

X-BOLT Orthopaedics, Unit 5,  
Northwood Court, Santry,  
Dublin 9, Ireland  
T: +353 (0) 1 845 6011  
www.x-bolt.com



## URGENT FIELD SAFETY NOTICE

Date: 28<sup>th</sup> May 2015

- Description:** Screwdriver, 3.5mm – hex, 4.5Nm torque limit.
- Catalogue No:** XHS - 035
- Lot No.:** 557962 & 565491
- Possible Risks:** There is the potential for the torque mechanism within the screwdriver to fail which could result in the following:
1. The X-Bolt® could fail to open
  2. The Surgeon may be unable to insert the cortical screws for the plate
- Action Required:**
1. Should the torque mechanism fail the operating Surgeon should use a manual 3.5mm hex screwdriver to expand the X-Bolt® and insert the cortical screws.
  2. Replacement torque limiting screwdrivers will be supplied to you in August 2015. At this time we request you to locate and remove from circulation the items shipped to your account as identified on page three of this notice and carefully follow the instructions on the enclosed "Response Form".

Dear Customer,

This letter is to inform you of a Medical Device Recall initiated by X-BOLT® Orthopaedics which involves the Screwdriver, 3.5mm – hex, 4.5Nm torque limit, part number XHS-035. Our records show that these parts, lots 557962 and 565491, have been shipped to your account. The contract manufacturer of these devices, Bradshaw Medical, has alerted X-BOLT® Orthopaedics that these torque handles feature a design that may allow the torque mechanism to fail, thereby, unintentionally delivering a torque that is either below or beyond the specification. X-BOLT® Orthopaedics has initiated this Field Safety Notice following the receipt of a Market Withdrawal Notice from Bradshaw Medical.

The investigation performed by X-BOLT® Orthopaedics found that the issue could result in delayed surgery while a replacement screwdriver is obtained. X-BOLT® Orthopaedics have conducted a complete risk assessment and we have concluded that it is safe to use the device until the replacement screwdrivers are available in August 2015.

This actions requires that a standard manual 3.5mm hex screwdriver should be used to expand the X-Bolt® and insert the cortical screws should the torque mechanism fail. Once the replacement



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screwdrivers are available we request that you immediately locate and discontinue use of the items identified on page three of this notice, and return them to X-BOLT® Orthopaedics. Specifically, you are required to take the following steps:

1. Immediately locate and remove from circulation the items shipped to your account as identified on page three of this notice.
2. Carefully follow the instruction on the enclosed "Response Form".
3. If you have further distributed these items, you must notify them of this action by providing a this letter to the person responsible for receiving recall notices.

Please complete the attached Acknowledgement Form and return it to X-BOLT Orthopaedics at the following address [info@x-bolt.com](mailto:info@x-bolt.com). Should you experience any issues with the Screwdriver, 3.5mm – hex, 4.5Nm torque limit, part number XHS-035, please report them to X-BOLT Orthopaedics at +353 1 845 6011 or [info@x-bolt.com](mailto:info@x-bolt.com).

If you have any questions regarding this information please contact X-BOLT Orthopaedics directly at the above contact details.

X-BOLT Orthopaedics is committed to providing quality products and service to its customers. We apologise for any inconvenience this situation may have caused.

The undersigned confirms that this notice has been notified the appropriate Regulatory Agency.

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Aisling O'Sullivan PhD  
Regulatory Affairs Manager,  
X-BOLT Orthopaedics.

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## Acknowledgement Form

<b>X-BOLT Reference</b>	VIG-003
<b>Hospital/Distributor Name</b>	
<b>Address</b>	
<b>Quantity &amp; piece number received:</b> XHS-035 Lot #557962	
XHS-035 Lot #565491	
<b>Quantity &amp; piece number returned:</b> XHS-035 Lot #557962	
XHS-035 Lot #565491	

We have physically checked all inventory and hospital locations and we do not have the following affected product:

<b>Quantity &amp; piece number unavailable:</b> XHS-035 Lot #557962	
XHS-035 Lot #565491	

Completed by: \_\_\_\_\_

Date: \_\_\_\_\_

Job Title: \_\_\_\_\_