



URGENT MEDICAL DEVICE RECALL NOTICE
January 29, 2016

DVR ePAKs
Part Numbers: reference page 4
Lots: all



Dear Surgeon,

This notification is to inform you of an Urgent Medical Device Recall initiated by Zimmer Biomet which involves all **DVR ePAKs** (reference page 4 for specific part numbers). All lots are affected by this recall.

Our records indicate that you may have used the implants/instruments contained with the ePAK.

Zimmer Biomet has initiated this action as evidence of iron oxidation has been found on components contained in the DVR ePAKs.

A delay in surgery, less than 30 minutes, may occur if the surgical staff proceeds to re-sterilize the product.

If oxidative material would flake off a component contained within the ePAK and enter the surgical field/wound an inflammatory reaction may occur. The inflammatory reaction may result in a foreign body reaction and/or metal hypersensitivity.

There have been no injuries or illnesses reported.

Please continue to monitor your patients.

The following actions are **REQUIRED**:

- ✓ Review this notification and ensure that all affected personnel are aware of its contents.
- ✓ Complete the enclosed **“Certificate of Acknowledgment”** and email a copy to 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 (form available to fax or mail), or
- Call (800)FDA-1088

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

Shipping Address:
56 E Bell Drive
Warsaw, IN 46582



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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
Field Action Specialist
audrey.daenzer@zimmerbiomet.com

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ZIMMER BIOMET

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Certificate of Acknowledgement

ATTENTION: Audrey Daenzer, Field Action Specialist
Email: CPWARFieldAction@zimmerbiomet.com
Regulatory Action: **URGENT MEDICAL DEVICE RECALL NOTICE**
Description: **DVR ePAKs**

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

Surgeon's Name: _____

Surgeon's Signature: _____

Date: _____

Telephone: _____

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All part numbers affected by this recall are listed below. All lots are affected.

PN	Description	PN	Description
811810050	DVR EPAK EX NRW LOCK PLT RIGHT	811899003	EPAK DVR C/LCK VOLR RIM RT DNI
811811040	DVR EPAK NRW MINI LOCK PLT R	811899004	EPAK DVR C/LCK VOLR RIM LT DNI
811811050	DVR EPAK NRW LOCK PLT R	811899005	EPAK DVR DORSAL PLATE RT DNI
811812040	DVR EPAK MINI LOCK PLT R	811899006	EPAK DVR DORSAL PLATE LT DNI
811812050	DVR EPAK DIST VLR PT STD R	811899007	EPAK DVR RDL COLUMN PLT RT DNI
811812060	DVR EPAK DISTAL VLR PLT MED RT	811899008	EPAK DVR RDL COLUMN PLT LT DNI
811812090	DVR EPAK DISTAL PLT LONG RT	811899009	EPAK DVR ULNA PLT BILAT DNI
811812125	DVR EPAK EXT LONG LOCK PLT R	811911050	DVR EPAK NRW LOCK PEG RT
811812175	DVR EPAK EX-EXT LONG LK PLT R	811912050	DVR EPAK LOCK PEG RT
811813050	DVR EPAK WIDE LOCK PLT R	811913050	DVR EPAK WIDE LOCK PEG RT
811814050	DVR EPAK VOLAR RIM PLATE RIGHT	811921050	DVR EPAK NRW LOCK PEG LT
811815050	DVR EPAK VOLAR RIM NRW PLT RT	811922050	DVR EPAK LOCK PEG LT
811817050	DVR EPAK DORSAL PLATE STD RT	811923050	DVR EPAK WIDE LOCK PEG LT
811817150	DVR EPAK DORSAL PLATE WIDE RT	811999001	DVR EPAK PEG RIGHT DNI
811818060	DVR EPAK RADIAL PLT STD RIGHT	811999002	DVR EPAK PEG LEFT DNI
811818160	DVR EPAK RADIAL PLATE WIDE RT		
811820050	DVR EPAK EX NRW LOCK PLT LEFT		
811821040	DVR EPAK NRW MINI LOCK PLT L		
811821050	DVR EPAK NRW LOCK PLT L		
811822040	DVR EPAK MINI LOCK PLT L		
811822050	DVR EPAK LOCK PLT L		
811822060	DVR EPAK MEDIUM LOCK PLT L		
811822090	DVR EPAK LONG LOCK PLT L		
811822125	DVR EPAK EXT LONG LOCK PLT L		
811822175	DVR EPAK EX-EXT LONG LK PLT L		
811823050	DVR EPAK WIDE LOCK PLT L		
811824050	DVR EPAK VOLAR RIM PLATE LEFT		
811825050	DVR EPAK VOLAR RIM NRW PLT LT		
811827050	DVR EPAK DORSAL PLATE STD LEFT		
811827150	DVR EPAK DORSAL PLATE WIDE LT		
811828060	DVR EPAK RADIAL PLATE STD LEFT		
811828160	DVR EPAK RADIAL PLATE WIDE LT		
811839050	DVR EPAK ULNA PLATE BILATERAL		
811899001	DVR EPAK RIGHT DNI		
811899002	DVR EPAK LEFT DNI		

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