Zimmer® Trabecular Metal™ Femoral Cone Augment

Surgical Technique

For use with NexGen® LCCK and Rotating Hinge Knee Systems

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Zimmer Trabecular Metal Femoral Cone Augment Surgical Technique

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Surgical Technique developed in conjunction with Arlen D. Hanssen, M.D. and David G. Lewallen, M.D., Mayo Clinic, Rochester, MN

Overview

The objective of the *Trabecular Metal* Femoral Cone Augment is to fill and reconstruct large bone deficiencies and cavitary defects (Fig. 1) in the distal femur and to provide for a stable platform for an LCCK or Rotating Hinge Knee femoral component.

The femoral cone implant that is selected must -

- Fit within the damaged area of the femoral cavity without significant removal of viable bone.
- Allow the selected femoral component and stem extension to be inserted through the cone and positioned into the femoral canal.
- Accommodate the femoral cone augment / femoral component / stem extension assembly to stabilize and reconstruct the distal femur in order to transfer and distribute load to distal femoral bone with sufficient structural integrity to support a TKR.

Fig. 1

- Allow for adjustments of femoral component rotation to re-establish appropriate epicondylar axis alignment.

The design of the *Trabecular Metal* Femoral Cone Augment is asymmetric, with left and right configurations available in Small, Medium and Large sizes. Each size is available in three height options of 30, 40 and 50mm (Fig. 2).

The femur and associated bony defect must be prepared to accommodate the *Trabecular Metal* Femoral Cone Augment and LCCK or Rotating Hinge Knee femoral component and associated stem extension. The femur is prepared via an iterative process of removing and sculpting bone and assessing fit and stability with the provisional implants (trials). Repeated trialing of various potential implant combinations should be performed to optimize:

1. The fit and stability of the *Trabecular Metal* Femoral Cone Augment with minimum removal of viable bone stock
2. The fit of the stem extension within the femoral canal
3. The position of the LCCK or Rotating Hinge Knee femoral component

Trabecular Metal Femoral Cone Augments **must be cemented** to the LCCK or Rotating Hinge Knee femoral component. *Trabecular Metal* Femoral Cone Augments must be cemented to the bone in the United States and may be used **with or without** bone cement outside the United States.

Table 1 M/L Dimension (mm)

Size	Height		
	30mm	40mm	50mm
Small	44.2mm	51.1mm	57.4mm
Medium	50.5mm	58.4mm	60.7mm
Large	56.9mm	63.0mm	65.0mm

Table 2 A/P Dimension (mm)

Size	Height		
	30mm	40mm	50mm
Small	25.9mm	31.2mm	31.2mm
Medium	30.5mm	36.6mm	36.6mm
Large	36.3mm	40.4mm	40.4mm

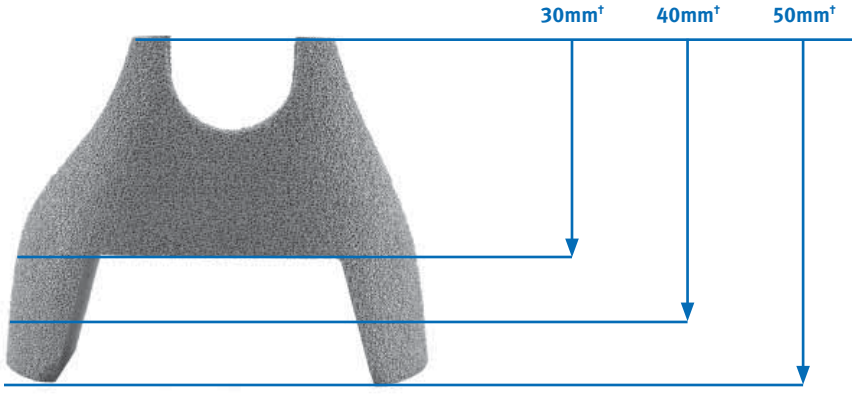

Fig. 2

† Note: Augment configuration is slightly different from size to size. See the x-ray templates for accurate height representations of each of the sizes.

