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Zimmer® Segmental System

Trabecular Metal™ Proximal Tibial Component

Surgical Technique

Table of Contents

Introduction

The Zimmer Segmental System is designed to address significant bone loss resulting from oncology, trauma, and/or the salvage of previously failed arthroplasty.

Proximal Tibial Replacement Options

The system includes a Trabecular Metal Proximal Tibial Component that enables tissue attachment to the implant via sutures and/or arms included in the optional Tissue Attachment Kit (Figure 1).

Figure 1

The Trabecular Metal Proximal Tibial Component may be implanted with the NexGen® Rotating Hinge Knee Distal Femoral Component or the Segmental Distal Femoral or Distal Femoral XT Component (Figure 2). Refer to the NexGen RH Knee Surgical Technique and Segmental Distal Femoral and Distal Femoral XT Surgical Technique before performing a Trabecular Metal Proximal Tibial Component implantation.

Note: The RH Knee Surgical Technique contains specific instruments regarding the Segmental Trabecular Metal Proximal Tibia. Please review before performing a proximal tibial replacement.

Option 1 Option 2* Option 3*

Figure 2

Proximal Tibial Replacement Options:

Option 1: Segmental Trabecular Metal Proximal Tibial Component

Option 2: NexGen RH Knee Non-Modular Proximal Tibial Component*

Option 3: NexGen RH Knee Modular Proximal Tibial Component*

*Refer to NexGen RH Knee Surgical Technique

System Compatibility

The Segmental Trabecular Metal Proximal Tibial Components may be implanted with the following as shown in Figure 3:

- Segmental Distal Femoral Component
- Segmental Stems
- Segmental Stem Collars
- Segmental Segments
- NexGen RH Knee Tibial/Femoral Components
- VerSys® Hip System 12/14 Heads and the Legacy 12/14 Heads

The Segmental Proximal Femoral Components and intercalary segments may be used with both fluted stems (cemented) and variable stiffness stems (press-fit) in many stem lengths and diameters. Variable stiffness stems are not indicated for use in the knee with the Segmental Proximal Tibial Components in the United States. All stems are compatible with both Trabecular Metal Collars and Tivanium® Ti-6Al-4V Alloy Collars.

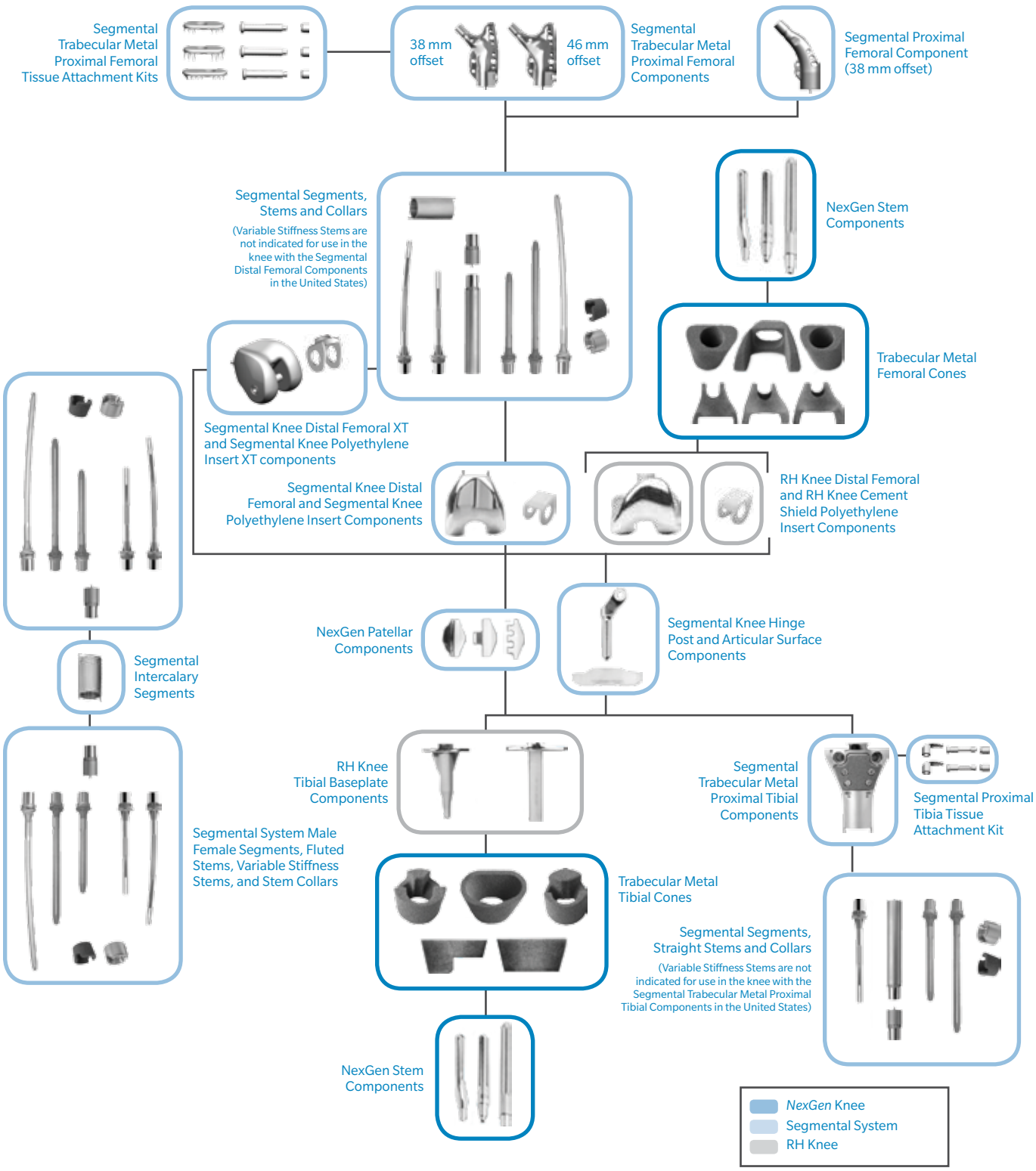

Segmental Trabecular Metal Proximal Femoral Tissue Attachment Kits
38 mm offset
46 mm offset
Segmental Trabecular Metal Proximal Femoral Components
Segmental Proximal Femoral Component (38 mm offset)
Segmental Segments, Stems and Collars
(Variable Stiffness Stems are not indicated for use in the knee with the Segmental Distal Femoral Components in the United States)
NexGen Stem Components
Trabecular Metal Femoral Cones
Segmental Knee Distal Femoral XT and Segmental Knee Polyethylene Insert XT components
Segmental Knee Distal Femoral and Segmental Knee Polyethylene Insert Components
RH Knee Distal Femoral and RH Knee Cement Shield Polyethylene Insert Components
NexGen Patellar Components
Segmental Knee Hinge Post and Articular Surface Components
Segmental Intercalary Segments
RH Knee Tibial Baseplate Components
Segmental Trabecular Metal Proximal Tibial Components
Segmental Proximal Tibia Tissue Attachment Kit
Segmental System Male Female Segments, Fluted Stems, Variable Stiffness Stems, and Stem Collars
Trabecular Metal Tibial Cones
Segmental Segments, Straight Stems and Collars
(Variable Stiffness Stems are not indicated for use in the knee with the Segmental Trabecular Metal Proximal Tibial Components in the United States)
NexGen Stem Components
NexGen Knee
Segmental System
RH Knee

Figure 3

Step 1: Tibial Preparation

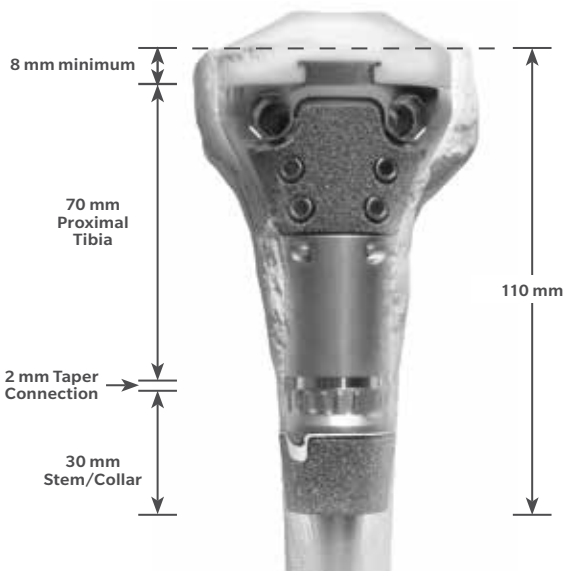


Figure 4

Resect Proximal Tibia

Extend the leg in a reproducible position.

