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GMRS® Proximal Tibia

Global Modular Replacement System

Surgical protocol

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Contents

This publication sets forth detailed validated procedures for using the GMRS Proximal Tibia 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 Proximal Tibia accepts the Modular Rotating Hinge (MRH) resurfacing hinge.

The GMRS Proximal Tibia is available in two sizes, standard and small.

The GMRS family of cemented stems offers two types: with or without extracortical porous-coated body sections.

Description of the Global Modular Replacement System Proximal Tibia

The GMRS System is designed to:

- Reconstruct large segmental defects of the proximal tibia.
- Reconstruct osteoarticular defects of varying sizes.
- Allow for variation and intraoperative changes of the surgical plan.

The system consists of proximal tibial components, tibial inserts, tibial sleeve, extension pieces and stems.

The modular implants utilize a male/female taper locking mechanism. The components are assembled during surgery by impacting them together. When impacted, the taper is designed to securely lock the components together.

Tibial components

The proximal tibial components have a replacement length of 80mm, measured to the sulcus of the thinnest 10mm tibial insert.

Note: The Global Modular Replacement System Standard Proximal Tibial Component (6495-3-102) accepts the Modular Rotating Hinge (MRH) Tibial Inserts. The Small Proximal Tibial Component (6495-3-101) accepts the Small GMRS Tibial Inserts (6495-3-0xx) and the Small GMRS Tibial Rotating Component (6495-3-601).

MRS cemented stems

Diameter	Cemented straight stems	Cemented straight stems with body
Ø8mm	6485-3-018	6485-3-008
Ø9mm	6485-3-019	6485-3-009
Ø10mm	6485-3-010	6485-3-000
Ø11mm	6485-3-111	6485-3-011
Ø13mm	6485-3-113	6485-3-013
Ø15mm	6485-3-115	6485-3-015
Ø17mm	6485-3-117	6485-3-017

The GMRS Proximal Tibia accepts the modular cemented stems, available with or without a 40mm extracortical porous body section. Optional stem centralizers are available for the 10-17mm diameter stems.

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.

MRH femoral components

The MRH femoral components are available in five sizes: X-SML, SML, MED, LRG, X-LRG in left and right configurations. These femoral components require a 9mm resection of the distal femur.

Indications for 6495-3-101/102/601 and 6495-6-030/040/050 /060/070/080 implants:

Indications for US 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 6485-3-XXX implants:

Indications for US 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 6478-6-XXX implants:

Indications for US 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.

Indications for 6481-2/2-XXX 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.

Contraindications for 6495-3-101/102/601 and 6495-6-030/040/050 /060/070/080 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 6485-3-XXX 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 6478-6-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.

Contraindications for 6481-2/2-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 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.

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).

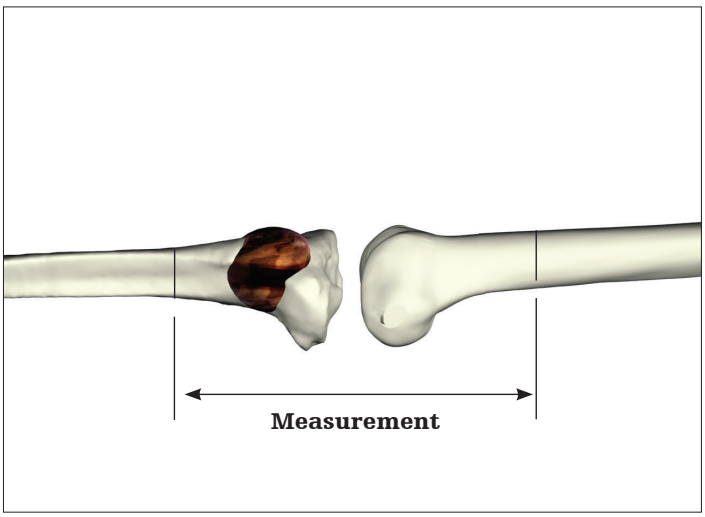

Figure 1

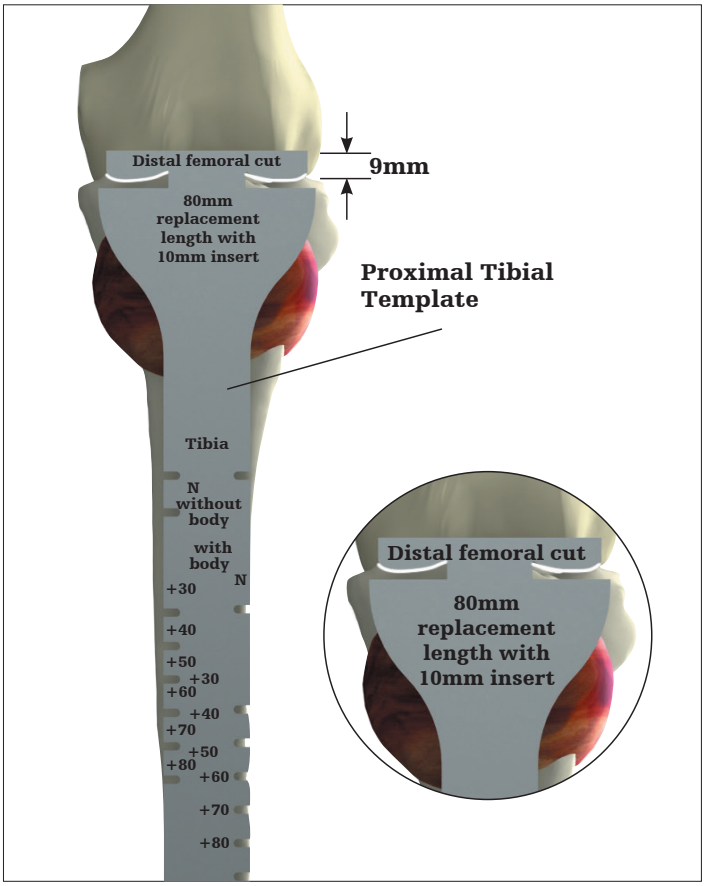

Figure 2

Measuring resection length

The Proximal Tibial Template may be used as a guide to determine resection location. The template can be positioned using either of two methods.

First, the proximal straight edge, engraved 'Distal Femoral Cut,' can be positioned 9mm proximal to the distal-most aspect of the condyles and determining the resection location from the appropriate slot **(Figure 2)**.

Second, the profile of the outline of the implant condyles on the template can be aligned with the distal-most aspect of the condyles by viewing them through the medial and lateral cut outs in the template **(Figure 2 inset)** and determining the resection location from the appropriate slot. Resection lengths indicated in the template are based on a 10mm insert and include the tibial bearing component length.

The minimum resection of the tibia is 99mm, which includes 8mm for the tibial bearing component, 80mm from the proximal tibial component with 10mm insert, and a bodiless stem (11mm replacement length).

6496-9-072
Proximal Tibial Template

GMRS Tray No: 2

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.

