URGENT: MEDICAL DEVICE RECALL

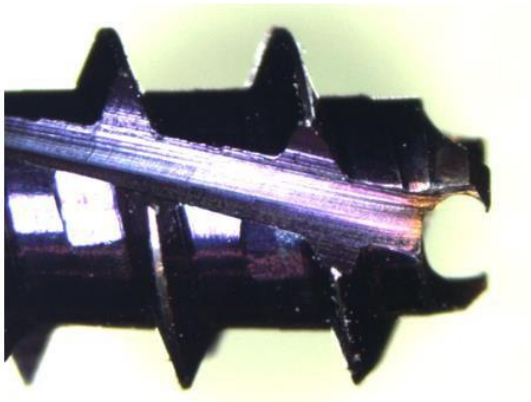
ACUTRAK 2 SCREW SYSTEM

Recall Number: R24-005 27 December 2024

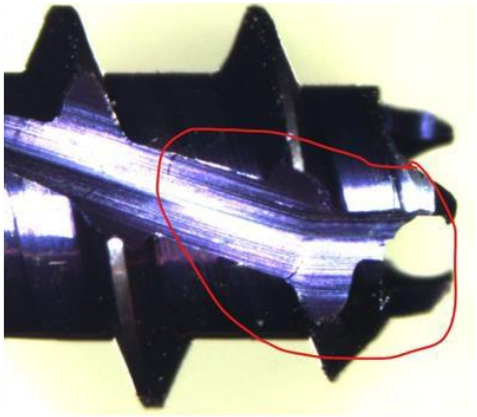
Dear Recipient,

This letter is to inform you that Acumed has initiated a Recall to remove the below listed Acutrak 2 Screw System devices due to the potential for the cutting flute of the screw to not be straight at the tip. To date, there have been no complaints or adverse events due to this issue.

It has come to Acumed's attention that there is the potential for an Acutrack 2 Screw, reference below for specific part and batch numbers, to be manufactured with the cutting flute of the screw not straight at the tip. The photo provided highlights the cutting flute that is not straight, on the right.



Conforming part



Nonconforming part

Please note, any potentially non-conforming screw may be difficult to identify if the label has already been removed. If the label has already been discarded, the screw can be identified by the physical marking on the part. If the number of the part reads as one of the below listed batch/lot numbers, please return this part to Acumed (see Actions to be taken).

A voluntary recall to withdraw the following product from the field has been issued for the batch/lot number listed in the table below.

Part Number	Description/Commercial Name	Batch/ Lot Number	UDI
30-0620	20.0mm Acutrak 2® - 4.7 Screw	649710	10806378019869-649710241113
30-0622	22.0mm Acutrak 2® - 4.7 Screw	650026	10806378019883-650026241114
30-0624	24.0mm Acutrak 2® - 4.7 Screw	619496	10806378019906-619496241001
30-0626	26.0mm Acutrak 2® - 4.7 Screw	647073	10806378019920-647073241017
30-0628	28.0mm Acutrak 2® - 4.7 Screw	620482	10806378019944-620482241008
30-0628	28.0mm Acutrak 2® - 4.7 Screw	649195	10806378019944-649195241108
30-0630	30.0mm Acutrak 2® - 4.7 Screw	636275	10806378019968-636275241011
30-0630	30.0mm Acutrak 2® - 4.7 Screw	647228	10806378019968-647228241018
30-0630	30.0mm Acutrak 2® - 4.7 Screw	647421	10806378019968-647421241021
30-0630	30.0mm Acutrak 2® - 4.7 Screw	648686	10806378019968-648686241104

Part Number	Description/Commercial Name	Batch/ Lot Number	UDI
30-0630	30.0mm Acutrak 2® - 4.7 Screw	648808	10806378019968-648808241105
30-0630	30.0mm Acutrak 2® - 4.7 Screw	648915	10806378019968-648915241106
30-0630	30.0mm Acutrak 2® - 4.7 Screw	649338	10806378019968-649338241111
30-0635	35.0mm Acutrak 2® - 4.7 Screw	640388	10806378019982-640388241014
30-0635	35.0mm Acutrak 2® - 4.7 Screw	619064	10806378019982-619064240923
30-0635	35.0mm Acutrak 2® - 4.7 Screw	647074	10806378019982-647074241017
30-0635	35.0mm Acutrak 2® - 4.7 Screw	647721	10806378019982-647721241023
30-0640	40.0mm Acutrak 2® - 4.7 Screw	647901	10806378020001-647901241025
30-0640	40.0mm Acutrak 2® - 4.7 Screw	647722	10806378020001-647722241023
30-0640	40.0mm Acutrak 2® - 4.7 Screw	650660	10806378020001-650660241121
30-0640	40.0mm Acutrak 2® - 4.7 Screw	647785	10806378020001-647785241024
30-0645	45.0mm Acutrak 2® - 4.7 Screw	620722	10806378020025-620722241009
30-0645	45.0mm Acutrak 2® - 4.7 Screw	620483	10806378020025-620483000000
30-0645	45.0mm Acutrak 2® - 4.7 Screw	626728	10806378020025-626728241010
30-0650	50.0mm Acutrak 2® - 4.7 Screw	648340	10806378020049-648340241030
30-0650	50.0mm Acutrak 2® - 4.7 Screw	648091	10806378020049-648091241028
30-0650	50.0mm Acutrak 2® - 4.7 Screw	648685	10806378020049-648685241104
30-0650	50.0mm Acutrak 2® - 4.7 Screw	649337	10806378020049-649337241111
30-0650	50.0mm Acutrak 2® - 4.7 Screw	650233	10806378020049-650233241115
30-0650	50.0mm Acutrak 2® - 4.7 Screw	650394	10806378020049-650394241118

