

Zimmer® NexGen® MIS Modular Tibial Plate and Keel

Cemented Surgical Technique





Introduction to the NexGen MIS Modular Tibial Plate and Keel

The plate and keel of this innovative tibial implant are designed to be assembled *in vivo* thereby facilitating minimally invasive total knee arthroplasty (TKA) procedures. Two-piece tibial components are not new in TKA. However, previous two-piece tibial components required back-table assembly.

This surgical protocol will describe the technique for *invivo* assembly with *PALACOS*[®] Bone Cement.*

Screw Compatibility

Secondary locking screw compatibility is an important factor when using the MIS Modular Tibial Plate and Keel. Only screws with circumferential grooves are compatible with the MIS Modular Tibial Plate and Keel. The screw compatibility chart below can be found on the label of all MIS Tibial Keel implant boxes. The locking screw packaged with the Tibial Keel is used in all situations unless one of the other two screws is required. The MIS Modular Flex Locking Screw is required when 17mm or thicker Flex articular surface components are used. The MIS Modular LCCK Locking Screw is used with all LCCK articular surface components.









 * PALACOS[®] Bone Cement is recommended for its longer working time or doughy phase due to its high viscosity.

PALACOS is a trademark of Heraeus Kulzer GmbH Under license from Heraeus Kulzer GmbH, Hanau, Germany.

NexGen MIS Modular Tibial Plate and Keel Surgical Technique

Table of Contents		
CTI	ON	PA
1	Using Posterior Hooks and Positioning the Sizing Plate	
	Posterolateral and posteromedial hooks on the sizing plate can be deployed to aid in size selection and positioning of the MIS Tibial Sizing Plate. The hooks provide an anchor on anatomy that is not easily visualized with a small incision on the medial or lateral side. The posterolateral hook is used with a medial incision and vice versa.	
	Several options are available, depending on various considerations. Be sure to clear all osteophytes and soft tissues, which could interfere with the proper positioning of the hook.	
	With a mini or open procedure, the tibia can be subluxed forward and better visualized. When neither posterior hook is deployed, traditional tibial anatomic landmarks may be used.	
	Deploying Hooks	
	Attaching MIS Sizing Plate Handle	
	Positioning Using the Posterior Hook.	
	Aligning the MIS Sizing Plate Using the Alignment Rod	
	Positioning the MIS Sizing Plate Based on Trial Range of Motion	
	Securing the Sizing Plate	
2	Preparing the Tibia for the Keel	
	The MIS Modular Drill Bushing and 18mm MIS Modular Cemented Drill are used to prepare the tibial IM canal for the MIS Modular Tibial Keel. There are two engraved lines on the drill corresponding to the depth of the shorter Nonstemmable ("NON") and longer Stemmable ("STM") Keel lengths.	
	To broach for the fins, attach the proper size broach to the MIS Broach Impactor. During broaching, ensure the broach handle remains in contact with the sizing plate and does not toggle.	
	Drilling	
	Broaching	
3	Inserting and Assembling the Plate and Keel Provisionals	
	The plate and keel provisionals should be assembled in the patient in the same fashion as the final implants, which can serve as a "dry-run" for final implant assembly.	
	The Keel Provisional is attached to the Keel Holder and inserted into the tibial IM canal. Next, the Plate Provisional is inserted by hand and the captured screw is threaded into the Keel Provisional.	
	Inserting the Keel and Plate Provisionals	•
	Removing the Keel and Plate Provisionals	

PAGE

SECTION

4

Cementing and Implantation

After the tibia is fully prepared and prior to mixing the PALACOS Cement, lay out the necessary assembly instruments in order of use. Implant components should be attached to the instruments at this point.



The MIS Modular Tibial Plate and Keel are designed for cemented use. The instrumentation prepares a cement mantle around the Keel; therefore, cement must be applied within the tibial medullary canal, as well as on the proximal tibial surface and/or under the Tibial Plate.

