California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Alphatec Spine, Inc. Recalls Non Sterile Implants and Convenience Kits for Spinal Fusion Procedures

Recall Date	Product Description	Recalling Firm	Recall Reason
01/30/2025	Calibrate CCX Interbody System for spinal fusion procedures: Implants: Calibrate CCX-O, 7 x 10 x 25mm 5 degrees, Part #325-07102505, nonsterile; Calibrate CCX-O, 7 x 10 x 25mm 10 degrees, Part #325-07102510, nonsterile; Calibrate CCX-O, 7 x 10 x 25mm 15 degrees, Part #325-07102515, nonsterile; Calibrate CCX-O, 7 X 10 X 30mm 5 degrees, Part #325-07103005, nonsterile; Calibrate CCX-O, 7 x 10 x 30mm 10 degrees, Part #325-07103010, nonsterile; Calibrate CCX-O, 7 x 10 x 30mm 15 degrees, Part #325-07103015, nonsterile; Calibrate CCX-O, 7 x 10 x 35mm 10 degrees, Part #325-07103510, nonsterile; Calibrate CCX-O, 7 x 10 x 35mm 15 degrees, Part #325-07103515, nonsterile; Calibrate CCX-O, 9 x 10 x 25mm 5 degrees, Part #325-09102505, nonsterile; Calibrate CCX-O, 9 x 10 x 25mm 10 degrees, Part #325-09102510, nonsterile; Calibrate CCX-O, 9 x 10 x 30mm 5 degrees, Part #325-09103005, nonsterile; Calibrate CCX-O, 9 x 10 x 30mm 10 degrees, Part	Alphatec Spine, Inc.	Complaints have been received regarding post-operative implant collapse.

	#325-09103010, nonsterile; Calibrate CCX-O, 11 x 10 x 30mm 10 degrees, Part #325-11103010, nonsterile; Calibrate CCX-S, 7 x 10 x 22mm 5 degrees, Part #326-07102205, nonsterile; Calibrate CCX-S, 7 x 10 x 22mm 10 degrees, Part #326-07102210, nonsterile; Calibrate CCX-S, 7 x 10 x 22mm 15 degrees, Part #326-07102215, nonsterile; Calibrate CCX-S, 7 x 10 x 26mm 5 degrees, Part #326-07102605, nonsterile; Calibrate CCX-S, 7 x 10 x 26mm 10 degrees, Part #326-07102610, nonsterile; Calibrate CCX-S, 7 x 10 x 26mm 15 degrees, Part #326-07102615, nonsterile; Calibrate CCX-S, 7 x 10 x 30mm 10 degrees, Part #326-07103010, nonsterile; Calibrate CCX-S, 9 x 10 x 22mm 5 degrees, Part #326-09102205, nonsterile; Calibrate CCX-S, 9 x 10 x 22mm 10 degrees, Part #326-09102210, nonsterile; Calibrate CCX-S, 9 x 10 x 26mm 5 degrees, Part #326-09102605, nonsterile; Calibrate CCX-S, 9 x 10 x 26mm 10 degrees, Part #326-09102610, nonsterile; and Calibrate CCX-S, 11 x 10 x 26mm 10 degrees, Part #326-11102610, nonsterile. Convenience kits containing affected implants: Calibrate CCX Oblique Implants, REF CLCCXOIMPA, containing 24 implants/kit, nonsterile; and Calibrate CCX Straight Implants, REF CLCCXSIMPA, containing 36 implants/kit, nonsterile.		

Recall Class	Product Identification	Distribution	Affected Dates
	Implants:	104 loose implants	January 2025 and

II	UDI-DI 00190376533308, Lot Numbers AP02103–AP03207 UDI-DI 00190376532967, Lot Numbers AP02104–AP02894 UDI-DI 00190376532974, Lot Numbers AP02105–AP03110 UDI-DI 00190376532998, Lot Numbers AP02114–AP02919 UDI-DI 00190376533001, Lot Numbers AP02106–AP02839 UDI-DI 00190376533018, Lot Numbers AP02107–AP02892 UDI-DI 00190376533049, Lot Numbers AP02108–AP02433 UDI-DI 00190376533056, Lot Number AP02144 UDI-DI 00190376533322, Lot Numbers AP02109–AP03180 UDI-DI 00190376533339, Lot Numbers AP02110–AP02962 UDI-DI 00190376533360, Lot Numbers AP02111–AP02438 UDI-DI 00190376533377, Lot Numbers AP02112–AP02773 UDI-DI 00190376532653, Lot Numbers AP02113–AP02921 UDI-DI 00190376530277, Lot Numbers AP02115–AP03100 UDI-DI 00190376530284, Lot Numbers AP02116–AP02896 UDI-DI 00190376530291, Lot Numbers AP02117–AP02623 UDI-DI 00190376530314, Lot Numbers AP02118–AP02875 UDI-DI 00190376530321, Lot Numbers AP02119–AP02843 UDI-DI 00190376530338, Lot Numbers AP02120–AP02922 UDI-DI 00190376530369, Lot Numbers AP02121–AP02423 UDI-DI 00190376530758, Lot Numbers AP02122–AP02424 UDI-DI 00190376530765, Lot Numbers AP02123–AP02625 UDI-DI 00190376530796, Lot Numbers AP02124–AP02844 UDI-DI 00190376530802, Lot Numbers AP02125–AP03095	distributed to distributors and subsequently to customers in California 2 Sterilization Convenience Kits distributed to distributors and subsequently to customers in California	Prior

	UDI-DI 00190376531281, Lot Numbers AP02126–AP02779 Convenience Kits: UDI-DI 00190376553535, Serial Numbers 2000494–2000503 UDI-DI 00190376553542, Serial Numbers 2000727–2000731		

For additional information, please visit the FDA Website.