



October 19, 2016

To: Hospital Representative, Cleaning units

Subject: **FIELD SAFETY NOTICE**

Affected Products: **Java Pedicle Screw System Instruments and containers, all lots**
Fidji Cervical Cage Instruments and containers, all lots
Fidji Lumbar Cage Instruments and containers, all lots
Wallis Posterior Dynamic Stabilization System instruments and containers, all lots

Zimmer Biomet is initiating a Field Safety Notice to provide updated cleaning and disinfection instruction that supersedes the ones related to the Java Posterior stabilization System (IFU, reference: 023ENAN0000T rev 1), Wallis® Posterior Dynamic Stabilization System (IFU, reference: 002WNAN0000T rev 1), Fidji® Cervical Cage (IFU, reference: 005ENAN0000T rev 1), Fidji® Lumbar Cage (IFU, reference: 001ENAN0000T rev 1)

Since the market launch of each products (2003 Java Posterior stabilization System, 2002 Wallis® Posterior Dynamic Stabilization System, 2002 Fidji® Cervical Cage and Fidji® Lumbar Cage), the instruments were distributed with Instruction for use related to the method for cleaning and disinfection at health care facilities; however, the method was not adequately validated.

Instruments cleaned, disinfected, under rev 1 IFU for the Java Posterior stabilization, Wallis Posterior Dynamic Stabilization and Fidji cervical and Lumbar cage systems may not be adequately cleaned and decontaminate resulting in a risk of infection.

One (1) complaint reported on Java Pedicle Screw System, within the specified timeframe, for a post-operative surrounding black color tissue formation around a Java implant found during a revision surgery, zero (0) within the last twenty-four months.

Zero (0) complaint reported on Fidji cervical and Lumbar cages system

Ten (10) complaints reported on Wallis for immediate post-operative infection/reaction, within the specified timeframe, with no link with the non-adequate cleaning of the instrumentation and Zero (0) within the twenty-four months.

Please find in attachment 2, the updated Instructions for cleaning and decontamination

Your Responsibilities

1. Review the notification and ensure your affected personnel are aware of the updated cleaning instructions contents by providing them this FSN and the attachments 1 and 2
2. Email a completed copy of Attachment 3 to your Zimmer Biomet local contact to confirm that you have received the updated cleaning and decontamination instructions.
3. New IFUs rev 2 that include updated cleaning and decontamination instructions are being provided to your Zimmer Biomet local contact.
4. If after reviewing this notification you have further questions or concerns please contact or email your Zimmer Biomet local contact

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

Java Posterior stabilization System

Description – Java TL Instruments	Device Reference
Tournevis 3.5 TL - TL 3.5 Screwdriver	SN2023-1-00400
Tournevis 3.5 avec fourreau - Sleeve 3.5 Screwdriver	SN2023-1-00401
Manche à Cliquet W - Ratchet handle	SN2023-1-00411
Pointe Carrée - Square awl	SN2023-1-00500
Clé Anti-Couple TL - TL Counter torque wrench	SN2023-1-00501
Gabarit de cintrage 100 mm - Trial rod 100 mm	SN2023-1-00505
Gabarit de cintrage 200 mm - Trial rod 200 mm	SN2023-1-00506
Palpeur Pédiculaire - Pedicular probe	SN2023-1-00510
Porte Verrou TL - TL Blocker holder	SN2023-1-00512
Curette - Curette	SN2023-1-00520
Marqueur Radio Droit - Right X-ray marker	SN2023-1-00530
Marqueur Radio Gauche - Left X-ray marker	SN2023-1-00531
Cintreuse de plaque - tige - Rod & plate bender	SN2023-1-00540
Pousse Tige - Rod pusher	SN2023-1-00541
Guide de Verrou - Blocker guide	SN2023-1-00550
Fer à Cintrer Gauche - Left rod bender	SN2023-1-00551
Fer à Cintrer Droit - Right rod bender	SN2023-1-00554
Pince Distractrice - Distraction forceps	SN2023-1-00590
Curette courbe - Pedicle finder	SN2023-1-00591
Pince Contractrice - Contraction forceps	SN2023-1-00600
Pince à Déroter - Derotation forceps	SN2023-1-00610
Pince porte tige - Rod holder	SN2023-1-00620
Taraud Ø5 mm - Tap Ø5 mm	SN2023-1-00705
Taraud Ø6 mm - Tap Ø6 mm	SN2023-1-00706
Taraud Ø7 mm - Tap Ø7 mm	SN2023-1-00707
Taraud Ø8 mm - Tap Ø8 mm	SN2023-1-00708
Taraud Ø5.5 mm - Tap Ø5.5 mm	SN2023-1-00715
Taraud Ø6.5 mm - Tap Ø6.5mm	SN2023-1-00716
Tournevis 4.5 - 4.5 Screwdriver	SN2023-1-00750
Tournevis 4.5 mesure de couple - Torque measuring 4,5 screwdriver	SN2023-1-00755
Persuadeur Mono/Poly - Persuader Mono-Poly	SN2023-1-00931
Conteneur TL implants - TL implant box	SN2023-2-00006
Conteneur Java instruments - Java instrument tray	SN2023-2-00010
Tournevis Monoaxial - Monoaxial Screwdriver	SN2036-1-00400
Tournevis monoaxial à fourreau - Sleeve monoaxial screwdriver	SN2036-1-00401
Conteneur java TL monoaxial - Java TL monoaxial container	SN2036-2-00006
TL 3.5 Screwdriver	SN23-100400
Reduced clearance 3,5 screwdriver	SN23-100401
Ratchet handle	SN23-100410
Ratchet handle	SN23-100411
Square awl	SN23-100500

