GMRS Distal Femur Global Modular Replacement System

Surgical protocol

Implants

Surgical protocol

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This publication sets forth detailed validated procedures for using the GMRS Distal Femur Global Modular Replacement System. It offers instructions 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.

Introduction

The GMRS standard Distal Femur accepts the Modular Rotating Hinge (MRH) Tibial Bearing Component, Bushings, Axle and Bumper allowing for seamless integration with the MRH resurfacing Tibial Baseplate.

The GMRS Distal Femur offers six cemented stem options: straight, curved and long curved; each type with or without extra-cortical porous-coated body sections.





Description of the Global Modular Replacement System

The GMRS was developed for reconstruction of large segmental defects for tumors, failed previous arthroplasty, or trauma. This system is designed to:

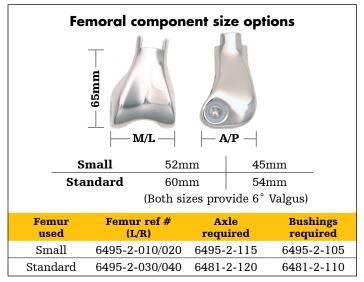
- Reconstruct large segmental defects of the knee.
- Reconstruct osteoarticular defects of varying sizes.
- Allow for variation and intra-operative changes of the surgical plan.

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



All distal femoral components have a built-in 6° Valgus offset and utilize the Modular Rotating Hinge (MRH) Knee components.

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

Stem components

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:

Stem diameter	Seat diameter	
Ø 8,9mm	Ø 22mm	
Ø 10,11mm	Ø 24mm	
Ø 13mm	Ø 28mm	
Ø 15mm	Ø 32mm	
Ø 17mm	Ø 36mm	

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.

Extension pieces

The Extension Pieces are used to customize the replacement length and are available in 30mm, 40mm, 50mm, 60mm, 70mm, 80mm, 100mm, 120mm, 140mm, 160mm, 180mm, 200mm and 220mm lengths. This component features a male and female taper. which attaches a stem to a 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 Bearing Component only (6481-2-103).

Note:

The All-Poly Tibial Component is intended for use only 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 Bearing Component only (6481-2-100).

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.

Total Femur Connection Pieces

The Total Femoral Replacement System consists of a proximal femoral component, connection piece, extension piece and condyle. The proximal femoral component, extension piece and condyle are the same mentioned previously. The connection pieces are available in left or right configuration and various lengths. There is a male taper on each end that assembles with the proximal femoral component, extension piece or distal condyle section. There are anti-rotation features adjacent to the male tapers for positioning with the other components. The GMRS connection pieces are manufactured from Wrought Titanium 6AI-4V Alloy conforming to ASTM standard F136.



Indications for 6495-2-115 and 6495-3-601 implants:

Indications for U.S. and rest of world:

The Modular Replacement Systems are intended for use in patients requiring extensive reconstruction of the hip joint and/or knee joint, including knee fusions, necessitated by extensive bone loss due to trauma, failed previous prothesis and/or tumor reaction.

Indications for EU, EMEA countries requiring the CE mark, and Australia:

The Modular Replacement Systems are intended for use in patients requiring extensive reconstruction of the hip joint and/or knee joint, necessitated by extensive bone loss due to trauma, failed previous prosthesis and/or tumor resection.

Indications for 6481-2-100, 6481-2-120, 6481-3-110, 6481-3-111, 6481-3-112, 6481-3-113 implants:

Rotating Hinge Knee Systems are intended to be implanted with bone cement for the following condition(s):

- 1. There is destruction of the joint surfaces, with or without significant bone deformity.
- 2. The cruciate and/or collateral ligaments do not stabilize the knee joint.
- 3. The ligaments are inadequate and/or the musculature is weak. And/or,
- 4. Revision is required of a failed prosthesis where there has been gross instability, with or without bone loss or inadequate soft tissue.

Indications for 6481-2-107, 6485-3-211, 6485-3-213, 6485-3-215, 6485-3-217 implants:

Indications for U.S. and rest of world:

The Modular Replacement System is intended for use in Oncology patients requiring extensive reconstruction of the proximal tibia and/or proximal humerus, including the knee joint and knee fusions, necessitated by extensive bone loss due to tumor resection. These prostheses are intended for use with bone cement as a means of intramedullary fixation.

The Proximal Femoral Segment is intended for use in patients requiring extensive reconstruction of the femur and/or hip joint necessitated by trauma, failed previous prosthesis and/ or tumor resection.

Indications for EU, EMEA countries requiring the CE mark, and Australia:

The Modular Replacement System is intended for use in Oncology patients requiring extensive reconstruction of the proximal tibia including the knee joint, necessitated by extensive bone loss due to tumor resection. These prostheses are intended for use with bone cement as a means of intramedullary fixation.

The Proximal Femoral Segment is intended for use in patients requiring extensive reconstruction of the femur and/or hip joint necessitated by trauma, failed previous prosthesis and/ or tumor resection.

Indications for 6878-6-XXX implants:

Indications for U.S. and rest of world:

Indications for use of total knee replacement prostheses include:

- 1. noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis or avascular necrosis;
- 2. rheumatoid arthritis;
- 3. correction of functional deformity;
- 4. revision procedures where other treatments or devices have failed;
- 5. post-traumatic loss of joint anatomy, particularly when there is patello-femoral erosion, dysfunction or prior patellectomy; and,
- 6. irreparable fracture of the knee

Indications for EU, EMEA countries requiring CE mark, and Australia:

When used with the Modular Rotating Hinge Knee System, these components are intended to be implanted with bone cement for the following.

- 1. There is destruction of the joint surfaces with or without significant bone deformity;
- 2. The cruciate and/or collateral ligaments do not stabilize the knee joint;
- 3. The ligaments are inadequate and/or the musculature is weak; and/or
- 4. Revision is required of a failed prosthesis where there has been gross instability, with or without bone loss in adequate soft tissue.

Pre-operative planning is an essential part of the procedure and templating should be performed prior to every case. The preoperative planning process should take qualitative and quantitative factors (including patient bone quality, density, and morphology) into consideration in order to evaluate and select the appropriate instrument/implant system for the patient. X-ray evaluation may also help detect anatomic anomalies that could prevent the intra-operative achievement of the established preoperative goals. Selecting potential implant style and sizes can facilitate operating room preparation and assure availability of an appropriate selection. When it is done using x-rays that have been suitably scaled for magnification, templating allows the surgeon to predict the style, size, and position of the implant that may help restore the correct anatomy of the individual patient. Template planning can be done using acetate templates for printed x-rays or preoperative planning software for digital studies. Use the template overlay {Global Modular Replacement System GMRS Template LTEMK29} available through your Stryker representative.

Warnings and precautions:

See package insert for warnings, precautions, adverse effects, information for patients and other essential product information. Before using instrumentation, verify:

- · Instruments have been properly disassembled prior to cleaning and sterilization;
- Instruments have been properly assembled post-sterilization;
- Instruments have maintained design integrity; and,
- Proper size configurations are available.
- For Instructions for Cleaning, Sterilization, Inspection and Maintenance of Orthopaedic Medical Devices, refer to LSTPI-B and SLI0001 (ifu.stryker.com).

Contraindications for 6495-2-115 and 6495-3-601 implants:

A. As related to bone tumors:

Not all bone tumors may be treated successfully by segmental resection. Any condition that may have already resulted in either local or distant spread of the tumor may be a contraindication.

Examples of such conditions include:

- 1. Pathological fracture;
- 2. Overt infection;
- 3. Inopportune placement of biopsy incision; and,
- 4. Rapid disease progression beyond a respectable margin.

Each patient must therefore be individualized and carefully evaluated by appropriate staging techniques prior to consideration of segmental replacement.

B. As related to failed previous prosthesis and trauma:

- 1. Any active or suspected latent infection in or about the operative joint.
- 2. Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complication in postoperative care.
- 3. Bone stock compromised by disease, infection, or prior implantation, which cannot provide adequate support and fixation of the prosthesis.
- 4. HA coated stems are contraindicated in situations where bone stock is inadequate to support press fit application.

Contraindications for 6481-2-100, 6481-2-120, 6481-3-110, 6481-3-111, 6481-3-112, 6481-3-113 implants:

Absolute contraindications include:

- 1. overt infection;
- 2. distant foci of infections (which may cause hematogenous spread to the implant site);
- 3. rapid disease progression as manifested by joint destruction or bone resorption apparent on roentgenogram;
- 4. skeletally immature patients;
- 5. cases where there is poor bone stock which would make the procedure unjustifiable.