Assess bone and soft-tissue quality, and determine the appropriate resection level (Table 1 and Figure 4).

Technique Tip: Resecting the tibia first will facilitate visualization of the distal femur.

Proximal Tibia	Stem/Collar	Segments	Total Length*
Size 1, 2, or 3 70 mm for implant + 8 mm minimum for bearing	30 mm	None	110 mm
		30 mm	142 mm
		35 mm	147 mm
		40 mm	152 mm
		45 mm	157 mm
		50 mm	162 mm
		55 mm	167 mm
		60 mm	172 mm
		35+30 mm	179 mm
		40+30 mm	184 mm
		40+35 mm	189 mm
		80 mm	192 mm
		40+45 mm	199 mm
		60+30 mm	204 mm
		60+35 mm	209 mm
		100 mm	212 mm
		60+45 mm	219 mm
		80+30 mm	224 mm
		80+35 mm	229 mm
		120 mm	232 mm
		80+45 mm	239 mm
		100+30 mm	244 mm
		100+35 mm	249 mm
		140 mm	252 mm
		100+45 mm	259 mm
		120+30 mm	264 mm
		120+35 mm	269 mm
		160 mm	272 mm
		120+45 mm	279 mm
		140+30 mm	284 mm
		140+35 mm	289 mm
		180 mm	292 mm
		140+45 mm	299 mm

Table. 1
Proximal tibia resection with stems, collars, and segments
*Each large taper connection adds 2 mm to the total length

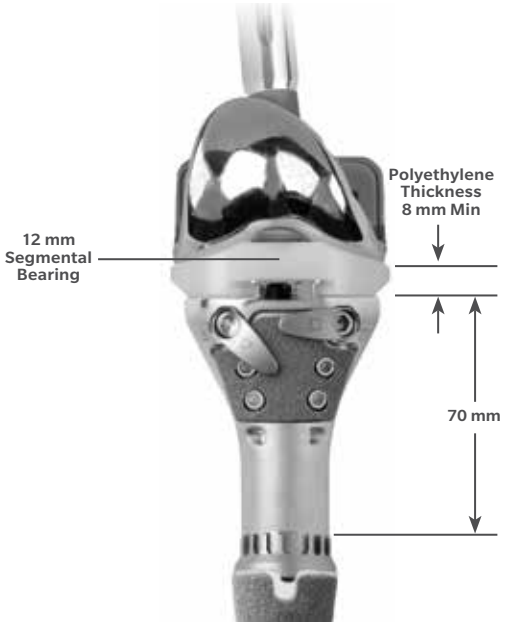


Figure 5a

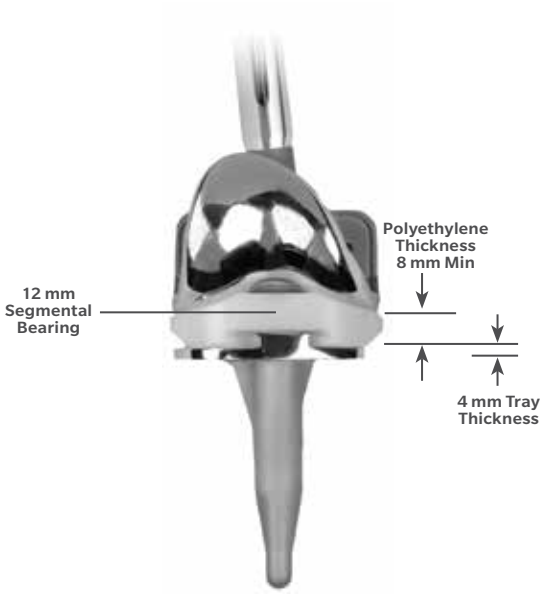


Figure 5b

Refer to NexGen RH Knee Surgical Technique

Resect Proximal Tibia (cont.)

Measure from the bearing of the proximal tibia, and make a horizontal line to mark the proposed resection level based on preoperative planning and the implant configuration.

Make a vertical mark below the resection level to reference tibial rotational alignment.

Resect the bone at the selected level.

Note: While the distal femur is being prepared, ensure that the remaining intact tissues and gastrocnemius transfer tissues are in a stable position on the operating table.

Note: The overall length and rotational alignment of the resected tibia should be carefully recorded and incorporated into the selection of segment length and stem rotation.

Note: The segment bearing is labeled as the bearing thickness plus 4 mm (the thickness of a RH Knee Tibial Baseplate). For example, a 12 mm bearing is 8 mm thick at the bearing space, accounting for a 4 mm thick tibial tray (Figures 5a & 5b).

Step 1: Tibial Preparation (cont.)

Stem IM Length	Stem Type	Stem Diameter (mm)										
		9	10	11	12	13	14	15	16	17	18	19
	130 mm Straight (Fluted & Variable Stiffness)											
	190 mm Straight (Fluted)											
	190 mm Bowed (Variable Stiffness)*											
	250 mm Bowed (Fluted)*											

Table 2
Stem Types and Lengths

Stem Size (mm)	Min. Ream Diameter for Fluted Stems (mm)	Min. Ream Diameter for VS Stems (mm)
9	11	8.5
10	12	9.5
11	13	10.5
12	14	11.5
13	15	12.5
14	16	13.5
15	17	14.5
16	18	15.5
17	19	16.5
18	20	17.5
19	21	18.5

Table 3
Minimum Reamer Diameters

Ream Canal

Select the desired stem type and length (Table 2).

Ream the proximal tibial canal until the reamer contacts cortical bone in the isthmus.

Reaming Considerations

Straight Stems

- Start with straight reamers from the VerSys Hip System.

Bowed Stems*

- Flexible reamers are recommended (Pressure Sentinel® Intramedullary Reaming System Expanded Hip Set or ZMR® Hip System Flexible Reamer Set).

Variable Stiffness Straight Stems

- For optimal fit, the Segmental 3/4 mm Reamers may be used.
- Flexible reamers may be used to allow for point contact in the canal.
- If insertion is difficult, consider reaming an additional time with the final 0.5 mm or 3/4 mm reamer diameter used.

Variable Stiffness Bowed Stems*

- It may be necessary to ream to a diameter equal to or slightly greater than the diameter of the stem to accommodate any difference between the bow of the stem and the anatomy of the patient.

Note: The diameter indicated for a stem represents the actual outer diameter (including the height of the splines for variable stiffness stems).

Note: Fluted stems require a different reamed diameter than variable stiffness stems to account for the cement mantle; therefore, determine reamer diameter from Table 3.

Note: Variable stiffness stems are not indicated for use in the knee in the United States.

*** Bowed stems are not commonly used in the tibia, but are available as part of the Zimmer Segmental System.**

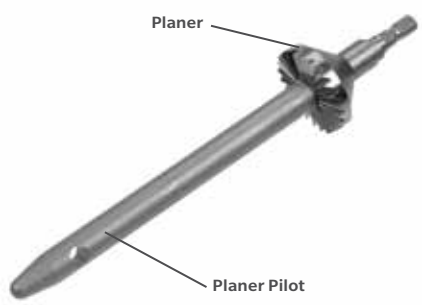


Figure 6

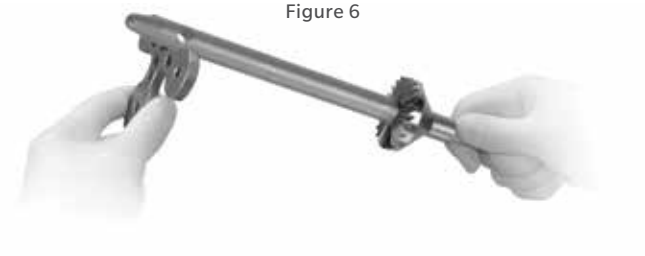


Figure 7

Stem Size	Planer Pilot Diameter (Fluted)	Planer Pilot Diameter (Variable Stiffness)
9 mm	9 mm	8 mm
10 mm	10 mm	9 mm
11 mm	11 mm	10 mm
12 mm	12 mm	11 mm
13 mm	13 mm	12 mm
14 mm	14 mm	13 mm
15 mm	15 mm	14 mm
16 mm	16 mm	15 mm
17 mm	17 mm	16 mm
18 mm	18 mm	17 mm
19 mm	19 mm	18 mm

Table 4
Recommended Planer Pilot Diameters

Plane Tibia

Thread the Segmental Planer Pilot (130 mm long) for the stem diameter selected onto the femoral/tibial planer (Figure 6).

