State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Alphatec Spine Recalls Lif Amp For Adjustable Awl

Recall Date	Product Description	Recalling Firm	Recall Reason
9/6/2023	**Lif Amp** Adjustable Awl, REF 117-165, Part of the AMP System. Used with Spine Lateral Interbody Systems, IdentiTi LIF, Transcend LIF and Battalion LLIF,	**ALPHATEC SPINE, INC.** Carlsbad, California	Awl instrument adjustable drill button assembly assembled in the incorrect orientation, preventing locking feature from engaging with shaft at the desired set point; instruments lack ability to control awl depth by means of adjustable shaft advancement stop, which may lead to over insertion, dural tear, vascular/neurologic injury, adjacent tissue damage, increased operative time, revision surgery.

Recall Class	Product Identification	Distribution	Affected Dates
II	**LIF AMP** UDI-DI: 00190376228037, Lot: EM50715	29 Units Nationwide including California	July 7, 2023 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

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