December 31, 2013

To: **Surgeons**

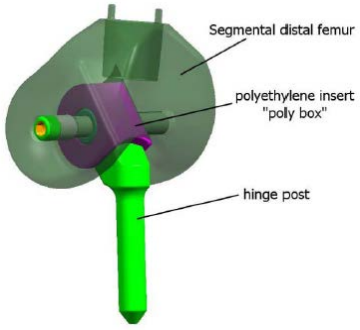
Subject: **URGENT MEDICAL DEVICE CORRECTION**
UPDATED SURGICAL TECHNIQUE AND INSTRUCTIONS FOR USE

Zimmer Reference: 1822565-11-06-2013-003-C

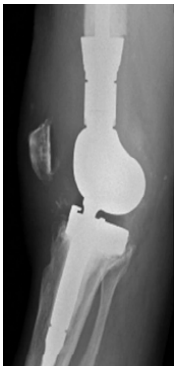
Affected Product: Zimmer® Segmental System Polyethylene Insert-Size B & Size C
Item Numbers: 00-5850-012-95 & 00-5850-013-95

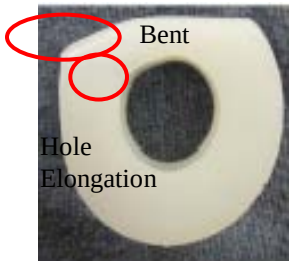
You are receiving this letter because our records indicate that you may be a current user of the Zimmer Segmental System.

Zimmer launched the Segmental System in 2007 and during the last 6 years, Zimmer has received 13 complaints related to hyper-extension. This represents a complaint rate of approximately 0.4% since the product was introduced. It is important to note that the 13 complaints only involved 9 patients due to repeat occurrences with multiple patients. In addition, analysis of the explanted polyethylene insert found that it typically exhibited anterior deformation in these 9 patients.



Segmental System Construct


Hyper-Extension



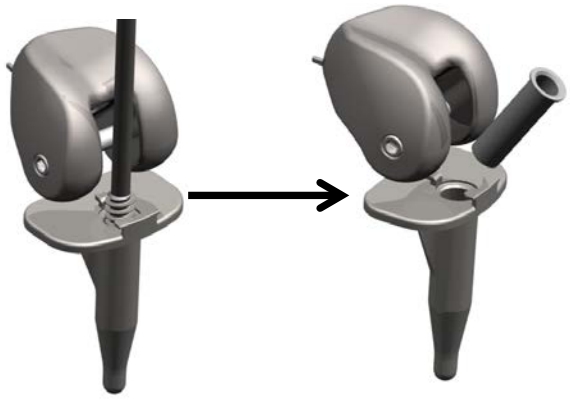
Explanted Polyethylene Insert

Based on the investigation of these complaints, Zimmer determined that updates to the labeling associated with the Zimmer Segmental System were required to provide additional instructions and patient conditions that may place excessive loading on the polyethylene insert. Specifically, Zimmer is updating the applicable surgical technique (97-5850-004-00) and instructions for use (87-6203-755-23).

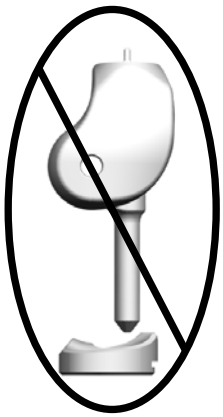
In addition, Zimmer is currently working on an enhanced design that will be offered in addition to the current polyethylene inserts.

The following information will be included in the surgical technique:

When servicing the Segmental Distal Femoral hinge or polyethylene insert (box), the tibial bushing (within the NexGen® Rotating Hinge Knee Tibial Component or Segmental Tibial Component) must be removed and replaced.



Stretching the knee to insert the Segmental Distal Femoral Hinge Post shank into the tibia component using back table hinge post assembly should not be performed with the Segmental Distal Femoral. In vivo assembly of the hinge pin to the hinge post is required.



The following information will be included in the instructions for use:
The following conditions may place excessive demand and/or severe loading on the Polyethylene Insert (box) component of the distal femoral construct:

- **Neuropathic arthropathy (Charcot's knee)**
- **Muscle deficiencies (quadriceps insufficiency or previous patellar tendon/tibial tubercle rupture)**
- **Refusal to modify postoperative physical activities**
- **Morbid obesity (Body Mass Index > 39)**

Risks

- Risks associated with revision surgery such as tissue and muscle damage, as well as risks related to anesthesia and blood loss.
- Increased pain from revision surgery potentially caused by supracondylar fracture and multiple total joint replacements.

Your Responsibilities

1. Review the notification and ensure affected personnel are aware of the contents.
2. If a patient is symptomatic with instability or pain associated with hyperextension of approximately 15 degrees or more, surgeon evaluation is recommended.
3. **If after reviewing this notification you have further questions or concerns please contact your Zimmer contact person**

Vigilance Information
This voluntary notification will be reported to the U.S. Food and Drug Administration and to the local Competent Authorities. 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. 8 to the local health authority in your country.

Please keep Zimmer informed of any adverse events associated with this device or any other Zimmer product. Adverse events may be reported to Zimmer at zimmer.per@zimmer.com., or to your local Zimmer representative.
Kind regards

[redacted]
Post Market Surveillance & Regulatory Compliance Associate Director

Attachment 1:

Confirmation of Receipt of Notice of Urgent Safety

FSA/FSCA: 1822565-11-06-2013-003-C

For confirmation of receipt of this notice, please complete and sign this document.

Please send this form to your Zimmer local contact.

Fax / Email: _____ _____

Don´t hesitate to contact Zimmer if you need further details.

This document confirms that you have received the Urgent Field Safety Notice on the product
Zimmer® Segmental System Polyethylene Insert-Size B & Size C

I certify that to it is my knowledge the content of the Urgent Field Safety Notice on the product
Zimmer® Segmental System Polyethylene Insert-Size B & Size C
and that it was given to me by Zimmer, for the protection of the interests and safety of patients.

(Printed Name of Surgeon)

(Signature and Date)

(Name of Hospital)