Back-table Component Layout		
Inserting the Keel	8	
Inserting the Tibial Plate and Engaging the Tapers	9	
Removing the Taper Seating Components		
Secondary Locking Screw		
C Madulay Diata Lias with Stom Extensions and Austrants		

5

MIS Modular Plate Use with Stem Extensions and Augments

The two locking mechanisms between the MIS Modular Tibial Keel (stemmable) and the stem extension implant are a Morse-type taper and two set screws.

When opening the stem extension from its sterile packaging, immediately remove the locking screw from the stem extension and discard since the two set screws packaged with the MIS Modular Tibial Keel act as the secondary locking mechanism.

Assembly of the Stem Extension to the MIS Modular Tibial Keel should take place on the back table. Once assembled, the Keel and Stem Extension construct can be inserted into the tibial IM canal.

- Stem Extension Provisional Assembly 14
- Stem Extension Implant Assembly...... 14
- Bone Preparation for Offset Stem Extension 16

MIS Modular Plate Use with LCCK or 17mm and Thicker Flex Articular Surfaces

When using any articular surface that requires a secondary locking screw (e.g., LCCK, 17mm or thicker Flex Articular Surfaces), remember that only screws with circumferential grooves are compatible with the MIS Modular Tibial Plate and Keel. These will come packaged separately (Refer to the Screw Compatibility Chart included at the beginning of this document).

Using Posterior Hooks and Positioning the Sizing Plate

Deploying Hooks

- Deploy the appropriate posterior hook corresponding to the opposite incision location (e.g., medial incision = lateral hook) using the Small Hexhead Screwdriver (Fig. 1).
- Placing the hook behind the posterolateral portion of the tibia provides an anchor to the anatomy that is not easily visualized with a small incision.
- If not using hooks, see *Technique Tip 1.A*.

1.A



SECTION

When not using hooks, pay special attention to the posterior "bumps" on the sizing plate to ensure they do not come into contact with the distal femur, which could push the plate anteriorly.



Deploying a posterior hook.

Attaching MIS Sizing Plate Handle

- Attach the MIS Sizing Plate Handle to the selected MIS Tibial Sizing Plate – insert the handle on the medial side of the sizing plate with medial incisions or on the lateral side of the sizing plate for lateral incisions.
- Clamp the lever to secure (Fig. 2).
- Note: This instrument contains several moving parts. If trigger becomes hard to engage, apply instrument lubrication.



Attaching the MIS Sizing Plate Handle.

N

Positioning Using the Posterior hook

- Locate the edge of the posterior tibial cortex with the deployed hook and rotate the MIS Sizing Plate into position (Fig. 3).
- Check that the plate sits level on the finished surface of the tibia. Under/overhang should be assessed (see *Technique Tip, 1.B and 1.C*).
- In extension, view or palpate the medial and lateral sides of the tibia to check sizing plate fit.

TECHNIQUE TIP

JE TIP

1.B

1.C

The A/P dimension of the proximal tibia is generally larger on the medial side compared to the lateral side. When the sizing plate is positioned correctly in rotation, there could be a tendency to slightly underhang the tibia on the posteromedial edge or overhang the tibia on the posterolateral edge.

TECHNIQUE TIP

Remove all posterior osteophytes from the back of the tibia as these may interfere with the placement and accuracy of the posterior tabs on the sizing plate.



Positioning the posterolateral hook on the MIS Sizing Plate.

Aligning the MIS Sizing Plate Using the Alignment Rod

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 MIS Sizing Plate Handle. There are two options (hole and slot) available for use of the alignment rod (Fig. 4).



MIS Sizing Plate Handle showing hole and slot.

- Slot varus/valgus and rotational alignment (Fig. 5).
- Round hole slope of tibial cut (distal end of rod should point to second metatarsal).
- Caution: Do not impact or forcefully lever the MIS Sizing Plate Handle – for alignment purposes only.

Positioning the MIS Sizing Plate Based on Trial Range of Motion

After preparing the patella, select the proper size MIS Tibial Sizing Plate, but do not deploy either the posteromedial or posterolateral hooks and follow the steps below.

