

# NexGen® Trabecular Metal™ Tibial Tray

Surgical Technique





# Table of Contents

<b>Surgical Technique</b> .....	2
Resect the Tibia.....	2
Finish the Tibia .....	2
Position Based Anatomic Landmarks.....	3
Position Based on Trial Range of Motion .....	5
Drilling Peg Holes.....	7
Trial Fit.....	8
Component Implantation.....	9
Assembling the Trabecular Metal Tibial Impactor	
Cementless Implantation Option	
Cemented Implantation Option	
Removing the Trabecular Metal Tibial Impactor .....	14
Optional Insertion Method Using the Locking Plate Inserter Prior to Impaction .....	15
Implant the Bearing .....	16
Technique for the Bearing Assembly	
Uses of the Trabecular Metal Tibial Tray Flex Bearing Locking Screw	
Technique for the Assembly of the Trabecular Metal Tibial Tray Flex Bearing	
Locking Screw <i>In vivo</i>	
Femoral Implantation.....	19

## Surgical Technique

### Resect the Tibia

Using any of the NexGen Instrumentation Systems listed and following the appropriate technique, establish the tibial cutting platform and resect the proximal tibia.

- MIS Multi-Reference® 4-in-1 Femoral Instrumentation System
- MICRO-MILL® Instrumentation System – Milling or 5-in-1 Saw Blade Option
- MIS Intramedullary Instrumentation System
- Epicondylar Instrumentation System
- MIS Quad-Sparing™ Instrumentation System

Proceed with the following steps to finish the tibia for implanting the NexGen Trabecular Metal Tibial Tray.

### Finish the Tibia

Select the appropriate size (2-8) trial sizing plate that provides the desired tibial coverage. The NexGen Trabecular Metal Tibial Tray is offered in sizes 2-8. **If sizes outside of this range are needed (sizes 1, 4+, 9 or 10), the standard NexGen Tibial Components and corresponding bearing must be selected for use.**

The NexGen Trabecular Metal Tibial Tray is only recommended for use with bearing thicknesses up to 17 mm. As such, it is strongly recommended that a trial range of motion to aid in tibial location be performed prior to drilling the peg holes. **If a tibial tray with bearing height of greater than 17 mm is required, the standard NexGen Tibial Components must be utilized.**

- The tibia can be finished prior to trial reduction if the implant position will be chosen based on anatomic landmarks.
- Alternatively, the femoral and bearing trials, in combination with the sizing plate, can be used to perform a trial range of motion to aid in determining appropriate tibial rotation.



Figure 1



Figure 3



Figure 2

## Position Based Anatomic Landmarks

Attach the offset sizing plate handle to the selected Trabecular Metal Tibial Sizer. The handle should be inserted on the medial side of the sizing plate to provide clearance for the patellar tendon.

ⓘ **Note:** If lateral incision is used, then attach to lateral side of the Trabecular Metal Tibial Sizer.

Extend the lever on the handle and engage the tabs on the handle with the grooves on the Trabecular Metal Tibial Sizer by positioning the lever away from the centerline of the sizer, and clamp the lever to secure (Figure 1).

ⓘ **Note:** This instrument contains several moving parts. If trigger becomes hard to engage, apply instrument lubrication.

ⓘ **Note:** Do not impact or lever the offset sizing plate handle; this instrument is designed for alignment purposes only.

In extension, place the knee in valgus to view or palpate the lateral side of the tibia to check sizing plate fit laterally. Be sure that the component is properly positioned rotationally. Tibial plate rotation and varus/valgus alignment can be checked by inserting the alignment rod through the hole or slot in the handle of the offset sizing plate handle (Figure 2). There are two options available for use of the alignment rod (Figure 3).

- **Slot** – check varus/valgus and rotational alignment.
- **Round hole** – check slope of tibial cut (distal end of rod should point to second metatarsal).



