URGENT MEDICAL DEVICE RECALL NOTICE
December 11th, 2012

PT Hybrid Glenoid Post
Part Numbers: PT-113950
Lot Numbers: specific

Dear OR Manager,

This notification is to inform you of an Urgent Medical Device Recall initiated by Biomet Orthopedics ("Biomet") which involves **Part Number PT-113950 PT Hybrid Glenoid** Post, an implant that has been consigned and/or invoiced to your account. Biomet has initiated this action following an investigation which identified that the male thread of the post may be oversized. This oversized condition can vary in degree and may lead to the following three events:

1) If the PT Hybrid Glenoid Post is not fully seated into the Hybrid Base and the implant construct is implanted, then a gap of 1-3 mm will be present.
2) If excessive torque is applied to assemble the post into the base, the PT Hybrid Glenoid Post drive tip could break off.
3) The PT Hybrid Glenoid Post may not thread at all into the Hybrid Glenoid Base, which would prevent assembly of the two implant components.

Risks associated with the use of this product may be:

1) **A PT Hybrid Glenoid Post that is implanted with a gap of 1-3mm present may lead to premature failure or fracture of the post-base assembly, which could potentially require a revision surgery.**

2) **If the drive tip breaks off or if the post does not thread at all onto the base, then another implant would need to be used, which could lead to a delay in surgery of less than 30 minutes.**

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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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

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 Coordinator, Regulatory Compliance
Biomet, Inc.
audrey.daenzer@biomet.com

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December 2012

FIELD SAFETY CORRECTIVE ACTION

Ref: PT Hybrid Glenoid Post PT-113950 Lot Number 984790

Dear Customer,

Our records show that Biomet UK Ltd has supplied you with Part Number PT-113950 a PT Hybrid Glenoid Post Lot 984790.

The manufacturer Biomet Orthopedics LLC has initiated this action following an investigation which identified that the male thread of the post may be oversized (see enclosed notice for full details).

It has been determined the risks associated with the use of this product may be:

1) A PT Hybrid Glenoid Post that is implanted with a gap of 1-3mm present may lead to premature failure or fracture of the post-base assembly, which could potentially require a revision surgery.

2) If the drive tip breaks off or if the post does not thread at all onto the base, then another implant would need to be used, this could lead to a delay in surgery.

On behalf of the manufacturer, Biomet Orthopedics LLC is issuing this FIELD SAFETY CORRECTIVE ACTION to make users aware of this issue and request them to immediately return the affected PT Hybrid Glenoid Post to their local Biomet distributor. Further details are in the attached FIELD SAFETY CORRECTIVE ACTION NOTICE.

Please distribute this field safety corrective action notice immediately to the appropriate people within your hospital.

Please complete and return without delay the attached “Fax-Back Response Form” acknowledging receipt of this letter and the attached FIELD SAFETY CORRECTIVE ACTION NOTICE and indicating the quantity of product you wish to return.

If you have any questions please contact the Biomet U.K. complaints department. Phone:- 01656 761678 , Fax :- 01656 645454

E-Mail:- uk.complaints@biomet.com www.biomet.com

Yours sincerely,

Richard Young
QA/RA Director UK
Biomet UK Healthcare Ltd

FAX BACK RESPONSE FORM

Biomet Reference Number:	**Glenoid Post FSCA**
Description:	**PT Hybrid Glenoid Post**
Part Numbers:	**PT-113950**
Lot Numbers:	**984790**

PLEASE TICK APPROPRIATE SECTION:

- ☐ WE CONFIRM ALL RELAVENT STOCK HAS BEEN PHYSICALLY CHECKED
- ☐ WE HAVE IDENTIFIED THE RELAVENT ITEMS IN OUR STOCK AND WOULD LIKE TO RETURN THE BELOW PARTS FOR REPLACEMENT, DETAILS TO BE LISTED BELOW.
- ☐ WE CONFIRM THAT ALL RELAVENT STOCK HAS BEEN CHECKED AND THAT THEY DO NOT CONTAIN THE AFFECTED ITEMS.

IIEM NUMBER and LOT NUMBER	**QTY**

Please sign and return this form to acknowledge receipt of this Field Safety Notice.

Name and Address:	********
Contact Name:	
Contact Title:	
Contact Signature:	
Contact Phone No:	
Date:	

We would appreciate it if you return this form within 3 business days to:

- ***Biomet UK Ltd, Waterton Industrial Estate, Bridgend, CF31 3XA***

Fax: 01656 645454 or E-Mail: uk.complaints@biomet.com