

February XX, 2016

To: Distributors, Sales Representatives, and Distribution Operation Managers

Subject: FIELD SAFETY NOTICE

**Affected Products: Instinct Java System Instruments, all lots
Universal Clamp System Instruments, all lots
UniWallis System Instruments, all lots**

Zimmer is initiating a Field Safety Notice to provide updated cleaning and disinfection instruction for use of Instinct® Java® System (IFU, reference: 046WAN0000T), Universal Clamp® System (IFU, reference: SN2027-N-90001 and SNA027-N-90001 for US market only) and UniWallis™ System (IFU, references: 038WNAN0000T). In addition, steam sterilization instruction for use were updated for Universal Clamp® System (IFU, reference: SN2027-N-90001) and UniWallis™ System (IFU, references: 038WNAN0000T).

Since the market launch of each products (2010 Instinct Java System, 2004 Universal Clamp system, 2009 UniWallis system), the instruments were distributed with Instruction for use related to the method for cleaning and disinfection and for steam sterilization at health care facilities; however, the method was not adequately validated. The affected instruments were distributed throughout United States, Europe, Asia-Pacific and South America.

Instruments cleaned, disinfected, and sterilized under the former IFU for the Instinct Java, Universal Clamp and/or UniWallis systems may not be adequately cleaned, disinfected and sterilized resulting in a risk of infection.

One (1) infection complaint for Universal Clamp was reported within the timeframe specified and zero (0) within the last twenty-four months.

Please immediately utilize the updated and attached Instructions For Use:

- Instinct Java System: 046WAN0000T rev 5
- Universal Clamp system: SN2027-N-90001 rev 5 rev and SNA027-N-90001 rev 6 for US market only
- UniWallis system: 038WNAN0000T rev 6

Your Responsibilities

1. Review the notification and ensure affected personnel are aware of the contents. Email a completed copy of Attachment 2 to dorothee.fleuri@zimmerbiomet.com
2. Confirm that you have received the new IFUs and are using them.
3. Destroy your inventory of old IFU and be sure to use the current IFU.
4. Indicate quantity of new IFU(s) needed on the attachment 2

5. Please notify Zimmer Biomet of any hospitals that you have further distributed the affected product to. Supply the information for any hospitals that you have identified. Using the distributor certification form which will be emailed to you for completion and return to dorothee.fleuri@zimmerbiomet.com
6. If after reviewing this notification you have further questions or concerns please contact Dorothee Fleuri to +33 5 24 72 1905 or email: dorothee.fleuri@zimmerbiomet.com, or contact your Zimmer Biomet Sales Representative.

Other Information

This voluntary notification will be reported to the local Competent Authorities.

Any adverse reactions experienced with the use of these products, and/or quality problems may also be reported according to MEDDEV 2.12-1 Rev. 8 to the local health authority in your country.

Please keep Zimmer Spine informed of any adverse events associated with these devices or any other Zimmer Biomet Spine product. Adverse events may be reported to Zimmer Spine at spine.per@zimmerbiomet , or to your local Zimmer Biomet representative.

ATTACHMENT 1

UniWallis

Part Number	Name
038W1AN00011	UniWallis - Sizer instrument
038W1AN00012	Uniwallis Sizer Narrow Tip
038W1AN00100	Tipped ring passer
038W1AN00400	Tension guide
038W1AN00401	Implant Holder
038W1AN00450	Torque indicating tensioning tool
038W1AN00451	Torque Indicating Tensioning Handle
038W1AN00510	Interspinous ligament remover
038W1AN00650	Interspinous distractor
038W1AN00720	Screwdriver
038W1AN00920	Right band passer
038W1AN00921	Left band passer
038W1AN00922	Right Band Passer Standard
038W1AN00923	Left Band Passer Standard
038W1AN00924	Right Band Passer Large
038W1AN00925	Left Band Passer Large
038W1AN00950	Band forceps
038W2AN00000	UniWallis instrument container lid
038W2AN00001	UniWallis instrument container base
038W2AN00002	- UniWallis instrument container upper tray
038W2AN00003	UniWallis instrument container lower tray
038W2AN00004	Uniwallis Container lower tray 4BP

Universal Clamp

Part Number	Name
SN2027-1-00100	Right elevator
SN2027-1-00101	Left elevator
SN2027-1-00102	Elevator 45° Right
SN2027-1-00103	Elevator 45° Left
SN2027-1-00104	Straight elevator
SN2027-1-00110	Band passer Right
SN2027-1-00111	Band passer left
SN2027-1-00112	Band passer 45° Right
SN2027-1-00113	Band passer 45° left
SN2027-1-00200	Reduction tool
SN2027-1-00270	Bengolea forceps
SN2027-1-00300	Coach screw reduction tool
SN2027-1-00401	Straight ratcheted handle
SN2027-1-00407	T ratcheted handle
SN2027-1-00512	Locking screw holder
SN2027-1-00570	3.5mm Screwdriver
SN2027-1-00600	Implant holder
SN2027-1-00610	Band forceps
SN2027-1-02100	Elevator 90° Right
SN2027-1-02101	Elevator 90° Left
SN2027-1-02102	Elevator 45° Right
SN2027-1-02103	Elevator 45° Left
SN2027-1-02104	Straight elevator
SN2027-1-02110	Band passer 90° Right
SN2027-1-02111	Band passer 90° left
SN2027-1-02112	Band passer 45° Right
SN2027-1-02113	Band passer 45° left
SN2027-1-02200	Reduction tool barrel
SN2027-1-02201	Reduction tool handle
SN2027-1-02270	Bengolea Forceps 20 cm
SN2027-1-02276	Bengolea Forceps 26 cm
SN2027-1-02512	Tapered Screw Starter
SN2027-1-02570	3.5mm Screwdriver
SN2027-1-02600	Implant Positioner
SN2027-2-00002	Instrument case
SN2027-2-00002D	Base
SN2027-2-00002E	Lid
SN2027-2-00002F	Tray
SN2027-2-00003	Instrument case for coach screw set
SN2027-2-00003A	Base
SN2027-2-00003B	Tray for coach screw set
SN2027-2-00003C	Lid
SN2027-2-02001	Lid
SN2027-2-02002	Case
SN2027-2-02003	Upper tray
SN2027-2-02004	Lower tray