Figure 4

## Position Based Anatomic Landmarks (cont.)

After the sizing plate position has been chosen, secure the plate with a short-head holding pin. When utilizing an anterior pin hole, a second pin should be inserted into the proximal hole on the opposite side of the sizing plate to assure plate stability (Figure 4). Verify that the sizing plate is in uniform contact with the resected tibia (no gaps).

**Technique Tip:** When pinning the Trabecular Metal Tibial Sizer to the bone through the anterior angled pin holes, verify the posterior edge of the Trabecular Metal Tibial Sizer does not lift-off from the bone from over tightening/seating.



Figure 5



Figure 6

## Position Based on Trial Range of Motion

Prepare the patella. (See existing NexGen Patella Surgical Technique for additional information). Select the proper size Trabecular Metal Tibial Sizer. Ensure that the plate chosen provides the desired tibial coverage. Insert the proper femoral trial, patellar trial, tibial sizing plate, and bearing trial. Select the color and/or alphanumeric designation of bearing provisional that is the same as the match chosen for the femoral trial and Trabecular Metal Tibial Sizer. Ensure soft tissue balance is appropriate. Flex and extend the knee with the trials in place. With proper soft tissue balancing complete, the tibial component tends to seat itself in the position where it best articulates with the femur.

ⓘ **Note:** If the alphabetic and numeric sizes are not on the bearing trial component, then use the color code to match the Trabecular Metal Tibial Sizer. If there is no match between the femoral trial and Trabecular Metal Tibial Sizer, adjust the size of the Trabecular Metal Tibial Sizer to obtain a match.

After this process has occurred, mark the position of the component with methylene blue, electrocautery, or by placing a short-head holding pin in the sizing plate anteriorly (Figures 5 and 6).



Figure 7

### Position Based on Trial Range of Motion (cont.)

Remove the bearing trial and pin the sizing plate in place with a short-head holding pin. It is recommended to use one anterior pin hole and one hole on the opposite side of the sizing plate on the plate face to assure plate stability (Figure 7). Ensure that the Trabecular Metal Tibial Sizer remains in the proper position when pinning. Remove the offset sizing plate handle from the Trabecular Metal Tibial Sizer.

**Technique Tip:** When pinning the Trabecular Metal Tibial Sizer to the bone through the anterior angled pin holes, verify the posterior edge of the Trabecular Metal Tibial Sizer does not lift-off from the bone from over tightening/seating. Ensure the bearing trial is appropriately sized with the corresponding femoral and tibial components.