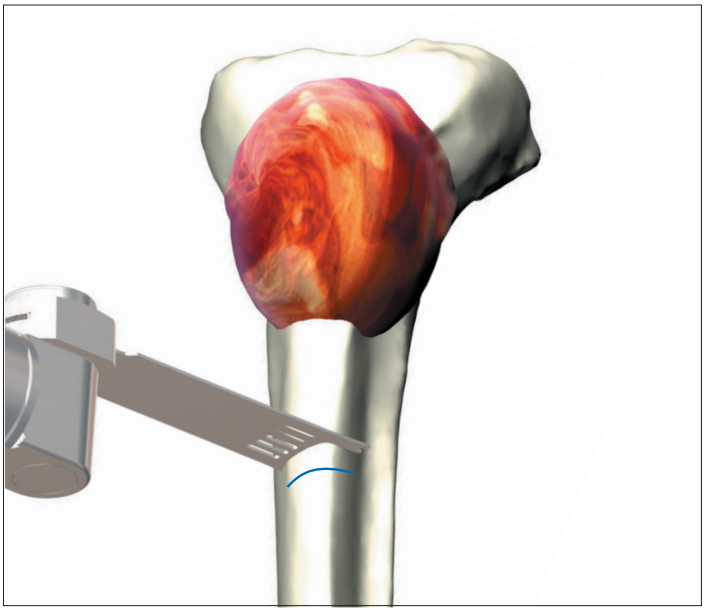

Figure 3

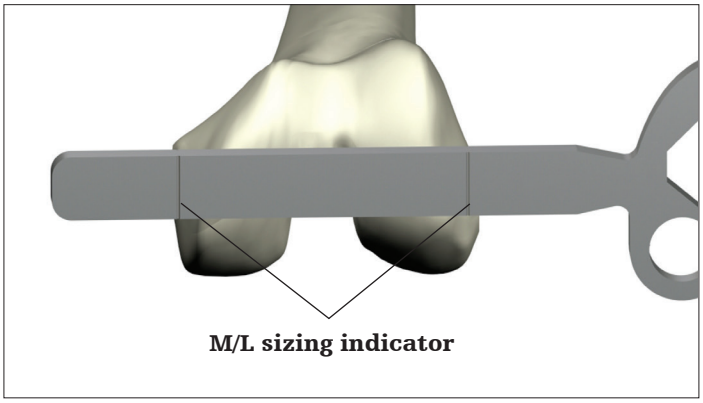

Figure 4a

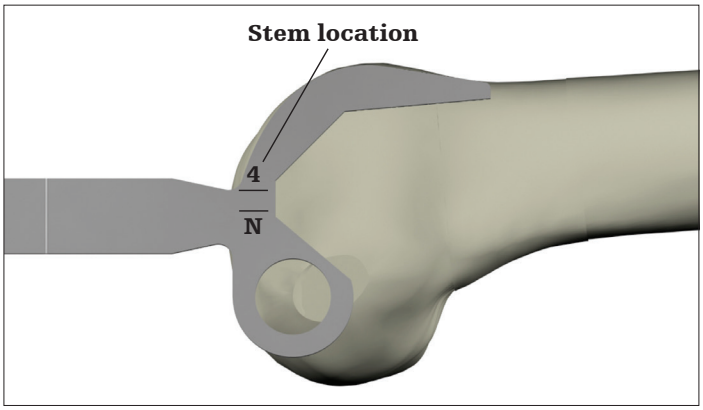

Figure 4b

Tibial osteotomy

All remaining soft tissue at the level of transection is cleared. The osteotomy, perpendicular to the tibial shaft, is performed after the surrounding tissues and structures have been protected and retracted **(Figure 3)**.

Surgical tip: Resect the tibia slightly proximal to the marked resection level to allow the facing reamer (see Figure 13, page 15) to plane accurately up to the mark at a 90° angle.

Note: It is extremely important not to distract the extremity following the resection to help protect the neurovascular structures. The end of the tibial osteotomy should be kept well padded to avoid injuring the vessels. The length of the resected specimen should be checked and measured again following resection.

Femoral sizing

In addition to preoperative templating, femoral sizing may be established using the Femoral Sizing Template. The Femoral Sizing Template may be used to evaluate the M/L width of distal femur **(Figure 4a)** or by evaluating the position of the anterior flange cut with respect to the IM canal **(Figure 4b)**.

If the two sizing methods differ, the smaller femoral size should be selected assuming that the smaller component will not notch the femur.

6481-1-02X
Femoral Sizing Template

MRH Instrument Tray H2

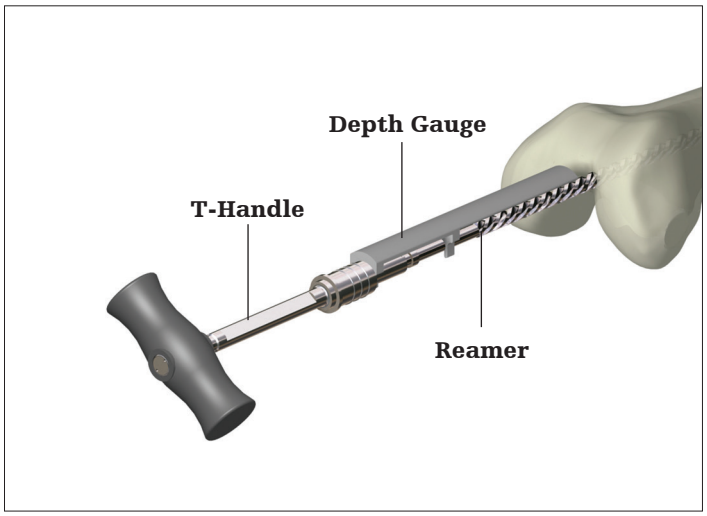

Figure 5

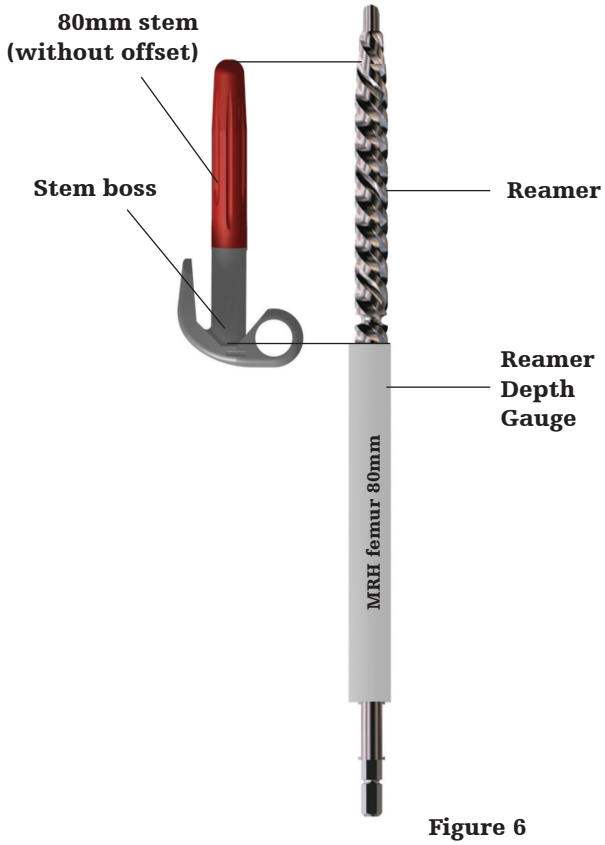

Figure 6

Femoral preparation for the Modular Rotating Hinge (MRH) femoral component

Femoral canal preparation

The Intracondylar Starter Drill should be used to create a hole immediately anterior to the insertion of the anterior cruciate ligament. A stem of at least 80mm must be used on the MRH femoral components. IM Reamers, available in diameters 8–23mm, are sequentially advanced into the canal until the tip of the appropriate Depth Gauge reaches the level of the most prominent bony aspect of the distal femur **(Figure 5)**.

Note: It is extremely important not to distract the extremity following the resection to help protect the neurovascular structures. The end of the tibial osteotomy should be kept well padded to avoid injuring the vessels. The length of the resected specimen should be checked and measured again following resection.

Figure 6 gives an example of depth stops marking and how it relates to preparation of the medullary canal for a given combination of implants. The reamers are designed to prepare the canal for a line-to-line fit for the Cobalt Chrome Stems and for a 1/2mm interference fit for the Titanium Fluted Stems.

Surgical tip: In situations where stem diameters of 14mm or less are being used, it is necessary to ream the medullary canal of the distal femur with a 15mm reamer to at least 52mm. This reaming provides the necessary clearance to fully seat the cutting guide instrument and the "stem boss" portion of the stemmed femoral component.

It is strongly recommended that the intramedullary reaming be performed manually to help avoid bone perforation and/or fracture.