TL Counter torque wrench	SN23-100501
Pedicular probe	SN23-100510
TL Blocker holder	SN23-100512
Pedicle finder handle	SN23-100515
Pedicle finder tips	SN23-100516
Curette	SN23-100520
Right X-ray marker	SN23-100530
Left X-ray marker	SN23-100531
Rod & plate bender	SN23-100540
Rod pusher	SN23-100541
Rod Fork	SN23-100543
Blocker guide	SN23-100550
Left rod bender	SN23-100551
Right rod bender	SN23-100554
3,5 standard driver	SN23-100570
Distraction forceps	SN23-100590
Pedicle finder	SN23-100591
Contraction forceps	SN23-100600
Derotation forceps	SN23-100610
Rod holder	SN23-100620
Tap Ø7 mm	SN23-100707
Tap Ø5,5 mm	SN23-100715
Tap Ø6,5 mm	SN23-100716
4.5 Screwdriver	SN23-100750
Torque measuring 4,5 screwdriver	SN23-100755
Persuader	SN23-100930
Persuadeur - Gun Type Persuader	SN23-100940
counter Handle Extension	SN23-101501
Trial rod Ø5mm - 100 mm	SN23-105100
Trial rod Ø5mm - 200 mm	SN23-105200
Trial rod Ø5mm - 300 mm	SN23-105300
Trial rod Ø5mm - 400 mm	SN23-105400
TL implants box	SN23-200007
Java complement box	SN23-200009
Java instruments box	SN23-200010

Wallis

Description – Wallis Instruments	Device Reference
Fantôme taille 8 - Trial spacer size 8	SN2002-1-00008
Fantôme taille 10 - Trial spacer size 10	SN2002-1-00010
Fantôme taille 12 - Trial spacer size 12	SN2002-1-00012
Fantôme taille 14 - Trial spacer size 14	SN2002-1-00014
Fantôme taille 16 - Trial spacer size 16	SN2002-1-00016
Porte fantôme - Trial spacer holder	SN2002-1-00507
Tendeur petite taille - Short clockwise tightener	SN2002-1-00544
Tendeur grande taille - Long clockwise tightener	SN2002-1-00545
Poignée de guide de tendeur - Tightener guide handle	SN2002-1-00560
Tendeur à mesure de couple - Torque measuring tightener	SN2002-1-00565
Pion taille 8 - Insert size 8	SN2002-1-00568
Pion taille 10 - Insert size 10	SN2002-1-00570
Pion taille 12,14 & 16 - Insert size 12,14 & 16	SN2002-1-00572
Passe-tresse - Band passer	SN2002-1-00590
Pince de préhension - Implant holder	SN2002-1-00605
Pince tire-tresse - Band forceps	SN2002-1-00610
Pince à sertir - Crimper	SN2002-1-00611
Distracteur interlaminaire - Interlaminar distractor	SN2002-1-00612
Porte clip - Clip holder	SN2002-1-00613
Pince à clipper - Clipping forceps	SN2002-1-00620
Passe bague - Ring passer	SN2002-1-00900
Guide de tendeur avec inserts - Tightener guide with sleeves	SN2002-1-00902
Conteneur Wallis - Instrument container	SN2002-2-00002
Short blocking tightener	SN2002-1-00536
Long blocking tightener	SN2002-1-00537
Blocking tightener guide	SN2002-1-00562
Wallis trial LP size 8	SN2002-1-10008
Wallis trial LP size 10	SN2002-1-10010
Wallis trial LP size 12	SN2002-1-10012
Wallis trial LP size 14	SN2002-1-10014
Wallis trial LP size 16	SN2002-1-10016
Guide de tendeur - Tightener guide	SN2002-1-00561
Intrument container	SN2002-2-00001
Short blocking tightener	SN2002-1-00536
Long blocking tightener	SN2002-1-00537
Guide de tendeur - Tightener guide	SN2002-1-00561