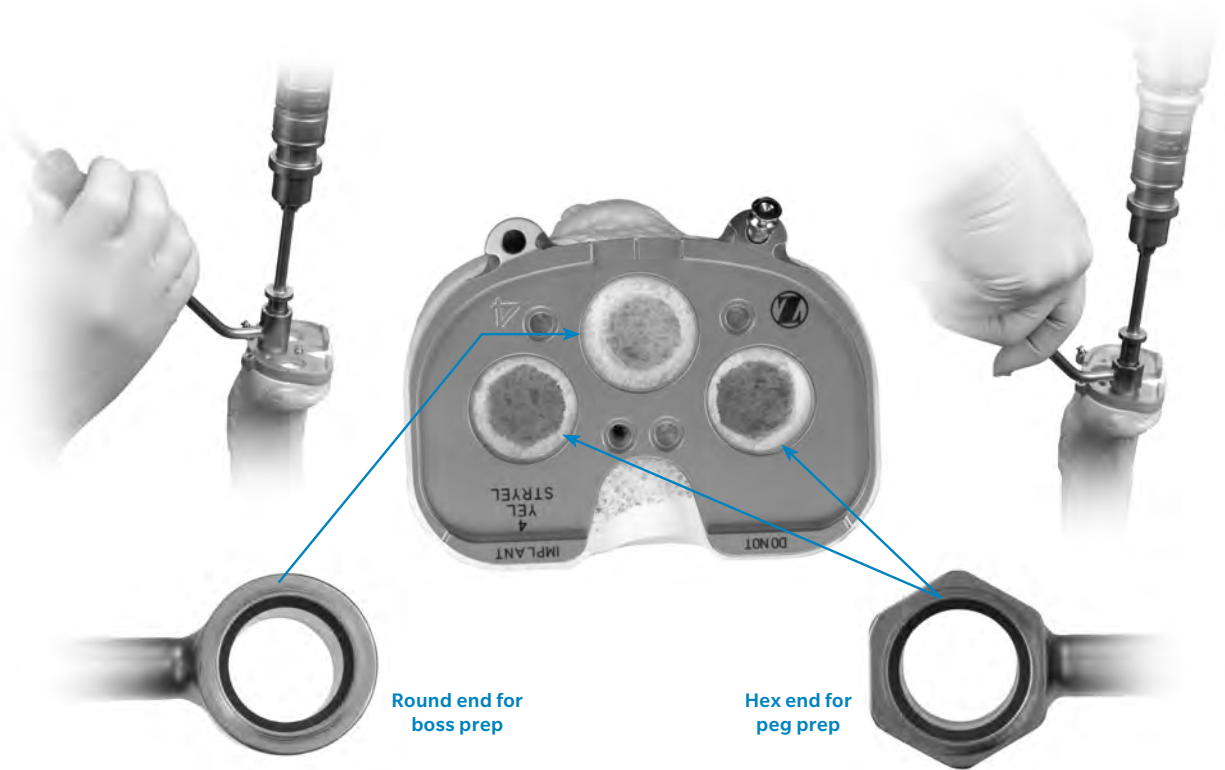


Figure 8

## Drilling Peg Holes

The Trabecular Metal Tibial Drill guide has two distinct ends that dictate the appropriate drill depth for either the central boss or the two hexagonal pegs (Figure 8).

- Utilize the side of the drill guide that has a hexagonal profile when drilling for the two 16 mm hexagonal posts.
- Use the side of the drill bushing that has a cylindrical profile when drilling for the cylindrical central boss.

With the sizing plate still pinned in position, place the appropriate end of the Trabecular Metal Tibial Drill guide (10.7 mm) into the corresponding hole of the sizing plate and insert the 10.7 mm drill with stop until it bottoms out on the drill guide.

**Technique Tip:** The holes must be drilled straight (90° to the resected tibial surface). Because the Trabecular Metal Tibial Drill Guide has a slight taper where it engages with the sizing plate, applying a small axial force will help ensure that the drill guide is oriented correctly. Angulation of the holes may prevent the Tibia from seating properly.

**Warning:** Once you have drilled the three holes for the NexGen Trabecular Metal Tibial Tray you cannot crossover to a Trabecular Metal Monoblock Implant (the hole locations are not compatible).

