPPLT		
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00810068567410 F230800441 PRES0420CPKPLT Prestige 4mm x 20cm (Ver. T) Prestige Plus Complex Pack PRES0420CPKPLT 00810068567489 F230800795 PRES0420CPKPLT Prestige 4mm x 20cm (Ver. T) Prestige Plus Complex Pack PRES0420CPKPLT 00810068567489 F230800796 PRES0517CPKPLT Prestige 5mm x 17cm (Ver. T) Prestige Plus Complex Pack PRES0517CPKPLT 00810068567519 F230800451 PRES0517CPKPLT Prestige 5mm x 17cm (Ver. T) Prestige Plus Complex Pack PRES0517CPKPLT 00810068567519 F230800664 PRES0517CPKPLT Prestige 5mm x 17cm (Ver. T) Prestige Plus Complex Pack PRES0517CPKPLT 00810068567519 F230800797 PRES0517CPKPLT Prestige 5mm x 17cm (Ver. T) Prestige Plus Complex Pack PRES0517CPKPLT 00810068567519 F230800831 PRES0540CPKPLT Prestige 5mm x 40cm (Ver. T) Prestige Plus Complex Pack PRES0540CPKPLT 00810068568028 F230800822 PRES0540CPKPLT Prestige 5mm x 40cm (Ver. T) Prestige Plus Complex Pack PRES0540CPKPLT 00810068568028 F230800886 PRES0540CPKPLT Prestige 5mm x 40cm (Ver. T) Prestige Plus Complex Pack PRES0540CPKPLT 00810068568028 F241200132 PRES0620CPKPLT Prestige 6mm x 20cm (Ver. T) Prestige		
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	Plus Complex Pack PRES0620CPKPLT 00810068567557 F230800458 PRES0620CPKPLT Prestige 6mm x 20cm (Ver. T) Prestige Plus Complex Pack PRES0620CPKPLT 00810068567557 F230800517 PRES0635CPKPLT Prestige 6mm x 35cm (Ver. T) Prestige Plus Complex Pack PRES0635CPKPLT 00810068567564 F230800511 PRES0635CPKPLT Prestige 6mm x 35cm (Ver. T) Prestige Plus Complex Pack PRES0635CPKPLT 00810068567564 F230800519 PRES0635CPKPLT Prestige 6mm x 35cm (Ver. T) Prestige Plus Complex Pack PRES0635CPKPLT 00810068567564 F230800766 PRES0650CPKPLT Prestige 6mm x 50cm (Ver. T) Prestige Plus Complex Pack PRES0650CPKPLT 00810068567571 F230800821 PRES0720CPKPLT Prestige 7mm x 20cm (Ver. T) Prestige Plus Complex Pack PRES0720CPKPLT 00810068567588 F230800440 PRES0720CPKPLT Prestige 7mm x 20cm (Ver. T) Prestige Plus Complex Pack PRES0720CPKPLT 00810068567588 F230800510 PRES0735CPKPLT Prestige 7mm x 35cm (Ver. T) Prestige Plus Complex Pack PRES0735CPKPLT 00810068567595 F230800518 PRES0735CPKPLT Prestige 7mm x 35cm (Ver. T) Prestige Plus Complex Pack PRES0735CPKPLT 00810068567595 F230800537		
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	PRES0153HXPPL 00818053027147 F230800524 PRES0204HXPPL Prestige Coil 2mm x 4cm Prestige Plus Helical Xtra Pac PRES0204HXPPL 00818053029943 F230800782 PRES0204CXPPL Prestige Coil 2mm x 4cm Prestige Plus Complex Xtra Pac PRES0204CXPPL 00818053027321 F230800809 PRES0204CXPPL Prestige Coil 2mm x 4cm Prestige Plus Complex Xtra Pac PRES0204CXPPL 00818053027321 F240501011 PRES0208HXPPL Prestige Coil 2mm x 8cm Prestige Plus Helical Xtra Pac PRES0208HXPPL 00818053029981 F230800863 PRES0208HXPPL Prestige Coil 2mm x 8cm Prestige