May 02, 2012

Subject: **URGENT MEDICAL DEVICE RECALL**

ZIMMER NEXGEN® COMPLETE KNEE SOLUTION POSTERIOR REFERENCING INSTRUMENTS (PRI) - FEMORAL AND PROVISIONAL IMPACTOR/EXTRACTOR

Dear Surgeon,

Zimmer is initiating a recall of the NexGen PRI Femoral and Provisional Impactor/Extractor and replacement kits. The Impactor/Extractor is a non-implanted reusable instrument that attaches to the femoral implant or provisional during TKA. During use the instrument is typically impacted with a mallet to aid in insertion or removal of the provisional or implant.

Zimmer initiated a field action of this instrument in March 2011, at which time an updated design to the spring clip for the jaw assembly was implemented; however, Zimmer has received additional complaints of fractures of the spring clip. Therefore, these instruments are being discontinued and Zimmer wants to ensure you are aware of the alternative instruments that can be used in place of these instruments during and after the execution of this recall.

See Figure 1 for a representative picture of a fractured spring clip. It is important to note that none of the complaints for the newly designed instrument have reported a loose fragment being left in a patient.

This notification is also intended to emphasize that this instrument is intended to only be used in a manner consistent with the NexGen PRI surgical technique (97-5905-002-00 Revision 2). In particular, it is important that the user does not impact the medial or lateral arms or the knob of the instrument, which is detailed in the surgical technique. The intended impaction area is at the ends of the instrument and can be seen on page 9 of the technique, as well as below in Figure 2.

Figure 1

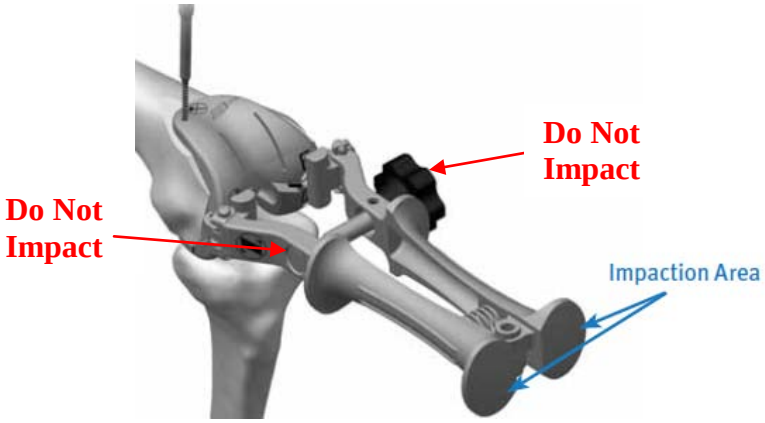


Figure 2

It is important to inspect the instrument before, during, and after surgery. This inspection includes ensuring that all parts of the instrument are accounted for during surgery. If the spring clip is found to be damaged or fractured during your inspection and an alternative instrument is not available, the jaw assembly can be exchanged with the replacement kit. Instructions for replacing the jaw assembly can be found on page 40 of the surgical technique. Please note that replacement kits will only be offered until alternate instruments are available.

Please stop using this instrument as soon as alternative instruments are available. The clinical risk implications are as follows:

Immediate:

- If the clip breaks during surgery and a fragment falls into the surgical site, there will be a short delay while the fragment is retrieved and while an alternate instrument is located/ prepared. A delay in surgery includes

additional exposure to anesthesia resulting in a minimal to moderate patient risk.
- If additional surgery is needed to remove the broken clip fragment if it breaks, falls into the surgical site, and is not detected until after the initial surgery is concluded, then this will pose additional related surgery risks.

Long term:
- If the clip breaks during surgery, a fragment falls into the surgical site, and this is not discovered at that time, there is an increased risk of pain, osteolysis, soft tissue irritation/damage, reduced ROM and shortened implant life due to foreign body irritation, bio-incompatibility, and/or wear. There is a potential, if the spring clip is not observed on post operative x-rays, the patient is at greater risk of requiring a revision to implant components if they are damaged by the presence of the foreign body.

We understand that you may have used the PRI Impactor/Extractor affected by this recall during total knee arthroplasty surgeries. Although Zimmer has no reports of this, the potential exists that a detached spring clip could go undetected and be left in the surgical site. In addition to the potential for intraoperative detachment, the spring clip could have also been lost during cleaning of this instrument. Of the 59 complaints Zimmer has received with the new spring clip design, there have been no reports of the spring clip being found in-vivo.

We want to communicate to you information that we believe will be helpful in your determination of any steps regarding your patients.

- The spring clip is metal, and therefore would likely be detectable on radiographs. Depending on the view taken the spring clip may be masked by the knee implant. If you review radiographs, it is recommended to examine multiple radiographic views of the patient.
- The spring clip is manufactured from 17-4 PH stainless steel or 17-7 PH stainless steel. Zimmer does not have data concerning long term effects of this material being implanted. This material does contain nickel, to which certain patients may have sensitivity.

Zimmer is providing this information to ensure you have the available facts when considering a course of action with your patients. We recommend monitoring your potentially affected patients via radiographs and office consultations, though any decision regarding patient care is at your discretion.

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.

Zimmer continually monitors the safety and effectiveness of its devices in all phases. We have taken corrective actions to eliminate the cause that led to the recall. We look forward to continued service to your patient needs.

Should you have any questions or concerns, please contact your Zimmer Sales Representative. Please complete the attached acknowledgement letter upon receipt of this letter and fax to Zimmer Inc. at (574) 372-4265.