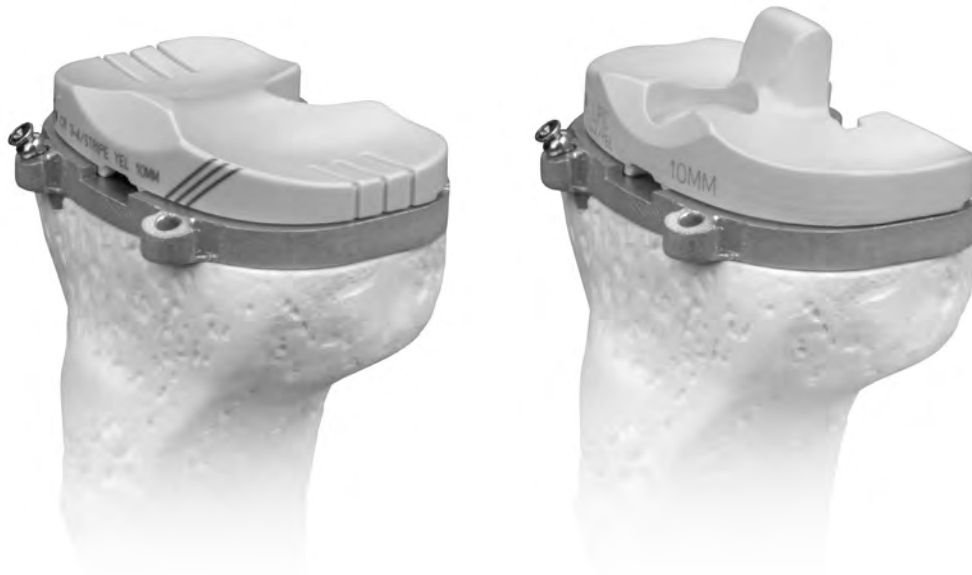


Figure 9

### Trial Fit

Re-insert all trials and check the range of motion and joint stability (Figure 9). In addition, insure that the Trabecular Metal Tibial Sizer is in uniform contact with the resected tibia. If any undesired gaps are present, remove the trial component and adjust the bone cuts until a good intimate fit is obtained. Perform any necessary soft tissue releases. After the trial reduction is complete, remove all trials.

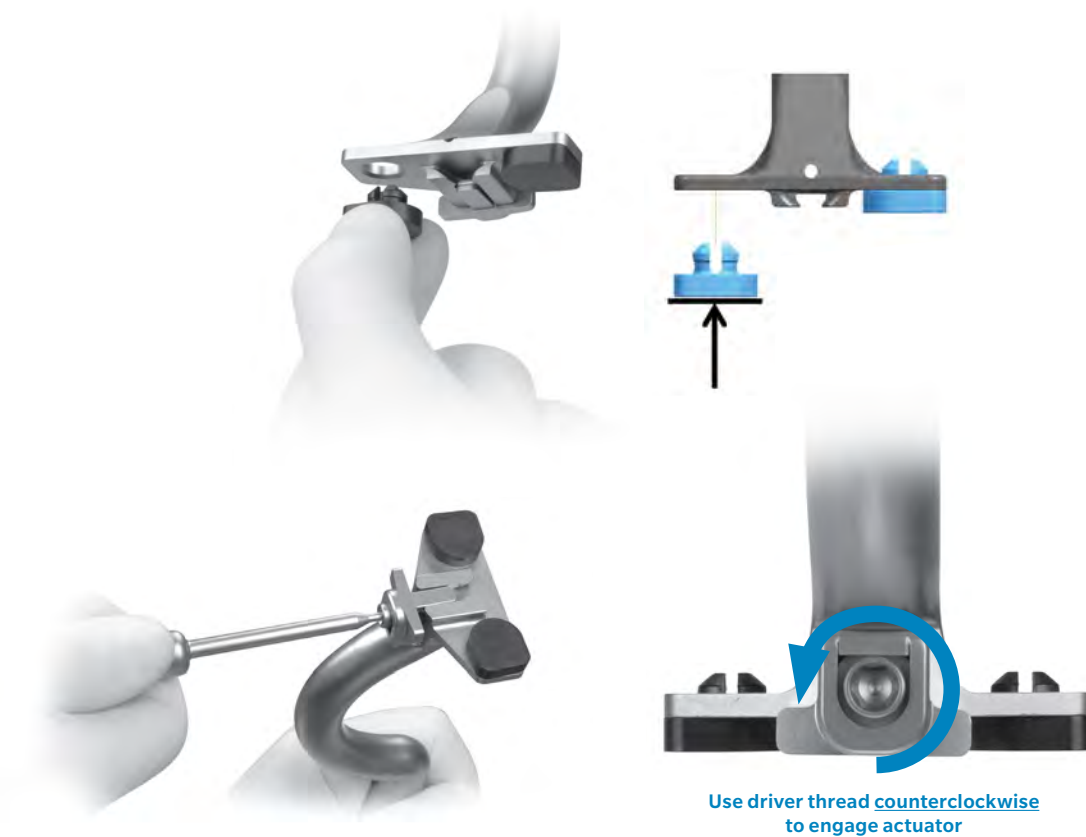


Figure 10

## Component Implantation

After the implants have been chosen, make a final check to ensure that the size chosen for the femoral, Trabecular Metal Tibial Tray, and tibial bearing components are compatible sizes.