Attach the assembly to a drill/driver with a Zimmer adapter.

Plane the proximal tibia until the bone is smooth and flat.

Remove the planer pilot from the planer by inserting the pin on the Segmental Collar Provisional Sizer through the cross-hole and, while securing the noncutting end of the planer, turning the shank counterclockwise (Figure 7).

Note: If the anatomy requires the use of a shorter planer pilot, use the 75 mm Segmental Planer Pilots.

Technique Tip: To facilitate insertion in a curved medullary canal, use a planer pilot 1-2 mm smaller than the stem diameter chosen (Table 4).

Technique Tip: If the canal is bowed, use the shorter planer pilots from the Segmental Variable Stiffness Stem Instrument Kit (KT-5853-008-00).

Step 1: Tibial Preparation (cont.)

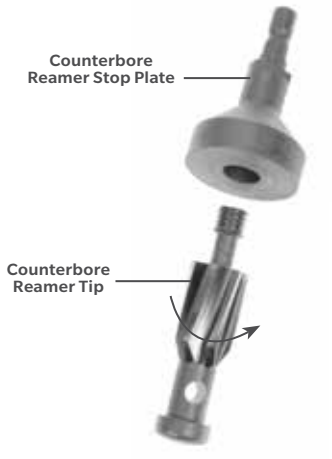


Figure 8

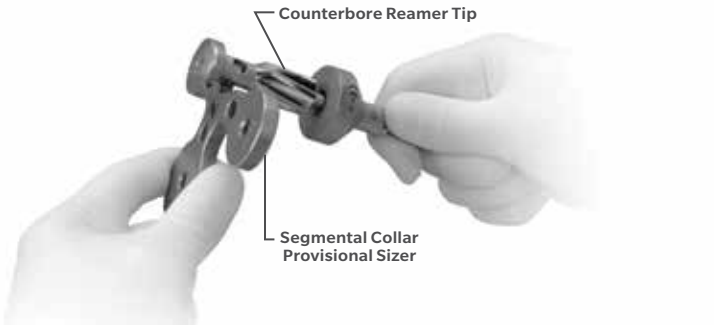


Figure 9

Figure 10

Counterbore Proximal Canal (Variable Stiffness Stems Only)

Counterboring the proximal portion of the canal is required because the full diameter of a variable stiffness stem proximal to the splines is 0.25 to 0.5 mm greater than the reamed diameter of the canal.

Thread the counterbore reamer tip into the counterbore reamer stop plate (Figure 8).

Insert the assembly into a drill/driver.

Insert the pin on the Segmental Collar Provisional Sizer through the cross-hole of the reamer tip and turn the collar tightly to secure it to the stop plate (Figure 9).

Insert the assembly into the reamed canal and counterbore the proximal canal (Figure 10).

Note: The counterbore reamer stop plate will serve as a stop when the appropriate depth is achieved.

Step 2: Initial Femoral/Patellar Preparation

Figure 11

Using the NexGen RH Knee Femoral Component

Refer to the NexGen RH Knee Surgical Technique for preparation of the distal femur and patella.

Using the Zimmer Segmental System Distal Femoral and Distal Femoral XT Component

Refer to the Segmental Distal Femoral and Distal Femoral XT Surgical Technique for preparation of the distal femur and patella.

Caution: When using the Segmental Proximal Tibial Component, the Segmental One-Piece Hinge Post must be used (Figure 11). The NexGen RH Knee Modular Hinge Post and hinge post extension are not indicated for use with the Zimmer Segmental System Proximal Tibia or Segmental Distal Femur.

Step 3: Trial Reduction

Figure 12

Prepare Stem Provisional

Use the Segmental Collar Provisional Sizer to select the collar size that provides the best coverage of the bone surface (Fig 12).

Confirm that the stem and collar sizes are compatible (Table 5).

Note: The collar sizer may be threaded onto the planer pilot to facilitate collar selection.

Stem Diameter	Smooth Collar (Item #) (Dimension A)	Trabecular Metal Collar (Item #) (Dimension A)
9-16 mm	 30 mm for 9-16 mm Stems (00-5852-042-09)	 25 mm for 9-16 mm Stems (00-5852-040-25)
		 30 mm for 9-16 mm Stems (00-5852-040-30)
		 35 mm for 9-16 mm Stems (00-5852-040-35)
 17-19 mm	30 mm for 17-19 mm Stems (00-5851-042-17)	 30 mm for 17-19 mm Stems (00-5852-041-30)
		 35 mm for 17-19 mm Stems (00-5852-041-35)

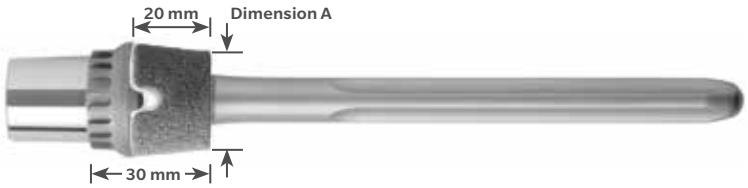


Table 5
Stem Collar Compatibility Chart

Stem Size	Provisional Stem Diameter (Fluted)	Provisional Stem Diameter (Variable Stiffness)
9 mm	9 mm	8 mm
10 mm	10 mm	9 mm
11 mm	11 mm	10 mm
12 mm	12 mm	11 mm
13 mm	13 mm	12 mm
14 mm	14 mm	13 mm
15 mm	15 mm	14 mm
16 mm	16 mm	15 mm
17 mm	17 mm	16 mm
18 mm	18 mm	17 mm
19 mm	19 mm	18 mm

Table 6
Recommended Stem Provisional Diameters

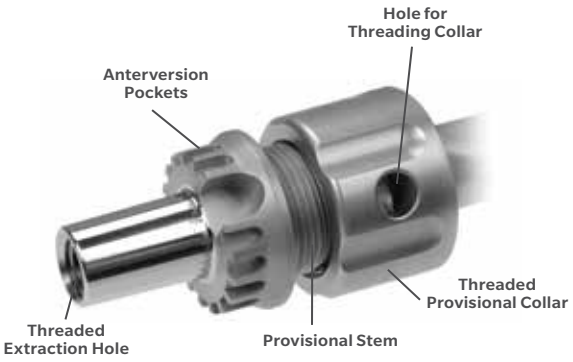


Figure 13

Prepare Stem Provisional (cont.)

Select the appropriate Segmental Stem Provisional (Table 6).

Thread the Segmental Collar Provisional onto the Segmental Stem Provisional (Figure 13).

Insert the assembly into the tibial canal.

- **Note:** If using a smooth collar, only the 30 mm diameter collar is available.

- **Note:** The diameters of the Segmental Stem Provisionals represent the actual diameters of the stems, e.g., a 14 mm stem provisional has a nominal 14 mm outer diameter.

- **Note:** The same set of provisionals is used for both the 130 mm Segmental Fluted Straight Stem and the 130 mm variable stiffness straight stem. Refer to Table 6 for provisional diameter recommendations per stem type.

- **Note:** Anterversion pockets allow for adjustment in 20 degree increments.