Conditions presenting an increased risk of failure include:

- 1. uncooperative patient or patient with neurologic disorder, incapable of following instructions;
- 2. osteoporosis;
- 3. metabolic disorders which may impair bone formation or cause bone loss:
- 4. osteomalacia; and,
- 5. previous arthrodesis.

A higher incidence of implant failure has also occurred in paraplegics, cerebral palsy and patients with Parkinson's disease.

Contraindications for 6481-2-107, 6485-3-211, 6485-3-213, 6485-3-215. 6485-3-217 implants:

Not all bone tumors may be treated successfully by segmental resection. Any condition that may have already resulted in either local or distant spread of the tumor may be a contraindication. Examples of such conditions include:

- 1. pathological fracture;
- 2. overt infection;
- 3. inopportune placement of biopsy incision; and,
- 4. rapid disease progression beyond a respectable margin.

Each patient must therefore be individualized and carefully evaluated by appropriate staging techniques prior to consideration of segmental replacement.

Contraindications for 6878-6-XXX implants:

Absolute contraindications include:

- 1. overt infection;
- 2. distant foci of infections (which may cause hematogenous spread to the implant site);
- 3. rapid disease progression as manifested by joint destruction or bone absorption apparent on roentgenogram;
- 4. skeletally immature patients;
- 5. cases where there is poor bone stock which would make the procedure unjustifiable.

Conditions presenting increased risk of failure include:

- 1. uncooperative patient or patient with neurological disorders who is incapable of following instructions;
- 2. osteoporosis;
- 3. metabolic disorders which may impair bone formation;
- 4. osteomalacia; and,
- 5. previous arthrodesis.

A higher incidence of implant failure has also occurred in paraplegics and patients with cerebral palsy or Parkinson's disease.



Figure 1a

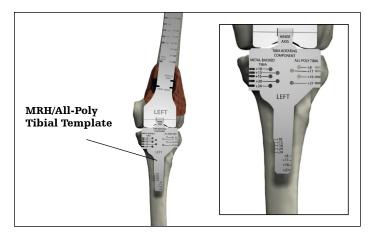


Figure 1b

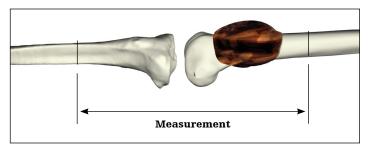


Figure 1c

Measuring resection length

The Distal Femoral Template is designed 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 are designed to 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**).

6496-9-069 Distal Femoral Template GMRS Tray No: 1A



6496-9-071 MRH/All-Poly Tibial Template

GMRS Tray No: 1A



Note:

Frame color around each instrument indicates the corresponding GMRS instrument tray color. Instruments without a colored frame are instruments from the MRH or the Duracon TS Instrument Trays.

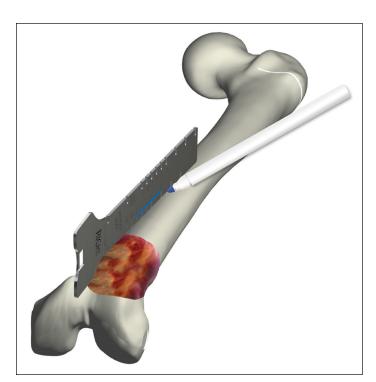


Figure 2



Figure 3

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. (**Figure 3**)

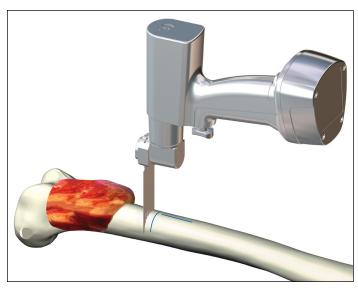


Figure 4

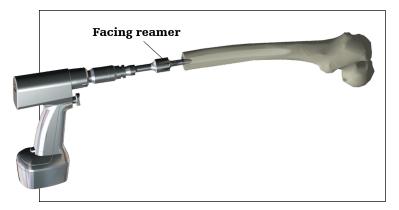


Figure 5

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 4); 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 facing reamer (Figure 5) 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 5**) is used to plane the osteotomy site so as to facilitate direct contact and accurate seating of the prosthesis upon the cortices.



Stem diameter	Suggested Flexible Reamer diameter	Seat diameter
Ø 8mm	Ø 10mm	Ø 22mm
Ø 9mm	Ø 11mm	Ø 22mm
Ø 10mm	Ø 12mm	Ø 24mm
Ø 11mm	Ø 13mm	Ø 24mm
Ø 13mm	Ø 15mm	Ø 28mm
Ø 15mm	Ø 17mm	Ø 32mm
Ø 17mm	Ø 19mm	Ø 36mm

The chosen Trial Stem is inserted to evaluate ease of insertion and an appropriate cement mantle. The trial cemented stems are designed to be 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.

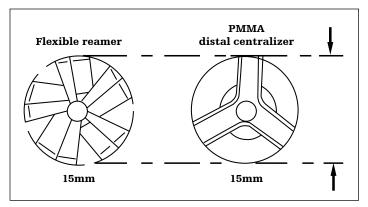


Figure 6

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 6**).

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 stems. The other three options can be reviewed in Appendix I.

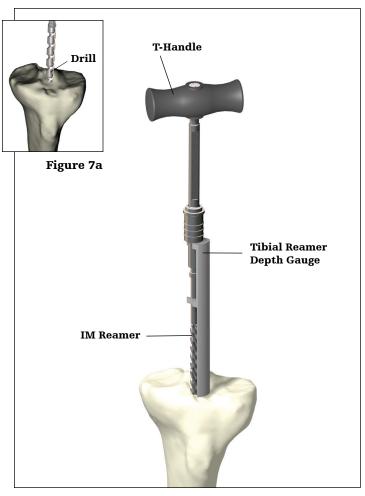


Figure 7b

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.

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 joint line, 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) 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 overhanging 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.

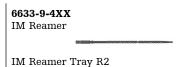
Using the 3/8" IM Drill an entry hole is prepared in the location determined by the pre-operative x-rays, or just anterior to the ACL insertion (Figure 7a).

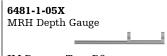
The proximal tibial canal is prepared manually with a T-Handle attached to a fluted IM Reamer to accept the appropriate stem of the baseplate. The Reamer has cutting teeth that are designed to cut when the Reamer turns in a clockwise direction while being advanced. If the reaming becomes difficult, the 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 7b).









IM Reamer Tray R2

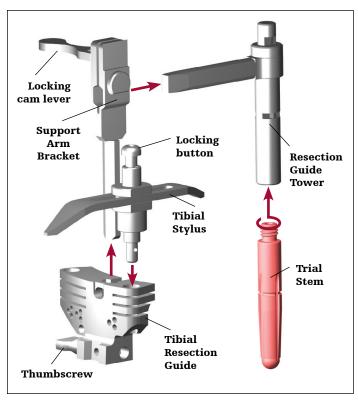


Figure 8a

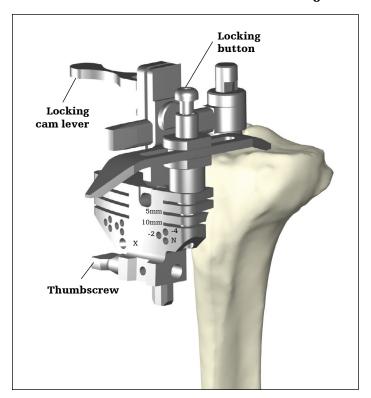


Figure 8b

Establishing the depth of the tibial cut

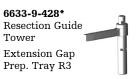
Based on the last size reamer used, the appropriate diameter and length Trial Stem is assembled to the Resection Guide Tower. Assemble the Tibial Stylus to the appropriate, left or right, Tibial Resection Guide by depressing the locking button on top of the Tibial Stylus, inserting the stylus into either 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 8a).

This instrument assembly is inserted into the tibial canal until the stylus references the desired point on the tibial plateau (Figure 8b). 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 Bearing 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 femoral assembly.







6496-9-051/052 Tibial Resection Guide Trial Stem Tray R6 OR Tray 8A

8200-0034 Support Arm Bracket

Trial Stem Tray R6

Locking cam lever

Support

Arm Bracket

Tibial

Resection

Guide

Thumbscrew

1/8" Drill

Pin

Figure 8c

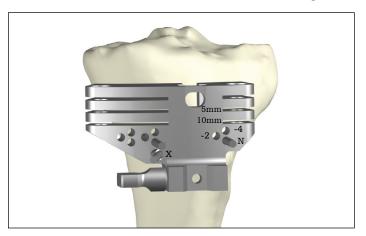


Figure 8d

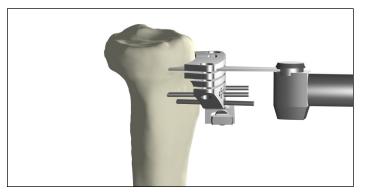


Figure 8e

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 8c**).