- Insert the proper Sizing Plate and Articular Surface, Femoral, and Patellar Provisionals.

TECHNIQUE TIP

Use the color and/or alphanumeric designations of the Articular Surface Provisional to match the Femoral Provisional and MIS Tibial Sizing Plate. If there is no match between the Femoral Provisional and MIS Tibial Sizing Plate, adjust the size of the MIS Tibial Sizing Plate to yield a match.

1.D

- Flex and extend the knee through a full range of motion and ensure soft tissue balance is appropriate – the tibial component tends to seat itself in the position where it best articulates with the femoral component.
- Finally, mark the position of the component with methylene blue, electrocautery, or by placing a pin or MIS Screw in the sizing plate anteriorly.



Rotation and Varus/Valgus check.



Inserting a screw in the MIS Sizing Plate.

Securing the Sizing Plate

It is recommended to use one anterior pin hole and one hole on the opposite face of the sizing plate to ensure stability.

- Insert a pin or MIS Screw into the anterior hole on the sizing plate (Fig. 6a).
- Insert a second pin or MIS Screw into the hole on the sizing plate (Fig. 6b).

TECHNIQUE TIP

When using the anterior pin holes, pay special attention to the posterior aspect of the sizing plate to ensure lift-off does not occur from over-tightening/seating.

1.E





Preparing the Tibia for the Keel

Drilling

• To prepare the intramedullary canal for the keel, place the MIS Modular Drill Bushing in the detents of the MIS Sizing Plate (Fig. 7).

TECHNIQUE TIP

The MIS Threaded Handle can be used to hold the Drill Bushing in position during drilling.

2.A

- Using the 18mm MIS Modular Cemented Drill, bore until the appropriate engraved line on the drill is in line with the top of the Drill Bushing.
 - The first engraved line (marked "NON") prepares the bone for the nonstemmable keels.
 - The second engraved line (marked "STM") readies the bone for the longer, stemmable keels.
- Remove the drill and bushing and proceed to broach assembly.
- Note: For bone preparation when use with a stem, please refer to page 16 "Bone Preparation for Stem Extension."

Broaching

- Attach the proper size broach to the MIS Broach Impactor as depicted (Fig. 8).
- Place the knee in appropriate flexion angle for broaching (see Technique Tip 2.B).

TECHNIQUE TIP

2.B

Lower flexion angles may facilitate easier broaching in smaller incisions.



Drilling the tibia.



Attaching Broach to MIS Broach Impactor



Tibial Sizing Plate in the detents and broach (Fig. 9).

• Impact the MIS Tibial Broach Impactor assembly with care to prevent fracture of the tibia. Impact until the instrument bottoms out on the handle stop (see Technique Tip 2.C).

TECHNIQUE TIP

During broaching, make sure that the Broach Handle:

2.C

- remains flush against the sizing plate and is in a vertical position (parallel to tibial shaft).
- is in full contact with the sizing plate, and
- does not toggle during broaching.





- Remove the Broach Impactor by tapping upward on the front of the handle stop (Fig. 10).
 - Take caution not to strike the Broach Impactor sideways.

Inserting and Assembling the Keel and Plate Provisionals

Inserting the Keel and Plate Provisionals

- Attach the Keel Holder to the indentation groove of the appropriately-sized Keel Provisional (Fig. 11).
 - Angle the Keel Holder handle away from the incision.
- Introduce the Keel Provisional into the broached bone.



Attaching Keel Holder to Keel Provisional.

• By hand, place the Plate Provisional in proper position so that the captured screw is aligned with the internal keel threads (Fig. 12).



Introducing Plate Provisional by hand and setting the captured screw into the internal keel threads of the keel.

- The fins on the Keel Provisional are slightly raised and fit intimately into the undersurface cut-out of the Plate Provisional (Fig. 13a). There are two small windows in the Plate Provisional to provide visual verification that the Keel Provisional is properly keyed (Fig. 13b).