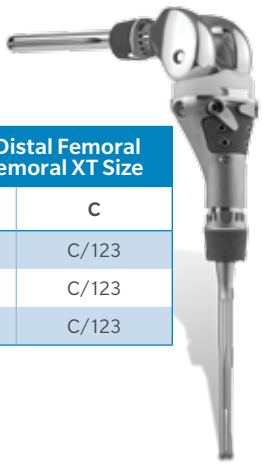
- **Technique Tip:** If the provisional assembly does not easily fit into a bowed canal, it may be necessary to perform additional reaming or to use the next smaller size stem provisional (Table 6).

- **Technique Tip:** For variable stiffness stems, if the provisional size that matches the stem size fits in the canal, there will likely not be enough press fit. Consider preparing for a larger stem diameter, or consider cementing a fluted stem.

Step 3: Trial Reduction (cont.)

		NexGen RH Knee Femoral Size				
		B	C	D	E	F
Segmental Proximal Tibial Size	1	B/123	C/123	D/123		
	2	B/123	C/123	D/123	E/23	
	3	B/123	C/123	D/123	E/23	F/3

Table 7
Segmental Proximal Tibial / RH Knee Compatibility Chart.
Interchangeability Chart - Segmental Knee System (using RH Knee Femoral and Segmental Proximal Tibial Components)



		Segmental Distal Femoral and Distal Femoral XT Size	
		B	C
Segmental Proximal Tibial Size	1	B/123	C/123
	2	B/123	C/123
	3	B/123	C/123

Table 8
Segmental Distal Femoral and Distal Femoral XT/
Segmental Proximal Tibial Components Compatibility Chart
Interchangeability Chart-Segmental Knee System
(using Segmental Distal Femoral, Distal Femoral XT and Segmental Proximal Tibial Components)

Prepare Proximal Tibial Provisional

Attach the Segmental Proximal Tibial Provisional (Table 7) and any segment provisionals to the stem provisional construct, ensuring that the rotational alignment marks are properly positioned and all tabs are engaged in the corresponding pockets.

If desired, lightly impact the provisional components.

Insert a temporary suture in the distal mediolateral hole of the proximal tibial provisional to secure the extensor mechanism.

Using the NexGen RH Knee Femoral Component

Refer to the NexGen RH Knee Surgical Technique for assembling the femoral provisional, balancing the knee and re-establishing the joint line (Table 7).

Prepare Distal Femoral Provisional

Establish Flexion/Extension Gap and Stability

Re-establish Joint Line

Caution: When using the Segmental Proximal Tibial Component, the Segmental One-Piece Hinge Post must be used.

The NexGen RH Knee Modular Hinge Post and hinge post extension are not indicated for use with the Zimmer Segmental System Proximal Tibia or Segmental Distal Femur.

The hinge post provisional used for trial reduction is available only in the shortest length, which may be shorter than the final hinge post being implanted. Thus, more distraction may be necessary to assemble the final implant.

Using the Zimmer Segmental System Femoral Component

Refer to the Segmental Distal Femoral and Distal Femoral XT Surgical Technique for assembling the femoral provisional, balancing the knee and re-establishing the joint line (Table 8).

Prepare Distal Femoral Provisional

Establish Flexion/Extension Gap and Stability

Re-establish Joint Line

Note: After selecting the final bearing thickness, verify the tibial rotation and update mark, if necessary.

Step 4: Tissue Attachment Assessment

Figure 14

Figure 15

Assess Tissue Attachment

Insert the tibial tissue depth tool into the octagonal hole of the proximal tibial provisional.

Place the tissue next to the gauge on the top surface of the provisional and gently compress the tissue.

Technique Tip: For the depth tool to indicate the correct amount of tissue available, the thickness of the tissue must be less thick than the bottom of the etch line (groove on the depth tool).

If the tissue is greater than 4 mm in thickness, make adjustments to decrease the thickness or do not use the Segmental Tissue Attachment Arms.

If the tissue thickness is 4 mm or less, insert the tibial arm provisionals (Figures 14 and 15) on either side of the patellar ligament and into the octagonal holes of the proximal tibial provisional, ensuring that the etchings on the tibial arm provisionals match those on the proximal tibial provisional.

Check to ensure that soft tissue will adequately cover the attachment arm provisionals, as well as the areas of Trabecular Metal Material, to prevent metal from contacting skin tissue.

Note: The tissue attachment arms can be used to attach tissue that is up to 4 mm thick or less, in any of the configurations shown (Figure 15).

Note: Tissue thicker than the etch mark/groove indicating 4 mm on the depth gauge will prevent proper engagement of the attachment arms/bolt thread.

Perform Trialing

Place the joint through a range of motion, and perform any necessary soft tissue releases.

If necessary, increase the thickness of the bearing provisional until the desired joint stability and range of motion is achieved.

Verify the rotation of the proximal tibial provisional. If the desired position is different than the initial mark made on the tibia, make a new mark.

Step 5: Final Distal Femoral Preparation & Trialing (NexGen RH Knee Femoral Only)

Figure 16

Refer to the NexGen RH Knee Surgical Technique for final femoral preparation and trialing.

Finish Femoral Preparation

Assemble and Insert Femoral Provisional Components

Insert Hinge Post Extension Provisional

Evaluate Patellar Tracking

Cautions:

The Segmental One-Piece Hinge Post must be used with the Segmental Trabecular Metal Proximal Tibial Component (Figure 16). The NexGen RH Knee Modular Hinge Post and Hinge Post Extension are not indicated for use with the Zimmer Segmental System Tibia or the Segmental Distal Femur.

The hinge post provisional used for trial reduction is available only in the shortest length, which may be shorter than the final hinge post being implanted. Thus, more distraction may be necessary to assemble the final implant.

Note: Use the RH Knee Segmental Hinge Post Provisional (not the Segmental Distal Femoral Hinge Post Provisional – gold color on its superior end). The Segmental Distal Femoral Hinge Post Provisional (gold) will not provide an accurate assessment of hyperextension during trial reduction.

Note: To secure the Segmental/RH Knee Segmental Hinge Post Provisional to the NexGen RH Knee Femoral Provisional/Cutting Guide, cross-pin with the Segmental RH Knee Hinge Pin Provisional.

Note: Do not use the Segmental/RH Knee Hinge Pin Aligner as there may not be a trephine hole in the medial side of the bone to place the hinge pin aligner through when trialing (common in oncology cases).

Note: The hinge pin aligner may be used to trial the hinge post provisional if revising a NexGen RH Knee to add the Segmental Tibia, requiring the NexGen RH Knee Trephine Guide Instruments to drill a hole for the implant hinge pin.

Step 6: Provisional Disassembly

Figure 17

Figure 18

Place the NexGen Femoral Slaphammer Extractor into the extraction slots on the distal femoral provisional to remove the component and/or hinge post assembly.

Use the Segmental Taper Separator to disengage the proximal tibial provisional and the male-female segment provisional (See Appendix A).

Thread the provisional slaphammer adapter (two grooves) (Figure 17) onto the slaphammer and thread it into the stem provisional.

Impact the slaphammer to remove the stem provisional.

Note: To protect the taper integrity of the provisional components, use only the Segmental Taper Separator with the turning handle to disassemble the provisional construct.

Note: The femoral stem extractor can also be used to remove the entire provisional construct (Figure 18).

Step 7: Gastrocnemius Transfer Preparation

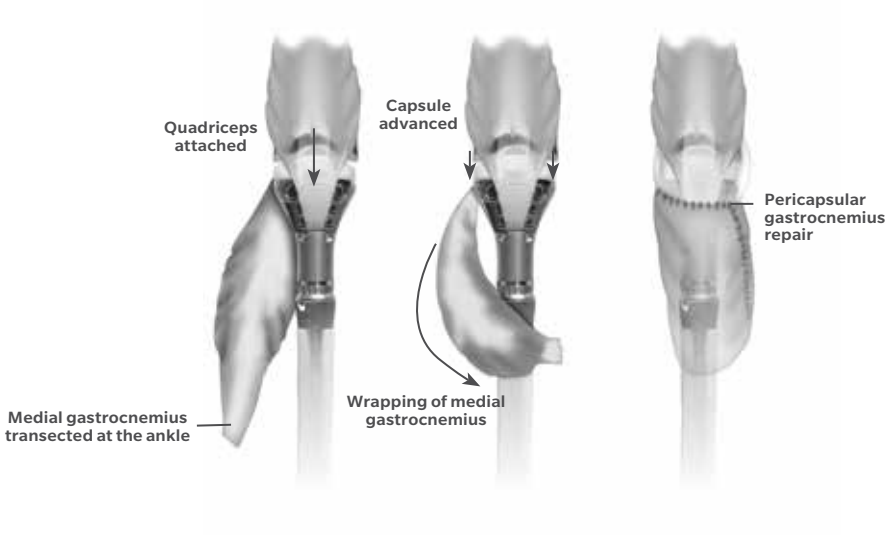


Figure 19

Assess the need for a gastrocnemius transfer (Figure 19).