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 8d**).

Resect the tibial plateau through the most proximal slot in the Tibial Resection Guide. Use of a .050" (1.27mm) sawblade is recommended (**Figure 8e**).

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 8d).

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.



6633-7-605 Pin Puller Extension Gap

Prep Tray R3



Use the Stem Extender Rod, attached to a Trial Stem,

Bushing to center the Tibial Template with the Stem

placed through the "NT" hole position of the Handle to

The tibial tubercle will normally be positioned just

lateral to the pin which should be centered distally

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"

through the Alignment Reamer Guide and Neutral

With the knee in full flexion, and the Alignment Handle attached to the Template, an Alignment Rod is

construct in the canal (Figure 9).

over the center of the ankle.

depth marking (Figure 10).

verify alignment.

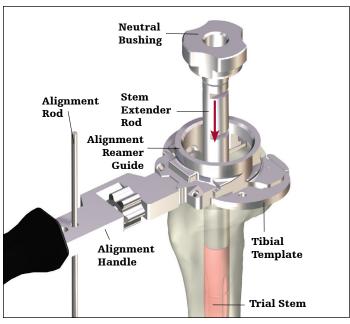
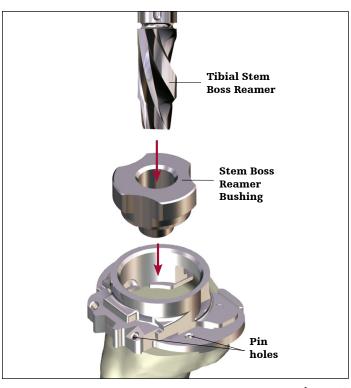


Figure 9



6778-6-XXX

Figure 10

6633-9-861

Alignment Reamer Guide



6633-9-426

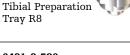
6838-7-2XO Alignment Rod Extension Gap

6633-9-900* Stem Boss Reamer Bushing



MRH Instrument Tray H1

MRH Instrument Tray H1



6633-9-8XX Tibial Template Tibial Preparation Tray R8

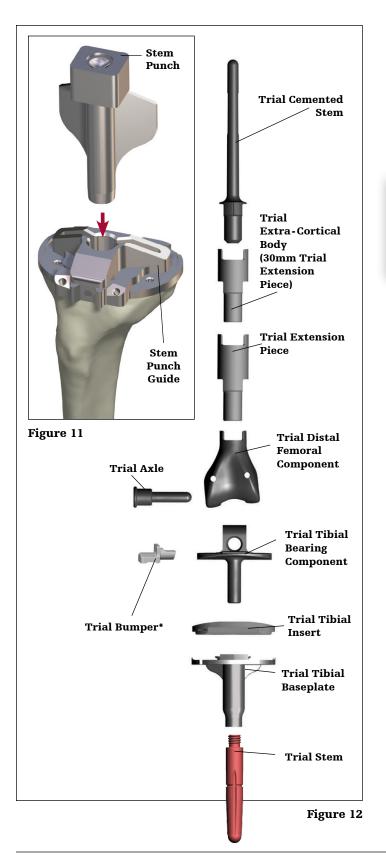
6481-8-520

6633-9-910* Neutral Bushing

Tibial Stem Boss Reamer



*This product is not CE marked in accordance with applicable EU regulations and directives. Stryker is not marketing or distributing this product in the EU. Any reference to this product is for presentation purposes only.



For the Keel Baseplate, the Stem Punch Guide is placed in the corresponding holes in the Tibial Template (Figure 11). 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 12).

Note:

The 30mm Trial Extension Piece also functions as the Trial Extra-Cortical Body (see Figure 12). Together with the Trial Cemented Stem, it forms the Trial Stem with extra-cortical porous-coated body.

6633-9-86X Stem Punch Guide

Tibial Prep Tray R8



6633-7-3XX Stem Punch Tibial Prep





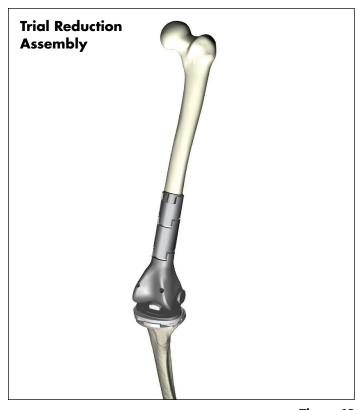


Figure 13

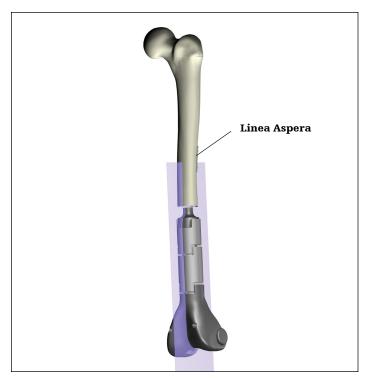


Figure 14

Trial reduction

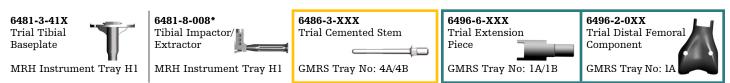
The purpose of the trial reduction is to determine the ease of insertion of the femoral and tibial components prior to cementing and to determine whether the length of the prosthesis is appropriate (Figure 13). If the prosthesis is too long, too much tension will be placed upon the neurovascular structures 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 14).



Insert the correct Trial Tibial Insert into the MRH Trial Baseplate. Insert the Trial Tibial Bearing Component into the Trial Baseplate assembly. Bring the Trial Tibial Bearing Component up between the femoral condyles and insert the Trial Axle. Then insert the Trial Bumper through the anterior hole of the Trial Tibial Bearing Component (Figure 15).

Manipulating the knee through its range of motion may help 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.

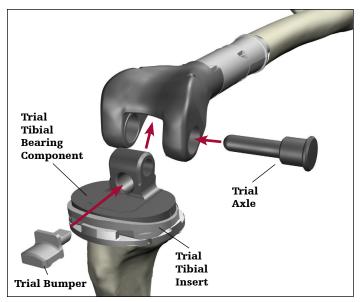


Figure 15

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 9).

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.

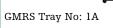
6481-3-XXX Trial Tibial Insert.





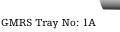


6496-2-115 Trial Axle





Trial Bumper



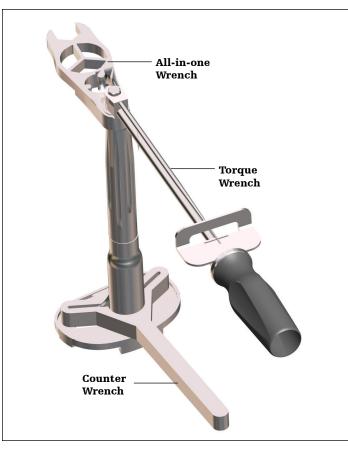


Figure 16



Figure 17

8200-0105* All-in-one Wrench MRH Instrument Tray H2

6633-9-986 Torque Wrench MRH Instrument Tray H2

6632-7-010 Counter Wrench

Tibial Prep Tray R8

Assembly of the tibial stem implant

To attach a CoCr Stem, or 80mm titanium fluted stem 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. Attach the Counter Wrench to the Tibial Baseplate and tighten to 120in/lbs – 180in/lbs (**Figure 16**).

Note:

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

Titanium tri-fluted stem option

When using a 155mm Titanium Fluted Stem, the trifluted 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 17**).

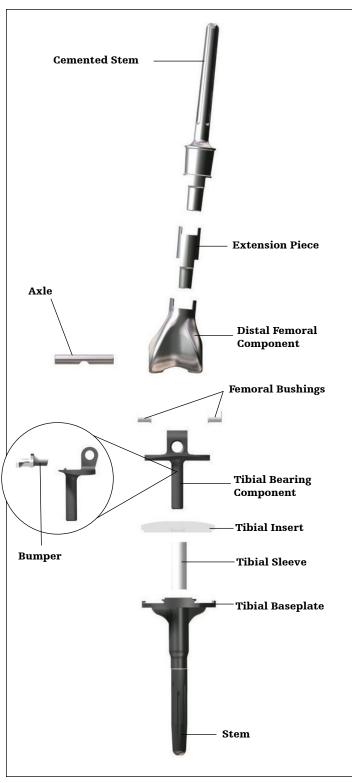


Figure 18

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 18). 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.

