ZIMMER BIOMET

URGENT MEDICAL DEVICE RECALL NOTICE
July 11, 2016

Various Kits Containing ACDA
Part Number: reference table below
Lot: reference table below

Dear Risk/Recall Manager,

This notification is to inform you of an Urgent Medical Device Recall initiated by Zimmer Biomet which involves **various kits containing ACDA. (reference table below for specific item and lot numbers)**.

These items have been invoiced to your account. Zimmer Biomet has initiated this action following an investigation which identified a defect with the ACDA 30 ml vial known as a split finish that could compromise product sterility. Split finishes occur during the glass bottle manufacturing process. Although our data shows that the risk of a sterility breach is rare <1% and the risk of injury to patients is remote <0.1%. The ACDA 30 ml vial is one of the items included in the kits detailed below.

Use may result in an infection. There have been no reported complaints to date.

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.

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

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.

[redacted]

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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Certificate of Acknowledgement

ATTENTION: Jennifer Nail, Field Action Specialist

Email: CPWARFieldAction@zimmerbiomet.com

Regulatory Action: **URGENT MEDICAL DEVICE RECALL NOTICE**

Description: **Various Kits Containing ACDA**

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: _____

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Part Numbers and Descriptions

Part Number	Description
800-0505A	GPS III MINI KIT W/30ML ACDA
800-0516	PLASMAX MINI KIT W/30ML ACDA
800-0517	PLASMAX PLUS KIT W/30ML ACDA
800-0534	FOOT-ANKLE BONE GRAFT KIT
800-0536	BONE GRAFT CONVENIENCE KIT-CUE
800-0560A	PLASMAX PLUS W/GPS3 &ACD-A
800-0610A	BIOCUE MINI KIT DOMESTIC
800-0611A	BIOCUE STD KIT DOMESTIC
800-0612A	BIOCUE MINI KIT ACD-A W/BD
800-0613A	BIOCUE STD KIT ACD-A W/BD
800-0660	RECOVER CONVENIENCE MINI KIT
800-0661	RECOVER KIT 30 W/ACDA
800-0662	RECOVER TUBE W/ACD-A 30CC 6PK
800-0665	RECOVER CONVENIENCE GPS3 KIT
800-0666	RECOVER KIT 60W/ACDA
800-0667	RECOVER TUBE W/ACD-A 60CC 6PK
800-0670A	GPS MINI KIT W /ACD-A & BD
800-0675A	GPS3 SINGLE KIT W/BLOOD DRAW
800-0680A	GPS 3 DOUBLE KIT W/BD & ACD-A
800-0724	CLOTALYST 2/GPS 3 MINI KIT
800-0724R	CLOTALYST 2/GPS 3 MINI KIT-INT
800-0726	CLOTALYST 2/GPS 3 SINGLE KIT
800-0726R	CLOTALYST 2/GPS 3 SNGL KIT-INT
800-1001A	GPS SINGLE KIT W/ACDA
800-1003A	GPS III SINGLE KIT W/30ML ACDA
800-1004A	GPS III DOUBLE KIT W/30ML
800-3000ST	NSTRIDE APS KIT WITH ACD-A
800-3000US	NSTRIDE APS
800-3004VET-6pk	RESTIGEN STD 6/PK

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