Note: The fins of the keel should be visible in both viewing windows.



The "keying" feature of the Keel and Plate Provisionals. Visual windows are identified by yellow circles.



- Connect the Plate and Keel Provisional by tightening the captured screw with the 3.5mm hex driver (Fig. 14).
- Remove Keel Holder and proceed through desired trialing.

TECHNIQUE TIP

Check to see that the trial prosthesis fits the cut surfaces of the proximal tibia. If any undesired gaps are present, remove the trial component and adjust the bone cuts until an intimate fit is obtained.

3.A

Removing the Keel and Plate Provisionals

• To remove the provisional, reverse the assembly process above and remove the plate separately from the keel in two pieces.



Tightening the captured screw with the 3.5mm hex driver.



Cementing and Implantation

Back-Table Component Layout

- After the tibia is fully prepared and prior to mixing the *PALACOS* Cement, lay out the necessary assembly instruments in order of use (Fig. 15). Implant components should be attached to the instruments at this point.
- Note: The MIS Modular Tibial Plate and Keel are designed for cemented use. The instrumentation prepares a cement mantle around the Keel; therefore, cement must be applied within the tibial medullary canal, as well as on the proximal tibial surface and/or under the Tibial Plate.

Inserting the Keel

- Securely attach the Keel Holder onto the proximal indentation groove of the Keel.
 - The Keel Holder handle is oriented to the incision location (e.g., medially for medial incision).
 - Place PALACOS Cement into the IM canal of the tibia.
- Press the Keel downward into the cement until the Keel Holder sits flush with the proximal tibia (Fig. 16).
 - The cement restrictor plug should remain attached to the Keel during this step in order to prevent cement from getting into the taper.

TECHNIQUE TIP

Insertion of the MIS Modular Keel prior to insertion of the MIS Modular Plate allows the tibia plateau to be cleaned and dried at this step.

4.A

4.B

• Once satisfactorily positioned, using an osteotome remove the Cement Restrictor Plug from the taper (Fig. 17).

TECHNIQUE TIP

The Keel Holder will help pressurize the cement as the Keel is lowered into the prepared bone. During these steps, have the Tibial Plate ready with the Locking Plate Inserter attached to the dovetail.



Back-table component layout.



The holder should be securely locked into the indentation groove on the Keel.



After insertion into the IM canal, remove the Cement Restrictor Plug.



Inserting the Tibial Plate and Engaging the Tapers

- After removing the taper plug, introduce the Tibial Base Plate using the attached Locking Plate Inserter (Fig. 18).
 - Take special care to ensure that cement does not migrate into the taper.
 - Identify the proper position where the two oval tapers mate and firmly press together so they engage.
- Note: The tapers were designed with an oval geometry to help accurately align or center the Tibial Plate to the Keel.



Introducing the Tibial Plate into the knee.

• Attach the Taper Seating Connector by threading it into the Keel through the central hole of the Tibial Plate and tighten securely/completely (Fig. 19).

TECHNIQUE TIP

N

SECTION

Turn the c-shaped head/hook of the Connector, as the knurled knob portion does not turn the threads. It ONLY facilitates easier removal once the Connector is fully disengaged (Fig. 19).

4.C



Attaching the Taper Seating Connector with the c-shaped hook and tightening.

- Remove the Keel Holder by squeezing the handles and unscrewing the locking nut.
- Note: The Taper Seating Connector is now threaded into the Keel, preventing the keel from migrating distally into the IM canal (Fig. 20).





• Ensure the handles on the Taper Seating Tool are completely open and connect the Taper Seating Tool to the Taper Seating Connector by dropping down and sliding the tool's tip into the c-shaped hook (Fig. 21).



Attaching and hooking the Taper Seating Tool to the c-shaped hook of the Taper Seating Connector.



Correct mating position of the Taper Seating Tool and Taper Seating Connector.

• Once "hooked," bring the white handles together until the tip drops into the seated position (Fig. 22).



