GMRS™ Distal Femoral Surgical Protocol

Global Modular Replacement System
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GMRS™ Distal Femoral components are marketed in the United States for use with bone cement.
# GMRS™ Distal Femoral Surgical Protocol

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Introduction

The GMRS™ Distal Femoral Components are based on over a quarter of a century of clinical history. Patella kinematics have been improved by incorporating a deepened patellar track to articulate with the Duracon® patellae. The GMRS™ standard Distal Femur accepts the Modular Rotating Hinge (MRH) Tibial Rotating Component, Bushings, Axle and Bumper for seamless integration with the MRH resurfacing Tibial Baseplate.
The Stem options for the GMRS™ Distal Femoral Replacement are unrivaled and now offer six cemented stem options: straight, curved and long curved; each type with or without extra-cortical porous-coated body sections.
GMRS™ Distal Femoral Surgical Protocol

Description of the Distal Femoral Modular Replacement System

The GMRS™ System was developed to meet the unique needs of patients who require reconstruction of large segmental defects for tumors, failed previous arthroplasty, or trauma. This system is designed to:

• Reconstruct large segmental defects of the knee
• Reconstruct osteoarticular defects of varying sizes
• Allow for variation and intra-operative changes of the surgical plan.

The system consists of distal femoral components, extension pieces and stems. It also includes a complete set of trial components and instrumentation.

The modular implants are assembled by impacting a male/female taper design, securely locking them together.

Distal Femoral Components

The distal femoral components are available in two sizes, small and standard, and both are available in left and right configurations. The standard size distal femoral component measures 60mm in the M/L and 54mm in the A/P. The small size distal femoral component measures 50mm in the M/L and 45mm in the A/P. Both sizes have a 65mm replacement length. All distal femoral components have a built-in 6° Valgus offset and utilize the Modular Rotating Hinge (MRH) Knee components.

**NOTE:** The small distal femoral component uses dedicated small bushings and a small axle.

Stem Components

Cemented Stems

The GMRS™ cemented stems are available in six styles: straight, curved and long curved; each style with or without extra-cortical porous-coated body sections. The extra-cortical porous-coated body section has a 40mm replacement length. The stems are also available without the extra-cortical porous-coated body section, with an 11mm replacement length.

All stems are available in 8mm, 9mm, 10mm, 11mm, 13mm, 15mm and 17mm diameters. Their respective seat diameters at the resection level are as follows:

<table>
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<tr>
<th>Stem Diameter</th>
<th>Seat Diameter</th>
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<td>Ø 8,9mm</td>
<td>Ø 22mm</td>
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<tr>
<td>Ø 10,11mm</td>
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The stems are designed to be cemented into the medullary canal. Optional stem centralizers are available for the 10-17mm diameter (for the straight and short-curved stems only).

**NOTE:** The small cemented stems (8mm, 9mm and 10mm diameters) are intended to be used with the small distal femoral component.
Tibial Components

All-Polyethylene Tibial Component

The All-Poly Tibial Component is available in five sizes (XS, S, M, L, XL), each in 4 thicknesses (8mm, 11mm, 16mm and 21mm). The component is designed to accept the long All-Poly Tibial Rotating Component only (6481-2-103).

NOTE: The All-Poly Tibial Component is intended for use when it can be adequately supported by cortical bone around its periphery.

Modular Rotating Hinge Tibial Baseplate

If the bone quality is suspect or the component cannot be properly supported, the Modular Rotating Hinge (MRH) tibial baseplate is recommended.

The MRH Tibial Baseplate is available in four sizes (Small 1, Small 2, Medium 2 and Large 2), with modular stem options (80mm and 155mm lengths, 10-23mm diameter). The tibial inserts are available in two sizes (Small 1 / Small 2 and Medium 2 / Large 2), each in 5 thicknesses (10mm, 13mm, 16mm, 20mm and 24mm). The MRH Tibial Baseplate is designed to accept the MRH Tibial Rotating Component only (6481-2-100). A comprehensive range of modular stem extensions are available to be assembled with these Tibial Baseplates.

Trial Components

The implant system is complemented with a complete set of trial components. The trial components are replicas of their corresponding implants; however, they have non-locking trunnions. The trials are satin-finished and have no coatings, so that they can easily be distinguished from the implants. A 30mm Trial Extension Piece also functions as the Trial Extra-Cortical Body. Together with the Trial Cemented Stem, it forms the Trial Stem with extra-cortical porous-coated body.
GMRS™ Distal Femoral
Surgical Protocol

Global Modular Replacement System
Distal Femoral Resection for
Large Segmental Replacements
Surgical Protocol

This publication sets forth detailed recommended procedures for using Stryker® Orthopaedics devices and instruments. It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required.
**Measuring Resection Length**

The Distal Femoral Template can be used to guide the resection to a level that can be reproduced by the available implants. The Distal Femoral Template is placed on the bone so that the silhouette of the template coincides with the distal condyles of the femur (Figure 1a).

The Distal Femoral Template is read at the appropriate marking depending on whether the stem being used is with or without extra-cortical porous-coated body section. The anterior cortex of the femur is marked with a Bovie or similar device to indicate the resection level. It is important to note that if the condyles of the prosthesis are placed at the level of the pre-operative condyles (i.e. the femoral prosthesis is the exact length of the resected distal femur), an 18mm tibial resection is required for an MRH baseplate. Typically, 10-12mm are removed from the proximal tibia. The femoral resection is therefore usually about 6-8mm longer than the prosthesis.

