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Orthopaedics

GMRS Proximal Femoral Surgical Protocol

Global Modular Replacement System
Proximal Femoral Resection for
Large Segmental Replacements

The information contained in this document is intended for healthcare professionals only.

GMRS
Proximal Femoral Surgical Protocol

Acknowledgements

Stryker would like to thank all of the surgeons for their contributions in developing the Global Modular Replacement System (GMRS). Stryker would especially like to thank the following surgeons for their contributions in developing the GMRS and/or for reviewing this surgical technique.

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Surgical Protocol

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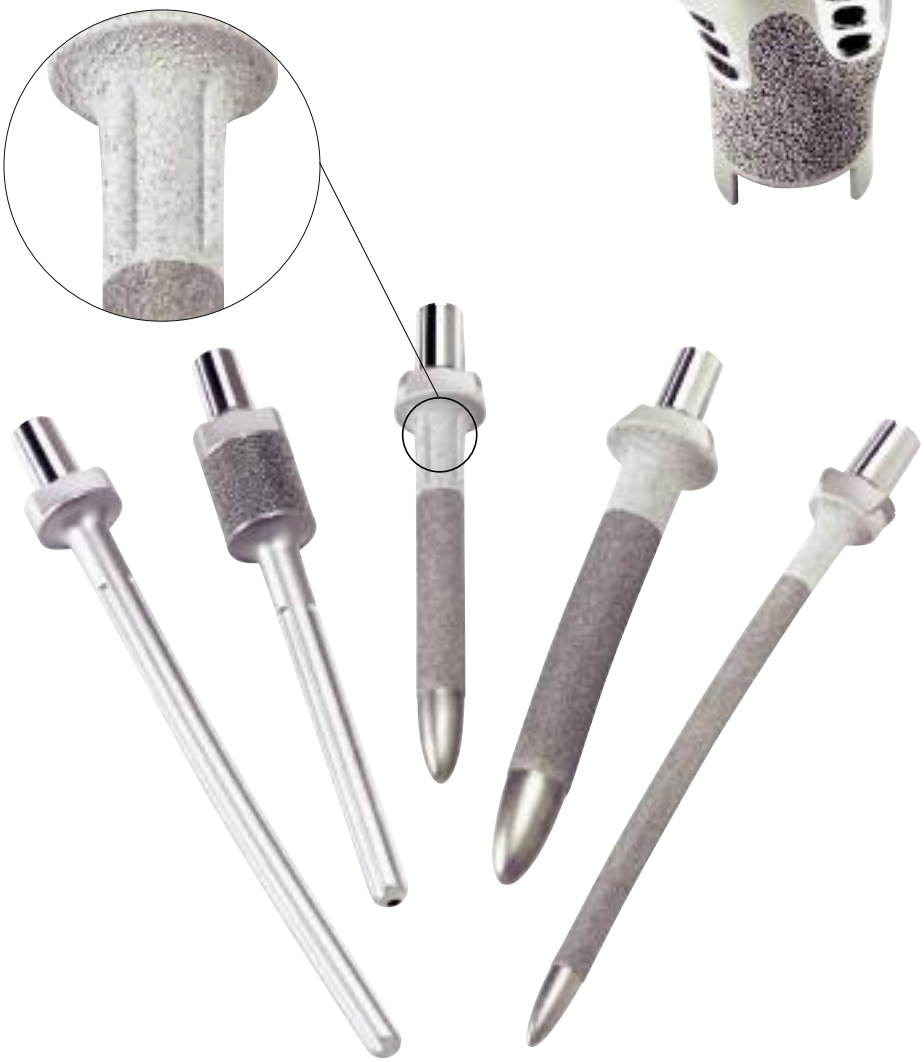
Introduction

The GMRS Proximal Femoral Components are based on over a decade of clinical history. The neck length has been increased to improve range of motion and better meet the needs of various patient anatomies. The GMRS Proximal Femoral Components are fully compatible with all Stryker Cobalt–Chrome V40 femoral heads. GMRS is not indicated for use with any ceramic head. The components continue to be available in two configurations, standard and trochanteric, but are now also available in neutral, left and right anteverted orientations.

The stem options for the GMRS Proximal Femoral Replacement are unrivaled and are now available in both cemented and press-fit stem options. The cemented stems are available in six configurations: straight, curved and long curved, each type with or without extra-cortical porous-coated body sections. The press-fit stems are available in three configurations: straight fluted, curved and long curved.



Description of the Proximal Femoral Global Modular Replacement System

Proximal Femoral Components

The proximal femoral components are available in two styles, standard and trochanteric. The components are also available in three different configurations, neutral, left and right, for use with curved stems that may dictate the orientation of the component based on the anatomy of the femur. The left and right components incorporate **15° of anteversion**. All components have a replacement length of 70mm, which is measured to the center of the standard length (zero offset) femoral head. The components accept Stryker femoral head implants with the 5°40' taper (V40 femoral heads). The proximal femoral components have a 135° neck angle and fixation holes to reattach the abductor mechanism.

Extension Pieces

The extension pieces are used to extend the replacement length, and are available in 30mm through 80mm lengths in 10mm increments and 100mm through 220mm lengths in 20mm increments. This component features a male and a female taper to attach a stem to the proximal femoral component. The body segments have an overall diameter of 26mm. The extension pieces can be stacked to achieve the desired reconstruction length.

