California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Spectranetics Corporation Intact Vascular Tack Endovascular System

Recall Date	Product Description	Recalling Firm	Recall Reason
02/14/2025	Intact Vascular Tack Endovascular System, to treat vascular dissections with Tack implant(s) following angioplasty: (4F,1.5-4.5mm), 150cm, REF: 154150041 Tack, 4F Gen 1.5, 150cm CE, REF: 154150042 Tack, 4F Gen 1.5, 90cm CE, REF: 154090042 (6F, 3.5 - 6.0mm), 135cm, REF: 156135061 (6F, 4.0 - 8.0mm), 135cm, REF: 206135061 Tack, 6F Gen 2.0, 135cm CE, REF: 206135062 Tack, 6F Gen 1.5, 135cm CE, REF: 156135062 Tack, 6F Gen 2.0, 80cm CE, REF: 206080062 Tack, 6F Gen 1.5, 80cm CE, REF: 156080062	Spectranetics Corporation	Use of Tack Endovascular system, designed to treat acute dissections of inner wall or lining of an artery by tacking damaged tissue to inner luminal surface, could result in problems with deployment and stability of device in vessel after deployment, which may cause failure to resolve dissection, migration of implant, bailout stenting, reintervention, unintended removal of tack devices, and ischemia.

Recall Class	Product Identification	Distribution	Affected Dates
I	UDI-DI: 00863328000189 REF: 154150041 Batch: 332905 – 349049 REF: 154150042 Batch: 328641 REF: 154090042 Batch: 322101 UDI-DI: 00863328000103 REF: 156135061 Batch: 332824 – 336121 UDI-DI: 00850003494043 REF: 206135061 Batch: 331281 – 336152 REF: 206135062 Batch: 328643 – 345567 REF: 156135062 Batch: 271330 – 283066 REF: 206080062 Batch: 321083 – 349035 REF: 156080062 Batch: 302251 - 349034	2939 units nationwide	January and prior

For additional information, please visit FDA Website.