California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Boston Scientific Corporation Recalls Boston Scientific Pacemaker

Recall Date	Product Description	Recalling Firm	Recall Reason
4/24/2026	Boston Scientific Cardiac Resynchronization Therapy (CRT) labeled as: VALITUDE CRT-P EL, Model Number U125; VALITUDE CRT-P EL MRI, Model Number U128; VISIONIST CRT-P EL, Model Number U225; VISIONIST CRT-P EL, Model Number U226; VISIONIST CRT-P EL MRI, Model Number U228.	Boston Scientific Corporation Saint Paul, MN	Updated software, Brady software maintenance release 6 (SMR6), is now available for the ACCOLADE" family of pacemakers and cardiac resynchronization therapy pacemakers.

Recall Class	Product Identification	Distribution	Affected Dates
I	The advisory population includes all models listed; however, the bounding differs by battery type: " All serialized DR-EL pacemakers and CRT-Ps from the ACCOLADE family are included in the advisory population.	685,776 Units Worldwide	March 2026 and prior

	" ACCOLADE DR-SL and SR-SLs with a use-by-date (UBD) on or before 30 June 2025 are included in the advisory population. Model number alone will not precisely identify individual DR-SL or SR-SL devices in the advisory population. To determine if a device is affected, enter a model/serial into the device lookup tool at BostonScientific.com/lookup		

For additional information, please visit the FDA website