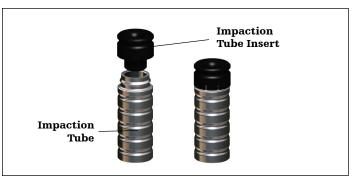


Figure 19a

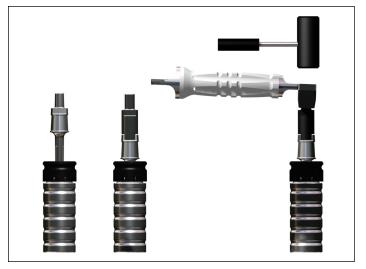


Figure 19b

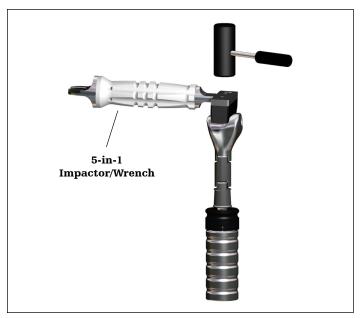
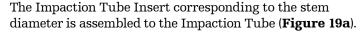


Figure 20a



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 19b**).

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-l 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 20a**).

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 20b**).



Figure 20b

6496-9-065/066 Impaction Tube Insert





6496-9-053 Impaction Tube





6496-9-063 5-in-1 Impactor

5-in-1 Impacto



6496-9-064

Impaction Support Block







Figure 21

Implantation and orientation of the tibial and femoral prostheses

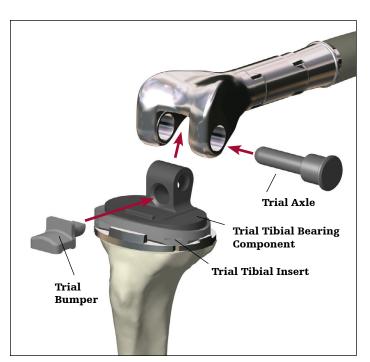
To implant the tibial baseplate, the medullary canal is irrigated and dried. Surgical bone cement is applied to the proximal tibia resection and the underside of the baseplate. The Tibial Impactor/Extractor (Figure 21) is used to impact the Tibial Baseplate to its full depth, ensuring the Keel engages 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, the Trial Axle with the Trial Tibial Bearing Component, Trial Bumper Insert and Trial Tibial Insert can be used to help verify that the desired 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 facilitate a proper bond between



Final implant assembly

implant and bone (Figure 22).

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 23).





Figure 23

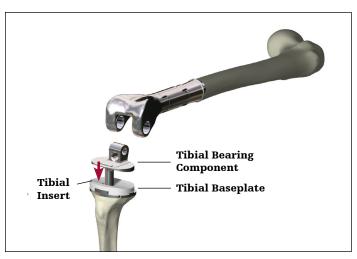


Figure 24a

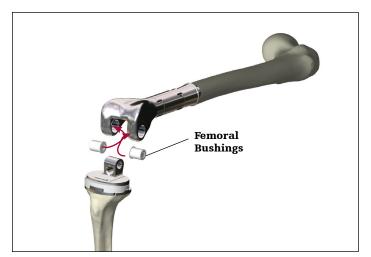


Figure 24b

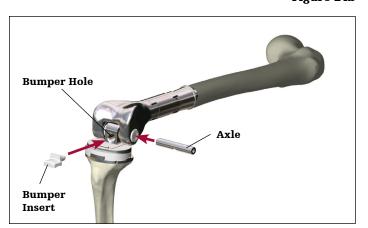


Figure 24c

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 Bearing Component (Figure 24a).

Insert the two Femoral Bushings into the Femoral Prosthesis so that the flanges are inside the intercondylar cut-out (Figure 24b).

Line up the Tibial Bearing Component with the holes of the Femoral Component Bushings and slide the implant Axle into the assembly (Figure 24c) until the "recess" in the Axle can be seen through the Tibial Bearing 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 Bearing Component until it is flush with the hinge housing and has cleared the locking tab on the Tibial Bearing Component (Figure 24c).

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.

Appendix I

Establishing the depth of the tibial cut



Figure 25a

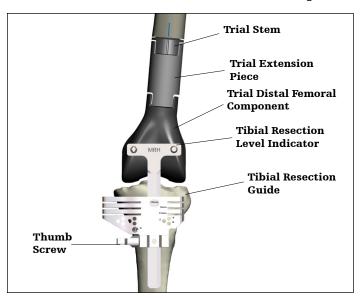


Figure 25b

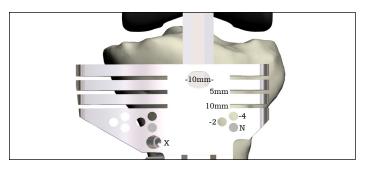


Figure 25c

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.

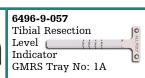
With the trial femoral construct in place, the Tibial Resection Level Indicator is inserted into the Trial Distal Femoral Component. The Tibial Resection Level Indicator (Figure 25a) is two-sided. The first side marked "MRH" applies when MRH Tibial Baseplates are used. When the Kinematic Rotating Hinge 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 is designed to denote 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 9).

The Tibial Resection Guide can be lined up to that mark and held in place by tightening the thumbscrew (**Figure 25b**). 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.

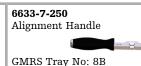
Begin by setting the Tibial Resection Guide for the thinnest Tibial Insert (**Figure 25c**). The Tibial Insert thicknesses are: 10mm, 13mm, 16mm, 20mm and 24mm. If the resection level will not remove any bone, the Resection Guide can be set for a thicker Tibial Insert. Be certain not to place too much tension on the tibia during distraction.

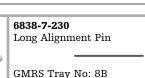
If the surgeon feels that too much tibial bone must be removed using the thinnest Tibial Insert, additional bone can be removed from the femur. The level of the patella is checked in reference to the prosthesis to ensure proper patellar tracking.











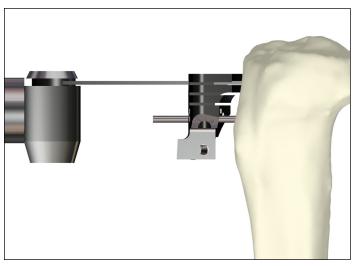


Figure 26

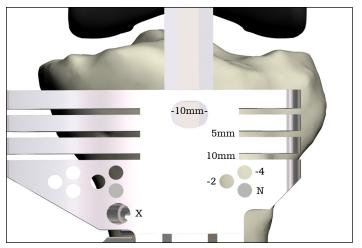


Figure 27

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 26**).

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 27**).

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.

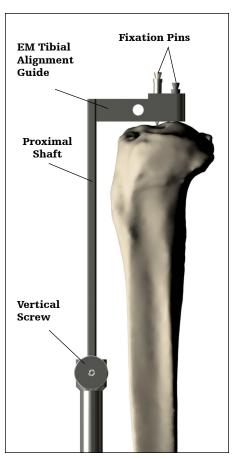
Option B:

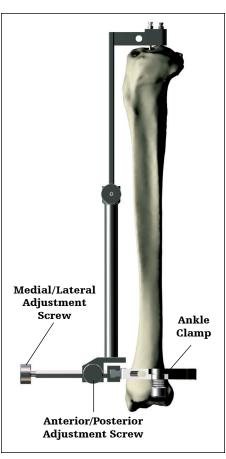
Extra-medullary referencing

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 28).

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 29, Figure 30).





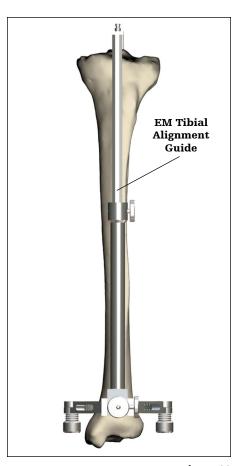
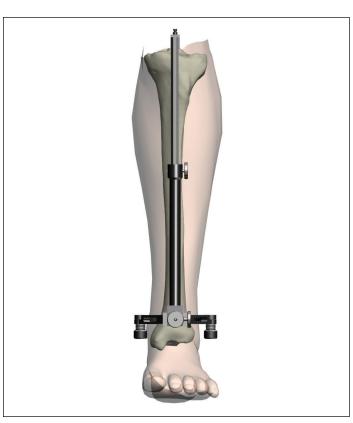


Figure 28

Figure 29

Figure 30

8000-1056 8000-1040 EM Tibial Alignment Guide Ankle Clamp GMRS Tray No: 8A GMRS Tray No: 8A



Landmarks used to help facilitate 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 31).

Once axial alignment is established, tighten the anterior/posterior and medial/lateral adjustment thumbscrews (Figure 32).



