



**URGENT MEDICAL DEVICE RECALL NOTICE**  
**April 1, 2016**

**Various Sports Medicine and Trauma Products**  
**Part Number: reference pages 3 and 4**  
**Lots: specific**

Dear Risk/Recall Manager,

This notification is to inform you of an Urgent Medical Device Recall initiated by Zimmer Biomet which involves **various sports medicine and trauma products (reference pages 3 and 4 for specific part numbers)**. The legal manufacturer of this product is Biomet Inc., including the subsidiaries of Biomet Sports Medicine and Biomet Trauma.

These implants/instruments have been further consigned to your facility by a Zimmer Biomet distributor. Zimmer Biomet has initiated this action following an investigation which identified that specific lots produced may have an inadequate adhesive transfer from the Tyvek to the film. A weak seal may be evident.

The seal could be jeopardized causing the sterile barrier to be compromised and the product could become non-sterile. **If the product becomes non-sterile and is used or implanted, it may lead to an infection.**

This action requires the immediate location and discontinued use of the product and its return to Zimmer Biomet.

The following actions are **REQUIRED**:

- ✓ Immediately locate and remove the identified device(s) listed below from circulation.
- ✓ Your Zimmer Biomet sales representative will remove the affected product from your facility.
- ✓ Review this notification and ensure that all affected personnel are aware of its contents.
- ✓ Carefully follow the instruction on the enclosed **“Certificate of Acknowledgment”** and email a copy to [CPWARFieldAction@zimmerbiomet.com](mailto:CPWARFieldAction@zimmerbiomet.com).

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA:

- Online: [www.fda.gov/Safety/MedWatch/HowToReport/default.htm](http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm) (form available to fax or mail), or
- Call (800)FDA-1088

Thank you in advance for your assistance and prompt attention. On behalf of Zimmer Biomet, I apologize for any inconvenience this may cause. Questions related to this notice should be directed to (574) 372-1570, Monday through Friday, 8 a.m. to 5 p.m.

Sincerely,

A handwritten signature in black ink that reads 'Audrey E. Daenzer'.

Audrey Daenzer  
Product Surveillance Senior Specialist  
[audrey.daenzer@zimmerbiomet.com](mailto:audrey.daenzer@zimmerbiomet.com)

**Mailing Address:**

P.O. Box 587  
Warsaw, IN. 46581-0587  
Toll Free: 800.348.9500  
Office: 574.267.6639  
Fax: 574-372-1683  
[www.zimmerbiomet.com](http://www.zimmerbiomet.com)

**Shipping Address:**

56 E Bell Drive  
Warsaw, IN 46582

## Certificate of Acknowledgement

**ATTENTION:** Audrey Daenzer, Product Surveillance Senior Specialist  
**Email:** [CPWARFieldAction@zimmerbiomet.com](mailto:CPWARFieldAction@zimmerbiomet.com)  
**Regulatory Action:** **URGENT MEDICAL DEVICE RECALL NOTICE**  
**Description:** **Various Sports Medicine and Trauma Products**

By signing the below, I acknowledge that the required actions have been taken in accordance with the Urgent Medical Device Recall Notice.

Printed Name: \_\_\_\_\_ Title: \_\_\_\_\_

Facility Name: \_\_\_\_\_

Facility Address: \_\_\_\_\_

Telephone: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**Mailing Address:**  
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All part numbers affected by this recall are listed below. Lot numbers are specific.