- The angled white handle should be locked into the first stop on the lever at approximately 30° to the vertical axis (Fig. 23).



Correct handle angle at approximately 30°.

• Next, bring the two white handles completely together until they touch, squeezing with both hands (Fig. 24).

- To ensure that the tapers are fully seated, tighten the connector by rotating the construct approximately a quarter turn clockwise, or until a tight feel is identified and proceed to squeeze the handles together again.



Note: When the handles are squeezed together, the force applied to the tapers is approximately 1,000 lbs.

TECHNIQUE TIP

After engaging the taper, a slight impaction of the Taper Seating Tool handle with a mallet can facilitate final seating of the implant onto the proximal tibial surface.

4.D



Engaging the tapers by squeezing the handles together completely.



Removing the Taper Seating Components

• Disengage the mated components by lifting up on the release lever and sliding the tip out of the hook (Fig. 25).

TECHNIQUE TIP

4.E

Turn the full construct a quarter turn counterclockwise to loosen the Connector from the keel, as the Connector's threads may be difficult to disengage by hand.



Turning the Taper Seating Tool counterclockwise and releasing the tool by lifting up on the release lever.

Fig. 26

Final removal of the Connector using c-shaped hook.

Secondary Locking Screw

N

• Introduce the Secondary Locking Screw down through the central hole of the plate (Fig. 27).

- Remove the connector by turning the c-shaped hook counterclockwise until fully loosened (Fig. 26).

removal of the potentially slippery component.

- Once fully loosened, the knurled knob can facilitate secure

- The Secondary Locking Screw should have one circumferential groove and is packaged with the Keel
 see Screw Compatibility Chart in the introduction section at the beginning of this technique.
- Note: The technique for Secondary Locking Screws used with LCCK or 17mm or thicker flex articular surface is described on page 17.



Inserting the Secondary Locking Screw.



- Tighten with the Hex Driver Bit until secure (Fig. 28).
- If the Locking Plate Inserter is not attached to the plate, attach it now to provide counter torque during final tightening.



- Attach the Torque Wrench to the Hex Driver Bit.
- Hold the Locking Plate Inserter handle which serves to provide counter torque during final tightening (Fig. 29).



Attaching the Torque Wrench to the Hex Driver Bit.



Torque to 95 in-lb and remove wrench and driver bit.

• Torque to 95 in-lb (Fig. 30).

MIS Modular Plate Use with Stem Extensions and Augments

Stem Extension Provisional Assembly

- Thread the Stem Extension provisional into the bottom of the Keel Provisional (Fig. 31).
- Attach the Keel Holder onto the indentation groove of the Keel Provisional and introduce the Keel and Stem Extension Provisional construct into the prepared IM canal and broached bone.
- Continue with provisional assembly as previously described in Section 3.



Attach desired stem extension ensuring a "snug" fit.

Stem Extension Implant Assembly

- Loosen the two set screws with the 2mm Set Screw Hex Driver (Fig. 32).
- Remove the distal polyethylene taper plug from the stemmable Keel and attach the stem extension ensuring a "snug" fit is achieved.
 - If toggle exists, further back out one or both of the set screws to ensure proper and full seating. **DO NOT tighten set screws until the tapers are seated by impaction.**
- Place the constructed component keel-side down onto a protected surface to avoid scratching or damaging the Keel.



Loosening the set screws on the stemmable Keel.



• Using a soft cloth for stem extension protection, strike it solidly once with a 2-lb. mallet (Fig. 33).



- Once fully seated, tighten the two set screws using the 2mm Set Screw Hex Driver, applying moderate torque to tighten each set screw (Fig. 34).
 - The hex drivers are designed to limit the amount of torque which can be applied to the set screws. *Torque by hand only.*
- Continue with cementing and implantation as previously described in Section 4.



Tightening set screws with the L-wrench hex driver.

