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: 13th November 2014

Description:	Guidewire Measuring Ruler
Catalogue No:	XMG-001
Lot No.:	1307674
Action Required:	Subtract 5mm from the measured value when taking readings in excess of 100mm with the guidewire measuring ruler.
Possible Risks:	There is the potential for the incorrect size X-Bolt® to be implanted.

Dear Customer,

This letter provides important information regarding the potential for the incorrect size X-Bolt® to be selected and implanted. To date there have been no deaths or serious adverse events. To ensure patient safety please follow the instructions below when using the guidewire measuring ruler, XMG-001:

1. Follow the steps detailed within the surgical technique for the Dynamic Hip Plating System, SURGT-XBOLT-001 Revision 2 up to Step 4.
2. At Step 4 measure the depth of the laser mark on the guidwire (XNI-010) shaft with the guidewire measuring ruler (XMG-001). Subtract 5mm from the measured value when taking readings of 110mm or greater.
3. Continue to Step 5: Ream of the surgical technique for the Dynamic Hip Plating System, SURGT-XBOLT-001 Revision 2.

This notice needs to be passed on to all personnel who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. X-BOLT Orthopaedics are currently in the process of manufacturing replacement XMG-001 parts and expect for these to be available on 16th December 2014. We request that you follow the instructions provided in this FSN until such time as the replacement device is available.

Please complete the attached Acknowledgement Form and return it to X-BOLT Orthopaedics at the following address info@x-bolt.com. Should you experience any issues with the Bone Compactor, please report them to X-BOLT Orthopaedics at +353 1 845 6011 or info@x-bolt.com.

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

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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.

Aisling O'Sullivan 13/11/2014.

Aisling O'Sullivan PhD

Regulatory Affairs Manager,

X-BOLT Orthopaedics,

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Acknowledgement Form

X-BOLT Reference	VIG-002
Hospital/Distributor Name	
Address	
Field Safety Notice Received	
Field Safety Notice Communicated	

Completed by: _____

Date: _____

Job Title: _____