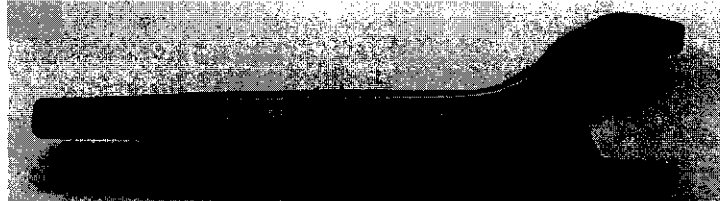




URGENT MEDICAL DEVICE RECALL NOTICE
September 24, 2014

Terr: X36

Discovery Elbow Right Humeral Trial 5mmx100mm with Flange
Part Number: 414837
Lot: 555011



Biomet Global Supply Chain Center B.V.
Hazeldonk 6530
4836 LD Breda
The Netherlands

Dear Distributor,

This notification is to inform you of an Urgent Medical Device Recall initiated by Biomet Orthopedics ("Biomet") which involves **Part Number: 414837 Lot: 555011 Discovery Elbow Right Humeral Trial 5mmx100mm with Flange**.

These trials have been consigned and/or invoiced to your account. Biomet has initiated this action following an investigation which identified that the trial was incorrectly manufactured as a left humeral trial but is etched as a right humeral trial.

No adverse health outcome is expected for the patient.

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

The following actions are **REQUIRED**:

- ✓ Immediately locate and remove the identified device(s) listed below from circulation.
- ✓ Carefully follow the instructions on the enclosed "**Response Form**".
- ✓ Email a copy of the Response Form to audrey.daenzer@biomet.com prior to return of product.
- ✓ Use priority carrier for your shipment.
- ✓ If you have further distributed this product, you **MUST** notify hospital personnel of this action via the enclosed "Dear Risk/Recall Manager" notice. This letter **MUST** be given to hospital personnel responsible for receiving recall notices. However, you are charged with the location and return of these products.

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 FDA (800)FDA-1088

Mailing Address:
P.O. Box 587
Warsaw, IN. 46581-0587
Toll Free: 800.348.9500
Office: 574.267.6639
Main Fax: 574-267-8137
www.biomet.com

Shipping Address:
56 E Bell Drive
Warsaw, IN 46582



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Please confirm receipt of this notice by sending back the Response Form **within three (3) business days**. Thank you in advance for your assistance and prompt attention. On behalf of 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,

Audrey Daenzer
Field Action Specialist, Regulatory Compliance
Biomet, Inc.
audrey.daenzer@biomet.com

Part Number	Lot Number	Quantity
414837	555011	2

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