## Assembling the Trabecular Metal Tibial Impactor

To assemble the Trabecular Metal Tibial Impactor (Figure 10):

- Push to snap the impactor pads into the impactor body.
- Push on the flat side of the pad with even force to snap the impactor pads into the impactor body. The flat side of the D-shaped pad should be facing out, and the curved portion of the D should be facing towards the impactor body.
- Turn the driver **counterclockwise** to thread the actuating pad into the impactor body.

☰ **Note:** Replacement impactor pads (PN 00-5953-056-06) are available for order in the event that a pad is misplaced or damaged.

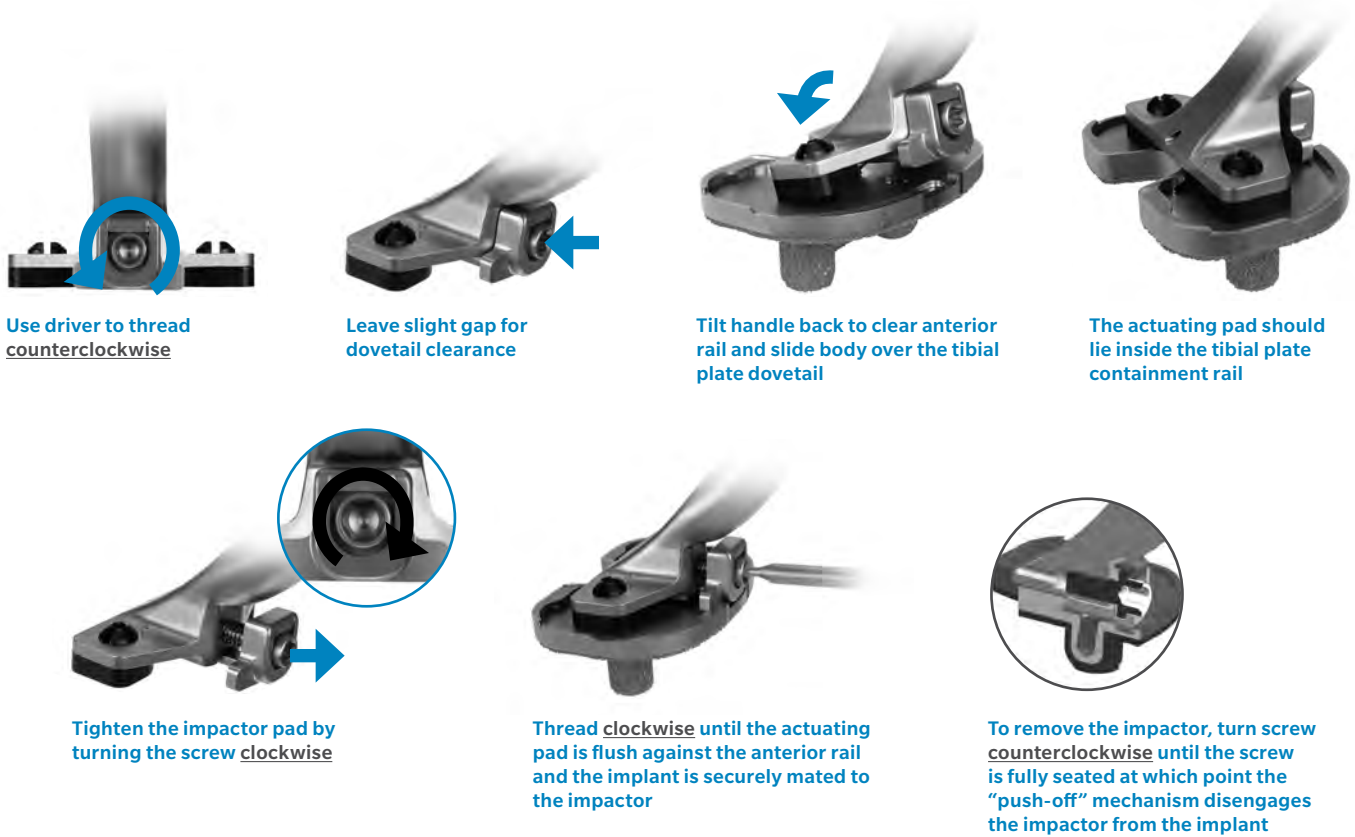


Figure 11

### Assembling the Trabecular Metal Tibial Impactor (cont.)

To attach the Trabecular Metal Tibial Impactor to the implant (Figure 11):