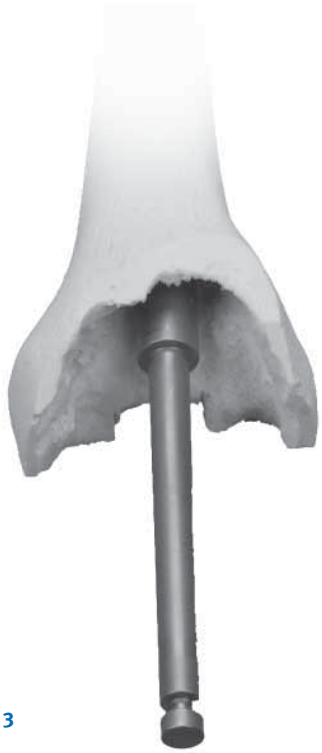

Fig. 3

Distal Femur Preparation

Minimally ream the femoral canal to the appropriate depth (of the selected stem extension) and diameter until stability of the reamer is tactily sensed. Remove the reamer and note the diameter. Select the appropriate diameter Stem Extension Provisional and attach it to a Stem Provisional Adapter. Insert the provisional components into the canal (Fig. 3).

Femoral Cone Augment Selection

Select one of the Femoral Cone Augment Provisional components that approximates the size and depth of the defect and insert it over the Stem Extension Provisional. **Hint: Invert the cone augment to simulate the size of distal void that the cone will accommodate (Fig. 4).** This will help provide an estimate of the A/P and M/L position of the defect, relative to the center of the IM canal (Fig. 5). Ensure that the stem extension can be removed from the femur when the provisional cone augment is in position (Fig. 6).

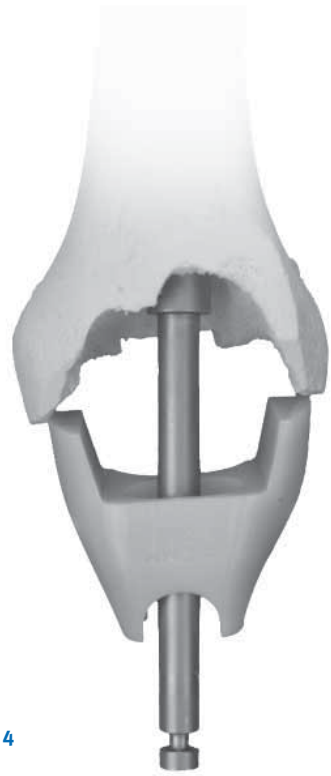

Fig. 4

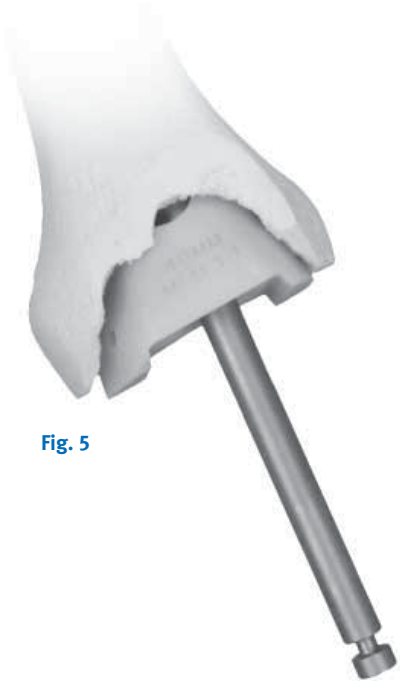

Fig. 5

Fig. 6

Stem Extension Provisional Selection

The *NexGen* system has several choices of stem extension components, in both sharp fluted and cemented designs, and in various lengths. Some limitation of flexibility in femoral construct positioning may be encountered dependent upon the size of the cone selected and diameter of the stem extension used in the IM canal. Critical in the selection process is the recognition that the **entire assembly of components** must simultaneously be able to be accommodated in the distal femur. In all cases, the selected stem extension must be smaller in diameter than the inside dimension of the cone augment (Fig. 7). The smaller the diameter of the stem extension, the greater the flexibility of positioning the augment relative to the femoral component.

