July 19, 2012

To: **Distributors, Sales Representatives, and Distribution Operation Managers Distributing the Zimmer Trabecular Metal™ Reverse Shoulder Instrumentation Liner Impactor**

Subject: **URGENT MEDICAL DEVICE RECALL-LOT SPECIFIC**

Affected Product: **Zimmer Trabecular Metal™ Reverse Shoulder Instrumentation Liner Impactor**

Zimmer is initiating a lot specific recall of the Trabecular Metal Reverse Shoulder Liner Impactors due to reports of alignment peg fractures occurring in approximately 0.4% of surgeries. See Figure 1 for a representative picture of a fractured alignment peg. The affected item and lot numbers can be found in Attachment 1. The specific lot numbers being recalled were manufactured from 455 stainless steel, which is the material that all of the reported fractured instruments were manufactured from. The remainder of the lot numbers that are not affected by this recall are manufactured from 13-8 stainless steel and have never had a report of an alignment peg fracture.

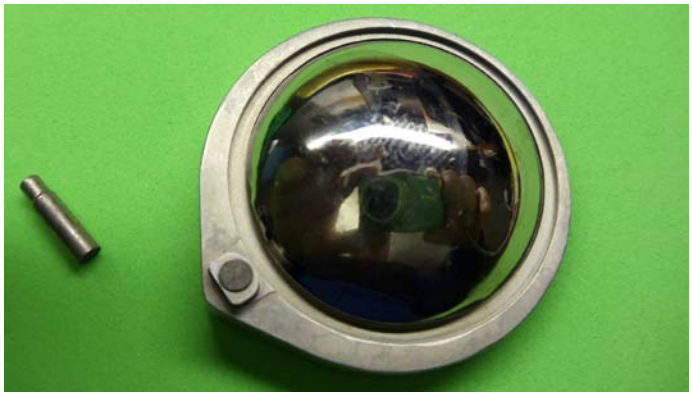

Figure 1

Risks:

Immediate:

- There may be a delay in surgery to locate an additional instrument to complete the surgery or to remove the fragment from the surgical site.
- The fragment may interfere with the placement of the liner implant.

Long term:

- If the alignment peg is left in the patient, there is a risk of an autoimmune reaction.
- In the event that the liner implant is not seated fully, this could result in premature wear and failure.

Your Responsibilities

1. Immediately inspect all TM Reverse instrument sets for affected lot(s)/instrument(s).
2. If you determine that you have possession of an identified lot(s)/instrument(s), immediately place an order to backfill the identified instrument(s) with Customer Service.
    a. The order will be shipped the same day it is received.
3. If an instrument is removed from customer inventory, please provide a copy of the Risk Manager letter upon retrieval of that instrument(s) to ensure the facility is aware of the removal.
4. Have all replacement orders in no later than Friday, August 3rd, 5:00 p.m. EST.

5. While waiting for a replacement instrument, please make every effort to use poly liner impactors that are not part of the lot-specific recall. If unable to do this, give the surgeon a copy of the risk manager letter to notify him/her of the lot-specific recall.
6. Return identified instruments no later than Wednesday August 8th after receiving the replacement instrument. Return the recalled instrument along with the completed Inventory Return Certification Form (Attachment 2) and the Sterilization Certification Form (Attachment 3).
7. If you have additional questions, please call Warsaw Customer Service at (800) 348-2759.

Other Information:

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 correction. 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.

Vigilance Reporting: Any adverse reactions experienced with the use of these products, and/or quality problems may also be reported according to MEDDEV 2.12-1 Rev. 6 to the local health authority in your country.

ATTACHMENT 1
Affected Item and Lot Numbers

Item	Lot	Item	Lot
00-4309-028-00	60443178	00-4309-028-01	60529860
	60545332		60574377
	60549563		60589079
	60605851		60605856
	60612791		60616574
	60720047		60684774
	60758647		60739623
	60773944		60842967
	60836577		60896979
	60896973		60936815
	60973522		61019785
	61019783		61051017
	61024158		
Item	**Lot**	**Item**	**Lot**
00-4309-029-00	60444332	00-4309-029-01	60535162
	60537066		60545338
	60549565		60576488
	60605852		60605855
	60612792		60637022
	60633381		60689253
	60708954		60772974
	60743404		60875277
	60773946		60918060
	60870480		60989817
	60915146		61011689
	60979391		61024161
	61004027		61051024

ATTACHMENT 2
Inventory Return Certification Form

Zimmer Trabecular Metal™ Reverse Shoulder System Instrumentation Liner Impactor
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

Return Product To:

Zimmer Product Service Department -or- Zimmer International Logistics GmbH
1777 West Center Street Attn: Fao Tanja Herold (Recall Warsaw)
Warsaw, IN 46580 Max-Immelmann-Allee 12
79427 Eschbach Germany

DO NOT RETURN RECALL PRODUCT WITH OTHER RETURNS.

Printed Name:_____ Signature:_____

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

Territory Number: _____Account Number: _____

Account Name: _____

Account Address: _____

ATTACHMENT 3

CERTIFICATE OF STERILIZATION

Zimmer Trabecular Metal™ Reverse Shoulder System Instrumentation Liner Impactor

By signing below, I acknowledge that the instrumentation being returned to Zimmer, Inc. has been clean and sterilized prior to being returned.

Describe the method of disinfecting: _____

Printed Name_____ Signature_____

Title _____ Telephone: ( ) _____-_____

Date: ____/____/____

Territory Number: _____

Account Name: _____