Fidji Cervical

Description – Fidji Cervical Instruments	Device Reference
Tasse greffon - Graft tamper	SN3005-1-00045
Support de cage - Cage jig	SN3005-1-00076
Fantôme de cage profondeur 12mm – largeur 15mm – hauteur 4.5mm - Trial cage depth 12mm – width 15mm – height 4.5mm	SN3005-1-00145
Fantôme de cage profondeur 12mm – largeur 15mm – hauteur 5.3mm - Trial cage depth 12mm – width 15mm – height 5.3mm	SN3005-1-00153
Fantôme de cage profondeur 12mm – largeur 15mm – hauteur 6.1mm - Trial cage depth 12mm – width 15mm – height 6.1mm	SN3005-1-00161
Fantôme de cage profondeur 12mm – largeur 15mm – hauteur 6.9mm - Trial cage depth 12mm – width 15mm – height 6.9mm	SN3005-1-00169
Fantôme de cage profondeur 12mm – largeur 15mm – hauteur 7.7mm - Trial cage depth 12mm – width 15mm – height 7.7mm	SN3005-1-00177
Fantôme de cage profondeur 12mm – largeur 17mm – hauteur 4.5mm - Trial cage depth 12mm – width 17mm – height 4.5mm	SN3005-1-00245
Fantôme de cage profondeur 12mm – largeur 17mm – hauteur 5.3mm - Trial cage depth 12mm – width 17mm – height 5.3mm	SN3005-1-00253
Fantôme de cage profondeur 12mm – largeur 17mm – hauteur 6.1mm - Trial cage depth 12mm – width 17mm – height 6.1mm	SN3005-1-00261
Fantôme de cage profondeur 12mm – largeur 17mm – hauteur 6.9mm - Trial cage depth 12mm – width 17mm – height 6.9mm	SN3005-1-00269
Fantôme de cage profondeur 12mm – largeur 17mm – hauteur 7.7mm - Trial cage depth 12mm – width 17mm – height 7.7mm	SN3005-1-00277
Fantôme de cage profondeur 14mm – largeur 17mm – hauteur 4.5mm - Trial cage depth 14mm – width 17mm – height 4.5mm	SN3005-1-00345
Fantôme de cage profondeur 14mm – largeur 17mm – hauteur 5.3mm - Trial cage depth 14mm – width 17mm – height 5.3mm	SN3005-1-00353
Fantôme de cage profondeur 14mm – largeur 17mm – hauteur 6.1mm - Trial cage depth 14mm – width 17mm – height 6.1mm	SN3005-1-00361
Fantôme de cage profondeur 14mm – largeur 17mm – hauteur 6.9mm - Trial cage depth 14mm – width 17mm – height 6.9mm	SN3005-1-00369
Fantôme de cage profondeur 14mm – largeur 17mm – hauteur 7.7mm - Trial cage depth 14mm – width 17mm – height 7.7mm	SN3005-1-00377
Fantôme de cage profondeur 14mm – largeur 19mm – hauteur 4.5mm - Trial cage depth 14mm – width 19mm – height 4.5mm	SN3005-1-00445



Description – Fidji Cervical Instruments	Device Reference
Fantôme de cage profondeur 14mm – largeur 19mm – hauteur 5.3mm - Trial cage depth 14mm – width 19mm – height 5.3mm	SN3005-1-00453
Fantôme de cage profondeur 14mm – largeur 19mm – hauteur 6.1mm - Trial cage depth 14mm – width 19mm – height 6.1mm	SN3005-1-00461
Fantôme de cage profondeur 14mm – largeur 19mm – hauteur 6.9mm - Trial cage depth 14mm – width 19mm – height 6.9mm	SN3005-1-00469
Fantôme de cage profondeur 14mm – largeur 19mm – hauteur 7.7mm - Trial cage depth 14mm – width 19mm – height 7.7mm	SN3005-1-00477
Impacteur - Impactor	SN3005-1-00506
Impacteur final - Final impactor	SN3005-1-00525
Pince à déclipper - Declipping device	SN3005-1-00530
Jauge de profondeur - Depth gauge	SN3005-1-00540
Pince de préhension - Trial holder	SN3005-1-00552
Porte fantôme - Trial cage holder	SN3005-1-00760
Curette double tête - Curette	SN3005-1-00800
Pince de retrait - Fin remover	SN3005-1-00900
conteneur Instruments - Instruments container	SN3005-2-00001
Special impactor handle	SN3005-1-00515
Porte fantôme special - Special trial cage holder	SN3005-1-00761

