

URGENT MEDICAL DEVICE RECALL NOTICE
November 15, 2012



Offset Tibial Tray 2.5mm Adaptor
Part Numbers: 141490
Lot Numbers: specific



Dear O.R. Manager,

This notification is to inform you of an Urgent Medical Device Recall initiated by Biomet Orthopedics ("Biomet") which involves **Part Number 141490 Offset Tibial Tray 2.5mm Adaptor**, an implant that has been consigned and/or invoiced to your account. Biomet has initiated this action following an investigation which identified that the square end of the adaptor locking insert is oversized and may not engage insert tool screwdriver (see image above).

It has been determined that **this issue presents a risk to patient health** due to a possible delay in surgery greater than 30 minutes, potentially exposing the patient to the increased risks from being under anesthesia for a longer duration.

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 "**FAX Back Response Form**".
- ✓ Fax a copy of the Response Form to 574-372-1683 prior to return of product.
- ✓ Use priority carrier for your shipment.
- ✓

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 East Bell Drive
Warsaw, IN 46582

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Please confirm receipt of this notice by calling (574) 372-1570. 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,

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

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