Primary clinical purpose of device:
This screw is part of the Acumed Acutrak 2 Screw System which may be used for fractures, fusions, or osteotomies of the clavicle, humerus, radius, ulna, ilium, femur, patella, fibula, tibia, talus, malleolus, and calcaneus.

Risks to Health:
Screws may not seat fully in the bone. A screw that does not seat in the bone could potentially cause a delay of surgery and/or cause malunion or nonunion. Other potential risks could include incomplete healing, nerve irritation, soft tissue irritation, device failure, and loss of reduction.

Actions to be taken:

IMMEDIATELY stop using and/or distributing the product and complete the following actions:

1) Perform a physical count of your inventory to identify product with the Part Number and Batch Numbers in the table above.
2) Remove the product identified in step 1, such that they are taken out of service (i.e., quarantined).
3) Record this data on the survey found at the end of this recall letter. **If you do not have product to return, you are still required to complete the survey.**
4) Return the completed survey via email to RecallNotification@acumed.net.
5) If you have product to return, please email RecallNotification@acumed.net. **so that a Return Authorization Number and return instructions can be provided.**
6) Return the product to Acumed as follows:
   - Independent Sales Consultants: please contact Acumed Agent Inventory via email at agentinventory@acumed.net
   - Domestic Direct Customers: please contact Acumed Business Services via email at businessservices@acumed.net or contact your agent directly to be assigned a Return Material Authorization (RMA) number and applicable shipping information.
   - International Customers: please contact Acumed Business Services via email at internationalbusinessservices@acumed.net or via phone at (888) 627-9957 Option 4 (US and Canada) or +001 (503) 627-9957 and choose Option 4 (outside of US and Canada) to be assigned a Return Material Authorization (RMA) number and applicable shipping information.

Physicians are urged to notify Acumed of any adverse events or product safety issues. Please report any adverse events or product safety issues to customercomplaints@acumed.net.

Please note that this recall extends to the user level. If you have distributed the affected product, please notify your consignees about this issue, and ensure that any inventory is taken out of service.

We appreciate your immediate attention and cooperation. Acumed sincerely regrets any inconvenience this action may cause. Please contact via email at RecallNotification@acumed.net with any questions regarding this notification.

Thank you for your cooperation,

Vice President of Quality Assurance & Regulatory Affairs

acumed®

R24-005 OUTSTANDING FIELD ACTION SURVEY

Indicate the quantity of the product that you are returning below:

Product Information		
Part Number	**Lot Number**	**Quantity to be Returned**

Please provide us with your information below. This serves as an acknowledgement of receipt of this notice and will assist Acumed with tracking responses.

Company		**Phone**	
Name		**Date**	
Title		**Signature**	

R24-005 Notification Letter

Final Audit Report 2024-12-30

Created:	2024-12-30 (Central Standard Time)
By:	Michelle Ellis (michelle.ellis@acumed.net)
Status:	Signed
Transaction ID:	CBJCHBCAABAAI52KoF_M143mOL16YP10DS7r36BcT8J9

"R24-005 Notification Letter" History

Document created by Michelle Ellis (michelle.ellis@acumed.net)
2024-12-30 - 7:44:42 AM CST- IP address: 107.140.216.160

Document emailed to Kathryn Jayne (kathryn.jayne@acumed.net) for signature
2024-12-30 - 7:45:18 AM CST

Email viewed by Kathryn Jayne (kathryn.jayne@acumed.net)
2024-12-30 - 7:46:49 AM CST- IP address: 104.47.58.126

Kathryn Jayne (kathryn.jayne@acumed.net) authenticated with Email OTP by verifying one-time code sent via email
Challenge: The user opened the agreement.
2024-12-30 - 7:47:14 AM CST

Kathryn Jayne (kathryn.jayne@acumed.net) authenticated with Email OTP by verifying one-time code sent via email
Challenge: The user completed the signing ceremony.
2024-12-30 - 7:49:13 AM CST

Document e-signed by Kathryn Jayne (kathryn.jayne@acumed.net)
Signing reason: I approve this document
Signature Date: 2024-12-30 - 7:49:14 AM CST - Time Source: server- IP address: 209.133.83.52

Agreement completed.
2024-12-30 - 7:49:14 AM CST