Alternatively, the **MRH/All-Poly Tibial Template** can be attached to the Distal Femoral Template. The slots in the Tibial Template coincide with the level of the proximal tibial resection for the different All-Poly Tibial components or the MRH Tibial Inserts (Figure 1b). This is a provisional marking only; no bone is cut at this stage.

**NOTE:** It is important to ensure proper patellar tracking. The length of the femoral resection and prosthetic replacement must be considered with the tibial resection to recreate leg length and establish proper patellar tracking. Patellar tracking, tibial cut, and leg length must be taken into consideration when making the femoral resection.

**SURGICAL TIP:** As an aid to restoring leg length, a reference measurement can be established across the joint. With a Bovie or similar device, a mark is made on the femur, proximal to the femoral resection, along with a mark on the tibia, distal to the tibial resection. The distance between these marks can be measured before the resection is made, and checked again, with the trials or implants in place, after the resection is made (Figure 1c).
Rotational Alignment

Using a straight edge (e.g. the Distal Femoral Template), the anterior cortex of the distal femur is marked above the resection level in line with the trochlear groove of the distal femur (Figure 2).

The line should be directly anterior to the linea aspera. This reference mark will be used later to aid in rotational orientation of the prosthetic components. Rotational alignment can also be determined or verified during trial evaluation.

The Stem Implants and Trials are marked in line with the trochlear groove of the Distal Femoral Component.

As a guide to rotational orientation, the alignment marking on the implant stem can be oriented to the mark made on the anterior cortex above the resection level.
Femoral Osteotomy

All remaining soft tissue at the level of transection is cleared. The osteotomy, perpendicular to the femoral shaft, is performed after the posterior and medial structures have been protected and retracted (Figure 3); special care is taken to protect the Femoral Artery.

**SURGICAL TIP:** It is preferable to resect the femur a millimeter or two distal to the marked resection level. This will allow the face reamer (see Figure 4 on page 11) to plane accurately up to the mark at a 90° angle.

**NOTE:** It is extremely important not to distract the extremity following the resection. The end of the femoral osteotomy should be kept well padded to avoid injuring the femoral vessels. The length of the resected specimen should be checked and measured again following resection.
**Preparation of the Femur**

A Flexible Guide Wire is inserted into the femoral canal. Flexible Reamers are utilized to progressively ream the canal to the appropriate diameter.

To permit an adequate cement mantle, the canal should be reamed to 2mm larger than the selected stem of the prosthesis. (Note: The seven stem diameters are 8mm, 9mm, 10mm, 11mm, 13mm, 15mm and 17mm).

The appropriate **Facing Reamer (Figure 4)** is used to plane the osteotomy site so as to ensure direct contact and accurate seating of the prosthesis upon the cortices.

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**Facing Reamer**

GMRS™ Tray No: 4A
The chosen Trial Stem is inserted to evaluate ease of insertion and an appropriate cement mantle. The trial cemented stems are exactly size for size as compared to the implant and do not include the cement mantle.

If there is any difficulty inserting the trial stem, continue reaming until the Trial Stem fits freely into the canal, or re-assess the Trial Stem size. It is extremely important to verify the close apposition of the seat of the Trial Stem to the cortex.

### Stem Diameter vs. Suggested Flexible Reamer Diameter vs. Seat Diameter

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<th>Stem Diameter</th>
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Optional stem centralizers are available for the 10-17mm diameter stems (for the 102mm and 127mm length stems only). The last size Flexible Reamer used corresponds to the diameter of the distal centralizer necessary for correct positioning of the stem tip (Figure 5).

### Proximal Tibial Resection

This technique illustrates the preparation for the Modular Rotating Hinge Tibial Baseplate which articulates with the GMRS™ Distal Femur. The technique for the Kinematic Rotating Hinge All-Poly Tibial Component which also articulates with the GMRS™ Distal Femur, is illustrated in Appendix II. The required proximal tibial cut is neutral to the tibial axis in all planes, i.e. cut in classic alignment with no posterior slope. The amount of bone to be removed, when taken into consideration with the femoral resection, will reconstruct the pre-operative joint line and leg length.

The instrumentation provides four options for determining the resection level of the proximal tibia. The first option illustrates the method for establishing the depth of the tibial cut referenced from intra-medullary trial stem extenders. The other three options can be reviewed in Appendix I.
**Tibial Preparation for the Modular Rotating Hinge (MRH) Tibial Baseplate**

The proximal tibial cut for the Modular Rotating Hinge baseplate is a neutral cut, i.e. classical alignment with no posterior slope.

The MRH Tibial Baseplate comes in four sizes (S1, S2, M2, L2) with multiple stem options. Each size of Tibial Baseplate has insert thicknesses of 10mm, 13mm, 16mm, 20mm and 24mm. The 4mm thickness of the baseplate is included in the insert thickness for the total thickness.

To properly re-establish the jointline, the articulating surface of the tibial insert should be at the correct level to ensure proper patellar position. Establishing the depth and performing the actual resection of the tibia for the Modular Rotating Hinge (MRH) Knee is as follows:

Select the appropriate Tibial Template by referencing the size determined during pre-operative planning. The correct size is the one that best covers the surface of the tibia without over-hanging the medial tibial plateau. The Templates are used for selecting the size of the Tibial Component and as a guide to locating the center of the cavity to be prepared for the stem. The center of the hole in the template can be marked with a sharp awl to facilitate canal preparation.

