URGENT: MARKET WITHDRAWAL

RECALL OF *ZIMMER ALUMINA CERAMIC FEMORAL HEAD*
DISTRIBUTED BY ZIMMER, INC.

May 29, 2009

INTENDED AUDIENCE	**Zimmer, Inc. Sales Force & Distributors (and User Facilities who received product from these entities)**	
PRODUCT	**Name of Product**	**Affected Part Number and Lot Number**
	ZIMMER ALUMINA CERAMIC FEMORAL HEAD	Part Number 00-6428-032-02 Lot Number 61007046

REASON FOR RECALL

Zimmer, Inc. is initiating a voluntary market withdrawal of one lot of the *Zimmer Alumina Ceramic Femoral Head,* item number 00-6428-032-02, lot number 61007046.

Some units in this lot may have the inner Tyvek peel tab trapped within the outer seal. This configuration could result in delamination of the inner Tyvek seal as the package is opened, complicating removal of the implant from the package while maintaining sterility.

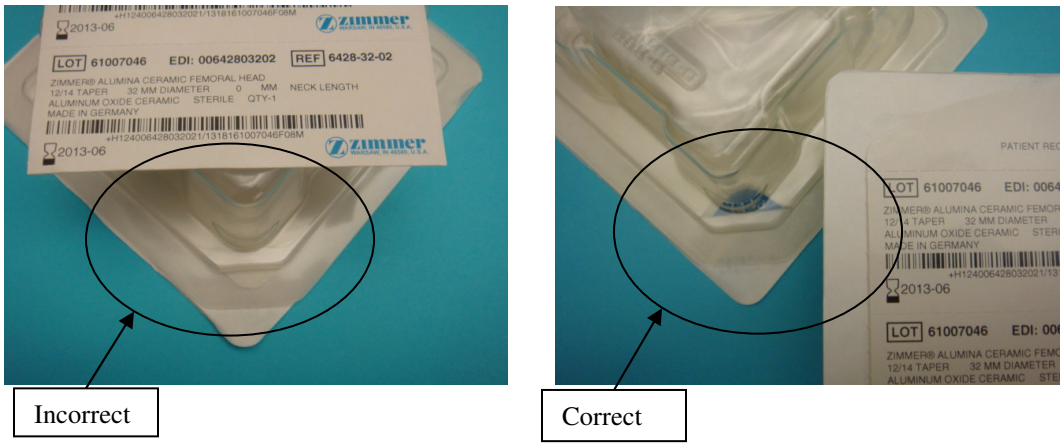

Figure 1: Nonconforming Unit from Lot 61007046 As Packaged

CLINICAL IMPLICATIONS (Risks to Health)

Should the Tyvek seal be compromised while opening, surgical delay could result as a suitable substitute is obtained. If a nonconforming device is used “as is”, the risk of patient infection may be increased.

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ACTION	1. **Locate any unused devices and quarantine them immediately**. 2. Please carry out a physical count of all affected product in your territory and record this data on the Inventory Return Certification Form included with this letter. 3. **Fax a copy of the completed Inventory Return Certification form to:** Zimmer, Inc. at (574) 372-4265 4. **Return the recalled product along with the completed Inventory Return Certification Form to:** Zimmer Distribution Center Attn: Product Service 1777 West Center Street Warsaw, IN 46580 *Important: If you have distributed this affected lot further, please provide a copy of this letter to these customers when you implement these recall instructions.*
OTHER INFORMATION	Notifications of this market withdrawal are being sent to all affected direct accounts of Zimmer, Inc. For shipping assistance, questions or assistance in notifying your accounts about the recall please contact Zimmer, Inc. at 1-800-613-6131. Zimmer, Inc. is committed to providing our customers with the highest level of service and product quality. We appreciate your cooperation, and we regret any inconvenience this action may cause your hospital and your staff. ***This voluntary recall will be reported to the U.S. Food and Drug Administration. The FDA will also receive from Zimmer progress reports on the implementation of this recall. Your urgent cooperation is requested.***
MEDWATCH REPORTING	Any adverse reactions experienced with the use of these products, and/or quality problems may also be reported to the FDA's MedWatch Program by phone at 1-800-FDA-1088, by Fax at 1-800-FDA-0178, by mail at MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at www.fda.gov/medwatch. Under 21 CFR Part 803, manufacturers are also required to report any serious injuries where a device has contributed to or may have contributed to the event. Please keep Zimmer informed of any adverse events associated with this device or any other Zimmer product.

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Market Withdrawal Certification Form

Fax back to: Zimmer, Inc. at (574) 372-4265

Use the table below to record quantities of the affected product in your territory.

Part Number	Lot Number	Quantity Returned
00-6428-032-02	61007046	

Return Product To:
Zimmer Product Service Department
1777 West Center Street
Warsaw, IN 46580

DO NOT RETURN RECALL PRODUCT WITH OTHER RETURNS.

If devices have been implanted, please indicate facilities where consumed:

Hospital Name	Address	Phone

Acknowledgement of Responsibility:
By signing below, I acknowledge that quantities of all **Zimmer Alumina Ceramic Femoral Head from lot 61007046 detailed in this notification** in our territory are listed above and have been returned to Zimmer, Inc. or accounted for in accordance with the Market Withdrawal notice.

Printed Name:_____ Signature:_____

Title _____ Telephone: ( ) _____-_____ Date:____/____/____

Territory Number: _____Account Number: _____

Account Name: _____

Account Address: _____