Size	Inside Dimension	Maximum Diameter Stem Extension
Small	17.8mm	17mm
Medium	17.8mm	17mm
Large	18.5mm	18mm

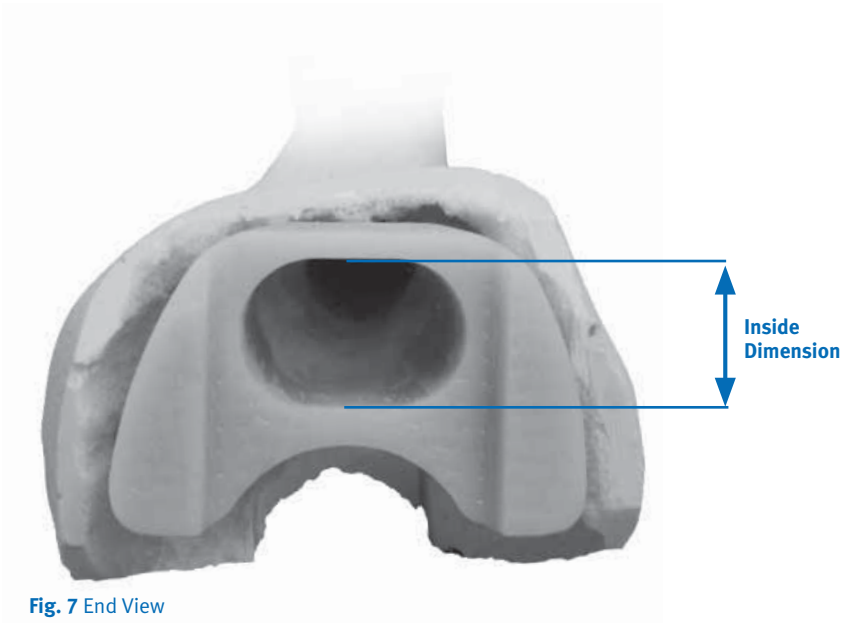

Fig. 7 End View

Provisional Femoral Cone Augment Selection

Select the Provisional augment implant combinations that satisfy the tradeoffs that will be encountered in the reconstruction. Concern with flexion/extension gap spacing and the ability to recreate a stable distal femoral construct must be considered and optimized. The ability to re-establish joint line height by selection of 30, 40 or 50mm Cone Augments, combined with the use of Distal and Posterior Femoral Augments to achieve rotational alignment, must also be considered (Fig. 8).