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6838-7-673
Intracondylar Starter Drill

IM Reamer Tray R2

6633-9-466*
6633-9-468*
IM Reamer

IM Reamer Tray R2

6266-5-410
T-Handle

IM Reamer Tray R2

6481-1-05X
IM Reamer Depth Gauge

MRH Instrument Tray H2

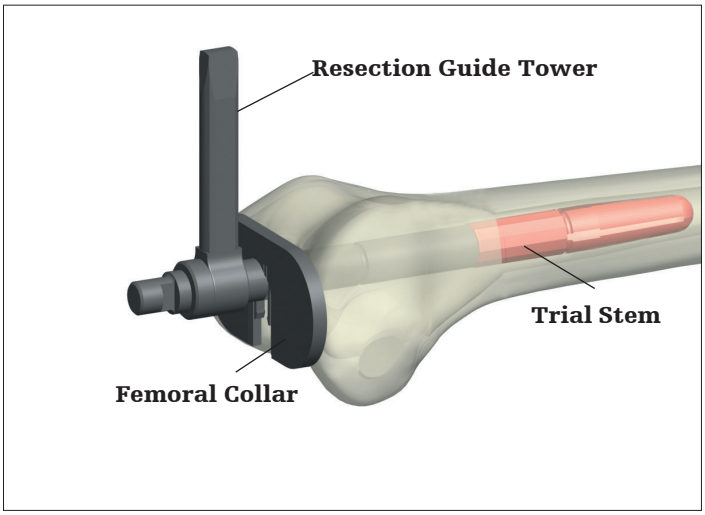

Figure 6a

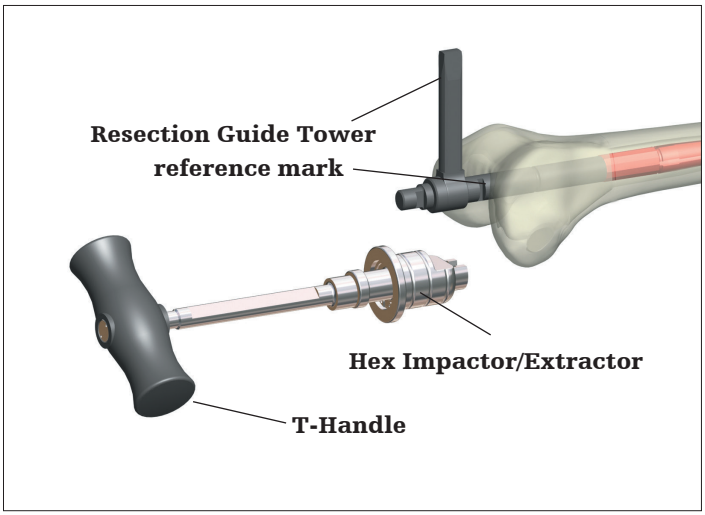

Figure 6b

Distal femoral resection

After preparing the medullary canal, the corresponding diameter Trial Stem is selected and attached to the Resection Guide Tower. The appropriate left or right Femoral Collar may be attached to the tower to assist in setting the final depth and rotation of the instrument **(Figure 6a)**. The assembly is inserted into the canal until the collar contacts the most prominent bony aspect of the distal femur.

Surgical tip: To insert and extract the assembly in and out of the medullary canal, the T-Handle and Impactor/Extractor can be utilized (Figure 6b).

6778-6-XXX
Trial Stem

Trial Stem Tray R6

6633-9-428
Resection Guide Tower

Extension Gap Prep. Tray R3

6633-9-48X
Femoral Collar

Extension Gap Prep. Tray R3

6633-9-404
Impactor/Extractor

Extension Gap Prep. Tray R3

6633-9-430
Femoral Resection Guide

Extension Gap Prep. Tray R3

6838-7-2X0
Alignment Rod

Extension Gap Prep. Tray R3

6633-7-250
Alignment Handle

Extension Gap Prep. Tray R3

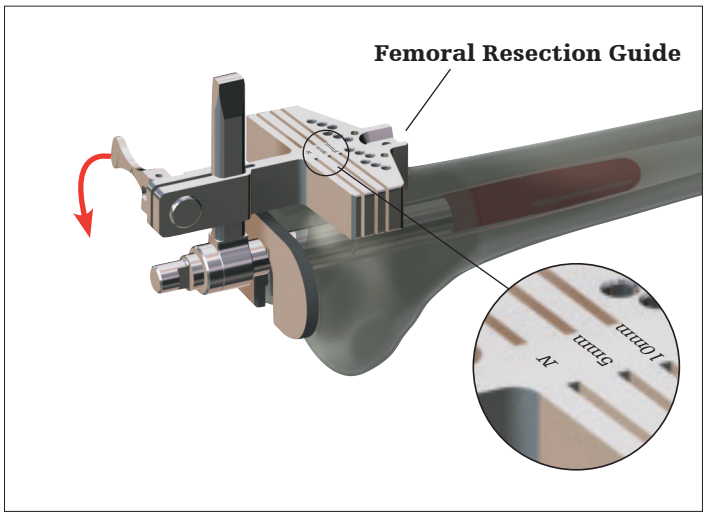

Figure 7a

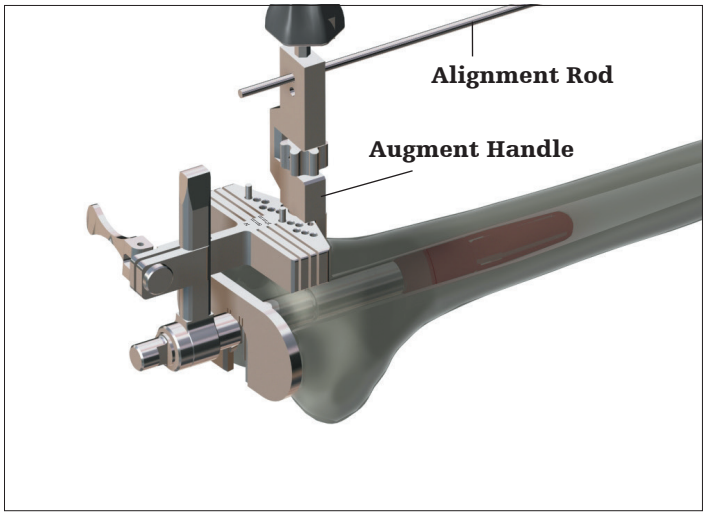

Figure 7b

The 6° valgus Femoral Resection Guide is assembled to the Resection Guide Tower such that the appropriate left or right marking is visible and slid down to touch the anterior femur and secured using the cam-lock mechanism **(Figure 7a)**. Further fixation to the femur can be achieved by adding 1/8" (3.2mm) Drills or pins through the Femoral Resection Guide.

With the Femoral Resection Guide pinned in place, the cam-lock mechanism is released and the Resection Guide Tower with the Trial Stem are removed. An additional Drill Pin is then inserted obliquely into the "X" drill hole to further stabilize the guide.

For an intact femur, the distal cut is performed through the "10mm" slot. For a revision, a 2mm "cleanup" cut is performed through the slot marked "N" for neutral and the "10mm" slot can be used to prepare for a 10mm distal femoral augment, if required.

Note: If a further resection is required, the cutting guide can be repositioned, referencing the pins placed on the distal femur through the 2mm or 4mm pinholes on the Resection Guide. If this is done, the medullary canal should be reamed a further 2mm or 4mm in order to help ensure the implant is fully seated.

Surgical tip: Before fixing the Resection Guide with 1/8" Drills, alignment can be verified by referencing the position of the femoral head with the Alignment Rod inserted through the "NF" hole on the Alignment Handle, attached to the Distal Femoral Resection Guide (Figure 7b).

Intramedullary alignment

The appropriate left or right 6° Valgus Stem Adaptor is assembled to the selected size Femoral A/P Chamfer Resection Guide and set to the "N" line on the resection block. The Trial Stem is then attached **(Figure 8a)**. The assembly is inserted into the canal until the Resection Guide rests against the cut distal femur **(Figure 8b)**.

If a 10mm distal augment cut has been made for a femur being revised, a magnetic 10mm Resection Guide Spacer may be attached to the Femoral Resection Guide **(Figure 8c)**.

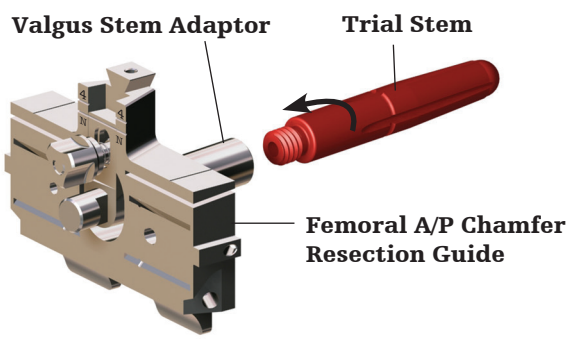

Figure 8a

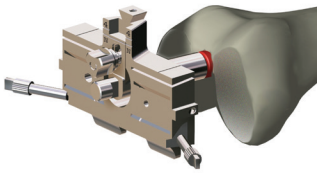

Figure 8b

Figure 8c

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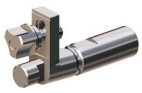
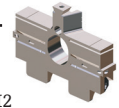
6633-9-46X
Valgus Stem Adaptor
MRH Instrument Tray H2



6481-1-009*
6481-1-010*
6481-1-011*
6481-1-012*
6481-1-013*
6481-1-014*
Femoral A/P Chamfer Resection Guide
MRH Instrument Tray H2



