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Field Safety Notice

Commercial name of the affected product

NexGen® Complete Knee Solution Rotating Hinge Knee Screw Driver

FSCA-identifier: Zimmer FSCA 1822565-2008-03

Type of action: Additional Instructions for Use

Date: 22-August-2008

Attention: Surgeon and hospitals who utilize these products.

Details on affected devices:

Catalog Numbers and Device Names of Affected Devices

Catalog Number: 00-5881-026-00

Device Name: *NexGen*® Complete Knee Solution Rotating Hinge Knee Screw Driver

Description of the problem:

Recently we have received requests from Sales Representatives and Surgeons concerning surgical technique options for the removal of the Rotating Hinge Knee Hinge Post Extension while servicing the hinge mechanism or in replacing the Rotating Hinge Knee Articular Surface. In the event that the Hinge Post Extension is unable to be removed with the recommended screwdriver (00-5881-026-00) the risks can include; extended surgery time, aborted surgery, or unplanned removal of devices.

Advise on action to be taken by the user:

Review the included surgical technique addendum for an alternative method for servicing of the hinge mechanism or the exchange of the articular surface. Note that the attached technique addendum refers to both the use of the Trepine instrumentation and/or the 18mm Femoral Stem Drill. In addition to the information contained in the attached technique addendum, please take the time to review the section of the Rotating Hinge Knee surgical technique dedicated to insertion of the hinge-post extension. Reinforce with your surgeons the importance of applying the recommended torque (130 in-lbs.) when tightening the RH Knee hinge-post extension. Exceeding this torque limit does not enhance stability or better secure the hinge-post extension.

Current inventory of the Zimmer® RH Knee surgical technique will have this technique addendum added to each copy in the appendix section; future prints of the technique will have this addendum included directly in the appendix section.

Transmission of this Field Safety Notice:

The information in this notice is to be provided to surgeons, hospitals, and any medical personnel who utilize this product.

Contact reference person (s):

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The undersign confirms that this notice has been notified to the appropriate Regulatory Agency



Associate Manager, Post Market Surveillance
Zimmer, Inc.


Alternate Method for Servicing of Hinge Mechanism or Exchange of Articular Surface

If you are having difficulty in removing the Hinge Post Extension while servicing the hinge mechanism or replacing the Articular Surface, it is recommended to use the following freehand drilling technique:

Freehand drilling using TREPINE or 18mm FEMORAL STEM DRILL**

- I. Locate & mark the drilling center point on the medial side of the bone at a distance of 'X' from the Anterior flange and a distance of 'Y' from the Distal Condyle surface as shown in Fig. G13.
- II. Measure the additional bone on the medial side (not covered by the implant) & add to 'Z' depth as shown in Fig. G12. This is the 'Total depth' to be drilled.
- III. Mark the total depth on Trepine (00-5881-050-00) or 18mm Femoral Stem Drill (00-5977-010-01)** with a marking pen and drill through the bone to the required depth (taking care not to drill into the actual component) to access the Hinge Pin.
- IV. Follow the steps as shown in Fig. G5 thru Fig. G8 to disassemble the parts.

'X', 'Y' & 'Z' dimensions for a given size of the Femoral component are listed below-

Femoral Size	'X' Dimension (mm)	'Y' Dimension (mm)	'Z' Dimension (mm)
B	32.5	17.5	16
C	32.5	22	19
D	35	23.5	21
E	37	25	23
F	38.5	27	25

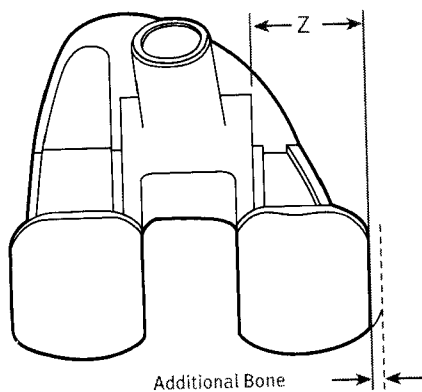


Fig. G12

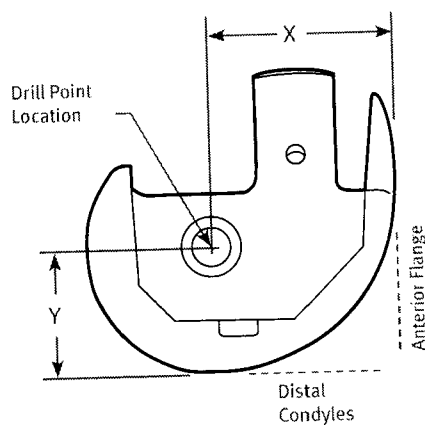


Fig. G13

** Use 18mm Femoral Stem Drill in place of Trepine if Service Kit is not available.