**NOTE:** All MRH related Instruments and Trial Components are located in the MRH Instrumentation Kit

Using the ¾" IM Drill an entry hole is prepared in the location determined by the pre-operative x-rays, or just anterior to the ACL insertion (Figure 6a).

The proximal tibial canal is prepared manually with a T-Handle attached to a fluted IM Reamer to accept the appropriate stem extender of the baseplate. The Reamer has cutting teeth that cut when the Reamer turns in a clockwise direction while being advanced. If the reaming becomes difficult, the Reamer should be removed, and its teeth should be cleared.

**Fluted IM Reamers**, available in diameters 8-23mm, are sequentially advanced into the medullary canal until the tip of the **Tibial Reamer Depth Gauge** reaches the level of the most prominent bony aspect of the proximal tibia (Figure 6b).

**NOTE:** Reamer Depth Gauges for tibial preparation are available in two lengths: 80mm and 155mm refer to the depth required to properly seat the implant with the respective 80mm and 155mm length Stem Extender.

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**Images:***

- **Figure 6a**: Diagram of a tibial component with a T-Handle and IM Reamer.
- **Figure 6b**: Diagram of a Tibial Reamer Depth Gauge.

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**Images with Product Information:**

- **6838-7-673**: ¾" IM Drill (IM Reamer Tray R2)
- **6266-5-410**: T-Handle (IM Reamer Tray R2)
- **6633-9-4XX**: IM Reamer (IM Reamer Tray R2)
- **6481-1-05X**: MRH Depth Gauge (IM Reamer Tray R2)
Establishing the depth of the tibial cut

Based on the last size reamer used, the appropriate diameter and length Trial Stem Extender is assembled to the Resection Guide Tower. Assemble the Tibial Stylus to the appropriate, left or right, Tibial Resection Guide by depressing the locking button on top of the Tibial Stylus, inserting the stylus into either the medial or lateral hole on the top of the Tibial Resection Guide and releasing the button to lock the stylus into place. Insert the Support Arm Bracket through the Tibial Resection Guide and tighten the thumbscrew to lock in place. The Tibial Resection Guide Assembly is then inserted onto the Resection Guide Tower Assembly (Figure 7a).

This instrument assembly is inserted into the tibial canal until the stylus references the desired point on the tibial plateau (Figure 7b). The locking cam lever on the Support Arm Bracket can be loosened to slide the Tibial Resection Guide against the tibia and then re-lock in place.

**NOTE:** The Tibial Stylus can be used to determine a 12mm or an 18mm resection level. If the distal most aspect of the femoral prosthesis is placed at the same location of the original anatomy, an 18mm resection is required (8mm for the Tibial Rotating Component + 10mm for the thinnest insert with the MRH Baseplate). Typically, 10-12mm is removed from the proximal tibia. Therefore, the femoral resection is usually about 6mm longer than the prosthesis.
Proximal Tibial Resection

Once the resection level is established, secure the Tibial Resection Guide to the anterior tibia using the 1/8" drill pins, drilling through the "N" holes (Figure 7c).

Once pinned to the tibia, loosen the thumbscrew of the Tibial Resection Guide and remove the Resection Guide Tower assembly and Tibial Stylus, leaving the Tibial Resection Guide pinned in place. Pinning through the "X" Pin Hole will further secure the Tibial Resection Guide to the tibia (Figure 7d).

Resect the tibial plateau through the most proximal slot in the Tibial Resection Guide. Use of a .050" (1.27mm) sawblade is recommended for an accurate resection (Figure 7e).

Additional bone may be resected by repositioning the Tibial Resection Guide over the pins in the -2 or -4 holes to resect an additional 2mm or 4mm of bone, respectively (see Figure 7d).

NOTE: If the "X" pin hole is used, this pin must be removed prior to repositioning the Tibial Resection Guide.

The Tibial Resection Guide is removed by first removing the "X" pin, then sliding the Tibial Resection Guide off over the two 1/8" drill pins and then removing the pins with the Pin Puller.

NOTE: The 5mm and 10mm slots in the tibial resection guide can be used in revision or trauma cases where bone loss or fracture respectively, necessitates the use of half or full tibial augments.
Use the Stem Extender Rod, attached to a Trial Stem Extender, through the Alignment Reamer Guide and Neutral Bushing to center the Tibial Template with the Stem construct in the canal (Figure 8).

With the knee in full flexion, and the Alignment Handle attached to the Template, an Alignment Rod is placed through the "NT" hole position of the Handle to verify alignment. The tibial tubercle will normally be positioned just lateral to the pin which should be centered distally over the center of the ankle.

When alignment is correct, the Template is secured with Headed Nails or pins through holes located anteriorly and posteriorly on the template.

Ream the Stem Boss using the Stem Boss Reamer Bushing and Tibial Stem Boss Reamer to the "Boss" depth marking (Figure 9).
For the Keel Baseplate, the Stem Punch Guide is placed in the corresponding holes in the Tibial Template (Figure 10). The Stem Punch is impacted through the cut-out on the guide.

**Femoral and Tibial Trial Assembly**

All trial components required for the trial reduction are shown in Figure 11.