Part Number	Name
046W1AN00100	Pedicular elevator
046W1AN00105	Laminar elevator
046W1AN00200	Laminar hook trial Small Narrow
046W1AN00201	Laminar hook trial Small Wide
046W1AN00210	Laminar hook trial Large Narrow
046W1AN00211	Laminar hook trial Large Wide
046W1AN00240	Pedicular hook trial Small
046W1AN00250	Pedicular hook trial Large
046W1AN00300	Speedlink II Final Driver
046W1AN00301	Hook forceps
046W1AN00302	Hook holder
046W1AN00310	Pusher
046W1AN00320	Lateral persuader forceps
046W1AN00321	Persuader pusher
046W1AN00322	Persuader handle
046W1AN00340	Frontal In Situ Bender Left
046W1AN00345	Frontal In Situ Bender Right
046W1AN00370	Autostable hook anti torque key
046W1AN00411	Crosslink Caliper
046W1AN00500	Square awl
046W1AN00505	Trial rod 100 mm
046W1AN00506	Trial rod 200 mm
046W1AN00520	Pedicular sounder straight flexible
046W1AN00530	Pedicule Probe
046W1AN00540	Rod bender
046W1AN00541	Rod pusher
046W1AN00542	Rod fork
046W1AN00550	Polyaxial 3.5 Screwdriver
046W1AN00551	Left rod bender
046W1AN00554	Right rod bender
046W1AN00555	Polyaxial 3.5 Screwdriver Universal
046W1AN00560	Monoaxial Screwdriver
046W1AN00565	Monoaxial Screwdriver Universal
046W1AN00570	Straight ratchet handle
046W1AN00580	Ratcheting T-handle
046W1AN00585	Straight Ratchet Handle II
046W1AN00590	Blocker holder
046W1AN00610	Derotation forceps
046W1AN00620	Rod holder
046W1AN00640	Final Screwdriver Shaft
046W1AN00641	Final Screwdriver Shaft II
046W1AN00650	Torque limiting T-handle



Part Number	Name
046W1AN00660	Countertorque wrench
046W1AN00661	Countertorque wrench Universal
046W1AN00670	Removal tab instrument
046W1AN00700	6N.m Final Screwdriver
046W1AN00701	6N.m Screwdriver tip
046W1AN00745	Tap Ø 4.5 mm
046W1AN00755	Tap Ø 5.5 mm
046W1AN00765	Tap Ø 6.5 mm
046W1AN00775	Tap Ø 7.5 mm
046W1AN00800	Distraction forceps
046W1AN00810	Contraction forceps
046W1AN00820	Derotation forceps
046W1AN00823	-Hook tip right
046W1AN00824	Hook tip left
046W1AN00830	Compression forceps
046W1AN00831	Autostable hook tip right
046W1AN00832	Autostable hook tip left
046W1AN00845	Tap 4.5mm Rigid
046W1AN00855	Tap 5.5mm Rigid
046W1AN00865	Tap 6.5mm Rigid
046W1AN00875	Tap Ø7.5 mm
046W1AN00885	Tap Ø8.5 mm
046W1AN00930	Alligator Persuader handle
046W1AN00931	Alligator Persuader sleeve
046W1AN00950	Inline Persuader
046W2AN00032	Instrument container base
046W2AN00033	Instrument container upper tray
046W2AN00034	Instrument container lower tray
046W2AN00035	Instrument container base
046W2AN00060	Iliac and Reduction Instrument base
046W2AN00061	Instinct Manipulation Tray

ATTACHMENT 2

IMMEDIATE RESPONSE REQUIRED –TIME SENSITIVE ACTION NEEDED

ACKNOWLEDGEMENT OF FIELD NOTIFICATION

Affected Product: Instinct Java System, Universal Clamp System, UniWallis Ssystem.

Territory Number: _____ **Account Number:** _____

Account Name: _____

Account Address: _____ **Phone Number:** _____

The following quantities of IFUs are needed to replace the additional instrument sets in my territory. Once they are received, all IFUs will be replaced immediately.

- _____ Instinct Java System: 046WAN0000T rev 5
- _____ Universal Clamp system: SN2027-N-90001rev 5
- _____ UniWallis system: 038WNAN0000T rev 6

Acknowledgement of Responsibility:

By signing below, I acknowledge that I have received the updated Instrument IFU for Instinct Java system (rev 5), Universal Clamp system (rev5), UniWallis System (rev 6); the required actions have been taken in accordance with the Field Safety Notice. I have provided copies of the Field notification to all my Instinct JavaSystem, UniWallis and or Universal Clamp System customers / users.

Printed
Name: _____ Signature: _____

Title _____ Telephone: () _____ - _____ Date: ____/____/____

Note: This form must be returned to Zimmer before this action can be considered closed for your account. It is your responsibility to complete this form and email a copy to: dorothee.fleuri@zimmer.com