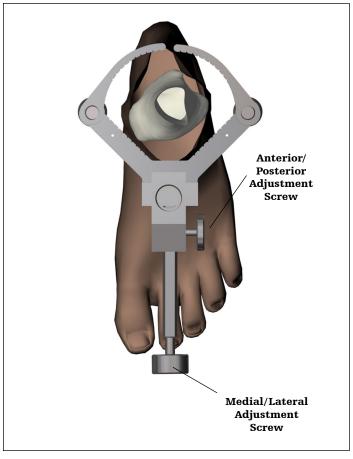


Figure 32

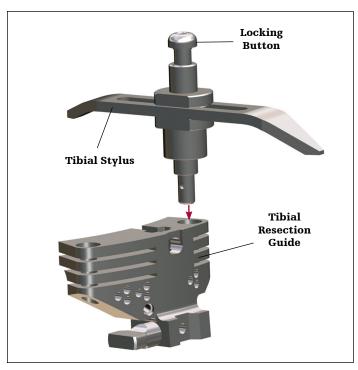


Figure 33



Figure 34



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 33).

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 34).

Figure 35

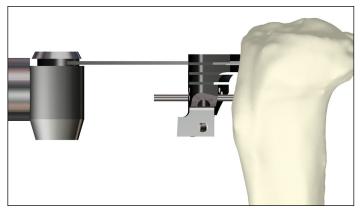


Figure 36

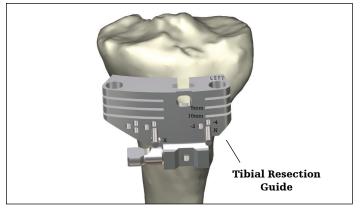


Figure 37

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 35**).

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 help verify proper alignment.

Resect the plateau using a .050" (1.27mm) saw blade (**Figure 36**).

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 37**).

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.

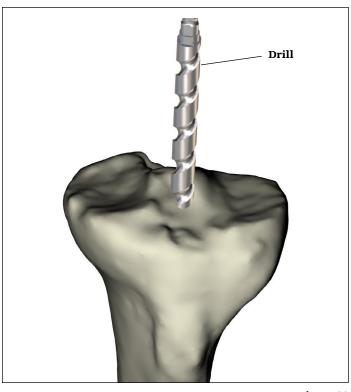


Figure 38

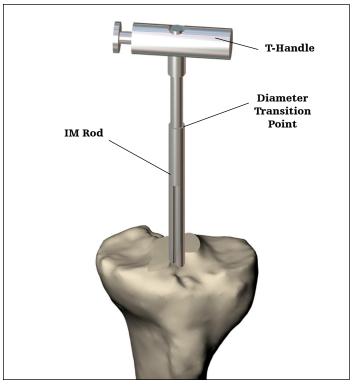


Figure 39

Option C:

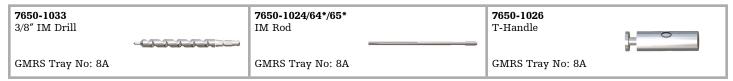
Intra-medullary referencing

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 38). 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 39).

Several steps may be taken to help 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.



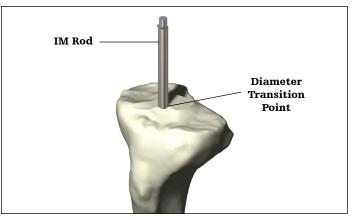


Figure 40

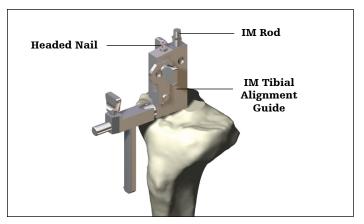


Figure 41

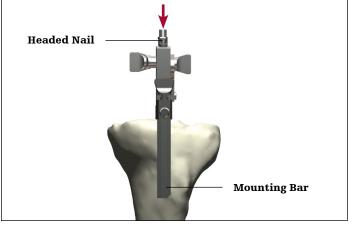
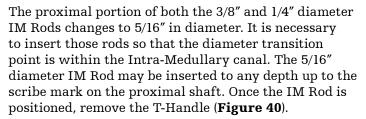


Figure 42



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 41).

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 42).

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 43).

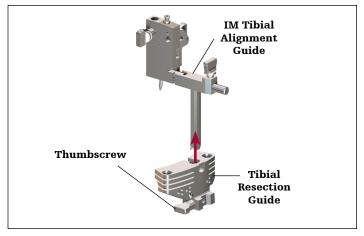
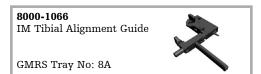


Figure 43



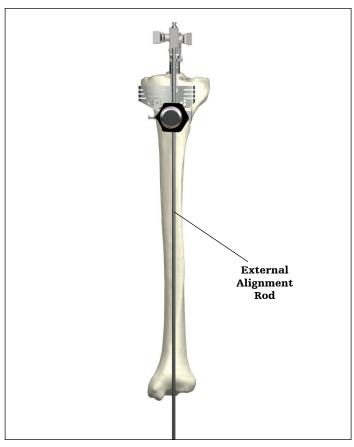


Figure 44

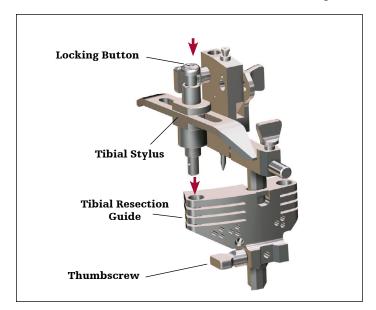


Figure 45

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 44).

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 45).

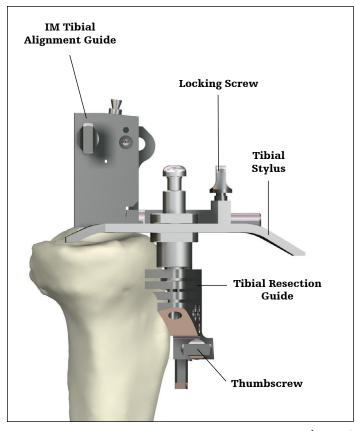


Figure 46

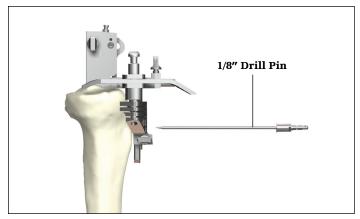


Figure 47

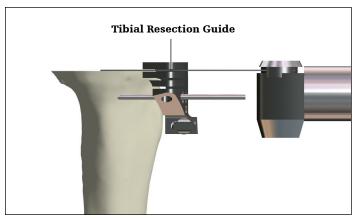


Figure 48

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 46**).

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 47**).

Resect the tibial plateau through the most proximal slot in the Tibial Resection Guide. Use of a .050" (1.27mm) Saw Blade is recommended (**Figure 48**).

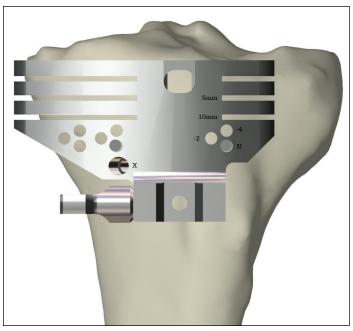


Figure 49

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 49).

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.

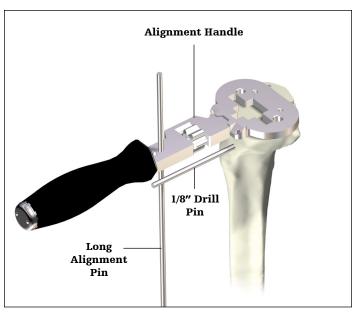


Figure 50

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 50).

6737-8-315/320/325/330/335 All Poly Tibial Template

6633-7-250 Alignment Handle

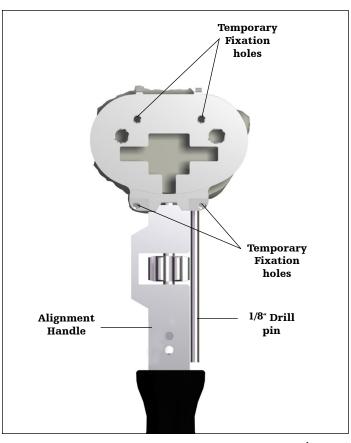
GMRS Tray No: 8B



6838-7-2X0 Alignment Pin

GMRS Tray No: 8B

GMRS Tray No: 8A



Rotational alignment is correct when the drill bit placed in a hole from the tibial resection step is parallel to the handle (Figure 51). 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.