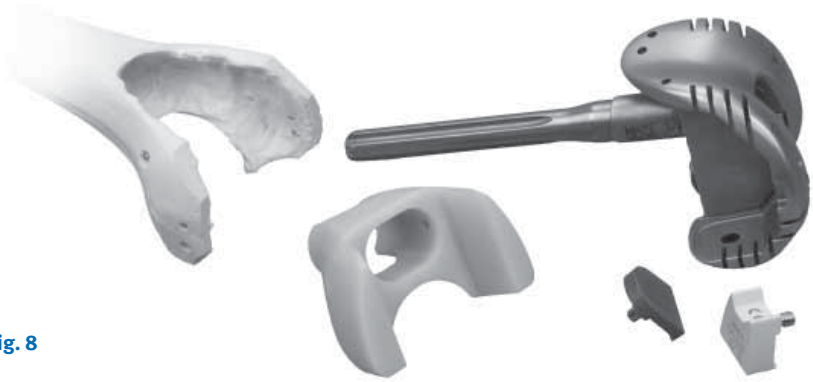

Fig. 8

Fig. 9

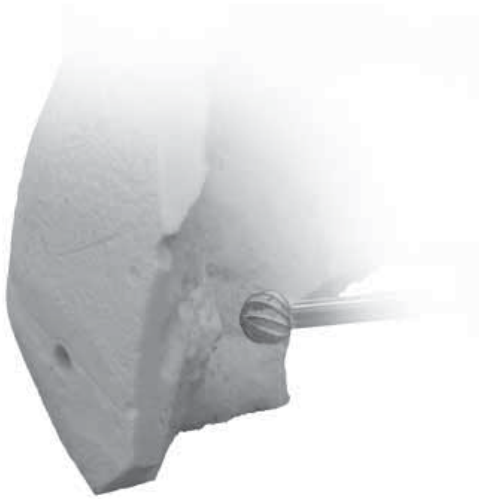

Fig. 10

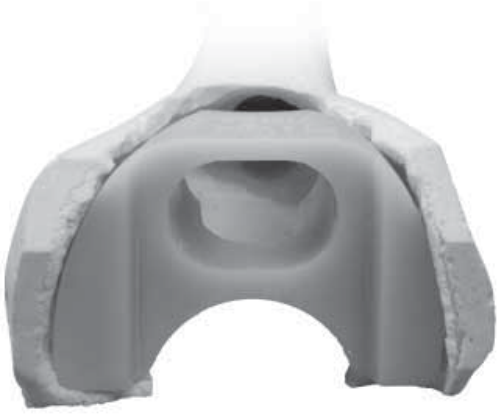

Fig. 11

Trial positioning of the Assembly

Assemble the combination of the selected stem extension provisional, selected femoral component provisional (with provisional distal and posterior augments attached) and the selected provisional femoral cone augment. Insert the provisional cone augment into the femoral void. Next, attempt to insert the provisional femoral component (with the stem extension provisional attached) through the provisional cone augment, into the femoral canal. Ascertain if a different combination of one or more of the provisional components is necessary to achieve stability while minimizing bone loss and optimizing femoral cone augment fit and stability (Fig. 9).

Remove the provisional femoral construct. Using a high-speed bur (Fig. 10), remove necessary endosteal bone from the distal femur in order to allow the selected cone augment (and then the full construct) to properly seat within the distal femur (Fig. 11). Repeat this step as necessary. Frequently confirm that the assembled provisional components can be inserted into the canal while the cone augment and femoral provisional assembly is properly positioned within the distal femur. Care must be taken to confirm alignment in all planes of the femoral component during this process.

Filling Voids Outside of the Cone Augment

If voids exist between the outside of the provisional cone augment and the endosteal surface of the femur, packing the voids with bone graft material should be considered (Fig. 12). The provisional femoral cone augment is then positioned in the void to the intended depth. If necessary, pack morsalized grafting material behind the provisional augment, and then re-insert it. Lastly, pack graft material around the sides of the provisional cone augment until sufficient stability is achieved.

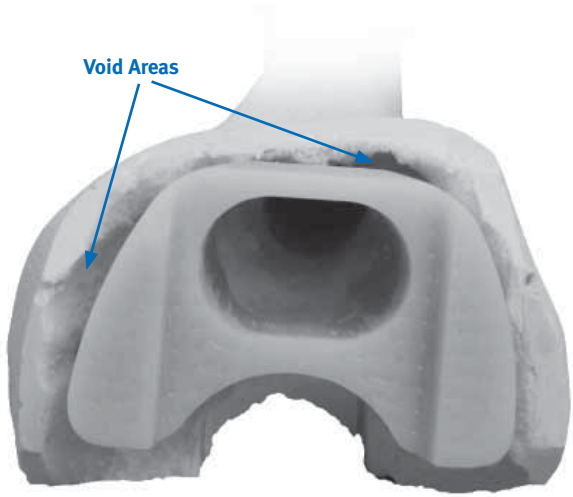

Fig. 12

Final Trialing

It is recommended that a final trial of the entire construct of the femoral provisional / cone augment provisional / stem extension provisional be conducted prior to implanting the devices. If satisfactory, remove the provisional femoral cone augment - taking care to not disturb any graft material between the outside of the provisional cone and endosteal surface (Fig. 13).