- Turn the driver counterclockwise to move the actuating pad toward the front of the impactor. Leave the actuating pad roughly one full thread revolution from the front of the impactor to allow clearance between the push-off feature dovetail of the tibial component.
- Place the dovetail connection of the impactor around the tibial plate dovetail clearing the inside of the anterior rail. For small sizes, you will need to angle the Impactor into place. Make sure that the blue plastic pads are in place and flush against the top face of the tibial plate.
- Using the driver, tighten the actuating pad by turning the screw clockwise until the impactor is firmly mated with the tibial tray).



Figure 12

**Assembling the Trabecular Metal Tibial Impactor (cont.)**

**Technique Tip:** Inverting the Trabecular Metal Tibial Impactor on the back table may assist in engagement of the tibial tray (Figure 12).

The NexGen Trabecular Metal Tibial Tray may be implanted with or without bone cement (cemented or cementless options).



Figure 13



Figure 14

### Cementless Implantation Option

Prior to implantation of a NexGen Trabecular Metal Tibial Tray, the resected tibial bone surface must be flat and free of bone debris and fragments. Also, when using the cementless option, the patient's bone quality must be assessed for density and quality to insure adequate support and fixation of the NexGen Trabecular Metal Tibial Tray. Bone stock of insufficient quality and/or density may not be capable of adequately supporting the component. If the bone stock is of questionable quality or density, the NexGen Trabecular Metal Tibial Tray should be cemented to the proximal tibia.

The tray is inserted with the knee fully flexed and the proximal tibia advanced anteriorly. The two hexagonal-shaped Trabecular Metal Pegs must be axially aligned with the prepared holes in the proximal tibia, the chamfered ends of the Trabecular Metal Pegs aid in

initial engagement of the implant and the prepared tibia. After initial engagement of the NexGen Trabecular Metal Tibial Tray with bone and prior to impaction via the Trabecular Metal Tibial Impactor, insure that the inferior surface of the implant and proximal tibia are parallel with respect to each other and that the Trabecular Metal Pegs are perpendicular to the proximal tibia. Once this visual check is performed, the NexGen Trabecular Metal Tibial Tray may be impacted into place (Figure 13).

**Note:** After impaction, it is extremely important to insure that the Trabecular Metal Tibial Tray is in uniform contact with the resected tibia, and that no gaps are present between the implant and bone, or fixation, support and/or stability may be insufficient (Figure 14).



Figure 15



Figure 16

### Cemented Implantation Option

The NexGen Trabecular Metal Tibial Tray is implanted with cement between the baseplate and bone only; the Trabecular Metal Pegs are implanted without bone cement (cementless). Bone cement should be applied in the doughy state in order to control its application to the Trabecular Metal Tibial Tray and/or bone. Bone cement is applied directly onto the Trabecular Metal Base Plate of the NexGen Trabecular Metal Tibial Tray in a uniform fashion; care must be taken to insure a consistent and continuous cement layer is applied to the tibial tray. Cement masks are provided in the instrument set for covering the Trabecular Metal Pegs; the cement masks prevent bone cement coming in contact with the Trabecular Metal Pegs (Figure 15). Bone cement may also be applied to the proximal tibia; the cement masks can be used to occlude the prepared holes and prevent the egress of bone cement (Figure 16). Once the cement has been applied to the tibial tray, the two hexagonal-shaped Trabecular Metal

Pegs are axially aligned with the prepared holes of the proximal tibia, and the NexGen Trabecular Metal Tibial Tray is inserted into the holes. After initial engagement of the Trabecular Metal Pegs and prior to impaction via the Trabecular Metal Tibial Impactor, insure that the inferior surface of the implant and proximal tibia are parallel with respect to each other and that the Trabecular Metal Pegs are perpendicular to the proximal tibia. Once this visual check is performed, the NexGen Trabecular Metal Tibial Tray may be impacted into place.