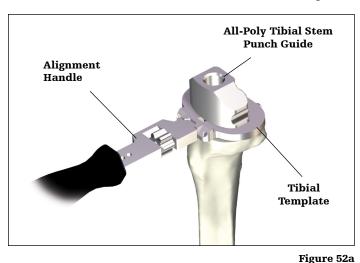
Note:

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

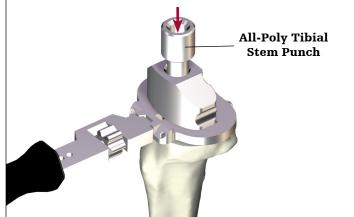
Round stem punch

To begin preparation for the Kinematic Rotating Hinge All-Poly Tibial Component, place the Stem Punch Guide (Figure 52a) on the Tibial Template. Insert the Stem Punch into the guide and slowly impact the punch until it is flush with the guide (Figure 52b).

Figure 51







6633-7-600/615 6737-8-340 6737-8-345 Stem Punch Guide Headed Nails Stem Punch GMRS Tray No: 8A GMRS Tray No: 8B GMRS Tray No: 8B

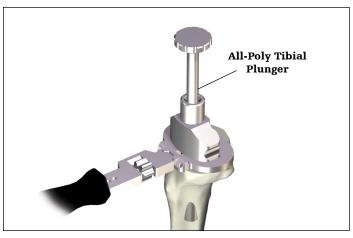


Figure 53a

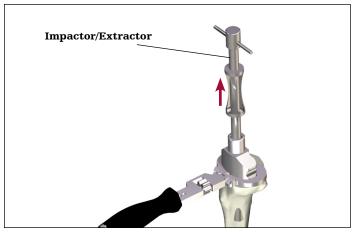
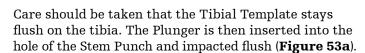


Figure 53b



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 53b**).

Initial fin punch

Place the rectangular Fin/Box Punch Guide on the Tibial Template (**Figure 54a**). 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 54b**).

Remove the Fin Punch with the Impactor/Extractor.

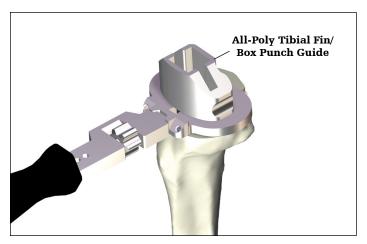


Figure 54a



Figure 54b











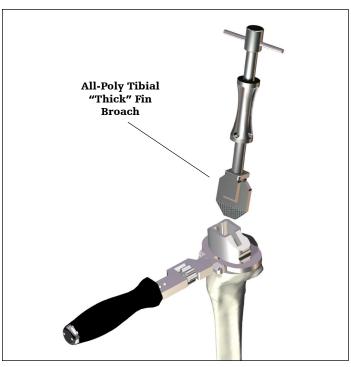


Figure 55

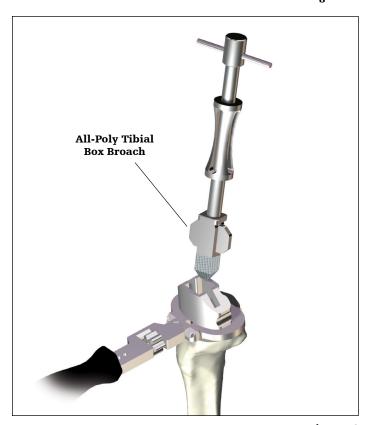


Figure 56

6737-8-365 6737-8-370 "Thick" Fin Broach Box Broach GMRS Tray No: 8B GMRS Tray No: 8B

Initial fin broach

Insert the "Thick" Fin Broach (Figure 55) into the cutout 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 56**) 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.

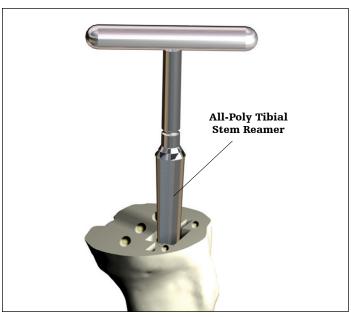


Figure 57

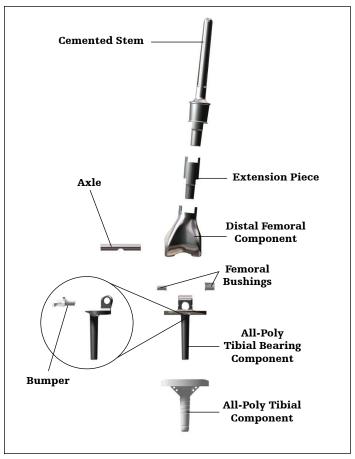
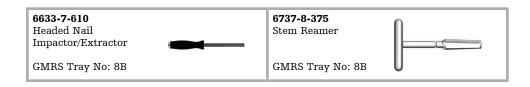


Figure 58



Final stem preparation

The tibial template is removed using the Headed Nail Impactor/Extractor and/or the Pin Puller. The Stem Reamer (Figure 57) 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 58) and Final Implantation follows the same steps as described on pages 18 through 26.

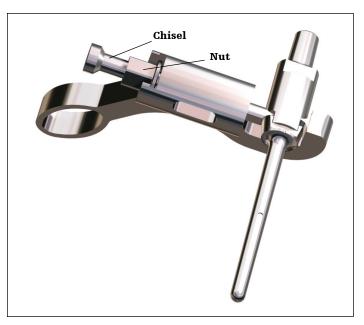


Figure 59a



Figure 59b

Appendix III Taper disassembly

Should it be necessary to disengage an assembled taper joint, a taper separator is provided. The taper separator utilizes 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 anti-rotation tabs of the implants. The correct orientation is in an anteriorto-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 59a). The wedges are then further advanced, using the wrench end of the 5-in-l 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 designed 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 59b). 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 taperlocked 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.



Distal femur resection length overview chart

Distal femoral component length	65mm
Stem without body	11mm
Stem with body	40mm

Extension Piece length	Stem without body	Stem with body
None	76mm	105mm
30mm	106mm	135mm
40mm	116mm	145mm
50mm	126mm	155mm
60mm	136mm	165mm
70mm	146mm	175mm
80mm	156mm	185mm
90mm (40 + 50)	166mm	195mm
100mm	176mm	205mm
110mm (50 + 60)	186mm	215mm
120mm	196mm	225mm
130mm (50 + 80)	206mm	235mm
140mm	216mm	245mm
150mm (50 + 100)	226mm	255mm
160mm	236mm	265mm
170mm (50 + 120)	246mm	275mm
180mm	256mm	285mm
190mm (50 + 140)	266mm	295mm
200mm	276mm	305mm
210mm (50 + 160)	286mm	315mm
220mm	296mm	325mm

Implant listing

Implant #	Trial #	Description	Size
	Distal fe	moral componer	nts
6495-2-030	6496-2-030	GMRS Distal Femur	Standard left
6495-2-040	6496-2-040	GMRS Distal Femur	Standard right
6495-2-010	6496-2-010	GMRS Distal Femur	Small left
6495-2-020	6496-2-020	GMRS Distal Femur	Small right
		Accessories	
6481-2-120	6481-2-220	Axle	
6481-2-130	6496-2-130	Neutral Bumper	
6481-2-133	6496-2-133	3° Bumper	
6481-2-110	_	Bushing	
6495-2-115	_	Small Axle	
6495-2-105	_	Small Bushing	
6481-2-140	_	Tibial Sleeve	

GMRS Intercala	ry Stems
with porous coated	body section

6485-3-211	GMRS Intercalary Stem	llmm
6485-3-213	GMRS Intercalary Stem	13mm
6485-3-215	GMRS Intercalary Stem	15mm
6485-3-217	GMRS Intercalary Stem	l7mm

Implant #	Trial #	Description	Size
	Ext	ension Pieces	
6495-6-030	6496-6-030	GMRS Extension Piece	30mm
6495-6-040	6496-6-040	GMRS Extension Piece	40mm
6495-6-050	6496-6-050	GMRS Extension Piece	50mm
6495-6-060	6496-6-060	GMRS Extension Piece	60mm
6495-6-070	6496-6-070	GMRS Extension Piece	70mm
6495-6-080	6496-6-080	GMRS Extension Piece	80mm
6495-6-100	6496-6-100	GMRS Extension Piece	100mm
6495-6-120	6496-6-120	GMRS Extension Piece	120mm
6495-6-140	6496-6-140	GMRS Extension Piece	140mm
6495-6-160	6496-6-160	GMRS Extension Piece	160mm
6495-6-180	6496-6-180	GMRS Extension Piece	180mm
6495-6-200	6496-6-200	GMRS Extension Piece	200mm
6495-6-220	6496-6-220	GMRS Extension Piece	220mm