Plus Helical Xtra Pac PRES0208HXPPL 00818053029981 F230800864 PRES0208HXPPL Prestige Coil 2mm x 8cm Prestige Plus Helical Xtra Pac PRES0208HXPPL 00818053029981 F230800865 PRES0208HXPPL Prestige Coil 2mm x 8cm Prestige Plus Helical Xtra Pac PRES0208HXPPL 00818053029981 F230800879 PRES0208HXPPL Prestige Coil 2mm x 8cm Prestige Plus Helical Xtra Pac PRES0208HXPPL 00818053029981 F230800880 PRES0315HXPPL Prestige Coil 3mm x 15cm Prestige Plus Helical Xtra Pac PRES0315HXPPL 00818053027178 F230800815 PRES0315HXPPL Prestige		
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Coil 4mm x 40cm Prestige Plus Helical Pack PRES0440HPKPL 00810068567830 F230800893 PRES0520HPKPL Prestige Coil 5mm x 20cm Prestige Plus Helical Pack PRES0520HPKPL 00818053027192 F230800438 PRES0520HPKPL Prestige Coil 5mm x 20cm Prestige Plus Helical Pack PRES0520HPKPL 00818053027192 F230800447 PRES0520HPKPL Prestige Coil 5mm x 20cm Prestige Plus Helical Pack PRES0520HPKPL 00818053027192 F230800498 PRES0520HPKPL Prestige Coil 5mm x 20cm Prestige Plus Helical Pack PRES0520HPKPL 00818053027192 F230800704 PRES0520HPKPL Prestige Coil 5mm x 20cm Prestige Plus Helical Pack PRES0520HPKPL 00818053027192 F230800943 PRES0520HPKPL Prestige Coil 5mm x 20cm Prestige Plus Helical Pack PRES0520HPKPL 00818053027192 F241200129 PRES0540HPKPL Prestige Coil 5mm x 40cm Prestige Plus Helical Pack PRES0540HPKPL 00810068567847 F230800445 PRES0540HPKPL Prestige Coil 5mm x 40cm Prestige Plus Helical Pack PRES0540HPKPL 00810068567847 F230800569 PRES0650HPKPL Prestige Coil 6mm x 50cm Prestige Plus Helical Pack PRES0650HPKPL 00810068567854 F230800448 PRES0650HPKPL Prestige Coil 6mm x 50cm Prestige Plus Helical Pack PRES0650HPKPL 00810068567854 F230800467 PRES0650HPKPL Prestige Coil 6mm x 50cm Prestige Plus Helical Pack PRES0650HPKPL 00810068567854 F230800570 PRES0650HPKPL Prestige		
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	Coil 6mm x 50cm Prestige Plus Helical Pack PRES0650HPKPL 00810068567854 F230800727 PRES0650HPKPL Prestige Coil 6mm x 50cm Prestige Plus Helical Pack PRES0650HPKPL 00810068567854 F230800810 PRES0720HPKPL Prestige Coil 7mm x 20cm Prestige Plus Helical Pack PRES0720HPKPL 00818053027215 F230800565 PRES0720HPKPL Prestige Coil 7mm x 20cm Prestige Plus Helical Pack PRES0720HPKPL 00818053027215 F240501363 PRES0720HPKPL Prestige Coil 7mm x 20cm Prestige Plus Helical Pack PRES0720HPKPL 00818053027215 F240501600 PRES0750HPKPL Prestige Coil 7mm x 50cm Prestige Plus Helical Pack PRES0750HPKPL 00810068567861 F230800891 PRES0830HPKPL Prestige Coil 8mm x 30cm Prestige Plus Helical Pack PRES0830HPKPL 00818053027222 F230800860 PRES0830HPKPL Prestige Coil 8mm x 30cm Prestige Plus Helical Pack PRES0830HPKPL 00818053027222 F240501413		
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For additional information, please visit the [FDA Website](#).