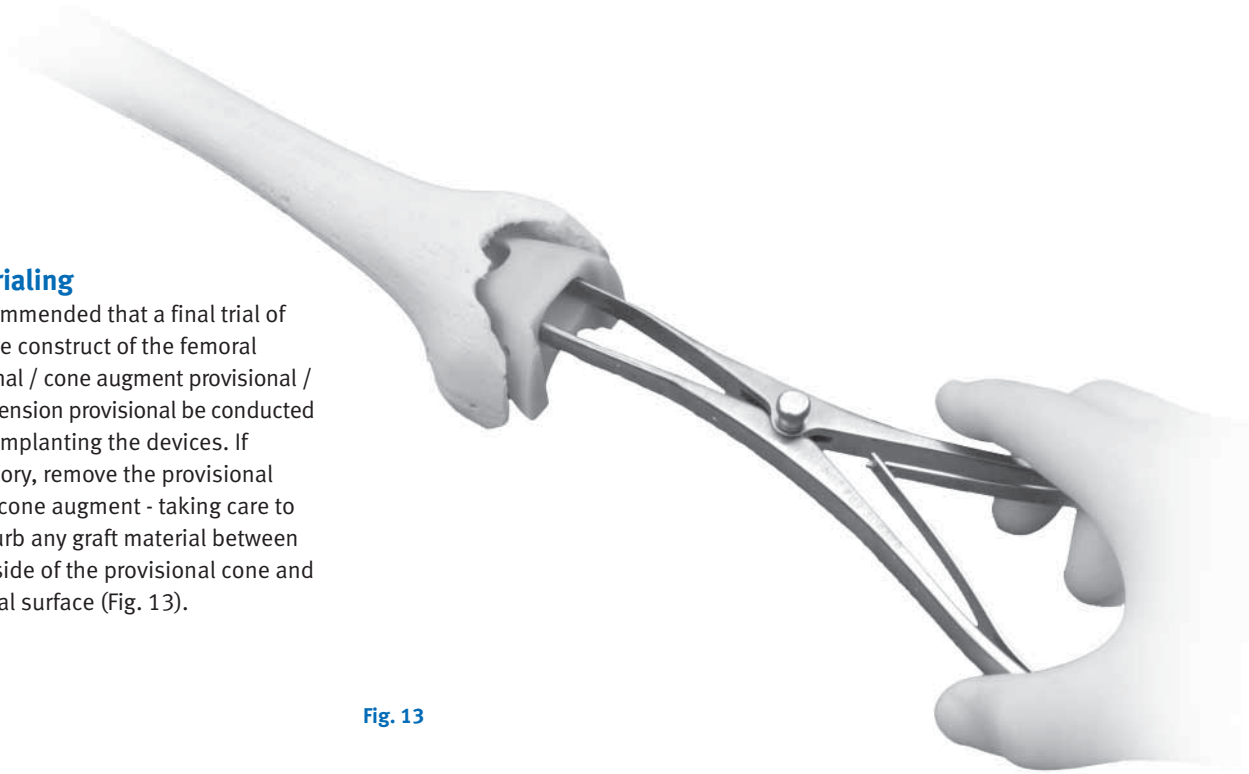

Fig. 13

Implantation of Femoral Cone Augment – Cemented Technique*

Apply bone cement to the outside periphery of the Femoral Cone Augment implant. Using gentle taps on the Femoral Cone impactor handle (Fig. 14), insert the implant into the prepared femoral void and remove excess bone cement (Fig. 15a). **Note: If excessive force is used to seat the implant, femoral fracture may occur. Additional bone should be removed to allow implant insertion.** The amount and viscosity of the bone cement will cause a tighter fit than that associated with the provisional augment. If necessary, remove some grafting material and/or bone to allow the implant to fully seat at the level indicated by the provisional trial.