**NOTE:** The 30mm Trial Extension Piece also functions as the Trial Extra-Cortical Body (see Figure 11). Together with the Trial Cemented Stem, it forms the Trial Stem with extra-cortical porous-coated body.
Distal Femoral Surgical Protocol

**Trial Reduction**

The purpose of the trial reduction is to determine the ease of insertion of the femoral and tibial components prior to cementing, and to determine whether the length of the prosthesis is appropriate (Figure 12). If the prosthesis is too long, too much tension will be placed upon the neurovascular structures when the knee is extended. In addition, the extensor mechanism will be tight, causing loss of flexion and difficulty in closing the soft tissues.

To determine the appropriate length, one must extend the knee and monitor the distal pulse with the trial prosthesis in place.

Insert the MRH Trial Tibial Baseplate into the tibia, and impact it using the MRH Tibial Impactor/Extractor until it is flush with the tibial osteotomy.

Construct the Trial Femoral Prosthesis by joining the Trial Cemented Stem with the Trial Extension Piece, if required, and with the Trial Distal Femoral Component.

Insert the stem of the trial femoral assembly into the femur. As a guide to rotational orientation, align the rotational alignment mark on the femoral stem segment with the rotational reference mark previously made on the anterior cortex of the femur (Figure 13).

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**Figure 12**

**Figure 13**

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**GMRS™ Tray No: 1A/1B**

**GMRS™ Tray No: 4A/4B**

**GMRS™ Tray No: 1A**
**SURGICAL TIP:** As an aid in checking leg length, the distance between the leg-length reference marks on the tibia and femur can now be rechecked (see Figure 1c, page 8).

If it is determined that the prosthetic construct is too long, the length of the distal femoral bone resected should be rechecked against the length of the assembled prosthesis. If the prosthesis is too long, either additional bone can be removed from the femur, the length of the prosthesis can be adjusted, or a thinner insert can be evaluated.

If the surgeon feels that removing additional bone from the femur or shortening the femoral prosthesis will have a negative effect on patellar tracking, additional bone must be removed from the tibial side.

A final test of the range of motion of the knee with the patella tracking in place is then performed. If the patella will be resurfaced, this must be done with the patellar trial in place. A full range of motion should be obtained. Note whether the capsular mechanism can be closed. These factors, taken together, will determine the adequacy of the length of the resection.

The two most important factors in accepting final length are:

1. Proper Patellar tracking
2. Distal pulses

The decision can now be made if a gastrocnemius flap or muscle transfer will be required, dependent upon the presence or absence of the capsule or portions of the quadriceps.

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**Figure 14**

Insert the correct Trial Tibial Insert into the MRH Trial Baseplate. Insert the Trial Tibial Rotating Component into the Trial Baseplate assembly. Bring the Trial Tibial Rotating Component up between the femoral condyles and insert the Trial Axle. Then insert the Trial Bumper through the anterior hole of the Trial Tibial Rotating Component (Figure 14).

Manipulating the knee through its range of motion may be used to determine the appropriate rotation of the femoral component. If the evaluation identifies a rotation different than that already marked, an additional mark should be made or the rotation should be noted relative to the existing mark. Slight external rotation may aid in patellar tracking.

Hold the trial femoral assembly in one hand to prevent rotation and extend the leg fully. Palpate the femoral vessels to determine the status of the pulse. If the pulse is diminished, flex the knee to determine if it increases. This will indicate the need for either modifying the length of the prosthesis or for removing additional bone from the distal femur or proximal tibia.
Assembly of the Tibial Stem Implant

To attach a Press-Fit Stem Extender, an 80mm titanium fluted stem extender or a cemented stem extender to the implant, hand tighten the stem into the Tibial Stem Boss as far as possible. Attach the All-in-one Wrench to the Torque Wrench, insert the male hex tip of the wrench into the hex recess on the Stem Extender. Attach the Counter Wrench to the Tibial Baseplate and tighten to 120in/lbs – 180in/lbs (Figure 15).

NOTE: A Stem Extender of at least 80mm should be used on the Tibial Baseplates.

Titanium Tri-Fluted Stem Option

When using a 155mm Titanium Fluted Stem Extender, the Tri-Fluted part of the All-in-one Wrench must be used to apply the final torque to the implant. This adapter is attached to the Torque Wrench and slid into the slots of the Stem until it has bottomed out on the implant. The Stem must be tightened to the final locking torque of 120in/lbs – 180in/lbs (Figure 16).
Assembly of the Femoral Prosthesis

The femoral prosthesis consists of the Stem, Extension Piece (when needed based on the length of the reconstruction), and the Distal Femoral Component (Figure 17). Check that the correct side (left or right) and size (standard or small) for the Distal Femoral Component and the correct sizes of all components have been chosen before assembly. If necessary, it is acceptable to stack two Extension Pieces to construct the necessary length. The instruments used for the assembly of the prosthesis are the Impaction Tube, the appropriate Impaction Tube Insert, the 5-in-1 Impactor and the Impaction Block, if necessary, along with a Mallet.