Part	Description
24415	.062 X 8 GUIDE WIRE
24416	.062" X 8" GUIDE WIRE
24445	CANNULATED 2.7MM AO DRILL
24616	16MM STEPPED GROWTH CON PLATES
27914	LAG SCREW GUIDE WIRE 3.2X460MM
27922	BEAD TIP GUIDE WIRE 3.0X98CM
27961	CALIBRATED DRILL 4.3MMX365MM
28234	TROCH NAIL LONG 11MM LEFT
28338	TROCH NAIL LONG 11MM RIGHT
28811	TROCHANTERIC NAIL SH 11MMX22CM
28813	TROCHANTERIC NAIL SH 13MMX22CM
28821	TROCHANTERIC NL XSH 11MMX17CM
29260	LAG SCR ASSY SOLID FIXED 105MM
29822	PTN-J NAIL SHORT 12MM X 17CM
41009	11.5MM - ONE STEP REAMER
200185	VHS LAG SCR 12.7X85 W/COMP SCR
200195	VHS LAG SCR 12.7X95 W/COMP SCR
200200	VHS LAG SCR 12.7X100 W/COMP SC
328010	THREADED TIP GDE PIN 2.5MMX9
900360	AQUALOC 7X75M DISP CANNULA 6PK
900364	AQUALOC 7X85M DISP CANNULA 6PK
900728	8MM DISPOSABLE CORING TREPHINE
900737	7MM DISP DOWEL HARVEST TUBE
900738	8MM DISP DOWEL HARVEST TUBE
900740	10MM DISP DOWEL HARVEST TUBE
904051	EZ PASS 45 DEGREE UP
904301	3.2MM TWIST DRILL BIT 5 INCH
904414	3.2MM TWIST DRILL BIT 5 INCH
904723	30MM TOGGLELOC TM W/ PE CL
904727	50MM TOGGLELOC TM W/ PE CL
904754	#7 PE 50IN ZPLP EXT TOGGLELOC
904755	#7 PE ZIPLOOP EXT TOGGLELOC
904756	#7 PE ZPLOP W/CONT LP 13MM TGL
904760	4.5MM CANN TOGGLE BUTTON DRILL
904781	9-10MM STANDARD EZLOC FEM FIXA

Part	Description
904834	ZIPTIGHT AC JOINT 1 ZIPLOOP
908518	3.5MM DOUBLE TOOTH DISP 5PK
908520	4.5MM DOUBLE TOOTH DISP 5 PK
909836	EZLOC/WASHERLOC DISPOSABLE KIT
912029	JGRKNT 2.9MM #2 BLUE MB SNGL
912030	JGRKNT SINGLE 1.4MM 1 #1 MB
912031	JGRKNT 1.5MM #2 MB SNGL
912037	1.5MM JUGGERKNOT FLEX DRILL
912046	JGRKNT 1.5MM DRILL SLV KIT
912050	JUGGERKNOT 2.9MM 2 #2 MB
912057	JUGGERKNOT 2.9MM DISP KIT
912068	JUGGERKNOT 1.4MM SHRT W/NDLS
912069	JGRKNT 1.4MM SHRT NDLS 10PK
912071	JGRKNT 1.4MM SHORT DRILL BIT
912073	JGRKNT 1.4MM SHORT DISP SET
912076	JGRKNT 1.0MM MINI 2-0 NDLS
912077	JGRKNT 1.0MM MINI STEP DRILL
912082	JGRKNT 1.0MM MINI 3-0 NDLS
912091	JGRKNT DRILL 2.9MM
916036	JGRKNT LONG FLEX DRILL
110003172	JGRKNTLESS LOW PRO DISP KIT
110003182	JGRKNTLESS LOW PRO DRILL
110004188	PRECISION FLX RMR 10.0MM DISP
110005093	JUGGERKNOT 2.9 W/CUTTING ND
110005096	JUGGERKNOT 2.9 W/ TAPERED NDLS
110005198	JUGGERKNOTLESS SS SINGLE
110005306	JGRKNT 2.9 DRILL BIT SHORT
110005307	JGRKNT SHORT RIGID SZ1 IMP/DRL
110008343	PRECISION SMALL GUIDE WIRE 5PK
110009769	MPF NITINOL SMALL GUIDE WIRE
110010579	PRECISION FLX RMR 9.5MM DISP
110016992	JKLONG FLEX DRILL WITH SLEEVE
131212112	SCREW CORTICAL 3.5MM X 12MM
131212113	SCREW CORTICAL 3.5MM X 13MM
131212114	SCREW CORTICAL 3.5MM X 14MM