- Determine whether adequate proximal tibial fascia exists to reattach to the patellar ligament.
- If the fascia is insufficient, consider a gastrocnemius transfer.

Assess the feasibility of a gastrocnemius transfer.

- Determine if there is an adequate length of patellar ligament to allow reattachment to the gastrocnemius transfer or implant to achieve function. A minimum of 3 cm is optimal.
- Determine if there will be adequate attachment of the gastrocnemius muscle to the tibial implant and adjacent soft tissues.

Identify the medial gastrocnemius muscle belly and its midline interphase with the lateral gastrocnemius muscle.

Dissect the distal muscle tendon complex at its medial border and deep surface.

Carefully transect the tendon complex distally where the musculotendonous portion attaches to the proximal Achilles tendon.

Note: The gastrocnemius transfer is strongly recommended in addition to the patellar ligament.

Note: The patellar ligament must be attached via suture and/or tissue attachment arms in a manner that will allow soft tissue healing to the patients remaining tibial tuberosity and the associated fascial envelope of the proximal tibia, and medial and lateral (antitibial) fascia or periosteum.

Note: The lateral gastrocnemius muscle could be used similarly.

Step 8: Final Assembly & Implantation

Stem iameter	Smooth Collar (Item #) (Dimension A)	Trabecular Metal Collar (Item #) (Dimension A)
9-16 mm	 30 mm for 9-16 mm Stems (00-5852-042-09)	 25 mm for 9-16 mm Stems (00-5852-040-25)
		 30 mm for 9-16 mm Stems (00-5852-040-30)
		 35 mm for 9-16 mm Stems (00-5852-040-35)
17-19 mm	 30 mm for 17-19 mm Stems (00-5851-042-17)	 30 mm for 17-19 mm Stems (00-5852-041-30)
		 35 mm for 17-19 mm Stems (00-5852-041-35)

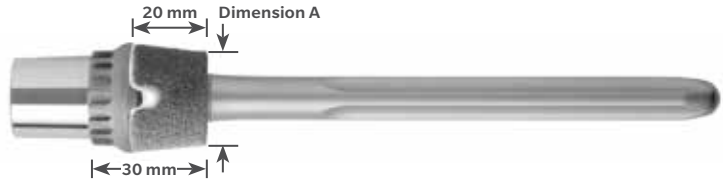


Table 9
Stem Collar Compatibility Chart

It is important to implant the tibial construct before the distal femoral construct to provide a platform for the bearing and subsequent pressure for the distal femoral component while the cement is curing.

Assemble Tibial Construct

There are two options for assembling and inserting the final implants.

Back Table Assembly

The final construct can be completely assembled on the back table and inserted as a single unit. This is the recommended method.

In Vivo Assembly

The stem and collar can be assembled and inserted first, and then the segment and proximal tibial component can be assembled and impacted onto the implanted stem (common when using variable stiffness stems).

Technique Tip: If cementing a patellar component, consider using two batches of bone cement. Use the first batch to cement the collar to the stem and to cement the patellar implant onto the bone. After the cement has set, use a second batch to cement the Fluted Stem when implanting the tibial construct.

Note: All Segmental Stems must be used with collars, and all collars must be cemented to the Stems.

Note: If implanting the complete construct as a single unit, all components of the construct must be assembled and impacted together before cementing the collar to the stem. This prevents the impaction force from being placed directly onto the cemented collar.

Note: Avoid notching, scratching, or directly striking implants during assembly.

Note: A space will exist between the components when the tapers are fully seated.

Note: Before opening the implant packages, verify that the collar is compatible with the stem size on the label (Table 9).

Step 8: Final Assembly & Implantation (cont.)

Figure 20

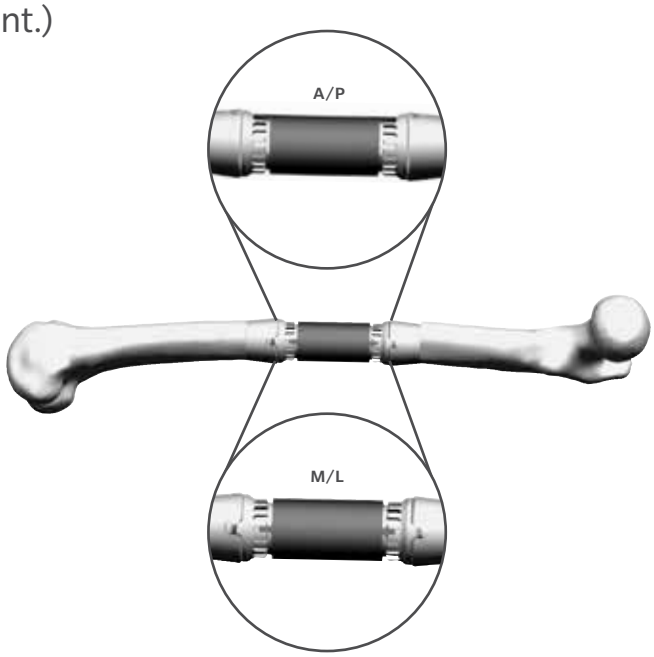


Figure 21

Assemble Tibial Construct (cont.)

Back-Table Assembly

Rest the tibial plateau of the Segmental Trabecular Metal Proximal Tibial Component on the Segmental Tibial Impactor Base on the back table (Figure 20).

Thoroughly clean and dry the tapers of all components.

Male-Female Segment Assembly

Insert the male-female segment into the tibial implant with the anteversion tabs aligned.

Attach the universal impactor handle to the segment impactor.

Apply the impactor assembly to the segment and impact it with a two-pound mallet.

Technique Tip: Position the anteversion tabs in either the direct A/P or M/L orientation to facilitate access for the Segmental Taper Separator should future disassembly be required (Figure 21).

Warning: Impacting the taper more than once may loosen the taper connection.

Figure 22

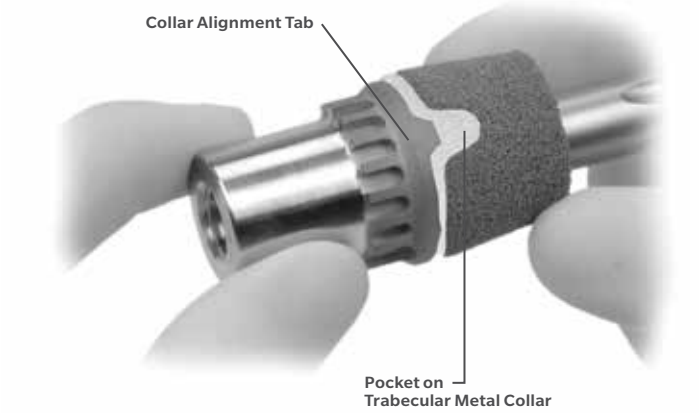


Figure 23

Back-Table Assembly (cont.)

Stem Assembly

Thoroughly clean and dry the tapers before assembling the remaining components

Insert the stem into the tibial implant or segment with the anteversion tabs aligned.

For a fluted stem, protect the end of the stem with gauze, and use a two-pound mallet to solidly impact the stem.

For a variable stiffness stem, slide the variable stiffness stem impaction sleeve over the stem until the notches on the sleeve capture the collar alignment tabs on the stem base (Figure 22).

Solidly strike the impaction head of the sleeve with a two-pound mallet.

Warning: Impacting the variable stiffness stem impaction sleeve more than once may loosen the taper connection.