After impaction, it is extremely important to insure that the cemented interface between the Trabecular Metal Tibial Tray and resected tibial bone is of uniform thickness and consistency. Excess bone cement must be removed from the periphery of the NexGen Trabecular Metal Tibial Tray, and there must be no bone cement on the top surface of the tibial tray.



Figure 17

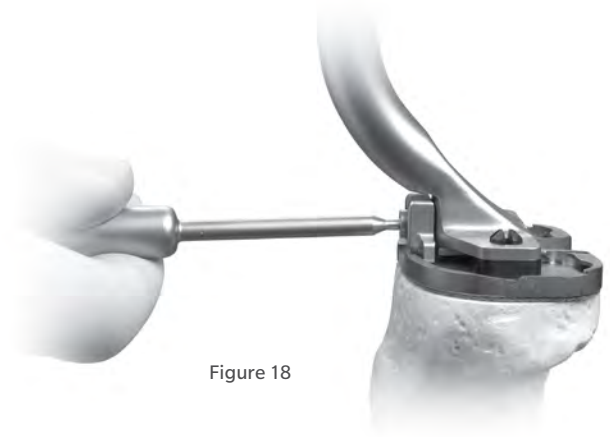


Figure 18



Figure 19

## Removing the Trabecular Metal Tibial Impactor

To remove the Trabecular Metal Tibial Impactor, loosen the actuator pad by turning the screw counterclockwise fully (Figure 17) (until the impactor pad is flush with the front of the impactor) and the impactor will disengage from the implant (Figures 18 and 19). The self release feature of the impactor will help prevent any disruption of implant preparation.

ⓘ **Note:** Fully support the NexGen MIS Trabecular Metal Tibial Impactor prior to instrument removal to prevent disruption of the peg to bone interface due to the weight of the impactor.

## Removing the Impactor Pads from the Impactor body

The impactor pads must be disassembled from the impactor for cleaning and sterilization. To disassemble the pads, apply even pressure on the backside of the pad, across all of the prongs, and push until the pads snap out of the impactor body. After removal of the pads, inspect them for any cracks or damage, including any cracks around the prongs. If any of the prongs are broken, or if any cracks or damage are observed, the pads can be replaced.





Figure 20

### Optional Insertion Method Using the Locking Plate Inserter Prior to Impaction

When utilizing a Quad-Sparing incision with minimal exposure it may be preferable to insert tibial implant with the knee in extension. Attach the locking plate inserter to the appropriate NexGen Trabecular Metal Tibial Tray (Figure 20).

- Release the screw lock.
- Place the dovetail connection of the locking plate inserter around the tibial plate dovetail. The handle should be positioned away from the patella. For small sizes, you will need to angle the locking plate inserter into place. Make sure that the bottom face of the instrument is against the top face of the tibial plate.
- Squeeze the handles together to lock the instrument onto the tibial plate.
- Tighten the screw lock.
- Once the tibial has been inserted, remove the locking plate Inserter and attach the Trabecular Metal Tibial Impactor (reference page 8). **Take care not to damage the prepared post hole while attaching the Trabecular Metal Tibial Impactor.**



Figure 21

## Implant the Bearing

Once you have implanted the appropriately-sized femoral and patellar components and allowed the bone cement to set (if utilizing the cemented implantation option), perform a trial reduction to identify the desired bearing thickness to best balance the soft tissues.

### Technique for the Bearing Assembly

The bearing insertion instrument applies both downward and posterior forces to help seat the bearing onto the tibial tray. Push the lever on the inserter fully to either side. Engage the hook on the insertion tool with the mating slot in the front of the plate and close the lever with your index finger. This should lock the insertion tool to the tray. Place the bearing onto the implant tray, engaging the dovetails.