6481-1-009*
Resection Guide Spacer
MRH Instrument Tray H2

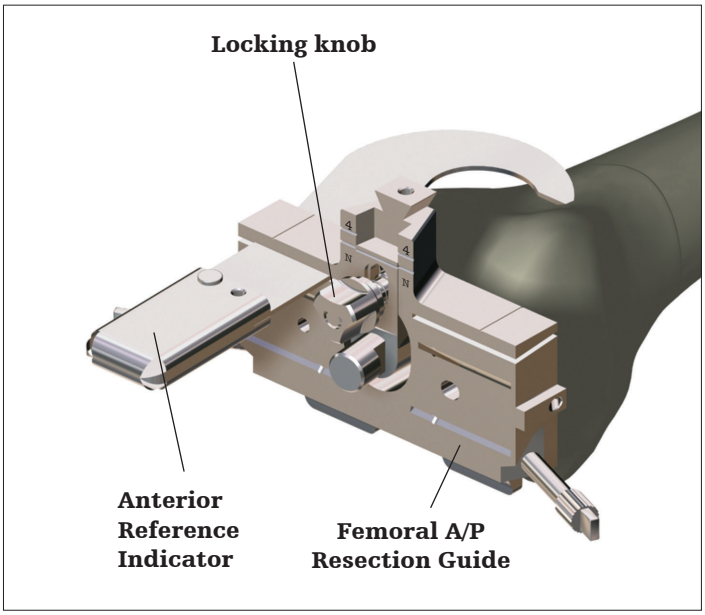


Figure 9

Femoral sizing and resection

Femoral sizing can be verified using the Anterior Reference Indicator referencing the anterior cortex **(Figure 9)**.

Correct internal/external rotation of the Femoral A/P Chamfer Resection Guide can be achieved by setting the Guide parallel to the transepicondylar axis. The guide can then be fixed using 1/8″ (3.2mm) Drills or pins.

Surgical tip: The tabs on the posterior aspect of the Femoral A/P Chamfer Resection Guide represent the posterior condyles of the Femoral Component.

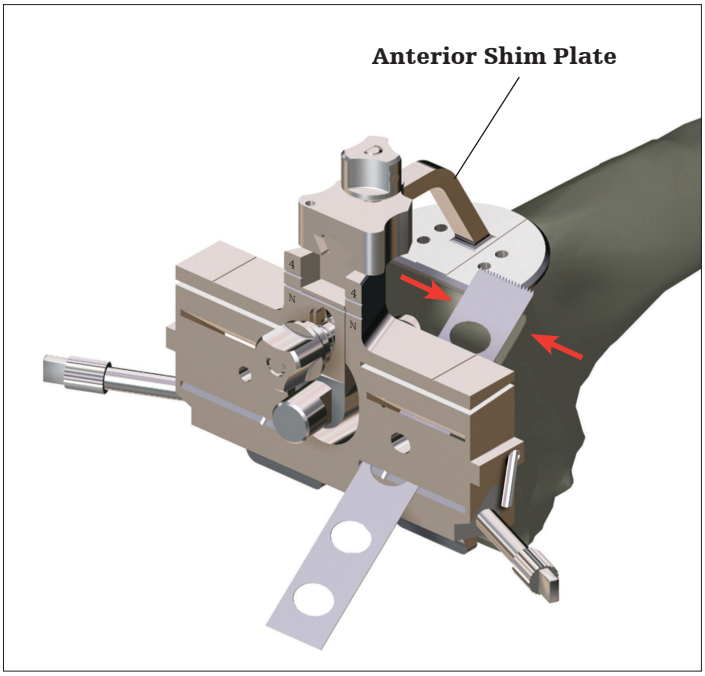


Figure 10

After making the anterior flange resection, the Anterior Shim Plate can be attached to the Femoral A/P Chamfer Resection Guide to provide stability for the Resection Guide Assembly during the anterior and posterior chamfer resections **(Figure 10)**.

Surgical tip: A narrow oscillating saw blade of approximately 1/2″ (12.7mm) is recommended for the chamfer cuts.

6633-9-464
Anterior Shim Plate

MRH Instrument Tray H2

6633-8-052
Anterior Reference Indicator

MRH Instrument Tray H2

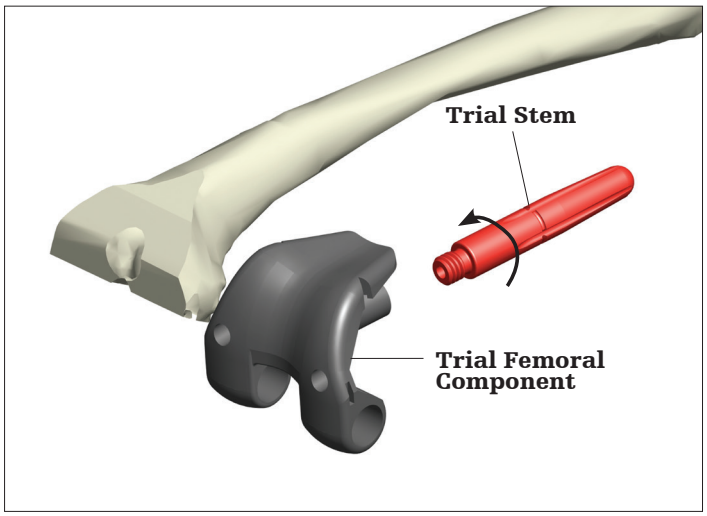


Figure 11

Femoral Trial positioning

The Trial Femoral Component can be fitted with the appropriate Trial Stem before being placed onto the prepared bone **(Figure 11)**.

6481-1-3XX
Trial Femoral Component
MRH Instrument Tray H1

6778-6-XXX
Trial Stem
Trial Stem Tray R6

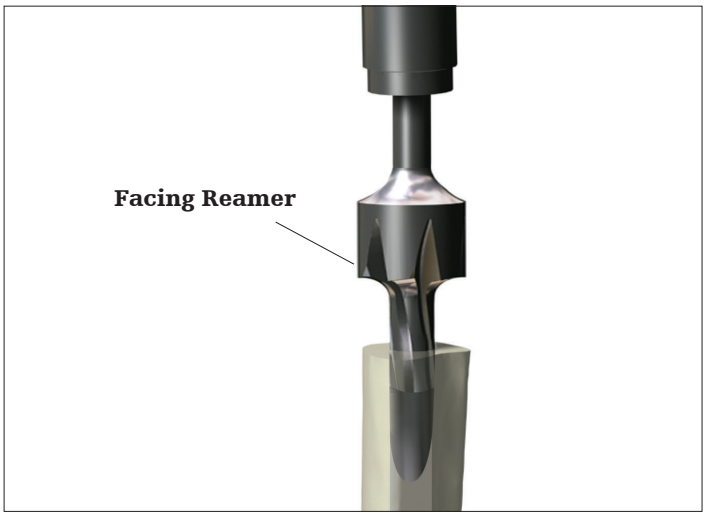


Figure 12

Preparation of the tibia

A flexible guide wire is inserted into the tibial canal. Flexible reamers are utilized to progressively ream the canal to the appropriate diameter. To permit an adequate cement mantle, a stem 2mm smaller than the final reamer diameter should be selected.

Note: The seven stem diameters are 8mm, 9mm, 10mm, 11mm, 13mm, 15mm and 17mm.

The appropriate Facing Reamer is used to plane the osteotomy site to help facilitate direct contact and accurate seating of the prosthesis by preparing for the radius at the stem/seat junction **(Figure 12)**.