Fidji Lumbar

Description – Fidji Lumbar Instruments	Device Reference
Alésoir taille 8 - Reamer size 8	SN3001-1-00500
Alésoir taille 9 - Reamer size 9	SN3001-1-00501
Alésoir taille 10 - Reamer size 10	SN3001-1-00502
Alésoir taille 11 - Reamer size 11	SN3001-1-00503
Alésoir taille 12 - Reamer size 12	SN3001-1-00504
Alésoir taille 13 - Reamer size 13	SN3001-1-00505
Alésoir taille 14 - Reamer size 14	SN3001-1-00506
Distracteur taille 9 - Distractor size 9	SN3001-1-00510
Distracteur taille 10 - Distractor size 10	SN3001-1-00511
Distracteur taille 11 - Distractor size 11	SN3001-1-00512
Distracteur taille 12 - Distractor size 12	SN3001-1-00513
Distracteur taille 13 - Distractor size 13	SN3001-1-00514
Distracteur taille 14 - Distractor size 14	SN3001-1-00515
Distracteur de départ - Initial distractor	SN3001-1-00520
Curette antérieure - Anterior curette	SN3001-1-00523
Curette postérieure - Posterior curette	SN3001-1-00524
Ecarteur petite taille - Small retractor	SN3001-1-00531
Ecarteur grande taille - Large retractor	SN3001-1-00532
Masse d'impaction - Sliding mallet	SN3001-1-00538
Impacteur - Impactor shaft	SN3001-1-00541
Tasse greffon Petite taille - Small graft tamper	SN3001-1-00545
Tasse greffon Grande taille - Large graft tamper	SN3001-1-00546
Support de cages - Cage jig	SN3001-1-00547
Impacteur final - Final impactor	SN3001-1-00550
Butoir d'extraction - Extraction blocker	SN3001-1-00551
Fantôme de grande cage antérieure taille 10-4° - Trial implant - Fidji anterior large cage size 10-4°	SN3001-1-00600
Fantôme de grande cage antérieure taille 11-4° - Trial implant - Fidji anterior large cage size 11-4°	SN3001-1-00601
Fantôme de grande cage antérieure taille 11-8° - Trial implant - Fidji anterior large cage size 11-8°	SN3001-1-00602
Fantôme de grande cage antérieure taille 12-4° - Trial implant - Fidji anterior large cage size 12-4°	SN3001-1-00603
Fantôme de grande cage antérieure taille 12-8° - Trial implant - Fidji anterior large cage size 12-8°	SN3001-1-00604
Fantôme de grande cage antérieure taille 14-4° - Trial implant - Fidji anterior large cage size 14-4°	SN3001-1-00605
Fantôme de grande cage antérieure taille 14-8° - Trial implant - Fidji anterior large cage size 14-8°	SN3001-1-00606
Fantôme de grande cage antérieure taille 16-4° - Trial implant - Fidji anterior large cage size 16-4°	SN3001-1-00607
Fantôme de grande cage antérieure taille 16-8° - Trial implant - Fidji anterior large cage size 16-8°	SN3001-1-00608
Fantôme de grande cage antérieure taille 10-0° - Trial implant - Fidji anterior large cage size 10-0°	SN3001-1-00609
Fantôme de grande cage antérieure taille 11-0° - Trial implant - Fidji anterior large cage size 11-0°	SN3001-1-00610

