



URGENT FIELD SAFETY NOTICE

FIRST NOTICE

FSCA Number: R22-006

14 December 2022

Dear Recipient,

It has come to Acumed's attention that two batches of Acumed sterile screws were impacted by a mix-up of labeling. The part number and batch/lot number on the medical chart label inside the box are different from the part number and batch/lot number on the outer box. This was due to a supplier error at the supplier's facility.

To date, there have been no reported incidents of injury associated with these products. A Field Safety Corrective Action (FSCA) to withdraw the following product from the field has been issued for the batches listed in the table below. The appropriate Competent Authorities have been made aware.

Please use the information in the table below to identify the affected product. What is listed in the table is how the affected product was packaged (outer box/package). Product with the outer box labeled with part number COL-3140-S batch/lot 546410 may contain a medical chart label with part number 30-0303-S batch/lot number 546510 listed on the label. Similarly, product with the outer box labeled with part number 30-0303-S batch/lot number 546510 may contain a medical chart label with part number COL-3140-S batch/lot number 546410 listed on the label. The part number of the actual screw itself within the package matches the part number listed on the outer box.

Part Number	Description	Batch/Lot Number	UDI	Dates Distributed
COL-3140-S	3.5mm x 14.0mm Locking Cortical Screw	546410	10806378063275-546410211021281020	Oct 2021
30-0303-S	3.0mm x 12mm Non-Locking Hexalobe Screw	546510	10806378017575-546510211022281021	Oct 2021

Figure 1 below illustrates an example of a product with the outer box labeled as part number COL-3140-S batch/lot 546410 that contains a medical chart label with part number 30-0303-S batch/lot number 546510 listed on the label.

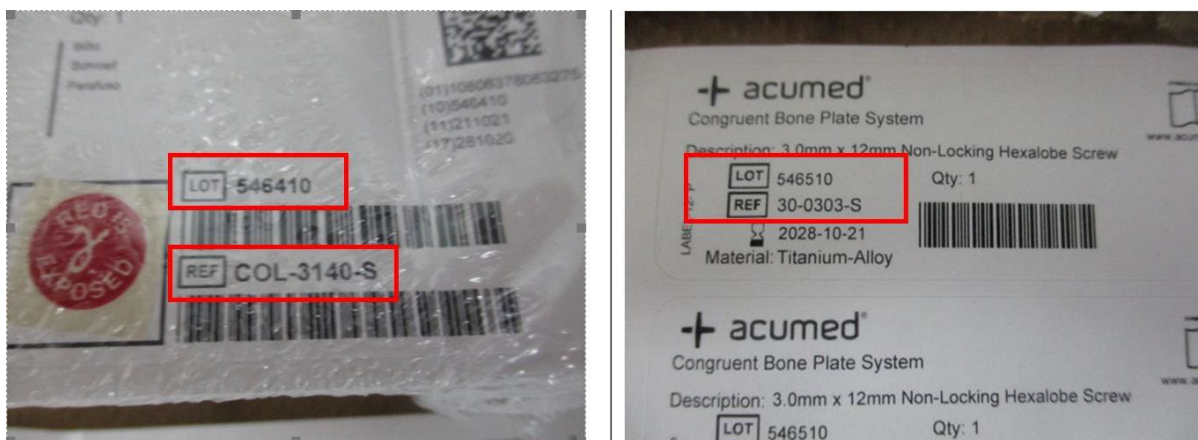


Figure 1. The part number (REF) and batch/lot number on the outer box (left) does not match the part number and batch/lot number listed on the medical chart label (right) found inside the box.

Intended use of device:



Both part number COL-3140-S and part number 30-0303-S are sterile packaged screws that are part of the Acumed Bone Plate Systems (Congruent Bone Plate System, Acumed Lower Extremity Bone Plate System, Polarus® Locking Proximal Humeral Plate System, and Scapula Congruent Bone Plate System). Based on the system, these screws are used in various applications as detailed below:

- In the Acumed Congruent Bone Plate System to provide fixation during fractures, fusions, and osteotomies for the clavicle, humerus, radius, ulna, metacarpal, metatarsal, malleolus, tibia, and fibula.
- In the Acumed Lower Extremity Bone Plate System to provide fixation during fractures, fusions, and osteotomies for the phalanges, metatarsals, tarsals fibula, and tibia bones.
- In the Acumed Polarus® Locking Proximal Humeral System for fracture fixation and osteotomies of the humerus.
- In the Acumed Scapula Congruent Bone Plate System to provide fixation during fractures, fusions, and osteotomies for the scapula.

Potential risk for health related to this corrective action:

If not identified prior to the start of a procedure after opening the packaging, the mislabeling error may result in the misidentification of the screws or for the incorrect screw length to be used. This could result in a delay in surgery. Additionally, a longer screw which may sit proud in the prepared hole during the procedure; proud screws could delay surgery. In addition, there is potential for the need for a secondary surgery/revision if the incorrect screw was used.

Replacement screws will be shipped. Please follow the instructions below to complete the recall actions.

Special Instructions

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

- 1) Perform a physical count of your inventory both in trays and in its packaging.
- 2) For product still in the packaging, review the part number and batch/lot number marked on the outer box packaging against the part number and batch/lot number on the medical chart label inside the box. If they **do not** match, **segregate** those products. Product that has matching part numbers and batch/lot numbers on both the medical chart label and the outer box do not need to be segregated as there is no issue with product that has matching labeling.
- 3) Remove the product segregated in step 2, such that they are taken out of service (i.e., quarantined).
- 4) Record this data on the survey found at the end of this Field Safety Notice. If you do not have product to return, you are still required to complete the form.
- 5) Return the completed form via email to RecallNotification@acumed.net.
- 6) Return the product to Acumed as follows:
 - 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.

Please note that this FSCA 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 Acumed Business Services via email at BusinessServices@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) with any questions regarding this notification.

Thank you for your cooperation,

12/14/2022

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Senior Director of Quality Assurance & Regulatory Affairs

R22-006 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

Company		Phone	
Name		Date	
Title		Signature	