NOTE: If the small Distal Femoral Component is selected, the small Femoral Bushings (6495-2-105) and the small Axle (6495-2-115) must be used.
The **Impaction Tube Insert** corresponding to the stem diameter is assembled to the **Impaction Tube** *(Figure 18a).* The Extension Piece, if required, and the cemented Stem are assembled first. The cemented Stem is placed into the Impaction Tube and the Extension Piece is mated with it. The **5-in-1 Impactor** is placed over the taper of the Extension Piece and impacted with several swift blows of a heavy **Mallet** to lock the tapers *(Figure 18b).*

Next, the Stem/Extension piece construct is assembled to the Distal Femoral Component. Place the Distal Femoral Component onto the Extension Piece or Stem. The 5-in-1 Impactor is inserted between the condyles of the Distal Femoral Component so that its handle is parallel to the axis of the bushing holes and impacted with a Mallet *(Figure 19a).*

If a 203mm long curved cemented Stem is to be implanted, the Distal Femoral Component is inserted into the **Impaction Support Block**. An Extension Piece, if required, is inserted into the Distal Femoral Component and then the appropriate diameter cemented Stem is inserted into the Extension Piece or Distal Femoral Component. Verify that the bow of the cemented Stem curves towards the posterior of the Distal Femoral Component. The Impaction Tube is inverted and placed over the cemented Stem and impacted with several blows of a heavy mallet, or by sliding the Impaction Tube over the stem like a Slap Hammer *(Figure 19b).*
**Implantation and Orientation of the Tibial and Femoral Prostheses**

To implant the tibial baseplate, the medullary canal is irrigated and dried. Surgical bone cement is applied to the proximal tibia resection and the underside of the baseplate for the press-fit application. The Tibial Impactor/Extractor (Figure 20) is used to impact the Tibial Baseplate to its full depth, ensuring the Keel engages in the prepared bone. The femoral canal is thoroughly irrigated. A cement restrictor is placed at the appropriate depth. This depth is checked by inserting the trial femoral stem and verifying complete seating. The femoral canal is again irrigated and dried. The soft tissues, especially those that are near the neurovascular structures, are protected and packed off with wet lap pads. Bone cement is mixed and injected into the canal to ensure proper filling of the canal. Some cement is then placed around the stem of the prosthesis.

**SURGICAL TIP:** If a stem centralizer is not being used, plug the hole in the stem with bone cement.

The prosthesis is then inserted into the femoral canal until the stem seat is flush with the host bone at the osteotomy site. Excess cement is removed from around the prosthesis. Care is taken to prevent cement from getting into the Extra-Medullary porous-coated section. It is firmly held in place at the rotational orientation determined by the trial reduction while the cement cures.
With the Femoral Prosthesis and Tibial Baseplate implanted, it is possible to use the Trial Axle with the Trial Tibial Rotating Component, the Trial Bumper Insert and Trial Tibial Insert to verify that the appropriate motion, stability and patellar tracking have been achieved. With the knee in full extension this also assists in loading the femoral and tibial baseplate components while the cement is curing to provide an optimal bond between implant and bone (Figure 21).

**Final Implant Assembly**

To complete the assembly of the final implant components, insert the Tibial Sleeve into the Tibial Baseplate until it is flush with the surface (Figure 22).
There are two sizes of Tibial Insert, Small 1/ Small 2 and Medium 2/ Large 2, which fit with the corresponding Tibial Baseplates. They both come in 5 different thicknesses of 10mm, 13mm, 16mm, 20mm and 24mm.

Snap-in the appropriate thickness Tibial Insert, chosen at the trialing stage and drop in the Tibial Rotating Component (Figure 23a).

Insert the two Femoral Bushings into the Femoral Prosthesis so that the flanges are inside the intercondylar cut-out (Figure 23b).

Line up the Tibial Rotating Component with the holes of the Femoral Component Bushings and slide the implant Axle into the assembly (Figure 23c) until the "recess" in the Axle can be seen through the Tibial Rotating Component from the front. Twist the Axle so that the "recess" is inferior. The grooves on the end of the axle which engage into the Axle Introducer Handle are a helpful indicator in aligning the Axle.

With the Axle correctly oriented the Bumper can now be inserted. This should be impacted into the Tibial Rotating Component until it is flush with the hinge housing and has cleared the locking tab on the Tibial Rotating Component (Figure 23c).

**NOTE:** With the Bumper inserted, the axle should not be further rotated.

The Bumper implant is available in two options, neutral and 3° flexion.

If a patellar component is used, it is implanted by applying sufficient amount of bone cement to the patellar implant and bone. Cement should be applied to both the bone surface and the back of the patellar implant, including the pocket.

**SURGICAL TIP:** Application of cement in a low-viscosity state will allow the implant to fully seat and facilitate interdigitation of cement into bone.
Option A: Femoral Referencing Method

Construct the Trial Femoral prosthesis by joining the Trial Stem with the Trial Extension Piece, if required, and the Trial Distal Femoral Component.

With the trial femoral construct in place, the Tibial Resection Level Indicator is inserted into the Trial Distal Femoral Component. The Tibial Resection Level Indicator (Figure 24a) is two-sided. The first side marked “MRH” applies when MRH Tibial Baseplates are used. When the Kinematic® Rotating Hinge All-Poly Tibial Components are used, the second side marked “ALL POLY” applies. With both MRH Tibial Components and All-Poly Tibial Components, the Tibial Resection Level Indicator denotes the proper tibial resection level through etched markings on the resection level indicator shaft. The tibia should be held out to length at the previously determined marking (see Figure 1c on page 8).

