



## URGENT FIELD SAFETY NOTICE

Recall Number: R21-006

05 November 2021

Dear Recipient,

It has come to Acumed's attention that two batches of T15 Stick Fit Hexalobe Drivers have features out of specification. The grooves appear rough, and the lobes are off center and larger than acceptable (as pictured in Image 1). This results in the tip of the driver not fitting into the Hexalobe feature of a screw. This situation occurred due to an internal manufacturing error.

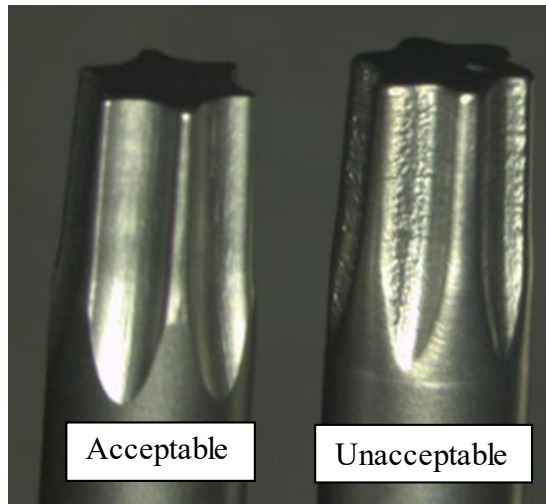


Image 1. Example of recalled batches pictured on the right

To date, there have been no reported incidents of injury associated with this product. A Field Safety Corrective Action (FSCA) to withdraw this product from the field has been issued for the batches listed in the table below. The appropriate CAs have been informed of the FSCA.

Part	Description	Batch	UDI	Dates Distributed
80-0760	T15 Stick Fit Hexalobe Driver	533818	10806378044557-533818210707	July 2021
80-0760	T15 Stick Fit Hexalobe Driver	533819	10806378044557-533819210707	July 2021

Replacement drivers will be shipped. Please follow the instructions below to complete the FSN actions.

### Special Instructions

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

- 1) Perform a physical count of your inventory.
- 2) Remove the affected drivers, such that they are out of service (i.e., quarantined). If you do not have product to return, you are still required to complete the form per number 4 below.
- 3) Record this data on the survey found following this FSN.
- 4) Fill out the survey (page 2 of this letter) and return it via email to [RecallNotification@acumed.net](mailto:RecallNotification@acumed.net).
- 5) To facilitate return of product to Acumed:  
Please contact Acumed Business Services via email at [internationalbusinessservices@acumed.net](mailto:internationalbusinessservices@acumed.net) or via phone at +001 (503) 627-9957 and choose Option 4 to be assigned a Return Material Authorization (RMA) number and applicable shipping information.
- 6) Once completed, please return the affected drivers to Acumed. Please contact Acumed for a return number.



Please note that this FSN 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](mailto:BusinessServices@acumed.net) or via phone at +001 (503) 627-9957 and choose Option 4 with any questions regarding this notification.

Thank you for your cooperation,

XXX

**R21-006 OUTSTANDING FIELD ACTION SURVEY**

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

<b>Product Information</b>		
<b>Part Number</b>	<b>Lot Number</b>	<b>Quantity to be Returned</b>

<b>Company</b>		<b>Phone</b>	
<b>Name</b>		<b>Date</b>	
<b>Title</b>		<b>Signature</b>	