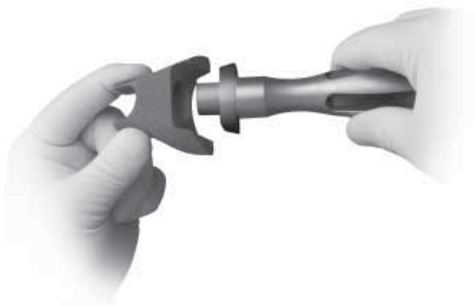

Fig. 14

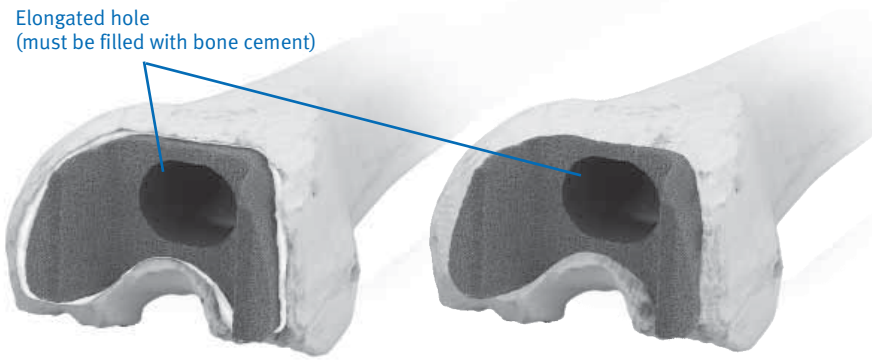

Fig. 15a Fully seated – Cemented (Remove excess cement)

Fig. 15b Fully seated – Cementless

* *Trabecular Metal* Femoral Cone Augments are cleared for use only with bone cement in the United States.

Implantation of Femoral Cone Augment – Cementless Technique

Outside the United States, *Trabecular Metal* Femoral Cone Augments may be cemented or used without bone cement (cementless interfaces with bone). When used without bone cement, it is extremely important that adequate host bone is present to stabilize and support the *Trabecular Metal* Femoral Cone Augment and associated components. **Note: Insufficient bone support of the femoral cone augment; specifically proximal flanges; may cause loosening or fracture of the implant and/or bone.** Gaps and voids at the interfaces between the *Trabecular Metal* material and bone are filled with bone graft materials. The stability and fit of the Femoral Cone is assessed via iterative bone removal, sculpting, grafting procedures, and trialing with the provisional femoral cones. Once stability and adequate support is confirmed with the provisional femoral cone, the *Trabecular Metal* Femoral Cone Augment is inserted by hand into the prepared femur and tapped into place with the impactor handle. **Note: If excessive force is used to seat the implant, femoral fracture may occur. Additional bone should be removed to allow implant insertion.** Because of the high friction of *Trabecular Metal* material against bone, the fit of the *Trabecular Metal* Femoral Augment may be tighter than that determined with the provisional. If necessary, bone graft material and/or bone may need to be removed to fully seat the *Trabecular Metal* Femoral Cone Augment to fully seat to the level originally indicated during the Final Trialing step (Fig. 15b). Upon final seating, the interfaces between the *Trabecular Metal* material and bone should be in intimate contact and free of gaps and voids.

Cementing of the LCCK/ Rotating Hinge Knee Femoral Implant Construct (U.S. and International)

Assemble the selected distal / posterior augments and the stem extension to the LCCK or Rotating Hinge Knee femoral implant. Form a “cone” of bone cement on the interior surface of the femoral component (including the intercondylar box region and up the stem extension of the femoral component). The amount of cement **must fill** the internal cavity of the cone augment (Fig. 16). **Note: In addition, the entire inside area of the elongated hole must be filled with cement (Figs. 15a and 15b).** Insert the femoral construct into the seated *Trabecular Metal* Femoral Cone Augment. Impact the implant assembly into position using light taps with a mallet and remove excess bone cement.

Continue with the remaining steps as detailed in the surgical technique of the LCCK or Rotating Hinge Knee implant system.