The Tibial Resection Guide can be lined up to that mark and held in place by tightening the thumbscrew (Figure 24b). The Alignment Handle can be assembled to the Tibial Resection Guide. Long Alignment Pins are then inserted through the handle to evaluate M/L and A/P alignment. Once alignment and resection level have been determined, pin the Tibial Resection Guide to the tibia using 1/8” pins through the ‘N’ holes.

Begin by setting the Tibial Resection Guide for the thinnest Tibial Insert (Figure 24c). The Tibial Insert thicknesses are: 10mm, 13mm, 16mm, 20mm and 24mm. If the resection level will not remove any bone, the Resection Guide can be set for a thicker Tibial Insert. Be certain not to place too much tension on the tibia during distraction.

If the surgeon feels that too much tibial bone must be removed using the thinnest Tibial Insert, additional bone can be removed from the femur. The level of the patella is checked in reference to the prosthesis to ensure proper patellar tracking.
Remove the Femoral Trial construct and the Tibial Resection Level Indicator by unlocking the thumb screw.

**Proximal Tibial Resection**

Slide the Tibial Resection Guide posteriorly until it comes in contact with the anterior tibia. Placing a 1/8” Drill Pin through the "X" pin hole will further secure the Resection Guide to the tibia.

The Alignment Handle may be used with an Alignment Rod, referencing the same landmarks as outlined previously to verify proper alignment.

Resect the tibial plateau using a .050” (1.27mm) Saw Blade (Figure 25).

If desired, 2mm or 4mm of additional bone may be resected by repositioning the guide over the pins through the -2 or -4 holes, respectively (Figure 26).

**NOTE:** If the "X" Pin hole is used, this pin must be removed prior to repositioning the Tibial Resection Guide.

The Tibial Resection Guide is removed by first removing the “X” pin, then sliding the guide off over the two 1/8” Drill Pins and finally removing the pins with the Pin Puller.

**NOTE:** The 5mm and 10mm slots can be used in revision or trauma cases where bone loss or fracture respectively necessitates the use of half or full tibial augments.
Option B: Extra-Medullary Referencing

With the knee flexed, place the EM Tibial Alignment Guide on the tibial shaft. Place the Ankle Clamp around the distal tibia just above the malleoli.

Place the Fixation Pins of the instrument over the tibial eminence. There should be a finger’s breadth clearance between the proximal shaft of the Alignment Guide and the anterior cortex when the Fixation Pins are positioned properly. Center the Proximal Fixation Pins over the tibial eminence and tap in the most posterior pin first to fix the anterior/posterior location of the head. Rotation is now adjusted and then set by anchoring the second pin. Tighten the vertical screw to secure the proximal shaft of the guide (Figure 27).

Axial alignment is achieved when the vertical shaft of the instrument parallels the long axis of the tibia in both the anterior/posterior and medial/lateral planes (Figure 28, Figure 29).

---

**Figure 27**

**Figure 28**

**Figure 29**
Landmarks used to obtain correct axial alignment and rotation are:

1. Tibial Tubercle – The alignment rod usually lies over the medial third of the tibial tubercle.

2. Second Metatarsal – The second metatarsal generally is in line with the center of the ankle (Figure 30).

Once axial alignment is established, tighten the anterior/posterior and medial/lateral adjustment thumbscrews (Figure 31).
**Tibial Resection Level**

Assemble the **Tibial Stylus** to the Tibial Resection Guide by depressing the locking button on the top of the Tibial Stylus, inserting the stylus into either the medial or lateral holes on the top of the Tibial Resection Guide and releasing the button to lock the Stylus into place (**Figure 32**).

The Stylus has two depth setting options for the Tibial Resection Guide, depending on which end of the stylus is used, 12mm or 18mm. An 18mm resection is required from the tibia if the distal most aspect of the femoral replacement is placed at the same level of the original anatomy. Typically, a 12mm resection would be preferred, which requires resecting an additional 6mm from the femur. The level of the patella should be checked to ensure proper patellar position.

Attach the Tibial Resection Guide/Tibial Stylus assembly to the External Tibial Alignment Guide by sliding it over the top of the proximal shaft, adjusting the stylus to reference the desired point on the tibial plateau (**Figure 33**).
Proximal Tibial Resection

Secure the Tibial Resection Guide to the proximal tibia using two 1/8” Drill Pins, drilling through the "N" holes.

Loosen the thumbscrew that holds the Tibial Resection Guide to the External Tibial Alignment Guide.

Loosen the vertical adjustment thumbscrew on the shaft of the Alignment Guide.

Extract the two headed Fixation Pins on the top of the Alignment Guide from the proximal tibia.

Remove the proximal shaft of the Alignment Guide by sliding it up through the top of the Resection Guide (Figure 34).

Slide the Tibial Resection Guide posteriorly until it comes in contact with the anterior tibia.

Placing a 1/8” Drill Pin through the "X" pin hole will further secure the Resection Guide to the tibia.

The Alignment Handle may be used with an Alignment Rod, referencing the same landmarks as outlined previously to verify proper alignment.

Resect the plateau using a .050” (1.27mm) Saw Blade (Figure 35).

If desired, 2mm or 4mm of additional bone may be resected by repositioning the guide over the pins through the -2 or -4 holes respectively (Figure 36).