Description – Fidji Lumbar Instruments	Device Reference
Fantôme de grande cage antérieure taille 12-0° - Trial implant - Fidji anterior large cage size 12-0°	SN3001-1-00611
Fantôme de petite cage antérieure taille 23*31*10-0° - Trial implant - Fidji anterior small cage size size 23*31*10-0°	SN3001-1-00650
Fantôme de petite cage antérieure taille 23*31*10-4° - Trial implant - Fidji anterior small cage size 23*31*10-4°	SN3001-1-00651
Fantôme de petite cage antérieure taille 23*31*11-0° - Trial implant Fidji anterior small cage size 23*31*11-0°	SN3001-1-00652
Fantôme de petite cage antérieure taille 23*31*11-4° - Trial implant Fidji anterior small cage size 23*31*11-4°	SN3001-1-00653
Fantôme de petite cage antérieure taille 23*31*11-8° - Trial implant Fidji anterior small cage size 23*31*11-8°	SN3001-1-00654
Fantôme de petite cage antérieure taille 23*31*12-0° - Trial implant Fidji anterior small cage size 23*31*12-0°	SN3001-1-00655
Fantôme de petite cage antérieure taille 23*31*12-4° - Trial implant Fidji anterior small cage size 23*31*12-4°	SN3001-1-00656
Fantôme de petite cage antérieure taille 23*31*12-8° - Trial implant Fidji anterior small cage size 23*31*12-8°	SN3001-1-00657
Fantôme de petite cage antérieure taille 23*31*14-4° - Trial implant Fidji anterior small cage size 23*31*14-4°	SN3001-1-00658
Fantôme de petite cage antérieure taille 23*31*14-8° - Trial implant Fidji anterior small cage size 23*31*14-8°	SN3001-1-00659
Fantôme de petite cage antérieure taille 23*31*16-4° - Trial implant Fidji anterior small cage size 23*31*16-4°	SN3001-1-00660
Fantôme de petite cage antérieure taille 23*31*16-8° - Trial implant Fidji anterior small cage size 23*31*16-8°	SN3001-1-00661
Fantôme de petite cage latérale taille 21*31*10-0° - Trial implant Fidji lateral small cage size 21*31*10-0°	SN3001-1-71000
Fantôme de petite cage latérale taille 21*31*10-4° - Trial implant Fidji lateral small cage size 21*31*10-4°	SN3001-1-71004
Fantôme de petite cage latérale taille 21*31*11-0° - Trial implant Fidji lateral small cage size 21*31*11-0°	SN3001-1-71100
Fantôme de petite cage latérale taille 21*31*11-4° - Trial implant Fidji lateral small cage size 21*31*11-4°	SN3001-1-71104
Fantôme de petite cage latérale taille 21*31*11-8° - Trial implant Fidji lateral small cage size 21*31*11-8°	SN3001-1-71108
Fantôme de petite cage latérale taille 21*31*12-0° - Trial implant Fidji lateral small cage size 21*31*12-0°	SN3001-1-71200
Fantôme de petite cage latérale taille 21*31*12-4° - Trial implant Fidji lateral small cage size 21*31*12-4°	SN3001-1-71204
Fantôme de petite cage latérale taille 21*31*12-8° - Trial implant Fidji lateral small cage size 21*31*12-8°	SN3001-1-71208
Fantôme de grande cage latérale taille 27*33*10-0° - Trial implant Fidji lateral large cage size 27*33*10-0°	SN3001-1-81000
Fantôme de grande cage latérale taille 27*33*10-4° - Trial implant Fidji lateral large cage size 27*33*10-4°	SN3001-1-81004
Fantôme de grande cage latérale taille 27*33*11-0° - Trial implant Fidji lateral large cage size 27*33*11-0°	SN3001-1-81100
Fantôme de grande cage latérale taille 27*33*11-4° - Trial implant Fidji lateral large cage size 27*33*11-4°	SN3001-1-81104
Fantôme de grande cage latérale taille 27*33*11-8° - Trial implant Fidji lateral large cage size 27*33*11-8°	SN3001-1-81108