Fig. 16

Zimmer Femoral Cone Augment Provisionals

Prod. No.	Description
00-5979-013-00	**Trabecular Metal Femoral Cone Instrument and Provisional Kit**
00-5451-012-31	Femoral Cone Augment Provisional, Small - 30mm Left
00-5451-012-32	Femoral Cone Augment Provisional, Small - 30mm Right
00-5451-012-43	Femoral Cone Augment Provisional, Small - 40mm Left
00-5451-012-44	Femoral Cone Augment Provisional, Small - 40mm Right
00-5451-012-53	Femoral Cone Augment Provisional, Small - 50mm Left
00-5451-012-54	Femoral Cone Augment Provisional, Small - 50mm Right
00-5451-014-31	Femoral Cone Augment Provisional, Med - 30mm Left
00-5451-014-32	Femoral Cone Augment Provisional, Med - 30mm Right
00-5451-014-43	Femoral Cone Augment Provisional, Med - 40mm Left
00-5451-014-44	Femoral Cone Augment Provisional, Med - 40mm Right
00-5451-014-53	Femoral Cone Augment Provisional, Med - 50mm Left
00-5451-014-54	Femoral Cone Augment Provisional, Med - 50mm Right
00-5451-015-31	Femoral Cone Augment Provisional, Large - 30mm Left
00-5451-015-32	Femoral Cone Augment Provisional, Large - 30mm Right
00-5451-015-43	Femoral Cone Augment Provisional, Large - 40mm Left
00-5451-015-44	Femoral Cone Augment Provisional, Large - 40mm Right
00-5451-015-53	Femoral Cone Augment Provisional, Large - 50mm Left
00-5451-015-54	Femoral Cone Augment Provisional, Large - 50mm Right

CE 0120

Zimmer Femoral Cone Augment Instruments

Prod. No.	Description
00-5451-007-00	Trabecular Metal Femoral Impactor (Fits all sizes)
00-5451-002-00	Impactor Handle (Same as Tibial Cone Handle)
00-5451-006-00	Provisional Cone Removal Tool
00-5451-090-00	Case

CE

Zimmer Trabecular Metal Femoral Cone Augments

Prod. No.	Description
00-5450-003-00	**Full Implant Kit**
00-5450-012-31	Trabecular Metal Femoral Cone Augment, Small - 30mm Left
00-5450-012-32	Trabecular Metal Femoral Cone Augment, Small - 30mm Right
00-5450-012-43	Trabecular Metal Femoral Cone Augment, Small - 40mm Left
00-5450-012-44	Trabecular Metal Femoral Cone Augment, Small - 40mm Right
00-5450-012-53	Trabecular Metal Femoral Cone Augment, Small - 50mm Left
00-5450-012-54	Trabecular Metal Femoral Cone Augment, Small - 50mm Right
00-5450-014-31	Trabecular Metal Femoral Cone Augment, Medium - 30mm Left
00-5450-014-32	Trabecular Metal Femoral Cone Augment, Medium - 30mm Right
00-5450-014-43	Trabecular Metal Femoral Cone Augment, Medium - 40mm Left
00-5450-014-44	Trabecular Metal Femoral Cone Augment, Medium - 40mm Right
00-5450-014-53	Trabecular Metal Femoral Cone Augment, Medium - 50mm Left
00-5450-014-54	Trabecular Metal Femoral Cone Augment, Medium - 50mm Right
00-5450-015-31	Trabecular Metal Femoral Cone Augment, Large - 30mm Left
00-5450-015-32	Trabecular Metal Femoral Cone Augment, Large - 30mm Right
00-5450-015-43	Trabecular Metal Femoral Cone Augment, Large - 40mm Left
00-5450-015-44	Trabecular Metal Femoral Cone Augment, Large - 40mm Right
00-5450-015-53	Trabecular Metal Femoral Cone Augment, Large - 50mm Left
00-5450-015-54	Trabecular Metal Femoral Cone Augment, Large - 50mm Right

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97-5450-003-00 Rev. 1 5MM Printed in USA

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Please refer to package insert for complete product information, including contraindications, warnings, precautions, and adverse effects.