**NOTE:** If the "X" Pin hole is used, this pin must be removed prior to repositioning the Tibial Resection Guide.

The Tibial Resection Guide is removed by first removing the “X” pin, then sliding the guide off over the two 1/8” drill pins and then removing the pins with the Pin Puller.
Option C: Intra-Medullary Referencing

Using the 3/8” IM Drill an entry hole is prepared in the location determined by the pre-operative X-rays, or just anterior to the ACL insertion. (Figure 37). Alternatively, a suitably sized Tibial Template can be used to locate the center of the cavity to be prepared for the Stem.

Attach the pre-determined diameter IM Rod (1/4”, 5/16”, or 3/8”) to the T-Handle by depressing the button, inserting the IM Rod fitting, and releasing the button to lock into place. Pre-operative X-ray templating will aid in the determination of the IM Rod diameter. Introduce the IM Rod into the entry hole and gradually advance it down the Intra-Medullary canal (Figure 38).

Several steps may be taken to avoid an increase in Intra-Medullary pressure:

A. Advance the IM Rod slowly;
B. Rotate the IM Rod within the canal during advancement;
C. Apply suction to the fitting on the end of the cannulated IM Rod.
D. Use next smallest IM Rod.
The proximal portion of both the 3/8" and 1/4" diameter IM Rods changes to 5/16" in diameter. It is necessary to insert those rods so that the diameter transition point is within the Intra-Medullary canal. The 5/16" diameter IM Rod may be inserted to any depth up to the scribe mark on the proximal shaft. Once the IM Rod is positioned, remove the T-Handle (Figure 39).

Intra-operative X-Rays may be obtained to confirm accurate position of the rod in the canal.

Slide the IM Tibial Alignment Guide over the Alignment Rod (Figure 40).

**Rotational Alignment**

With the body of the IM Tibial Alignment Guide resting on the proximal tibia, alignment is achieved by rotating the instrument about the IM Rod so that the tibial tubercle appears slightly lateral to the vertical mounting bar. The Headed Nail is impacted, fixing rotational alignment (Figure 41).

Assemble the appropriate Tibial Resection Guide to the IM Tibial Alignment Guide by sliding the Tibial Resection Guide onto the mounting bar of the Alignment Guide and tightening the thumbscrew on the Resection Guide (Figure 42).
Attach the Alignment Handle to the Resection Guide, and slide a Long Alignment Rod into the Alignment Handle. When proper varus/valgus alignment is attained, the pin should be centered over the ankle (Figure 43).

Assemble the Tibial Stylus to the Tibial Resection Guide by depressing the button on the top of the Tibial Stylus, inserting the stylus into either the medial or lateral hole on the top of the Tibial Resection Guide, and releasing the button to lock the stylus into place (Figure 44).
Loosen the thumbscrew and position the Tibial Resection Guide/Tibial Stylus Assembly to reference the desired point on the tibial plateau. Secure the Tibial Resection Guide/Tibial Stylus Assembly to the IM Tibial Alignment Guide by retightening the thumbscrew (Figure 45).

**Proximal Tibial Resection**

Once the resection level is established, secure the Tibial Resection Guide to the anterior tibia using the 1/8” Drill Pins, drilling through the “N” holes.

Remove the Tibial Stylus by depressing the button and pulling the stylus out.

Release the IM Tibial Alignment Guide from the Tibial Resection Guide by loosening the thumbscrew on the Resection Guide. Re-attach the T-Handle to the IM Rod and extract both the IM Rod and IM Tibial Alignment Guide together, leaving the Tibial Resection Guide pinned in place.

Pinning through the “X” Pin Hole will further secure the Tibial Resection Guide to the tibia (Figure 46).

Resect the tibial plateau through the most proximal slot in the Tibial Resection Guide. Use of a .050” (1.27mm) Saw Blade is recommended for an accurate resection (Figure 47).
Additional bone may be resected by repositioning the Tibial Resection Guide over the pins in the -2 or -4 holes to resect an additional 2mm or 4mm of bone, respectively (Figure 48).

**NOTE:** If the "X" Pin hole is used, this pin must be removed prior to repositioning the Tibial Resection Guide.

The Tibial Resection Guide is removed by first removing the 'X' Pin, then sliding the Block off over the two 1/8" drill pins and then removing the pins with the Pin Puller.

**NOTE:** The 5mm and 10mm slots can be used in revision or trauma cases where bone loss or fracture respectively necessitates the use of half or full tibial augments.
APPENDIX II

Tibial Preparation for the All-Poly Tibial Component
Appendix II

Tibial Preparation for the All-Poly Tibial Component

The proximal tibial cut for the All-Poly Tibial Component is a neutral cut, i.e. classical alignment with no posterior slope.

The All-Poly Tibial component comes in five sizes: XSML, SML, MED, LRG and XLRG. Each size component has four thicknesses: 8mm, 11mm, 16mm and 21mm.

Establishing the depth of the tibial cut for the All-Poly Tibial components is the same as described in Appendix I. With regard to the Femoral Referencing Method (Option A), the Tibial Resection Level Indicator is used with the side marked "ALL POLY".

Verifying Alignment

Select the appropriate All Poly Tibial Template and lock it onto the Tibial Alignment Handle. The appropriate size Template will achieve cortical support around the periphery of the template. The long Alignment Pin assembled with the Alignment Handle verifies rotational, Varus/Valgus, and flexion-extension alignment (Figure 49).
Rotational alignment is correct when the drill bit placed in a hole from the tibial resection step is parallel to the handle (Figure 50). Varus/Valgus and flexion/extension is verified with a Long Alignment Pin.