Do not strike the tip of the variable stiffness stem with any instrument, as this may damage the prongs created by the slots.

Stem Collar Attachment

Apply cement in the doughy state to the base/taper end of the stem.

With the pockets toward the knee joint, slide the collar over the stem.

Clean off excess cement while advancing the collar to the shank area where cement was applied.

Ensure that the collar is fully engaged into the tabs on the stem (Figure 23).

Allow the cement to fully harden before inserting the construct into the canal.

Note: Be careful to prevent cement from contacting the taper, the anteversion adjustment pockets, and the external surfaces of Trabecular Metal Material specifically where the collar will contact the cortical bone.

Step 8: Final Assembly & Implantation (cont.)

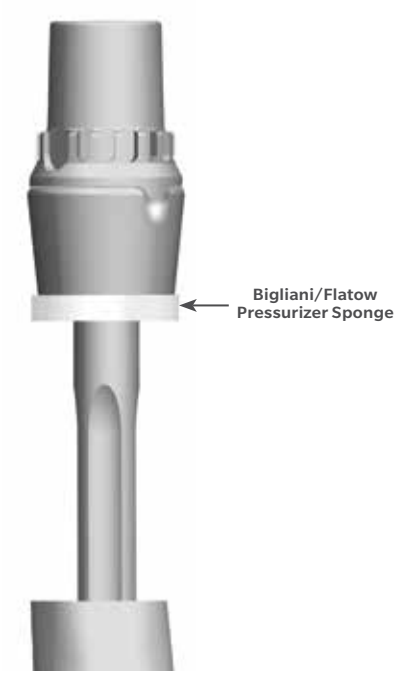


Figure 24

Back-Table Assembly (cont.)

Tibial Component Implantation with Fluted Stem

Inject cement into the medullary canal.

Apply cement to the shank of the stem and, if using a smooth collar, to the base of the collar.

Insert the implant into the canal and use the tibial impactor and a mallet to tap it until fully seated, cleaning off excess cement as the implant advances.

Note: If desired, use a plastic cement restrictor for manual cement pressurization. A Bigliani/Flatow® Pressurizer Sponge may be used to prevent cement from extruding out of the tibial canal and onto the face of the Trabecular Metal Collar that contacts the planed surface of the tibial cortex (Figure 24). If using this technique, slide the sponge onto the stem until it contacts the base of the collar.

Note: Be careful to keep cement off of the external surfaces of the Trabecular Metal Collar, the entire surface of the tapers, and the crevices of the anteversion adjustment pockets.

Note: As the stem advances into the canal, use the vertical mark on the bone to assess the rotational alignment.

Note: If using the Bigliani/Flatow Pressurizer Sponge, remove the sponge just before the collar sits flush with the prepared cortex and before the cement cures. Do not implant the sponge.

Note: Be careful not to leave any foam material in the wound or on the Trabecular Metal Material.

Figure 25

Back-Table Assembly (cont.)

Tibial Component Implantation with Variable Stiffness Stem

If using a smooth collar, apply cement to the base of the collar.

Insert the tibial construct into the canal.

Attach the universal impactor handle to the appropriate size tibial impactor.

Use the impactor assembly and a mallet to tap the construct until fully seated while observing the vertical mark on the bone to assess the rotational alignment (Figure 25).

Technique Tip: If the stem fits too tightly in the bone, remove the stem and pass the last reamer used through the canal several more times. This can increase the hole diameter slightly, which will permit the stem to be more easily impacted into the bone. The Segmental 3/4 mm Reamers can also be used for optimal fit for the 130 mm straight variable stiffness stems.

Note: Variable stiffness stems are not indicated for use in the knee in the United States.

Note: There is one Segmental Tibial Impactor for the size 1 and 2 Trabecular Metal Tibial Components, and one impactor for size 3 components.

Step 8: Final Assembly & Implantation (cont.)

Figure 26

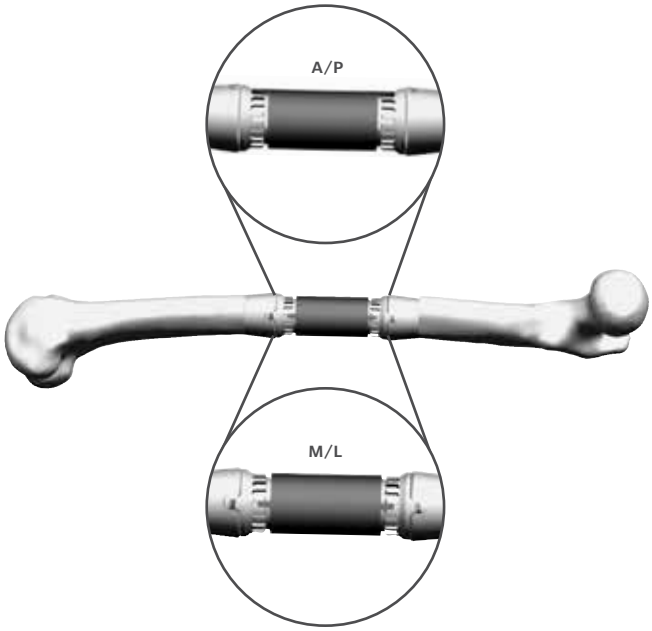


Figure 27

In Vivo Assembly

Attach the collar as detailed in the previous section, "Stem Collar Attachment," and allow the cement to fully harden before inserting the construct into the canal.

Insert the stem/collar assembly into the tibial canal.

Attach the universal impactor handle to the stem impactor.

Apply the impactor assembly to the stem construct and tap the handle with a mallet until fully seated, using the vertical mark on the bone to assess the rotational alignment.

Technique Tip: If the stem fits too tightly in the bone, consider removing the stem and passing the last reamer used through the canal several more times. This can increase the hole diameter slightly, which will permit the stem to be more easily impacted into the bone. The Segmental 3/4 mm Reamers can also be used for optimal fit.

Male-Female Segment Assembly (Optional)

Rest the tibial plateau of the Segmental Trabecular Metal Proximal Tibial Component on the Segmental Impactor Base on the back table (Figure 26).

Thoroughly clean and dry the tapers of all components.

Insert the male-female segment into the tibial implant with the anteversion tabs aligned.

Attach the universal impactor handle to the segment impactor.

Apply the impactor assembly to the segment and impact it with a two-pound mallet.

Technique Tip: Position the anteversion tabs in either the direct A/P or M/L orientation to facilitate access for the Segmental Taper Separator should future disassembly be required (Figure 27).

Figure 28

Figure 29

Figure 29a

In Vivo Assembly (cont.)

Tibial Assembly

Place the tibial assembly onto the stem taper in the canal.

Attach the universal impactor handle to the appropriate size tibial impactor.

Use the impactor assembly and a mallet to impact the components at the appropriate rotation per the vertical mark below the resection.

Warning: Impacting a taper more than once may loosen the taper connection.

Intraoperative Disassembly

If disassembly is necessary during surgery, the Segmental Taper Separator can be used to separate the junctions between segments, stem, and tibial/femoral implants without damaging the tapers (Figure 28). See Appendix A for complete instructions.

Assemble Distal Femoral Construct

Using the NexGen RH Knee Femoral Component

Refer to the NexGen Rotating Hinge Knee Surgical Technique for assembling & implanting the femoral construct.

Using the Zimmer Segmental System Distal Femoral Component

Refer to the Segmental Distal Femoral and Distal Femoral XT Surgical Technique for assembling and implanting the femoral construct.

Warning: Do not use the Segmental Polyethylene Insert with the NexGen RH Knee Femoral Component. Only use the items indicated in the appropriate size Segmental bearing and NexGen RH Knee Cement Shield Hinge Service Kit (Appendix B)(Figure 29).

Caution: When using the Segmental Trabecular Metal Proximal Tibial Component with a Segmental Distal Femur, you must use the Segmental One-Piece hinge post. The Segmental Proximal Tibial Component is not indicated for use with the NexGen RH Knee Modular Hinge Post and Hinge Post Extension.

Note: If the proximal tibial bushing is not assembled in the package, insert the tibial bushing into the tibial body (Figure 29a) and press into place until flush.