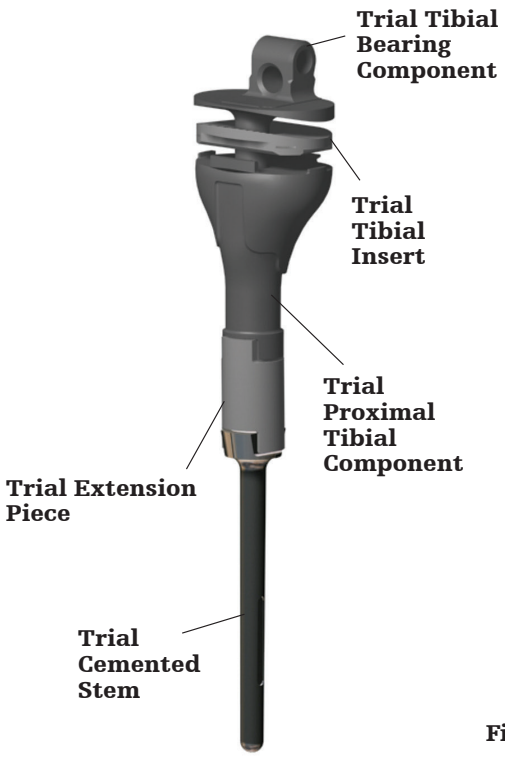


Figure 13

Trial assembly

Construct the Trial Tibial Prosthesis by joining the Trial Stem with the Trial Proximal Tibia Component, and Trial Extension Piece, if necessary. The Trial Insert is seated onto the trial proximal tibial component and the Trial Tibial Bearing Component is inserted through the trial insert into the Trial Proximal Tibia Component **(Figure 13)**.

6496-9-2XX
Facing Reamer

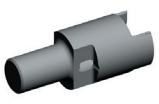
GMRS Tray No: 4A

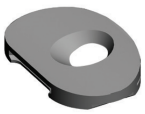
6486-3-XXX
Trial Stem

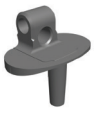
GMRS Tray No: 4A

6496-3-10X
Trial Proximal Tibial Component

GMRS Tray No: 2

6496-6-0X0
Trial Extension Piece

GMRS Tray No: 2

6481-3-5XX
6496-3-0XX
Trial Inserts

GMRS Tray No: 2

6496-3-60X
Trial Tibial Bearing Component

GMRS Tray No: 2

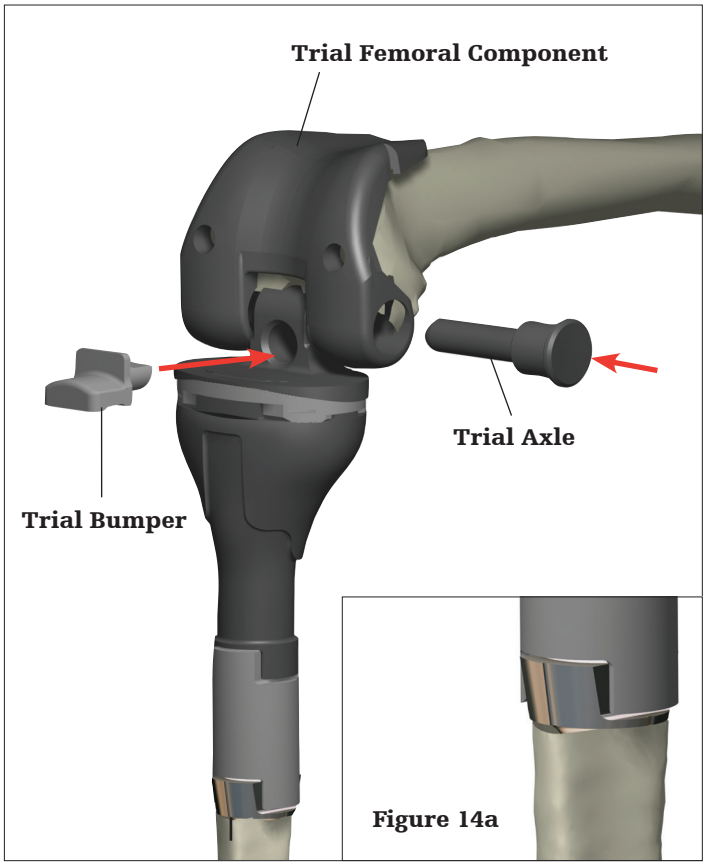


Figure 14

Trial reduction

Insert the trial tibial component construct into the tibia until it is flush with the osteotomy. Insert the Trial Femoral Component construct into the femur until it is flush with the cut surfaces.

Line up the Trial Tibial Bearing Component with the holes of the Trial Femoral Component and slide the Trial Axle into the assembly. Insert the Trial Bumper into the Trial Tibial Rotating Component **(Figure 14)**.

Note: The Trial Bumper is available in two configurations, neutral and 3º flexion.

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. If the prosthesis is too long, tension will be placed on the neurovascular structures when the knee is extended. In addition, the extensor mechanism may be tight, causing a loss of flexion and difficulty in closing the soft tissues.

To determine the appropriate length, extend the knee and monitor the distal pulse with the trial prosthesis in place. Leg length can be further evaluated by verifying the measurement made previously between the marks made on the femur and the tibia (see **Figure 1,** page 8). The extensor mechanism should also be pulled out to length with the leg in full extension to evaluate patellar position and reattachment of the patellar tendon.

Based on the trial reduction and kinematics, different thickness insert trials can be used to optimize kinematics and patellar tracking.

Rotational Alignment of the tibial trials can be optimized at this stage. Once optimal alignment is established, a mark should be made on the tibia in line with the rotational reference mark on the Trial Stem. **(Figure 14a)**. Typically, this reference mark will not be aligned with the center of the tibial crest.

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6481-1-3XX
Trial Femoral Component

MRH Instrument Tray H1

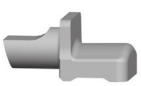
6778-6-XXX
Trial Stem

Trial Stem Tray R6

6496-2-115
Trial Axle

GMRS Tray No: 2

6496-2-130*
Trial Bumper



GMRS Tray No: 2

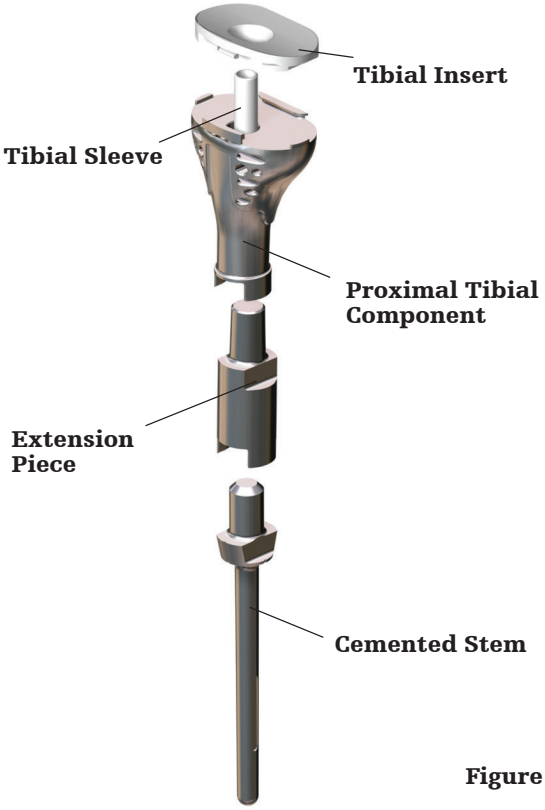


Figure 15a

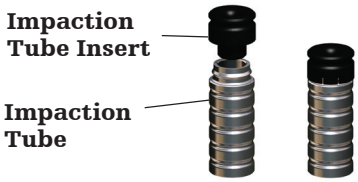


Figure 15b

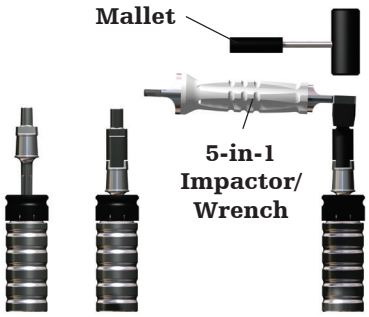


Figure 15c

Tibial implant assembly

The Proximal Tibia prosthesis consists of the Cemented Stem, Extension Piece (when needed based on the length of the reconstruction), the Proximal Tibia replacement, the Tibial Insert and Tibial Sleeve **(Figure 15a)**. 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, Impaction Tube Insert, 5-in-1 Impactor and a Mallet.

Note: Before joining any of the tapers, make sure the male and female components are completely clean and dry.

Insert the appropriate size Impaction Tube Insert (7-11, or 13-17) into the Impaction Tube **(Figure 15b)**. The selected size stem implant is inserted into the Impaction Tube assembly. If an Extension Piece is required, it is assembled onto the male taper of the stem, and the male taper of the Extension Piece is impacted by placing the appropriate size hole of the 5-in-1 Impactor over it and hitting with a Mallet **(Figure 15c)**. The Proximal Tibial Component is then mounted onto the male taper of the Stem or Extension Piece. The 5-in-1 Impactor can be used to impact the assembly by aligning the two holes of the impactor with the two tabs of the Proximal Tibia segment and hitting with a Mallet **(Figure 15d)**.