Bone Preparation for Stem Extension

- When using a Stem Extension with the MIS Modular Plate, it is necessary to drill further distally into the IM Canal than the second engraved line (marked "STM"). When preparing the IM canal for the MIS Modular Keel, drill approximately 10mm deeper than the second engraved line (marked "STM") on the 18mm MIS Modular Cemented Drill until the end of the drill is flush with the top of the drill bushing. This step ensure adequate clearance for the transition length of the proximal and distal diameters of the stem extension (Fig. 35).
- Failure to attain the correct drill depth may cause slight interference fit during implantation. Remove the drill and drill guide. If the tibia has already been reamed to a 18mm diameter or greater, this drilling step is not required.
- Pre-operative x-ray templating is recommended when Stem Extensions are used.

Augment Assembly

- Tibial Augments can be used with the MIS Modular Keel and Plate System.
- Attach the *NexGen* Augment Provisional to the Plate Provisional prior to connecting it to the Keel Provisional. *NexGen* augments attach identically to both the MIS Modular Plate Provisional and the standard *NexGen* Tibial Plate Provisional.
- Attach NexGen Augments to the MIS Modular Plate in the same manner as the standard NexGen Tibial Component (Fig. 36).



Fig. 35 Drilling for a stem extension.



SECTION

Drill 10mm past

MIS Modular Plate Use with LCCK or 17mm and Thicker Flex Articular Surfaces

Technique

SECTION

When using an LCCK or 17mm or thicker Flex Articular Surface, the following key steps must be observed to ensure proper component assembly and seating.

- Following the seating of the tapers and the removal of the taper seating hardware (Section 4), proceed to the insertion of the Secondary Locking Screw as depicted in Fig. 27, Page 12.
 - Hand-tighten the screw until taut (Fig. 28, Page 13) and remove the Hex Driver Bit.
- At this time, DO NOT torque the screw because it will need to be removed after the cement cures.
- Perform desired final impaction and thoroughly clean up all excess cement allow cement to fully cure.
- Remove the previously-inserted Secondary Locking Screw with the Hex Driver Bit and discard.
- Open the sterile packaging of the chosen LCCK or 17mm and thicker Flex Articular Surface component and IMMEDIATELY DISCARD the pre-packaged locking screw.

Warning: The screws that come packaged with the LCCK and Flex Articular Surfaces WILL NOT work properly with the MIS Modular Tibial Plate and Keel.

Note: For 17mm or thicker Flex Articular Surfaces, there is no need to use the *NexGen* Flex Taper Plug as the Locking Screw threads directly into the keel threads.

- Open the separately packaged MIS Modular LCCK or MIS Modular Flex Locking Screw, which can be easily identified by their three or two circumferential grooves, respectively (refer to the Screw Compatibility Chart at the beginning of this document).
- Insert the LCCK or Flex Articular Surface onto the tibial plate.
- Insert the MIS Modular LCCK or MIS Modular Flex Locking Screw and finger-tighten it with the Hex Driver Bit (Fig. 37).
 - Leave the driver bit set in the screw head.



Hand-tighten the locking screw.

• For counter torque purposes, attach the LCCK Tibial Plate Wrench to the tibial component or Flex Counter Torque to the anterior tab of the tibial component (Figs. 38a and 38b).

Note: Countering the force of the Torque Wrench helps to avoid disruption of the cement mantle.

N

• Attach the Torque Wrench to the Hex Driver Bit and tighten to 95 in-lb (Figs. 38a and 38b).



Attaching LCCK Tibial Plate Wrench and tightening of MIS Modular LCCK Locking Screw with the Torque Wrench.



Attaching Flex Counter Torque and tightening of MIS Modular Flex Locking Screw with the Torque Wrench.





This documentation is intended exclusively for physicians and is not intended for laypersons. Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice in whole or in part. Please refer to the package inserts for important product information, including, but not limited to, contraindications, warnings, precautions, and adverse effects.

CE 0086

Contact your Zimmer representative or visit us at www.zimmer.com

The CE mark is valid only if it is also printed on the product label.





97-5960-002-00 Rev. 1 1104-K21 XML Printed in USA ©2006, 2011 Zimmer, Inc.