Steady the surface on the tray with one hand by applying downward pressure near the posterior cruciate cutout. Squeeze the handles of the insertion tool to seat the bearing (Figure 21). Open the lever and remove the insertion tool. Insert a bearing only once. Never reinsert the same bearing onto a tibial tray. Insertion and removal of a bearing will deform the polyethylene.

ⓘ **Note:** To help stabilize the NexGen Trabecular Metal Tibial Tray, the bearing can be inserted with the knee in extension.



Figure 22

### Uses of the Trabecular Metal Tibial Tray Flex Bearing Locking Screw

If flex implants are being used and the bearing thickness is 17 mm, the following technique describes use of the NexGen Trabecular Metal Tibial Tray Flex Bearing Locking Screw (Figure 22).

ⓘ **Note:** A locking screw is not required for 10, 12, and 14 mm bearings.

**Warning:** Do not use the NexGen Trabecular Metal Tibial Tray with the 20 mm or 23 mm flex bearings. The fixation integrity is unknown.

**Warning:** Do not use LCCK bearing components with the NexGen Trabecular Metal Tibial Tray – they were not designed to be compatible.

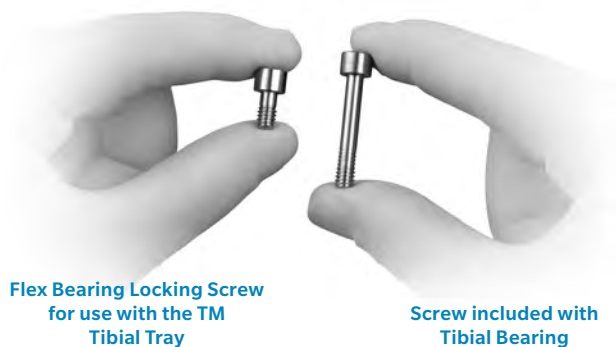


Figure 23



Figure 25



Figure 24

### Technique for the Assembly of the Trabecular Metal Tibial Tray Flex Bearing Locking Screw *In vivo*

Discard the screw included with the tibial bearing. Open a flex bearing locking screw as this screw will be used with the Trabecular Metal Tibial Tray (Figure 23).

ⓘ **Note:** When using Prolong® Highly Crosslinked Polyethylene Bearing Components, the metal locking insert must be assembled prior to proceeding.

ⓘ **Note:** When using the secondary locking screw, the components may be assembled on the back table or in the patient; however, **the Trabecular Metal Tibial Impactor will not engage the NexGen Trabecular Metal Tibial Tray with the bearing in place.**

Attach the flex counter torque instrument to the tab in the anterior of the Trabecular Metal Tibial Tray (Figure 24). (This is the same tab that the bearing inserter tool attaches to.) Tighten the threaded screw on the flex counter torque instrument.

Place the Trabecular Metal Tibial Tray Flex Bearing Locking Screw through the hole in the tibial bearing component. Manually thread in until fully seated with knurled 4.5 mm hex driver bit (Figure 25).



Figure 26



Figure 27

### Technique for the Assembly of the Trabecular Metal Tibial Tray Flex Bearing Locking Screw *In vivo* (cont.)

Use the 95 in-lb torque wrench attached to the 4.5 mm hex driver to torque the screw to 95 in-lb (Figure 26). Use the flex counter torque to counter act the torque. Do not over-torque or under-torque (Figure 27).

Recheck the ROM and stability of the knee.

Prior to closure, the surgical site should be thoroughly cleansed of bone chips, bone cement, and any other debris. Foreign particles at the articular interface may cause excessive wear.

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

## Femoral Implantation

After the NexGen Trabecular Metal Tibial Tray is in place, the NexGen CR or NexGen LPS Femoral Component may be inserted per the associated surgical technique. The knee should be flexed to 90°, and the femoral component impacted in place.





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