Step 8: Final Assembly & Implantation (cont.)

		NexGen RH Knee Femoral Size				
		B	C	D	E	F
Segmental Proximal Tibial Size	1	B/123	C/123	D/123		
	2	B/123	C/123	D/123	E/23	
	3	B/123	C/123	D/123	E/23	F/3

Table 10
Segmental Proximal Tibial / RH Knee Compatibility Chart
Interchangeability Chart - Segmental Knee System (using RH Knee Femoral and Segmental Proximal Tibial Components)

		Segmental Distal Femoral Size XT	
		B	C
Segmental Proximal Tibial Size	1	B/123	C/123
	2	B/123	C/123
	3	B/123	C/123

Table 11
Segmental Distal Femoral and Distal Femoral XT/
Segmental Proximal Tibial Components Compatibility Chart
Interchangeability Chart-Segmental Knee System
(using Segmental Distal Femoral, Distal Femoral XT and Segmental Proximal Tibial Components)

Implant Distal Femoral Construct and Bearing

Make a final check to ensure that the femoral, tibial, and bearing components match (Tables 10 and 11).

Using the NexGen RH Knee Femoral Component

Refer to the NexGen RH Knee Surgical Technique for femoral construct and bearing implantation.

Caution: If there is concern regarding insufficient tissue distraction, assemble the components via the In Vivo Assembly technique (trephine hole required), in the NexGen RH Knee Surgical Technique Appendix F.

Using the Zimmer Segmental System Distal Femoral Component

Refer to the Segmental Distal Femoral and Distal Femoral XT Surgical Technique for Distal Femoral and bearing implantation.

Step 9: Tissue Attachment

Figure 30

Figure 31

Figure 32

Insert the tibial tissue depth tool into the octagonal hole on the Segmental Proximal Tibial Component.

Place the tissue next to the gauge on the top surface of the implant and gently compress the tissue.

Technique Tip: For the depth tool to indicate the correct amount of tissue available, the thickness of the tissue must be less thick than the bottom of the etch line/groove on the depth tool.

Check to ensure that the tissue is no thicker than the etch mark on the gauge. The Segmental Proximal Tibial Component can be used with suture attachment only, regardless of tissue thickness.

Use the distal suture hole to extend the patellar ligament distally until taut.

If needed, use the tibial soft tissue awl to create holes through the tissue into the octagonal holes on the tibial component (Figure 30).

Using the appropriate right or left tissue attachment arm and the tibial tissue arm forceps, insert the octagonal peg of the arm through the hole in the tissue and into the octagonal hole on the tibial component.

Insert the tissue attachment arms on either side of the patellar ligament and into the octagonal holes of the Segmental Proximal Tibial Component in one of the three pictured configurations (Figure 31).

Caution: Ensure the tissue attachment arm symbol and the symbol on the Segmental Proximal Tibial Component match. The tissue attachment arms have teeth that are in opposing directions to properly secure the tissue (Figure 32).

Note: The etch mark on the tibial tissue depth tool indicates the maximum thickness (4 mm) to allow for proper engagement of the tissue attachment arms/bolt thread.

Step 9: Tissue Attachment (cont.)

Figure 33

Figure 35

Figure 34

Insert the tibial attachment arm bolt into the hole within the arm and tighten it using the 4.5 mm hex head screwdriver (Figure 33) until the tissue is held tightly enough for joint stability when combined with the gastrocnemius transfer or other surrounding tissues.

Place the joint through a range of motion, and perform any necessary soft tissue adjustments.

Caution: Be careful not to overtighten the sutures and/or tissue attachment arms against the tibial component as overtightening may compromise circulation and may lead to tissue necrosis. After the tourniquet is released, check the soft tissues to be sure they return to their normal color. If not, the sutures may need to be replaced with looser knots tied around the tibia, or the tissue attachment arms may need to be loosened.

Avoid placing the suture in direct contact with the Trabecular Metal Material pad as it may weaken the suture.

Adjust the tissue attachment arms, if necessary, and insert tissue attachment arm set screws medially and laterally (Figure 34), torquing them with the blue-handled torque wrench (130 in-lb.) (Figure 35).

Note: In addition to using the tissue attachment arms, it is recommended that soft tissue structures be sutured to pull the tissue against the Trabecular Metal Material pad for ingrowth.

Note: Tissue attachment arm bolts are used to adjust the compression of the tissue attachment arms over the tissue. Once the desired compression is achieved, the bolts must be secured with tissue attachment arm set screws and torqued to 130 in-lb.

Step 10: Final Gastrocnemius Transfer & Closure

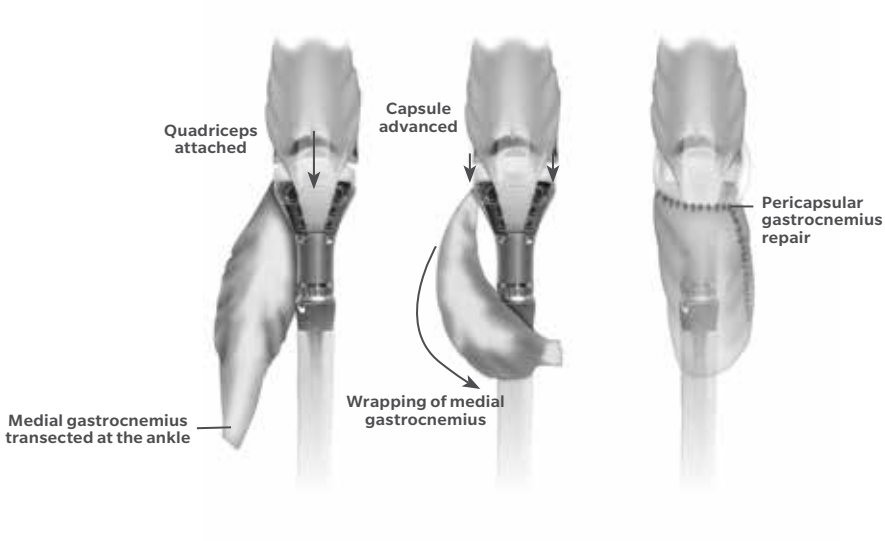


Figure 36

Reattach the tendon of the gastrocnemius transfer and the patellar ligament using nonabsorbable sutures and/or tissue attachment arms via one of the following procedures:

Option 1: Attach the gastrocnemius transfer to the proximal tibial component first. Then attach the patellar ligament to the superfascial tendonous gastrocnemius transfer.

Option 2: Attach the patellar ligament to the tibial component with sutures and/or tissue attachment arms first. Cover the implant with the gastrocnemius transfer and suture the gastrocnemius tissue to the patellar ligament and/or surrounding tissue (Figure 36).

Perform a final range of motion.

Perform the final soft tissue repair.

Thoroughly clean the surgical site of bone chips, bone cement, and any other debris.

Perform final closure.

Note: Be careful to preserve the innervation and blood supply of the proximal third of the gastrocnemius muscle.

Note: Avoid placing suture in direct contact with the Trabecular Metal Material pad as it may weaken the suture.

Appendix A: Component Disassembly

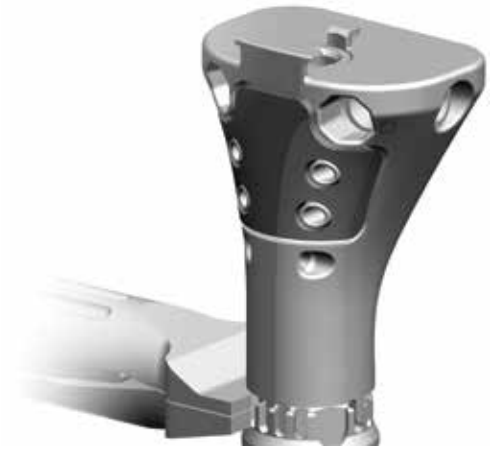


Figure 37

Figure 38

Using the Segmental Taper Separator

The Segmental Taper Separator is designed to enable separation of the junctions between provisionals, segments, stem, and tibial implants without damaging the tapers.

Ensure that the inside wedging portion of the separator is fully retracted and centered within its housing.

