California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Orthofix U.S. LLC Orthofix Pillar SA Ti Spacer System Intervertebral Body Fusion Spinal Device

Recall Date	Product Description	Recalling Firm	Recall Reason
03/21/2025	Orthofix Pillar SA Ti Spacer System Intervertebral Body Fusion Spinal Device, sterile, implant grade titanium alloy: REF: 82-3300SP 33mm W x 24mm D x 10mm H, 7 degrees REF 82-3700SP 37mm W x 28mm D x 10mm H, 7 degrees REF 82-4000SP 40mm W x 32mm D x 10mm H, 7 degrees	Orthofix U.S. LLC	The product is mislabeled with the incorrect anterior height of 10mm, but the laser marking on the implant and corresponding trial both show the correct anterior height of 10.5mm.

Recall Class	Product Identification	Distribution	Affected Dates
	REF: 82-3300SP Lot Number: 001 UDI: 18257200160426 REF: 82-3700SP Lot Number: 001 UDI: 18257200160884	5 units in California	February and prior

	REF 82-4000SP - Lot Number 001, UDI 18257200161270.		

For additional information, please visit the FDA Website.