California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Abiomed, Inc. Recalls Impella CP Set with SmartAssist / Impella Controller (AIC)

Recall Date	Product Description	Recalling Firm	Recall Reason
6/18/2026	**Product 1** Impella CP Set with SmartAssist. Product Codes: 1000080, 1000851, 0048-0014, 0048-0024-JP	Abiomed, Inc. Danvers, MA	Exposure to the low purge pressure occurrence may result in persistent low purge pressure alarms and, in some cases, interruption or loss of mechanical circulatory support.
5/28/2026	**Product 2** Automated Impella Controller (AIC) with the below product descriptions and corresponding Product Codes. Impella Controller, Packaged, CA; Product Code: 0042-0000-CA. Impella Controller, Packaged, EU; Product Code: 0042-0000-EU. Impella Controller, Packaged, UK; Product Code: 0042-0000-UK. Impella Controller, Packaged, US; Product Code: 0042-0000-US.	Abiomed, Inc. Danvers, MA	Retrospective submission for following issues identified: Alarm failures, power-path faults, electrical-short risks, and inaccurate motor-current sensing were identified in certain AIC consoles. There is improper alignment between the purge cassette and the motor drive in the AIC. This can result in a piston

			block event and lead to the inability to complete priming of the purge system, requiring the user to switch to backup AIC console.
6/25/2026	**Product 3** Abiomed Impella CP Set with SmartAssist (10th Generation) containing affected 14Fr Low Profile Introducer Kits. Product Codes: 1000413, 1000834	Abiomed, Inc. Danvers, MA	Potential for thrombus formation during prolonged use of the introducer.
6/25/2026	**Product 4** Abiomed 14 Fr x 25 cm Low Profile Introducer Kit for Impella CP. Impella Set Product Code: 1000435. Introducer Product Code: 1000435.	Abiomed, Inc. Danvers, MA	Potential for thrombus formation during prolonged use of the introducer.

Recall Class	Product Identification	Distribution	Affected Dates
I	**Product 1** GTIN: 00813502012279. Product Codes (Serial Number): 1000080 (677223, 672986, 673252, 644591, 645428, 644314, 613525), 1000851 (636173), 0048-0014 (499250), 0048-0024-JP (661216)	10 Units US distribution to GA, IA, NE, PA, TX, WA, WI	May 2026 and prior
I	**Product 2** Product Code Information	625 Units Worldwide California	January 2011 and prior
I	**Product 3** Impella Set Product Code: 1000413; GTIN: 00813502013566; Serial numbers: 649727, 649728,	168 Units Worldwide California	May 2026 and prior

	649729, 649730, 649731, 654349, 654348, 654342, 654341, 654340, 654339, 654338, 654336, 654335, 654334, 654333, 653010, 653009, 653008, 653007, 653006, 653005, 653004, 653003, 653002, 653001, 655735, 655733, 654357, 654356, 654382, 654383, 654381, 654380, 654378, 654367, 654366, 654364, 654365, 654362, 654363, 654361, 654360, 654359, 654358, 654379, 655734, 654386, 654355, 654385, 654384, 654353, 654352, 654351, 654350, 654387, 657649, 657648, 657646, 657647, 657645, 657644, 655742, 655739, 655741, 655740, 655738, 655737, 655736, 656743, 656738, 653050, 653049, 653048, 653047, 653045, 653044, 653043, 653042, 653041. Introducer Product Code: 2000684; Batch Numbers: 2026724558, 2027818724. Product Code: 1000834. GTIN: 00813502013948. Serial numbers: 653474, 653471, 653485, 653470, 653469, 653468, 653467, 653465, 653466, 653463, 653464, 653482, 653483, 653484, 653481, 653490, 653462, 653478, 653479, 653489, 653488, 653487, 653486, 653476, 653477, 656002, 656001, 656000, 655998, 655997, 655993, 655996, 655995, 655994, 656737, 656736, 656735, 656734, 656733, 656730, 656731, 656729, 656728, 656346, 656343, 656342, 656341,		

	656340, 656338, 659804, 659795, 656347, 650264, 659801, 659802, 659800, 659799, 659798, 656363, 656367, 656362, 656361, 656360, 656359, 656358, 659794, 659793, 659791, 659792, 659790, 659789, 659788, 659786, 659787, 659785, 661408, 661407, 661405, 661404, 661392, 661391, 661389, 661403, 661402, 661401, 661400, 662657, 662654. Introducer Product Code: 2000785; Batch Numbers: 2026787668, 2027818660. Distributed in Japan.		
I	**Product 4** Impella Set Product Code: 1000435; GTIN: 00813502013009; Serial Numbers: N/A. Introducer Product Code: 1000435; Batch Numbers: 2038707, 2045782	17 Units Worldwide California	May 2026 and prior

For additional information, please visit Product 1 , Product 2 , Product 3 , Product 4