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URGENT FIELD SAFETY NOTICE

Date: 19th December 2013

Description:	X-BOLT® Bone Compactor
Catalogue No:	XBC-001
Lot No.:	137878-01 & 137667-01
Action Required:	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.
Possible Risks:	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).