Insert the tabs of the separator into the anteversion pockets with the flat of the separator toward the anatomical joint as etched on the instrument (Figure 37).

Slowly turn the handle clockwise until the tapers disengage, taking care not to pinch fingers against the rotating impactor cap.

If necessary, lightly tap the impactor cap on the instrument to facilitate taper disassembly.

Technique Tip: If additional force is needed to disengage the taper, use two Segmental Taper Separators, one on each side (Figure 38).

Figure 39

Figure 41

Figure 40

Using the Femoral Stem Extractor

The femoral stem extractor can also be used if removal of the entire femoral or tibial construct is necessary (Figure 39).

Note: Do not reuse an implant after extraction as the threads may be damaged.

The femoral stem extractor can be used in the tissue attachment bolt hole or set screw hole (Figure 39).

Servicing the Segmental Tibial Tissue Attachment Arms

Use the 4.5 mm screw driver and the torque wrench (blue-handle) to remove the set screws from the medial and lateral sides of the device (Figure 40).

Use the 4.5 mm hex head screwdriver to remove both bolts from the anterior aspect of the device (Figure 41).

Use the MIS Threaded Handle in conjunction with the tibial arm remover to remove the arms.

Note: If necessary, use a slaphammer to facilitate removal of the tissue attachment arms.

Note: Alternatively, the Segmental Tibial Tissue Arm Forceps can be used to remove the tissue attachment arms.

Appendix A: Component Disassembly (cont.)

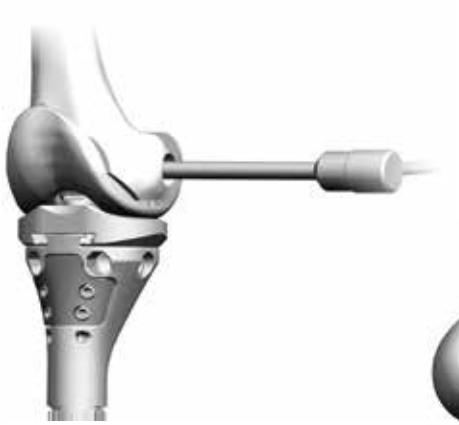


Figure 42

Figure 43

Figure 44

Removing an Implanted Hinge Pin & Components

Drill a hole through the side of the femoral condyle (see NexGen RH Knee Trephine Guide Instrument Technique in the NexGen RH Knee Surgical Technique Appendix F).

Use the hinge pin polyethylene plug removal tool to remove the hinge pin plug.

Remove the hinge pin using the 4.5 mm screw driver and RH Knee Removal Wrench (black-handle) or deflection beam torque wrench (blue-handle) (Figure 42).

Remove the remaining internal hinge components (Figure 43).

Remove the bearing.

Use the tibial bushing removal tool to remove the tibial bushing from the tibial plate stem (Figure 44).

Note: This procedure assumes that there is a well-fixed distal femoral component and a well-fixed Segmental Trabecular Metal Proximal Tibial Component.

Note: Be careful to avoid scratching the surface of the Segmental Trabecular Metal Proximal Tibial Component.

Appendix B: NexGen RH Knee and Segmental Articular Surface/Hinge Kit Compatibilities

NexGen RH Knee & Segmental Articular Surface/Hinge Kit Compatibilities

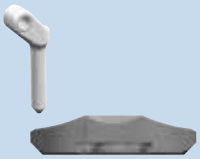
Picture/Item Number	Item Description	Use On/With	Do Not Use With/Why
1  00-5850-020_060-12_26	Segmental Articular Surface • Segmental One piece Hinge Post • Segmental Articular Surface Piece	Segmental Distal Femoral and XT(00-5850-012_013-01/02), (00-5850-042_043-01/02) Segmental Trabecular Metal Proximal Tibial (00-5850-001_003-10) NexGen RH Knee Distal Femoral (00-5880-012_016-01/02) NexGen RH Knee Tibial Plate (00-5880-001_006-00/02) Segmental Articular Surface can be used with the NexGen RH Knee Hinge Post Extension (from Item 2 below) EXCEPT with the Trabecular Metal Proximal Tibial (see next page for the Servicing Kit Compatibility Chart)	Segmental One-piece Hinge Post with NexGen RH Knee Articular Surface Piece • Mating components are not compatible RH Knee Modular Hinge Post Extension + Segmental Articular Surface + Segmental Trabecular Metal Proximal Tibial • Only Segmental One-piece Hinge Post is indicated with the Segmental Trabecular Metal Proximal Tibial
2  00-5880-020_060-12_26	NexGen RH Knee Articular Surfaces • NexGen RH Knee Hinge Post Extension • NexGen RH Knee Articular Surface Piece	NexGen RH Knee Distal Femoral NexGen RH Knee Tibial Plate	Segmental Distal Femoral and XT Segmental Trabecular Metal Proximal Tibial Segmental One-piece Hinge Post • Mating components are not compatible
3  00-5850-075-12_16	NexGen RH Knee Cement Shield Hinge Service Kit • Poly Insert with Shield • Shoulder Bolt Hinge Pin • Hinge Pin Plug • Tibial Bushing	NexGen RH Knee Distal Femoral with Segmental Articular Surface & Segmental One-Piece Hinge Post (Item 1 above)	NexGen RH Knee Distal Femoral with NexGen RH Knee Hinge Post Extension • Mating components are not compatible
4  00-5850-070-12_13	Segmental Hinge Service Kit • Segmental Poly Insert • Segmental Hinge Pin • Segmental Hinge Pin Set Screw • Tibial Bushing	Segmental Distal Femoral Segmental Articular Surface with Segmental One-piece Hinge Post (Item 1 above)	NexGen RH Knee Distal Femoral • Mating components are not compatible Segmental Distal Femoral XT

Appendix B: NexGen RH Knee and Segmental Articular Surface/Hinge Kit Compatibilities (cont.)

NexGen RH Knee & Segmental Articular Surface/Hinge Kit Compatibilities (cont.)

Picture/Item Number	Item Description	Use On/With	Do Not Use With/Why
5  00-5880-090-12_16	NexGen RH Knee Hinge Service Kit • Poly Box Insert • Hinge Post • Shoulder Bolt Hinge Pin • Hinge Pin Plug • Tibial Bushing	NexGen RH Knee Distal Femoral NexGen RH Knee Articular Surface and RH Knee Hinge Post Extension (Item 2 above)	Segmental Distal Femoral and XT NexGen RH Knee Distal Femoral with Segmental One-piece Hinge Post • Mating components are not compatible
6  00-5850-012_013_96	Segmental Poly Insert XT	Segmental Distal Femoral XT Segmental Articular Surface with Segmental One-Piece Hinge Post (Item 1 above)	NexGen RH Knee Distal Femoral • Mating components are not compatible Segmental Distal Femoral
7  00-5850-071-12_13	Segmental Hinge Service Kit XT • Segmental Poly Insert • Segmental Hinge Pin • Segmental Hinge Pin Set Screw • Tibial Bushing	Segmental Distal Femoral XT Segmental Articular Surface with Segmental One-Piece Hinge Post (Item 1 above)	NexGen RH Knee Distal Femoral • Mating components are not compatible Segmental Distal Femoral
8  00-5850-012_013-95	Segmental Poly Insert	Segmental Distal Femoral Segmental Articular Surface with Segmental One-piece Hinge Post (Item 1 above)	NexGen RH Knee Distal Femoral • Mating components are not compatible Segmental Distal Femoral XT

Servicing Kit Compatibility Chart

RH Knee	Hinge Servicing Kit Used	Compatible Articular Surfaces and Hinge Components	
			Segmental Articular Surface (with the Hinge Post)
 Base Component System	 NexGen RH Knee Hinge Servicing Kit	 NexGen RH Knee Articular Surface (with the Hinge Post Extension)	 Segmental Articular Surface with the Segmental One-Piece Hinge Post
 Base Component System	 NexGen RH Knee Cement Shield Servicing Kit	 Segmental Articular Surface with the Segmental One-Piece Hinge Post	

Segmental Articular Surface (with the Hinge Post)
 NexGen RH Knee Articular Surface (with the Hinge Post Extension)

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