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131212116	SCREW CORTICAL 3.5MM X 16MM
131212118	SCREW CORTICAL 3.5MM X 18MM
131212216	PEG SMOOTH 2.0MM X 16MM
131212218	PEG SMOOTH 2.0MM X 18MM
131212220	PEG SMOOTH 2.0MM X 20MM
131212222	PEG SMOOTH 2.0MM X 22MM
131212224	PEG SMOOTH 2.0MM X 24MM
131212316	PEG THREADED 2.5MM X 16MM
131212318	PEG THREADED 2.5MM X 18MM
131212320	PEG THREADED 2.5MM X 20MM
131212322	PEG THREADED 2.5MM X 22MM
231201303	K-WIRE SS 1.6X127MM .062 ST
231201307	4.0X90MM DRILL FAST SHORT STE
281001080	BALL NOSE GUIDE WIRE 80CM
281001100	BALL NOSE GUIDE WIRE 100CM
805065080	6.5 SOLID CORT FT LCK 80MM ST
856135016	3.5X16MM CORT LOCK SCR STE
856135018	3.5X18MM CORT LOCK SCR STE
856135020	3.5X20MM CORT LOCK SCR STE
856135022	3.5X22MM CORT LOCK SCR STE
856135024	3.5X24MM CORT LOCK SCR STE
856135026	3.5X26MM CORT LOCK SCR STE
856135030	3.5X30MM CORT LOCK SCR STE
856135034	3.5X34MM CORT LOCK SCR STE
856135036	3.5X36MM CORT LOCK SCR STE
856135038	3.5X38MM CORT LOCK SCR STE
856135040	3.5X40MM CORT LOCK SCR STE
856135042	3.5X42MM CORT LOCK SCR STE
14-400428	TI-DOUBLE LEAD CORTICAL SCREW
14-400436	TI-DOUBLE LEAD CORTICAL SCREW
14-401440	1.6 X 150 MM GUIDE WIRE

Part	Description
14-405032	TI-DBLE LEAD CORT 5.0X32MM SCR
14-405040	TI-DBLE LEAD CORT 5.0X40MM SCR
14-440066S	PHOENIX ANKLE ARTHRODESIS NAIL
14-440118	ANKLE LOCKING NAIL 10 X 180MM
14-440121	ANKLE LOCKING NAIL 10 X 210MM
14-441280	OFFSET END CAP 0MM
14-450360	1.8X200MM K-WIRE W/TROCAR 5PK
14-450365	3.2X250MM K-WIRE W/TROCAR 5PK
14-450380	1.6X150MM K-WIRE TROC THRD 5PK
14-450390	3.2X250MM K-WIRE TROC THRD 5PK
16-235136	VHS 4.5 SS CORT SCR W S/T 36MM
35-351208	K-WIRE DIA PT BOTH .062X4 S/S
35-351534	K-WIRE TRC BOTH .045X9 PK S/S
35-351564	K-WIRE TRC BOTH .062X9 PK S/S
35-361681	STEINMANN PIN TRC/PL SHNK
900360H	AQUALOC RIGID 7X75 CANNULA 6PK
900360HI	AQUALOC RIGID 7X75 CANN SINGLE
900363H	AQUALOC RIGID 8.5X75 CANN 6PK
900364I	7MMX85 AQUALOC CANN-SINGLE
912036R	JUGGERKNOT LG SHANK BIT 1.4MM
912037R	JUGGERKNOT LG SHANK BIT 1.5MM
912040R	JUGGERKNOT 1.4MM DISP KIT RGD
912141C	JGRKNT 1.5MM CRVD KIT W SLV
HAA60-11030	DFS HA CORT SCREW 110/30 MM
HAA60-13030	DFS HA CORT SCREW 130/30 MM
HAA60-15040	DFS HA CORT SCREW 150/40 MM
HAA60-16040	DFS HA CORT SCREW 160/40 MM
HAA60-18040	DFS HA CORT SCREW 180/40 MM

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