



CALIFORNIA DEVICE RECALL INFORMATION SHEET

Acumed LLC Recalls Acutrak Series Bone Hardware for Lack of Premarket Clearance

Recall Date	Product Description	Recalling Firm	Recall Reason
1/04/2023	30mm Acutrak® Fusion Device 6mm Nose	Acumed LLC, Hillsboro, Oregon	Distribution without Pre-Market Clearance.
1/04/2023	Acutrak 2® Screw 20.0 & 22.0 mm - 4.7 25.0 - 45.0 mm - 5.5 40.0 & 45.0mm - 7.5	Acumed LLC, Hillsboro, Oregon	No Pre-Market Clearance.
1/04/2023	Acutrak Fusion Device 16.0 - 37.0mm	Acumed LLC, Hillsboro, Oregon	No Pre-Market Clearance.
1/04/2023	Mini Acutrak® Fixation Screw & Mini Acutrak 2® Bone Screw 10.0 - 30.0mm	Acumed LLC, Hillsboro, Oregon	No Pre-Market Clearance.
1/04/2023	Micro Acutrak 2® Bone Screw 8.0 - 30.0mm	Acumed LLC, Hillsboro, Oregon	No Pre-Market Clearance.
1/04/2023	Acutrak 4 / 5 Bone Screw 25.0 - 50.0mm Devices	Acumed LLC, Hillsboro, Oregon	No Pre-Market Clearance.
1/04/2023	Acutrak 6 / 7 Fixation Screw 45 - 100mm	Acumed LLC, Hillsboro, Oregon	No Pre-Market Clearance.
1/04/2023	Acutwist Acutrak Compression Screw 10 - 30mm	Acumed LLC, Hillsboro, Oregon	No Pre-Market Clearance.

1/04/2023	Standard Acutrak 2 Bone Screw 16.0 - 34.0mm	Acumed LLC, Hillsboro, Oregon	No Pre-Market Clearance.
1/04/2023	Dual-Trak Clavicle Screw 3.0-3.8mm x 80-120mm	Acumed LLC, Hillsboro, Oregon	No Pre-Market Clearance.

Recall Class	Product Identification	Distribution	Affected Dates
II	30mm Acutrak® Fusion Device 6mm Nose 30-0033-S	391 Devices in California	June 2009 to August 2022
II	Acutrak 2® Screw 4.7 30-0620 - 30-0622 5.5 30-0021 - 30-0029 7.5 30-0740 - 30-0745	11,616 Devices in California	April 2012 to September 2022
II	Acutrak Fusion Device ATF-160-S - ATF-370-S	2,355 Devices in California	January 2009 to September 2022
II	Mini Acutrak® Fixation Screw & Mini Acutrak 2® Bone Screw ATM-100-S - AT2-M30	31,077 Devices in California	January 2009 to September 2022
II	Micro Acutrak 2® Bone Screw AT2-C08 - AT2-C30-S	29,314 Devices in California	January 2009 to September 2022
II	Acutrak 4 / 5 Bone Screw AM-0025-S - AM-0050-S	460 Devices in California	January 2009 to May 2020
II	Acutrak 6 / 7 Fixation Screw AP-6745-S - AP-67100-S	1,297 Devices in California	January 2009 to September 2019
II	Acutwist Acutrak Compression Screw AI-0010-S - AI-0030-S	1,614 Devices in California	April 2009 to September 2022
II	Standard Acutrak 2 Bone Screw AT2-S16-S - AT2-S34-S	11,616 Devices in California	January 2009 to September 2022

II	Dual-Trak Clavicle Screw 40-0136 - 40-0147	189 Devices in California	April 2011 to September 2022
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FOR ADDITIONAL INFORMATION, PLEASE EMAIL [ACUMED POSTMARKET SURVEILLANCE](#) OR VISIT THE [FDA WEBSITE](#)

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