Sincerely,

Jaime Weeks
Zimmer, Inc
Principal Quality Engineer

Certificate of Acknowledgement

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

By signing below, I acknowledge that I have received and understand the content of the letter subject to Zimmer Inc. Recall of the NexGen® Complete Knee Solution Posterior Referencing Instrument – Femoral and Provisional Impactor/Extractor

Printed Name:_____ Signature:_____

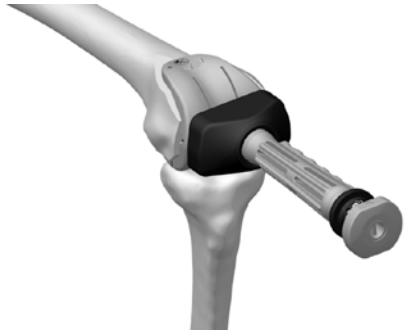
Hospital Name: _____

Hospital Address: _____

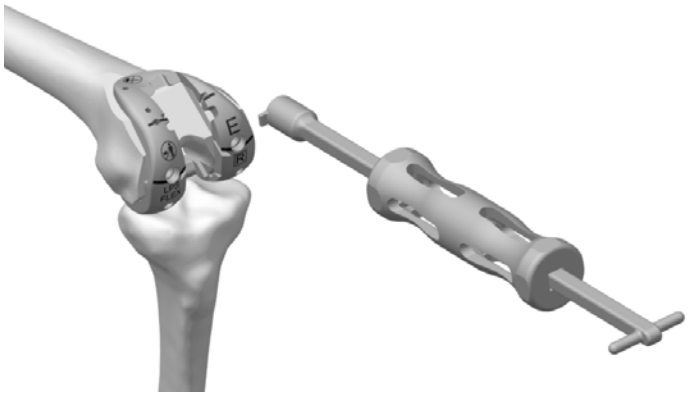
ATTACHMENT 2

ALTERNATIVE FEMORAL PROVISIONAL INSERTION & EXTRACTION OPTIONS

OPTION 1-PROVISIONALS



The PRI Femoral Provisional can be placed on the femur by hand and impacted with the assembled PRI Femoral Impactor Head (00-5901-032-00) and PRI Quick Connect Handle (00-5901-034-00)

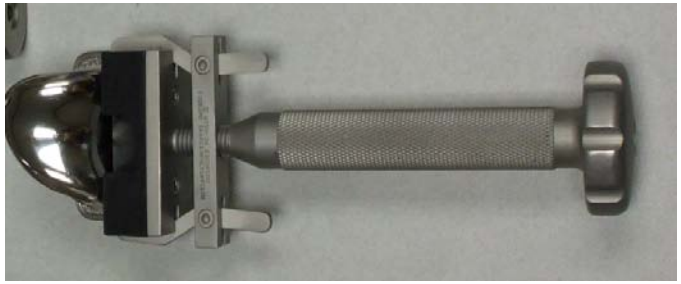


The PRI femoral provisional can be removed from the femur by inserting the PRI Slaphammer (00-5901-024-00) into the side slot on the PRI Femoral Provisional

OPTION 2-PROVISIONALS

The PRI Femoral Provisional can be inserted and extracted using the PRI Femoral Provisional Inserter/Extractor (00-5901-036-00) and PRI Quick Connect Handle (00-5901-034-00)

OPTION 3-PROVISIONALS

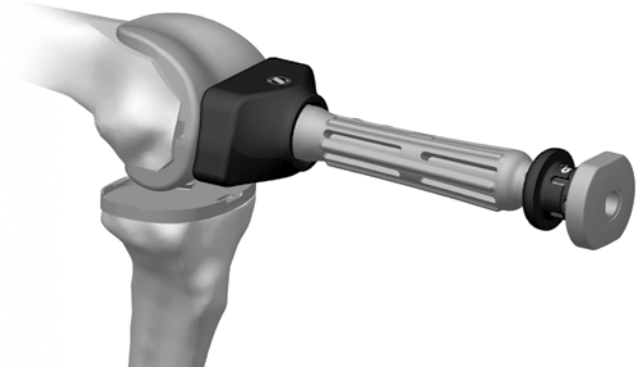


The PRI Femoral Provisional can be inserted and extracted using the existing NexGen Locking Inserter/Extractor (00-5120-034-00)

ATTACHMENT 2 CONTINUED

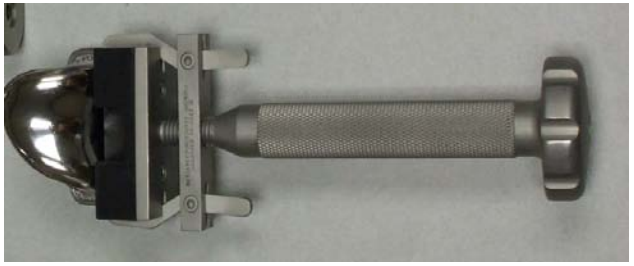
ALTERNATIVE FEMORAL IMPLANT COMPONENT INSERTION & EXTRACTION OPTIONS

OPTION 1-IMPANTS



The NexGen Femoral Components can be placed on the femur by hand with final impaction occurring with the assembled PRI Femoral Impactor Head (00-5901-032-00) and PRI Quick Connect Handle (00-5901-034-00)

OPTION 2-IMPLANTS



The NexGen Femoral Components can be inserted and extracted using the existing NexGen Locking Inserter/Extractor (00-5120-034-00)

OPTION 3-IMPLANTS

The NexGen Femoral Components can be inserted and extracted using the existing NexGen MIS Femoral Inserter/Extractor
(00-5983-092-00)

- Does not work with PRI femoral provisionals
- Only use with NexGen femoral component implants