California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Ethicon Endo Surgery, LLC PDS Plus VIO, PDSII VIO, PROLENE BLU, and ETHIBOND EXCEL GRN

Recall Date	Product Description	Recalling Firm	Recall Reason
04/03/2025	PDS Plus VIO 30IN (75CM) USP6-0 (M0.7) D/A C-1 MP PDSII VIO 30IN (75CM) USP6-0 (M0.7) D/A C-1 PROLENE BLU 18IN(45CM) USP6-0(M0.7) S/A P-1 PRM ETHIBOND EXCEL GRN 36IN(90CM) USP2-0(M3) D/A MH	Ethicon Endo Surgery, LLC	Identified curing issues with the silicone during the needles manufacturing process.

Recall Class	Product Identification	Distribution	Affected Dates
II	Product Code: PDP127H-14 GMDN: 47362 UDI-DI: 10705031047907 Lot number: 104M7E Product Code: Z127H-50 GMDN: 16584 UDI-DI: 10705031060227 Lot number: 104BQC Product Code: (1) 8706H-15 (2) 8711H-16 GMDN: 13909	792 units nationwide 1,080 units nationwide 37,080 units nationwide	March and prior

	UDI-DI: (1) 10705031019430 (2) 10705031019560 Lot number: 104E88 - 104SER Product Code: X843H-56 GMDN: 13906 UDI-DI: 10705031058088 Lot number: 10489X	2,556 units nationwide	

For additional information, please visit: FDA Website (PDS), FDA Website (PDSII), FDA Website (PROLENE), and FDA Website (ETHIBOND).