

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: 19<sup>th</sup> December 2013

<b>Description:</b>	X-BOLT® Bone Compactor
<b>Catalogue No:</b>	XBC-001
<b>Lot No.:</b>	137878-01 & 137667-01
<b>Action Required:</b>	Up-dated Instructions for Use detailing the amended manual and automated steps to be used for the X-BOLT® Plating Instruments including the Bone Compactor.
<b>Possible Risks:</b>	There is the potential for patient infection due an inadequately sterilized device.

Dear Customer,

This letter provides important information regarding the potential for inadequate cleaning of the X-BOLT Orthopaedics Bone Compactor. Specifically the existing washing instructions within the Instructions for Use, RPI-SOTA-XINST-001 Revision 2, may not be sufficient to adequately remove all soil following use of the device. This could result in an ineffective sterilisation process. To date there have been no deaths or serious adverse events. To ensure patient safety please clean the X-BOLT Plating Instruments using only washing techniques which comply with the washing instructions as detailed within RPI-SOTA-XINST-001 Revision 3. The washing steps are detailed below:

### Manual Cleaning

1. Submerge the instruments in enzymatic detergent (Cidezyme 0.8%) and soak for 20 minutes. The Bone Crusher shall be actuated in the enzymatic solution.
2. While submerged in the enzymatic detergent, scrub all the instruments with a soft bristled brush, paying special attention to the proximal end of the Bone Crusher. Clean the lumen of the Bone Crusher with a long, narrow soft-bristled brush.
3. Remove the instruments from the enzymatic detergent and rinse thoroughly in purified water for a minimum of three minutes. Thoroughly flush the lumen of the Bone Compactor with a water jet pistol.
4. Soak the instruments in an ultrasonic bath for 15 minutes at 40°C with enzymatic detergent (0.8% CideZyme). Fix the Bone Compactor in the open position to ensure that all the surfaces are wetted.
5. Remove the Bone Compactor from the ultrasonic bath after 10 minutes and rinse once from the distal to proximal end and twice from the proximal to the distal end of the device. Return the device to the ultrasonic bath for a further 5 minutes at 40°C with enzymatic detergent (0.8% CideZyme).



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6. Remove the instruments from the ultrasonic bath and rinse. When rinsing the Bone Compactor ensure to rinse the entire device and its lumen. Ensure to rinse the device on the pin area from both sides from the distal to proximal and proximal to distal ends.

### **Automated Cleaning**

#### **Manual Pre-Clean:**

1. Submerge the instruments in enzymatic detergent (Cidezyme 0.8%) and soak for 20 minutes. The Bone Crusher shall be actuated in the enzymatic solution.
2. While submerged in the enzymatic detergent, scrub all the instruments with a soft bristled brush, paying special attention to the proximal end of the Bone Crusher. Clean the lumen of the Bone Crusher with a long, narrow soft-bristled brush.
3. Remove the instruments from the enzymatic detergent and rinse thoroughly in purified water for a minimum of three minutes. Thoroughly flush the lumen of the Bone Compactor with a water jet pistol.
4. Soak the instruments in an ultrasonic bath for 15 minutes at 40°C with enzymatic detergent (0.8% CideZyme). Fix the Bone Compactor in the open position to ensure that all the surfaces are wetted.
5. Remove the Bone Compactor from the ultrasonic bath after 10 minutes and rinse once from the distal to proximal end and twice from the proximal to the distal end of the device. Return the device to the ultrasonic bath for a further 5 minutes at 40°C with enzymatic detergent (0.8% CideZyme).
6. Remove the instruments from the ultrasonic bath and rinse. When rinsing the Bone Compactor ensure to rinse the entire device and its lumen. Ensure to rinse the device on the pin area from both sides from the distal to proximal and proximal to distal ends

#### **Automated Cleaning**

1. Following the manual pre-cleaning steps clean the instruments in a validated washer disinfectant using a pH neutral cleaning agent intended for use in automated cleaning.
2. The cleaning cycle should incorporate the following steps;
  - a. Pre washing – soak all the instruments in cold tap water for 2 minutes.
  - b. Drain the and clean with deionised water and enzymatic detergent for 5 minutes at 55°C.
  - c. Rinse the instruments for 3 minutes using deionised water
  - d. Drain and complete a final 2 minutes rinse using deionised water.

Upon completion of the washing steps inspect the instruments for any visible signs of soil. All exterior and interior lumens of the Bone Compactor should be inspected and the cleaning process should be repeated if any soil is visible.

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.



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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 Bone Compactor, 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,