Total Femur Connection Piece

6495-6-008 6496-6-008	Left	80mm
6495-6-009 6496-6-009	Left	90mm
6495-6-018 6496-6-018	Right	80mm
6495-6-019 6496-6-019	Right	90mm

Implant #	Trial #	Description	Size
	Ti	bial Inserts	
6481-3-210	6481-3-510	Tibial Insert	S1/S2, 10mm
6481-3-213	6481-3-513	Tibial Insert	S1/S2, 13mm
6481-3-216	6481-3-516	Tibial Insert	S1/S2, 16mm
6481-3-220	6481-3-520	Tibial Insert	S1/S2, 20mm
6481-3-224	6481-3-524	Tibial Insert	S1/S2, 24mm
6481-3-310	6481-3-610	Tibial Insert	M2/L2, 10mm
6481-3-313	6481-3-613	Tibial Insert	M2/L2, 13mm
6481-3-316	6481-3-616	Tibial Insert	M2/L2, 16mm
6481-3-320	6481-3-620	Tibial Insert	M2/L2, 20mm
6481-3-324	6481-3-624	Tibial Insert	M2/L2, 24mm
	Tibi	al Baseplates	
6481-3-110	6481-3-410	MRH Tibial Baseplate	S1
6481-3-111	6481-3-411	MRH Tibial Baseplate	S2
6481-3-112	6481-3-412	MRH Tibial Baseplate	M2
6481-3-113	6481-3-413	MRH Tibial Baseplate	L2
	Tibial Be	aring Components	i
6481-2-100	6496-3-602	MRH/GMRS Tibial Bearing Component	All
6481-2-103	6481-4-103	All Poly Tibial Bearing Component	All
6481-2-104	6481-4-104	KRH/MRS Tibial	All
6481-2-107	6481-4-107	Pediatric All Poly Tibial Bearing Component	All
6495-3-601	6496-3-601	GMRS Small Proximal Tibial Bearing Component	All

Implant #	Trial #	Description	Size	
All Poly Tibial Components				
6485-2-008	6486-8-008	All Poly Tibial Component	XS, 8mm	
6485-2-011	6486-8-011	All Poly Tibial Component	XS, 11mm	
6485-2-016	6486-8-016	All Poly Tibial Component	XS, 16mm	
6485-2-021	6486-8-021	All Poly Tibial Component	XS, 21mm	
6485-2-108	6486-8-108	All Poly Tibial Component	SM, 8mm	
6485-2-111	6486-8-111	All Poly Tibial Component	SM, 11mm	
6485-2-116	6486-8-116	All Poly Tibial Component	SM, 16mm	
6485-2-121	6486-8-121	All Poly Tibial Component	SM, 21mm	
6485-2-208	6486-8-208	All Poly Tibial Component	MED, 8mm	
6485-2-211	6486-8-211	All Poly Tibial Component	MED, 11mm	
6485-2-216	6486-8-216	All Poly Tibial Component	MED, 16mm	
6485-2-221	6486-8-221	All Poly Tibial Component	MED, 21mm	
6485-2-308	6486-8-308	All Poly Tibial Component	LRG, 8mm	
6485-2-311	6486-8-311	All Poly Tibial Component	LRG, 11mm	
6485-2-316	6486-8-316	All Poly Tibial Component	LRG, 16mm	
6485-2-321	6486-8-321	All Poly Tibial Component	LRG, 21mm	
6485-2-408	6486-8-408	All Poly Tibial Component	XL, 8mm	
6485-2-411	6486-8-411	All Poly Tibial Component	XL, 11mm	
6485-2-416	6486-8-416	All Poly Tibial Component	XL, 16mm	
6485-2-421	6486-8-421	All Poly Tibial Component	XL, 21mm	

Size

Implant #	Trial #	Description	Size
wit		Straight Stems Coated Body Section	
6485-3-008		GMRS Straight Stem with Porous Coated Body Section	8mm
6485-3-009		GMRS Straight Stem with Porous Coated Body Section	9mm
6485-3-000		GMRS Straight Stem with Porous Coated Body Section	10mm
6485-3-011		GMRS Straight Stem with Porous Coated Body Section	llmm
6485-3-013		GMRS Straight Stem with Porous Coated Body Section	13mm
6485-3-015		GMRS Straight Stem with Porous Coated Body Section	15mm
6485-3-017		GMRS Straight Stem with Porous Coated Body Section	17mm

GMRS Straight Stems without Porous Coated Body Section

		-	
6485-3-018	6486-3-018	GMRS Straight Stem without Porous Coated Body Section	8mm
6485-3-019	6486-3-019	GMRS Straight Stem without Porous Coated Body Section	9mm
6485-3-010	6486-3-010	GMRS Straight Stem without Porous Coated Body Section	10mm
6485-3-111	6486-3-111	GMRS Straight Stem without Porous Coated Body Section	llmm
6485-3-113	6486-3-113	GMRS Straight Stem without Porous Coated Body Section	13mm
6485-3-115	6486-3-115	GMRS Straight Stem without Porous Coated Body Section	15mm
6485-3-117	6486-3-117	GMRS Straight Stem without Porous Coated Body Section	17mm

GMRS Curved Stems without Porous Coated Body Section

6485-3-308	GMRS Curved Stem with Porous Coated Body Section	8mm
6485-3-309	GMRS Curved Stem with Porous Coated Body Section	9mm
6485-3-300	GMRS Curved Stem with Porous Coated Body Section	10mm
6485-3-711	GMRS Curved Stem with Porous Coated Body Section	llmm
6485-3-713	GMRS Curved Stem with Porous Coated Body Section	13mm
6485-3-715	GMRS Curved Stem with Porous Coated Body Section	15mm
6485-3-717	GMRS Curved Stem with Porous Coated Body Section	17mm

GMRS Curved Stems without Porous Coated Body Section

Description

Trial #

Implant #

** 1	111001 1 0100	s coulca body section	
6485-3-318	6486-3-318	GMRS Curved Stem without Porous Coated Body Section	8mm
6485-3-319	6486-3-319	GMRS Curved Stem without Porous Coated Body Section	9mm
6485-3-310	6486-3-310	GMRS Curved Stem without Porous Coated Body Section	10mm
6485-3-811	6486-3-811	GMRS Curved Stem without Porous Coated Body Section	llmm
6485-3-813	6486-3-813	GMRS Curved Stem without Porous Coated Body Section	13mm
6485-3-815	6486-3-815	GMRS Curved Stem without Porous Coated Body Section	15mm
6485-3-817	6486-3-817	GMRS Curved Stem without Porous Coated Body Section	17mm

GMRS Long Stems with Porous Coated Body Section

	_	
6485-3-311	GMRS Long Stem with Porous Coated Body Section	llmm
6485-3-313	GMRS Long Stem with Porous Coated Body Section	13mm
6485-3-315	GMRS Long Stem with Porous Coated Body Section	15mm
6485-3-317	GMRS Long Stem with Porous Coated Body Section	17mm

GMRS Long Stems without Porous Coated Body Section

6485-3-611	6486-3-611	GMRS Long Stem without Porous Coated Body Section	llmm
6485-3-613	6486-3-613	GMRS Long Stem without Porous Coated Body Section	13mm
6485-3-615	6486-3-615	GMRS Long Stem without Porous Coated Body Section	15mm
6485-3-617	6486-3-617	GMRS Long Stem without Porous Coated Body Section	17mm