Description – Fidji Lumbar Instruments	Device Reference
Fantôme de grande cage latérale taille 27*33*12-0° - Trial implant Fidji lateral large cage size 27*33*12-0°	SN3001-1-81200
Fantôme de grande cage latérale taille 27*33*12-4° - Trial implant Fidji lateral large cage size 27*33*12-4°	SN3001-1-81204
Fantôme de grande cage latérale taille 27*33*12-8° - Trial implant Fidji lateral large cage size 27*33*12-8°	SN3001-1-81208
Fantôme de grande cage latérale taille 27*33*14-4° - Trial implant - Fidji lateral large cage size 27*33*14-4°	SN3001-1-81404
Fantôme de grande cage latérale taille 27*33*14-8° - Trial implant Fidji lateral large cage size 27*33*14-8°	SN3001-1-81408
Fantôme de grande cage latérale taille 27*33*16-4° - Trial implant Fidji lateral large cage size 27*33*16-4°	SN3001-1-81604
Fantôme de grande cage latérale taille 27*33*16-8° - Trial implant Fidji lateral large cage size 27*33*16-8°	SN3001-1-81608
Conteneur instruments - Instrument tray	SN3001-2-00003
Conteneur fantômes - Tray for trial implants	SN3001-2-00004
Reamer size 8	SN01-100500
Reamer size 9	SN01-100501
Reamer size 10	SN01-100502
Reamer size 11	SN01-100503
Reamer size 12	SN01-100504
Reamer size 13	SN01-100505
Reamer size 14	SN01-100506
Distractor size 9	SN01-100510
Distractor size 10	SN01-100511
Distractor size 11	SN01-100512
Distractor size 12	SN01-100513
Distractor size 13	SN01-100514
Distractor size 14	SN01-100515
Initial distractor	SN01-100520
Posterior curette	SN01-100524
Small retractor	SN01-100531
Large retractor	SN01-100532
Sliding mallet	SN01-100538
Impactor shaft	SN01-100541
Small graft tamper	SN01-100545
Large graft tamper	SN01-100546
Cage jig	SN01-100547
Final impactor	SN01-100550
Extraction blocker	SN01-100551
Container	SN01-200001

ATTACHMENT 2

(Immediately applicable and supersede **CLEANING AND DECONTAMINATION** instructions described in

- Java Posterior stabilization System: 023ENAN0000T rev 1
 - Wallis® Posterior Dynamic Stabilization System: 002WNAN0000T rev 1
 - Fidji® Cervical Cage : 005ENAN0000T rev 1
 - Fidji® Lumbar Cage: 001ENAN0000T rev 1)
-

2. CLEANING AND DISINFECTION:

- a. Clean all instruments before use and as soon as possible after use. Avoid letting blood, bodily fluids or debris dry on the instruments. If cleaning must be delayed, place the instruments in a closed container with a suitable detergent or an enzyme solution in order to slow drying.
- b. Remove and/or disassemble moving parts of the instruments.
- c. Metal brushes or scouring pads must not be used during manual cleaning procedures. These materials will damage the surface and finish of the devices. Soft-bristled, nylon brushes and pipe cleaners should be used.
- d. Completely submerge the instruments in an enzyme or alkaline (pH ≤12) solution and allow to soak and sonicate for 10 minutes at 45-50 kHz. If using enzymatic cleaning agents, use a soft nylon-bristled brush to gently scrub the device until all visible soil has been removed. Particular attention must be given to crevices, lumens, mated surfaces, connectors and other hard-to-clean areas. Lumens should be cleaned with a long, narrow, soft nylon-bristled brush (e.g. pipe cleaner).
- e. Remove instruments from the cleaning solution and rinse in purified water for a minimum of 1 minute. Thoroughly and aggressively flush lumens, blind holes and other difficult-to-reach areas.
- f. Place instruments in a suitable washer/disinfector basket and process through a standard instrument washer/disinfector cleaning cycle. The following minimum parameters are essential for thorough cleaning and disinfection.

Step	Description
1	5 minute pre-rinse with cold tap water
2	10 minute alkaline cleaning agent wash at 55°C
3	2 minute rinse with neutralizer
4	1 minute rinse with cold tap water
5	Disinfection at 93°C with hot purified water until A ₀ 3000 is reached (approximately 10 minutes)
6	40 minutes hot air drying at 110°C

Note: The washer/disinfector manufacturer's instructions should be strictly adhered to. Use only cleaning agents recommended for the specific type of automated washer/disinfector. A washer/disinfector with approved efficacy (e.g. CE mark, FDA approval, and validation according to ISO 15883) should be used.

ATTACHMENT 3

IMMEDIATE RESPONSE REQUIRED –TIME SENSITIVE ACTION NEEDED

ACKNOWLEDGEMENT OF FIELD NOTIFICATION

Affected Product: Java Pedicle Screw System, Fidji Cervical Cage, Fidji Lumbar Cage, Wallis Posterior Dynamic Stabilization

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

Account Name: _____

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

Acknowledgement of Responsibility:

By signing below, I acknowledge that I have received the updated cleaning and decontamination instructions for Java Pedicle Screw System, Fidji Cervical Cage, Fidji Lumbar Cage, Wallis Posterior Dynamic Stabilization; the required actions have been taken in accordance with 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 your local Zimmer Biomet contact

ZFA 2016-133