Figure 15d

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6496-9-06X
Impaction Tube Insert
GMRS Tray No: 4A

6496-9-053*
Impaction Tube
GMRS Tray No: 4A

6496-9-063
5-in-1 Impactor
GMRS Tray No: 3

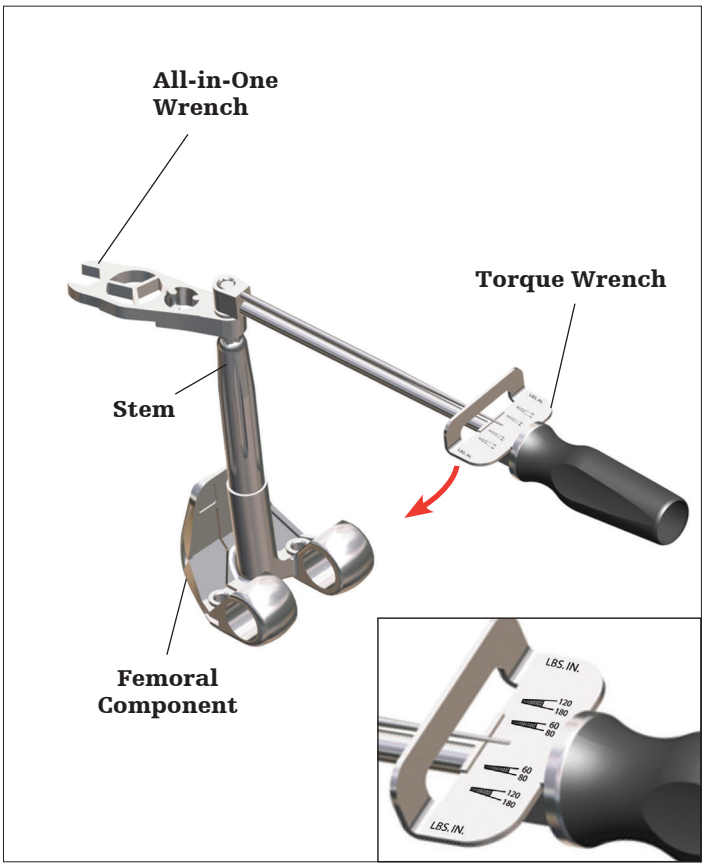


Figure 16a

Femoral implant assembly

To attach a CoCr Stem to the implant, hand tighten the stem into the 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 of the stem and tighten to 120-180 in/lbs **(Figure 16a)**.

Note: If using a 155mm Titanium Fluted Stem, tighten to 120–180 in/lbs with the tri-fluted section of the All-in-One Wrench (Figure 16b).

Note: Orient the All-in-One Wrench with the long axis of the Torque Wrench.

Note: A stem of at least 80mm must be used on the MRH femoral components.

The Distal Femoral Augments are attached by screw fixation to the distal condylar area of the femoral component. The Torque Wrench is attached to the Distal Locking Screw Adaptor via the 3/8″ Square Drive Adaptor. A locking torque of 60-80 in/lbs is applied to the screw head in order to lock the Augment and femoral component together **(Figure 16c)**.

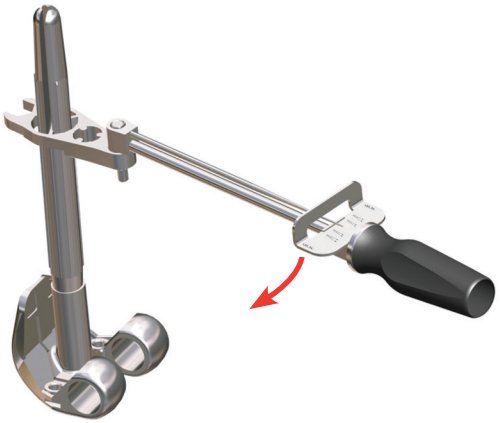


Figure 16b

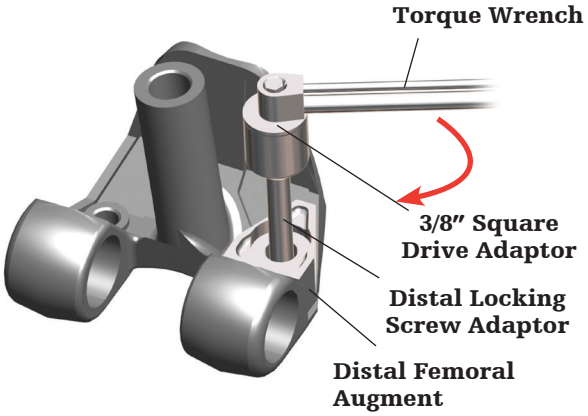
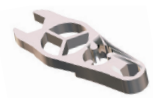


Figure 16c

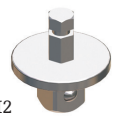
8200-0105
All-in-One Wrench

MRH Instrument Tray H2

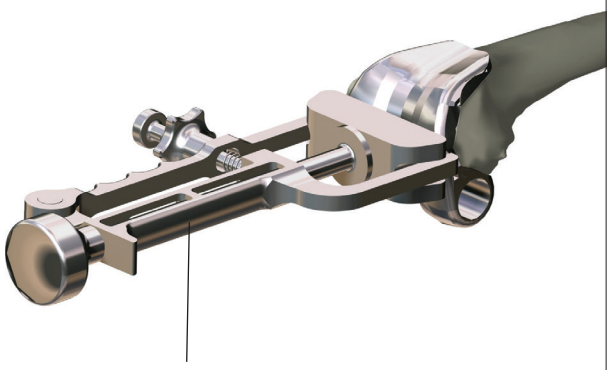
6633-9-986
Torque Wrench

MRH Instrument Tray H2

6633-8-230
Distal Locking Screw Adaptor

MRH Instrument Tray H2

6633-9-989
3/8″ Square Drive Adaptor

MRH Instrument Tray H2



Femoral Impactor/Extractor

Figure 17

Implantation and orientation of the femoral and tibial prostheses

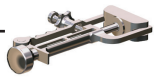
Note: If a stem centralizer is not being used, plug the hole in the stem with bone cement. Failure to plug the hole may lead to increased porosity of the cement at the stem tip, where peak stresses occur in the cement and may initiate cracks in the cement at the stem tip.

The prosthesis is then inserted into the tibial canal until the stem seat is flush with the host bone at the osteotomy site and aligned with the mark previously made on the tibia. Excess cement is removed from around the prosthesis.

Surgical bone cement is applied to the cut surfaces of the distal femur and to the inner surfaces and around the boss of the femoral implant construct. To implant the femoral component, the medullary canal is irrigated and dried. The prosthesis is attached to the Femoral Impactor/Extractor **(Figure 17)** and guided onto the femur and impacted until it is flush with the cut surfaces.