Holes are located on the anterior face and posterior surface of the Template. Headed Nails or drills through these holes may be used to temporarily fix the Template.

**NOTE:** It is important that the correct size be selected to fully support the All-Poly Tibial Component around the periphery with cortical bone.

---

**Round Stem Punch**
To begin preparation for the Kinematic® Rotating Hinge All-Poly Tibial Component, place the Stem Punch Guide (Figure 51a) on the Tibial Template. Insert the Stem Punch into the guide and slowly impact the punch until it is flush with the guide (Figure 51b).
Care should be taken that the Tibial Template stays flush on the tibia. The Plunger is then inserted into the hole of the Stem Punch and impacted flush (Figure 52a).

This will position a bone plug at the distal tip of the Tibial Component stem, plugging the canal. Remove the plunger. The Stem Punch can be removed with the Impactor/Extractor (Figure 52b).

Initial Fin Punch

Place the rectangular Fin/Box Punch Guide on the Tibial Template (Figure 53a). Insert the initial “Thin” Fin Punch into the cut-out of the guide and slowly impact the punch until it is flush with the surface of the guide. During insertion, it is important to precisely control the Stem Punch, maintaining it perpendicular to the resected surface. Slowly impact the Fin Punch to allow expansion of the bone (Figure 53b).

Remove the Fin Punch with the Impactor/Extractor.
Initial Fin Broach

Insert the “Thick” Fin Broach (Figure 54) into the cut-out of the guide and slowly impact the broach until it is flush with the surface of the guide. During insertion, it is important to precisely control the Fin Broach, maintaining it perpendicular to the resected surface.

Remove the Fin Broach with the Impactor/Extractor.

Box Broach

Insert the Box Broach (Figure 55) into the cut-out of the guide and slowly impact the broach until it is flush with the surface of the guide. During insertion, it is important to precisely control the Box Broach, maintaining it perpendicular to the resected surface.

Remove the Box Broach with the Impactor/Extractor.

---

**Initial Fin Broach**

Insert the “Thick” Fin Broach (Figure 54) into the cut-out of the guide and slowly impact the broach until it is flush with the surface of the guide. During insertion, it is important to precisely control the Fin Broach, maintaining it perpendicular to the resected surface.

Remove the Fin Broach with the Impactor/Extractor.

Box Broach

Insert the Box Broach (Figure 55) into the cut-out of the guide and slowly impact the broach until it is flush with the surface of the guide. During insertion, it is important to precisely control the Box Broach, maintaining it perpendicular to the resected surface.

Remove the Box Broach with the Impactor/Extractor.

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6737-8-365

“Thick” Fin Broach

GMRS™ Tray No: 8B

6737-8-370

Box Broach

GMRS™ Tray No: 8B
Final Stem Preparation

The tibial template is removed using the Headed Nail Impactor/Extractor and/or the Pin Puller. The Stem Reamer (Figure 56) is inserted into the center hole of the tibia and slowly turned in a clockwise direction and advanced into the tibia until the circumferential depth mark is flush with the cut surface of the tibia.

SURGICAL TIP: Several shallow drill holes can be made in the proximal tibia to enhance cement fixation.

The Trial Assembly/Trial Reduction/Implant Assemblies (Figure 57) and Final Implantation follows the same steps as described on pages 17 through 25.

Figure 56

Figure 57
APPENDIX III
Taper Disassembly
Appendix III

Taper Disassembly

Should it be necessary to disengage an assembled taper joint, a taper separator is provided. The taper separator utilizes the mechanical advantage of a wedge(s) and lever arm to overcome the locking forces of the tapers and separate the components. It is important that the separator be positioned so that the wedge(s) does not act against the antirotation tabs of the implants. The correct orientation is in an anterior-to-posterior direction. The implants are designed to withstand the forces generated by the separator in this direction. Placement of the separator wedges against the anti-rotation tabs may damage them, making disengagement difficult. The separator may be used via three different methods.

Method 1
The wedges are initially advanced by hand to bring them in contact with the implant at the joint to be disengaged. The wedges are advanced by turning the nut in a clockwise direction, until resistance is felt (Figure 58a). The wedges are then further advanced, using the wrench end of the 5-in-1 impactor provided, until the tapers disengage.

Method 2
The wedges of the separator are advanced until they are sufficiently tight against the taper junction to be separated using the wrench end of the 5-in-1 impactor. A mallet can then be used to impact the chisel component of the separator. The separator is design to allow the nut and chisel to travel a small distance when impacted to ease separation.

Method 3
The separator can be disassembled and the chisel component of the assembly can be used by itself to separate a taper junction (Figure 58b). The chisel is inserted anteriorly at the location to be separated and impacted with a mallet until separation is achieved.

Caution should be taken when disengaging any taper-locked joint. The high forces that hold a taper-locked joint together may result in a sudden and forceful action upon disengagement along the axis of the tapers.
IMPLANT LISTING
and
RESECTION LENGTH
OVERVIEW CHART
### Distal Femoral Surgical Protocol

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<th>Description</th>
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<th>MEDIUM Cat. No.</th>
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<th>X-LG Cat. No.</th>
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### Distal Femur Resection Lengths

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