September 21, 2012

To: **Surgeons at facilities using Zimmer NexGen® Stemmed Nonaugmentable Tibial Component**

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

Affected Product: **Zimmer NexGen® Stemmed Nonaugmentable Tibial Component**

Item	Lot	Manufacture Quantity
00-5986-047-02	62049114	63
	62045235	60

Zimmer is initiating a lot specific recall of the Zimmer NexGen® Stemmed Nonaugmentable Tibial Component due to the devices being processed through a manufacturing cleaning operation that was operating outside of the validated parameters. As a result, the devices may contain residual particulate from the manufacturing process.

Risks:

Immediate:

- Allergic reaction due to the foreign material.

Long term:

- Late onset of allergic reaction and accelerated polyethylene wear caused by third body particles.

Your Responsibilities:

1. **Locate these implants and quarantine them immediately**.
2. Please carry out a physical count of all affected product in your facility and record this data on the Inventory Return Certification Form included with this letter in Attachment 1.
3. Return the recalled product along with the completed Inventory Return Certification Form.
4. If product is found to have been implanted, provide a copy of this letter to the affected surgeon(s).
    a. Zimmer recommends that the surgeon continue with their normal post-operative follow-up practice.

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. 7 to the local health authority in your country.

ATTACHMENT 1
Inventory Return Certification Form

NexGen® Stemmed Nonaugmentable Tibial Component
Fax back toYour Zimmer contact person

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

Part Number	Lot Number	Quantity Returned	Quantity Implanted

Return Product To:
Zimmer International Logistics GmbH
Attn: Fao Tanja Herold (Recall Warsaw)
Max-Immelmann-Allee 12
79427 Eschbach Germany

_____Credit My Account OR _____Send a Replacement

DO NOT RETURN RECALL PRODUCT WITH OTHER RETURNS.

Printed Name:_____ Signature:_____

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

Territory Number: _____Account Number: _____

Account Name: _____

Account Address: _____