8000-8080

Femoral Impactor/ Extractor



Extension Gap Prep. Tray R3

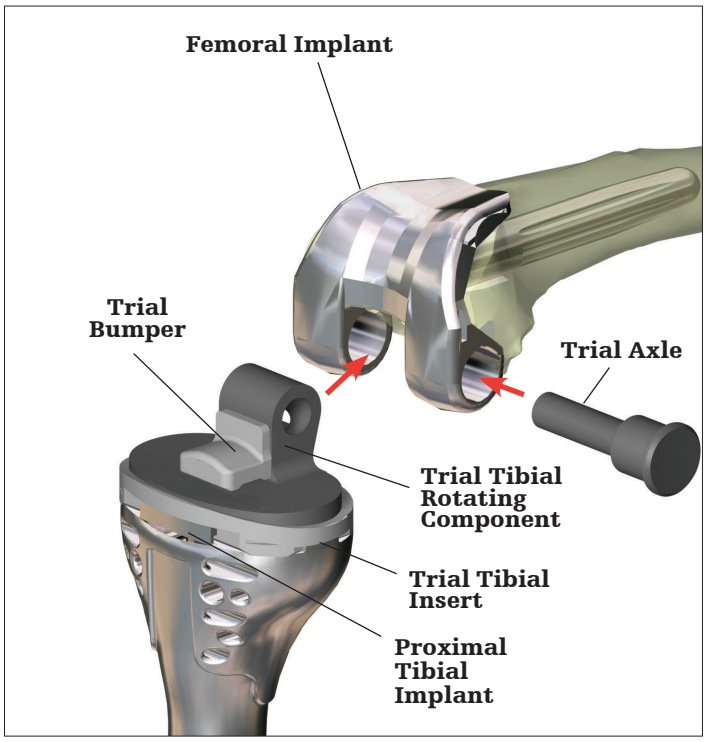


Figure 18

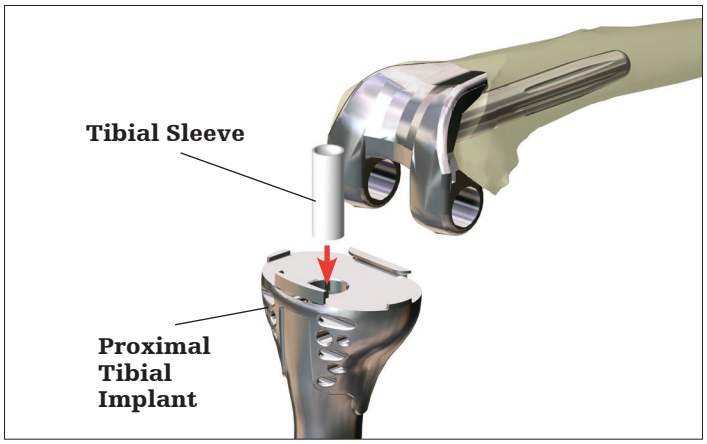


Figure 19a

Final trial articulation with prostheses

With the femoral and tibial prostheses in place, the Trial Axle, the Trial Bumper, Trial Tibial Rotating Component and the Trial Tibial Insert can be used to help verify that the desired motion, stability and patellar tracking will be achieved **(Figure 18)**. With the knee in full extension, this also assists in loading the femoral and tibial components while the cement is curing to facilitate a proper bond between implant and bone.

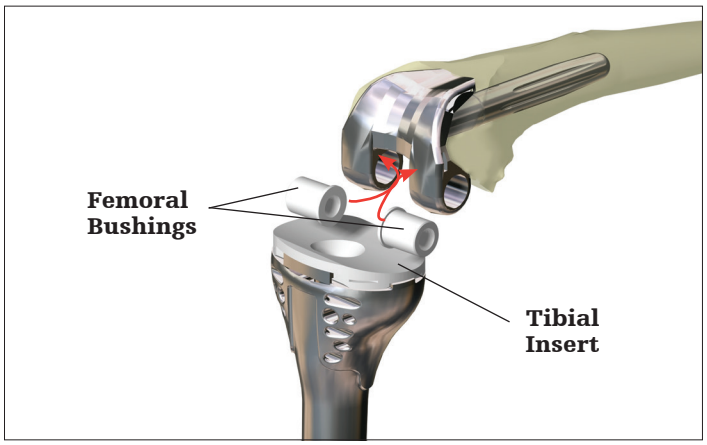


Figure 19b

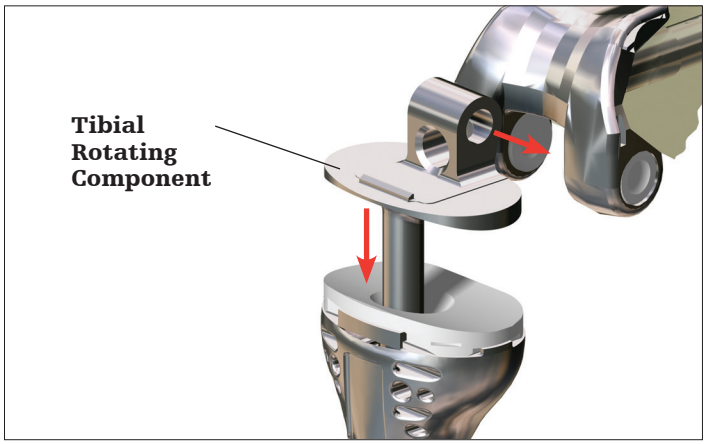


Figure 19c

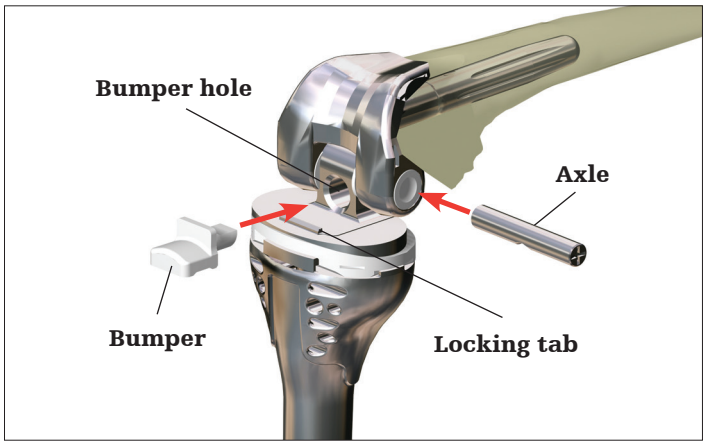


Figure 19d

The Tibial Sleeve is inserted into the Proximal Tibia **(Figure 19a)**. The appropriate size Tibial Insert is impacted onto the Proximal Tibia. The two bushings are inserted into the femoral component from the center line of the implant outward as shown **(Figure 19b)** . The Tibial Rotating Component is inserted into the Proximal Tibia and brought between the bushings **(Figure 19c)**. The Axle is then introduced as shown **(Figure 19d)**. A recess or cutout exists on the Axle to accept the Bumper. By viewing through the bumper hole, verify the recess of the Axle is aligned with the hole. The Bumper is then inserted as shown **(Figure 19d)** to lock the assembly together. It should be impacted until flush with the Tibial Rotating Component, and has cleared the locking tab.

Surgical tip: The Axle Guider Rod can be threaded into the end of the Axle implant to help guide and align the holes of the bushings with the hole of the TRC during assembly. The Axle Introducer can be used to rotate the Axle to align the recess in the axle with the bumper hole to assemble the bumper.

Note: After the bumper is in place, the axle should not be rotated. It will be in its final position.

Assembly of Rotating Hinge mechanism

The parts needed to assemble the Rotating Hinge mechanism are shown in **Figure 19e**.

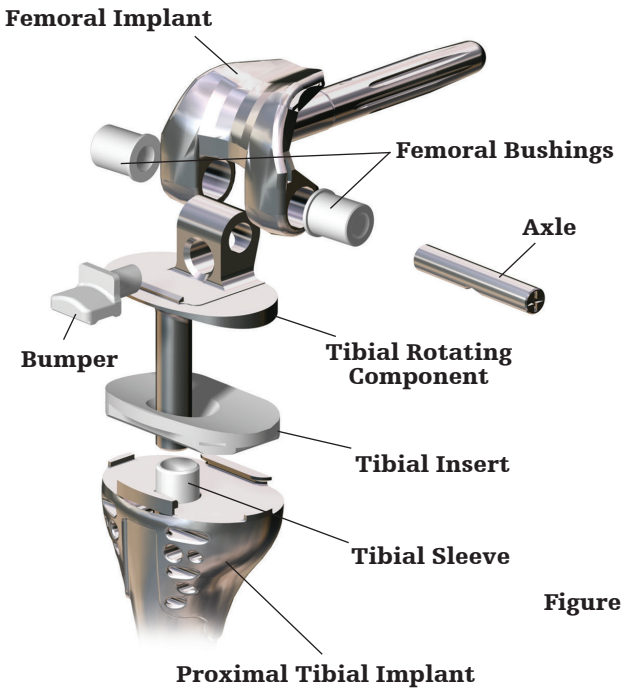


Figure 19e

6481-1-008
Axle Guider Rod

MRH Instrument Tray H1

6483-9-008
Axle Introducer

MRH Instrument Tray H1

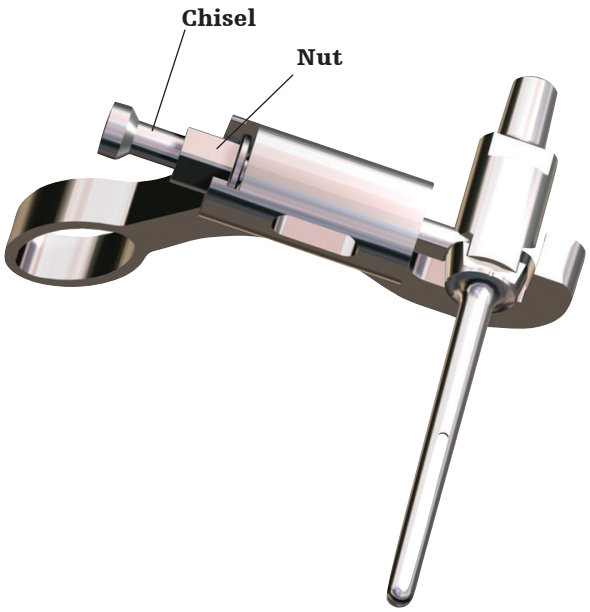


Figure 20a

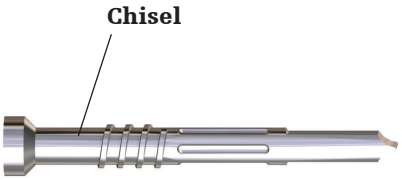


Figure 20b

Appendix - taper disassembly

Should it be necessary to disengage an assembled taper joint, a Taper Separator is provided. 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 20a)**. 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 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 20b)**. 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.

