

February 29, 2016

To: Hospital Representative, Cleaning and Steam Sterilization units

Subject: FIELD SAFETY NOTICE

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

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 to confirm that you have received the new IFUs and are using them.
2. Destroy your old inventory of old IFU and be sure to use the current IFU. If after reviewing this notification you have further questions or concerns please contact dorothee.fleuri@zimmerbiomet.com

3. If after reviewing this notification you have further questions or concerns please 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 | 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 |

| Instinct Java | |
|----------------------|-------------------------------------|
| 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

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

Account Name: _____

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

Acknowledgement of Responsibility:

By signing below, I acknowledge that I have received the updated Instrument IFU for Instinct Java system (rev5) Universal Clamp system (rev5) and/or UniWallis (rev6); and I have destroyed all old IFUs for these devices as directed in the Field Notification.

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@zimmerbiomet.com

ZFA 2015-154