Implant #	Trial #	Description	Size		Implant #	Trial #	Description	Size
-		rome Stems Baseplate)					luted Stems Baseplate)	
6478-6-395	6778-6-395	CoCr Stem	10 x 80mm	=	6478-6-600	6778-6-395	Ti Fluted Stem	10 x 80mm
6478-6-396	6778-6-396	CoCr Stem	11 x 80mm	=	6478-6-605	6778-6-396	Ti Fluted Stem	11 x 80mm
6478-6-397	6778-6-397	CoCr Stem	12 x 80mm	-	6478-6-610	6778-6-397	Ti Fluted Stem	12 x 80mm
6478-6-398	6778-6-398	CoCr Stem	13 x 80mm	=	6478-6-615	6778-6-398	Ti Fluted Stem	13 x 80mm
6478-6-399	6778-6-399	CoCr Stem	14 x 80mm	=	6478-6-620	6778-6-399	Ti Fluted Stem	14 x 80mm
6478-6-400	6778-6-400	CoCr Stem	15 x 80mm	=	6478-6-625	6778-6-400	Ti Fluted Stem	15 x 80mm
6478-6-405	6778-6-405	CoCr Stem	16 x 80mm	=	6478-6-630	6778-6-405	Ti Fluted Stem	16 x 80mm
6478-6-410	6778-6-410	CoCr Stem	17 x 80mm	=	6478-6-635	6778-6-410	Ti Fluted Stem	17 x 80mm
6478-6-415	6778-6-415	CoCr Stem	18 x 80mm	=	6478-6-640	6778-6-415	Ti Fluted Stem	18 x 80mm
6478-6-420	6778-6-420	CoCr Stem	19 x 80mm	=	6478-6-645	6778-6-420	Ti Fluted Stem	19 x 80mm
6478-6-425	6778-6-425	CoCr Stem	21 x 80mm	=	6478-6-655	6778-6-425	Ti Fluted Stem	21 x 80mm
6478-6-430	6778-6-430	CoCr Stem	23 x 80mm	=	6478-6-665	6778-6-430	Ti Fluted Stem	23 x 80mm
6478-6-435	6778-6-435	CoCr Stem	10 x 155mm	=	6478-6-680	6778-6-435	Ti Fluted Stem	10 x 155mm
6478-6-436	6778-6-436	CoCr Stem	11 x 155mm	=	6478-6-685	6778-6-436	Ti Fluted Stem	11 x 155mm
6478-6-437	6778-6-437	CoCr Stem	12 x 155mm	-	6478-6-690	6778-6-437	Ti Fluted Stem	12 x 155mm
6478-6-438	6778-6-438	CoCr Stem	13 x 155mm	=	6478-6-695	6778-6-438	Ti Fluted Stem	13 x 155mm
6478-6-439	6778-6-439	CoCr Stem	14 x 155mm	=	6478-6-705	6778-6-439	Ti Fluted Stem	14 x 155mm
6478-6-440	6778-6-400	CoCr Stem	15 x 155mm	=	6478-6-710	6778-6-400	Ti Fluted Stem	15 x 155mm
6478-6-445	6778-6-445	CoCr Stem	16 x 155mm	-	6478-6-715	6778-6-445	Ti Fluted Stem	16 x 155mm
6478-6-450	6778-6-450	CoCr Stem	17 x 155mm	-	6478-6-720	6778-6-450	Ti Fluted Stem	17 x 155mm
6478-6-455	6778-6-455	CoCr Stem	18 x 155mm	-	6478-6-725	6778-6-455	Ti Fluted Stem	18 x 155mm
6478-6-460	6778-6-460	CoCr Stem	19 x 155mm	-	6478-6-730	6778-6-460	Ti Fluted Stem	19 x 155mm
6478-6-465	6778-6-465	CoCr Stem	21 x 155mm	-	6478-6-740	6778-6-465	Ti Fluted Stem	21 x 155mm
6478-6-470	6778-6-470	CoCr Stem	23 x 155mm	-	6478-6-750	6778-6-470	Ti Fluted Stem	23 x 155mm
-				-				

Left Implant #	Left Trial #	Right Implant #	Right Trial #	Description	Size					
	Tibial Augments									
6630-6-125	6633-9-505	6630-6-105	6633-9-506	Hemi Flat Wedge 5mm	Small 1					
6630-6-170	6633-9-505	6630-6-150	6633-9-506	Hemi Flat Wedge 5mm	Small 2					
6630-6-270	6633-9-509	6630-6-250	6633-9-510	Hemi Flat Wedge 5mm	Medium 2					
6630-6-370	6633-9-513	6630-6-350	6633-9-514	Hemi Flat Wedge 5mm	Large 2					
6630-6-130	6633-9-523	6630-6-110	6633-9-524	Hemi Flat Wedge 10mm	Small 1					
6630-6-175	6633-9-523	6630-6-155	6633-9-524	Hemi Flat Wedge 10mm	Small 2					
6630-6-275	6633-9-527	6630-6-255	6633-9-528	Hemi Flat Wedge 10mm	Medium 2					
6630-6-375	6633-9-531	6630-6-355	6633-9-532	Hemi Flat Wedge 10mm	Large 2					
6630-6-510	6630-6-710	6630-6-510	6630-6-710	Full Flat Block 10mm	Small 1					
6630-6-515	6630-6-710	6630-6-515	6630-6-710	Full Flat Block 10mm	Small 2					
6630-6-525	6630-6-720	6630-6-525	6630-6-720	Full Flat Block 10mm	Medium 2					
6630-6-535	630-6-730	6630-6-535	6630-6-730	Full Flat Block 10mm	Large 2					

Part number	Description
6496-9-963	GMRS All Poly Tibia Trial Tray
6496-9-964	GMRS All Poly Upper Insert Tray
6496-9-965	GMRS All Poly Lower Insert Tray
6496-9-966	GMRS All Poly Tibia Prep Tray
6496-9-967	GMRS All Poly Tibia Prep Tray

Template number Description					
	Acetate templates				
LTEMK29	Global Modular Replacement System Acetate Templates				

Preoperative templates

The surgeon may apply the outlines on the implant acetate template to an X-ray image to assist in preoperative sizing.

Part number	Description	
6496-9-951	GMRS Femoral Replacement Tray	
6496-9-952	GMRS Femoral Replacement Tray	
6496-9-955	GMRS Impaction Tray	
6496-9-957	GMRS Cemented Stem Trial Tray	
6496-9-958	GMRS Cemented Stem Trial Tray	
6496-9-963	GMRS All Poly Tibia Tub/Lid	
6496-9-964	GMRS All Poly Tibia Tray	
6496-9-965	GMRS All Poly Tibia Tray	
6496-9-966	GMRS All Poly Tibia Prep Tray	
6496-9-967	GMRS All Poly Tibia Prep Tray	



GMRS Femoral Intercalary Stem

Surgical protocol addendum



System overview:

The Femoral Intercalary allows for replacement of a diaphyseal resection of the femur. The implant's female taper is designed to mate with any Extension Piece or cemented stem.

Minimum resection: 48mm (Stem without body)
77mm (Stem with body)

Loaner kits available: S13 and S13-I

Workflow overview*:

- Mark the area to be resected as well as the axis of the femur to verify rotation during trial and implantation.
- Determine resection based on the available implants and Intramedullary (IM) canal length.
- Ream IM canals 2mm larger than selected stem size, proximal and distal, to help ensure proper cement mantle.
- Face ream for the seat of both stems.
- Insert appropriate size trial stems and evaluate for leg length and rotation.
- Cement implants, verify rotation and impact tapers together.
- Compress implant construct and hold rotation while cement cures.
- * See protocol GMRS-SP-3 for indications, contraindications and additional workflow description

Stem diameter	Seat diameter	Stem length	Trial ref number	Implant ref number
11mm	24mm	127mm	6486-3-211	6485-3-211
13mm	28mm	127mm	6486-3-213	6485-3-213
15mm	32mm	127mm	6486-3-215	6485-3-215
17mm	36mm	127mm	6486-3-217	6485-3-217



Compatibility matrix GMRS, MRH, KRH and MRS systems

Use the tal	ole below to:				Tibi	a		
 Match femoral, tibial and bearing components Get information on corresponding inserts, axles, bushings and bumpers. 		KRH All Poly Tibia 6485-2-008/421	MRS Pediatric All Poly Tibia 6485-2-508/611	KRH Tibial Baseplate (Small) 6485-7-005/020 or MRS Proximal Tibia 6485-6-000	KRH Tibial Baseplate (Medium) 6485-7-025/040	MRH Tibial Baseplate (SI/S2) 6481-3-110/111 or GMRS Standard Proximal Tibia 6495-3-102	MRH Tibial Baseplate (M2/L2) 6481-3-112/113	GMRS Small Proximal Tibia 6495-3-101
	Products available for sale Products no longer available for sale*			6485-4-111/13/16/21	6485-4-211/13/16/21	6481-3-210/13/16/20/24 Tibial Sleeve 6481-2-140	6481-3-310/13/16/20/24	6495-3-010/13/16/20/24 Tibial Sleeve 6481-2-140
MRH Femoral 6481-1-100/141 or GMRS Standa Distal Femur 6495-2-030/040	Bumper 6481-2-130/33 Bushings 6481-2-110 Axle 6481-2-120 Rumper 6481-2-130/33	6481-2-103	6481-2-107	6481-	-2-104	6481-2-100		6495-3-601
MRS Small Distal Femur 6485-0-005/075 KRH Femoral 6475-3-931/932 or MRS Standard Distal Femur 6485-0-010/020	Bumper 6485-4-100/25/45/60 Bushings 6485-2-460 Axle 6475-3-940 Bumper 6485-4-100/25/45/60	6475-3-933	6485-8-450	6485-8-435		6481-2-108		No crossover possible

^{*}This table is intended to be used as a reference for revision surgeries. Some products listed in this document are no longer available for sale, but may be found implanted in the patient.

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A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

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