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6496-9-055*
6496-9-056*

Taper Separator

GMRS Tray No: 3

Implant listing

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

Description	Size	Implant Left	Trial	Implant Right	Trial	M/L	A/P
MRH Femoral Component	XS	6481-1-100	6481-1-300	6481-1-101	6481-1-301	60mm	54mm
MRH Femoral Component	Small	6481-1-110	6481-1-310	6481-1-111	6481-1-311	65mm	55mm
MRH Femoral Component	Medium	6481-1-120	6481-1-320	6481-1-121	6481-1-321	70mm	61mm
MRH Femoral Component	Large	6481-1-130	6481-1-330	6481-1-131	6481-1-331	75mm	64mm
MRH Femoral Component	XL	6481-1-140	6481-1-340	6481-1-141	6481-1-341	80mm	66mm

Description	Size	Implant	Trial
Cemented Stem Extender	80mm	6476-8-260	6778-7-060
Cemented Stem Extender	155mm	6476-8-270	6778-7-065

Description	Size	Implant	Trial (all sizes)
Femoral Distal Block 10mm	XS	6481-1-200	
Femoral Distal Block 10mm	Small	6481-1-210	
Femoral Distal Block 10mm	Medium	6481-1-220	6481-1-400
Femoral Distal Block 10mm	Large	6481-1-230	
Femoral Distal Block 10mm	XL	6481-1-240	

Description	Size	Implant	Trial
Offset Adapter	4mm	6478-6-490	6778-6-490
			6778-6-485 jam nut trial

Description	Size	Implant
MRH Axle	All Sizes	6481-2-120*
MRH Femoral Bushing	All Sizes	6481-2-110
Tibial Sleeve	All Sizes	6481-2-140
Bumper Insert	Neutral	6481-2-130
Bumper Insert	3 Degrees	6481-2-133
MRH Tibial Rotating Component	3mm offset	6481-2-101

Description	Size	Implant	Trial
GMRS Tibial Rotating Component for Small Proximal Tibia only	Small	6495-3-601	6496-3-601
MRH Tibial Rotating Component for Standard Proximal Tibia only	Standard	6481-2-100	6496-3-602

Description	Thickness	Implant	Trial
GMRS Tibial Insert for Small Proximal Tibia	10mm	6495-3-010	6481-3-510
GMRS Tibial Insert for Small Proximal Tibia	13mm	6495-3-013	6481-3-513
GMRS Tibial Insert for Small Proximal Tibia	16mm	6495-3-016	6481-3-516
GMRS Tibial Insert for Small Proximal Tibia	20mm	6495-3-020	6481-3-520
GMRS Tibial Insert for Small Proximal Tibia	24mm	6495-3-024	6481-3-524

Description	Thickness	Implant S1/S2	Trial
MRH Tibial Insert for Standard Proximal Tibia	10mm	6481-3-210	6481-3-610
MRH Tibial Insert for Standard Proximal Tibia	13mm	6481-3-213	6481-3-613
MRH Tibial Insert for Standard Proximal Tibia	16mm	6481-3-216	6481-3-616
MRH Tibial Insert for Standard Proximal Tibia	20mm	6481-3-220	6481-3-620
MRH Tibial Insert for Standard Proximal Tibia	24mm	6481-3-224	6481-3-624

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Description	Size	Implant	Trial	M/L	A/P
Proximal Tibial Component	Small	6495-3-101	Trial - Small	52mm	41mm
Proximal Tibial Component	Standard	6495-3-102	Trial - Standard	65mm	54mm

Description	Length	Implant	Trial
Extension Piece	30mm	6495-6-030	30mm
Extension Piece	40mm	6495-6-040	40mm
Extension Piece	50mm	6495-6-050	50mm
Extension Piece	60mm	6495-6-060	60mm
Extension Piece	70mm	6495-6-070	70mm
Extension Piece	80mm	6495-6-080*	80mm

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Description	Diameter	Straight stem		Trial
		With porous-coated body section	Without porous-coated body section	
Cemented Stem (102mm Length)	8mm	6485-3-008	6485-3-018	6486-3-018 (8mm trial)
Cemented Stem (102mm Length)	9mm	6485-3-009	6485-3-019	6486-3-019
Cemented Stem (102mm Length)	10mm	6485-3-000	6485-3-010	6486-3-010
Cemented Stem (127mm Length)	11mm	6485-3-011	6485-3-111	6486-3-111
Cemented Stem (127mm Length)	13mm	6485-3-013	6485-3-113	6486-3-113
Cemented Stem (127mm Length)	15mm	6485-3-015	6485-3-115	6486-3-115
Cemented Stem (127mm Length)	17mm	6485-3-017	6485-3-117	6486-3-117 (17mm trial)

Template number	Description
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
6496-9-953	GMRS Proximal Tibial Replacement Tray

Resection length chart

Proximal Tibial Component length (including 10mm Tibial Insert) = 80mm
Tibial Rotating Component = 8mm
Stem without body = 11mm
Stem with body = 40mm

Extension Piece length	Stem without body	Stem with body
None	99mm	128mm
30mm	129mm	158mm
40mm	139mm	168mm
50mm	149mm	178mm
60mm	159mm	188mm
70mm	169mm	198mm
80mm	179mm	208mm

Compatibility matrix GMRS, MRH, KRH and MRS systems

Use the table below to:

- Match femoral, tibial and bearing components
- Get information on corresponding inserts, axles, bushings and bumpers.

Products available for sale

Products no longer available for sale*

			Tibia						
			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 (S1/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
					Inserts 6485-4-111/13/16/21	**Inserts** 6485-4-211/13/16/21	**Inserts** 6481-3-210/13/16/20/24	**Inserts** 6481-3-310/13/16/20/24	**Inserts** 6495-3-010/13/16/20/24
							Tibial Sleeve 6481-2-140		**Tibial Sleeve** 6481-2-140
Femur	**GMRS Small Distal Femur** 6495-2-010/020	**Bushings** 6495-2-105	6481-2-103	6481-2-107	6481-2-104		6481-2-100		6495-3-601
		Axle 6495-2-115							
		Bumper 6481-2-130/33							
	MRH Femoral 6481-1-100/141 or **GMRS Standard Distal Femur** 6495-2-030/040	**Bushings** 6481-2-110							
		Axle 6481-2-120							
		Bumper 6481-2-130/33							
	MRS Small Distal Femur 6485-0-005/075	**Bushings** 6485-2-465	6475-3-933	6485-8-450	6485-8-435		6481-2-108		No crossover possible
		Axle 6485-8-460							
		Bumper 6485-4-100/25/45/60							
	KRH Femoral 6475-3-931/932 or **MRS Standard Distal Femur** 6485-0-010/020	**Bushings** 6485-2-460							
		Axle 6475-3-940							
		Bumper 6485-4-100/25/45/60							

Bearing components

*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.

Joint Replacement

This document is intended solely for the use of healthcare professionals.

GMRS Proximal Tibial components are marketed in the United States for use with bone cement.

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.

The information presented is intended to demonstrate the breadth of Stryker's product offerings. A surgeon must always refer to the package insert, product label and/or instructions for use before using any of Stryker's product. Except where noted, the products depicted are CE marked according to the Medical Device Regulation 2017/745 or the Medical Device Directive 93/42/EEC. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your sales representative if you have questions about the availability of products in your area.

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