Stem Components

Cemented Stems

The cemented stems are available in two styles. The first style incorporates an extra-cortical porous-coated section with a 40mm replacement length. The stems are also available without the porous-coated section with a 11mm replacement length. The stems are available in the following diameters: 11, 13, 15 and 17mm. The cemented stems are available in both straight and curved configurations. They have a stem length of 127mm in both straight and curved configurations and have a stem length of 203mm in the curved configuration only. Optional cement centralizers are available for the 127mm long cemented stems. The cemented stems are manufactured from forged cobalt-chrome.

Press-fit Stems

The press-fit stems are available in three styles: straight fluted (125mm stem length), bowed (150mm stem length) and long bowed (200mm stem length). The press-fit stems have a 11mm replacement length. The stems are made of titanium alloy with titanium plasma spray. The proximal 3cm of the stem is coated with PureFix hydroxylapatite (HA). The stems are available in diameters 11-19mm in 1mm increments.

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 metal trials are satin-finished so that they can easily be distinguished from the prosthesis.** The extension piece trials are made of plastic. The 30mm extension piece trial can be mated with the trial cemented stems without the extra-cortical porous coating to trial for the cemented stems with the extra-cortical porous coating.

Indications

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 prosthesis and/or tumor resection.

Contraindications

A. As related to Bone Tumors:

Not all bone tumors may be treated successfully by segmented resection. Any condition on 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 fractures;
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 for application.

See Package Insert for warnings, precautions, adverse effects and other essential product information.

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GMRS Proximal Femoral
Surgical Protocol

Global Modular Replacement System
Proximal Femoral Resection for
Large Segmental Replacements

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

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Surgical Protocol

Measuring Resection Length

Pre-operative planning is imperative to determine the appropriate resection location and is typically measured from the tip of the greater trochanter. The **proximal femoral template** can be used to guide the resection to a level that can be reproduced by the available implants (**Figure 1**). The template has markings on both sides, which indicate the resection lengths for the various constructs. The lateral side of the template has markings, which indicate the resection lengths for an assembly including a stem with the porous-coated section. The medial side of the template has markings, which indicate the resection lengths for an assembly including a stem without the porous-coated section. The numbers (30, 40, 50, etc.) indicate the available extension piece lengths that can be inserted in between the stem and the proximal femoral component to achieve the desired resection length. If the desired resection length best lines up with the 'N' on the template, no extension piece is used, i.e., either stem style is assembled directly to the proximal femoral component. A 1/8" diameter drill can be inserted into the center of the femoral head. The template can then be placed over the drill pin to evaluate femoral head offset in addition to resection length. Once the desired resection length is determined, the anterior cortex of the femur is marked with a bovie or similar device to indicate the resection level.

Marking Anterior Aspect of Femur

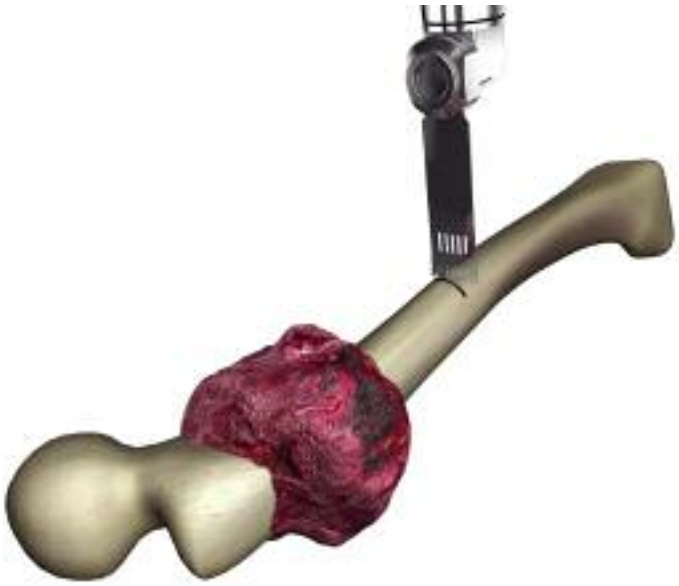
A longitudinal line representing the anterior point on the femur should now be marked distal to the resection level to aid in rotational orientation of the prosthesis (**Figure 2**). A guide to the placement of this mark is the linea aspera on the posterior aspect of the femur. The anterior mark should be a line formed at the intersection of a sagittal plane passing anteriorly through the linea aspera and the anterior cortex of the femur.

6496-9-070
Proximal Femoral Template

GMRS Tray No: 1A

Note: Frame color around each instrument indicates the corresponding GMRS instrument tray color.

3



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Femoral Osteotomy

The remaining soft-tissue attachments around the femur are transected. A malleable retractor is placed medially to the femoral shaft to prevent inadvertent injury to the soft-tissue structures. An oscillating saw or other cutting device is used for the osteotomy (**Figure 3**). The cut should be at a right angle to the shaft. It is important not to distract the extremity following removal of the proximal femur in order to avoid placing tension on the sciatic nerve and the femoral vessels.

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

Dislocation of Hip

The hip is dislocated either anteriorly or posteriorly, depending on the approach used.

Cemented Stems

Preparation of the Femur

A flexible guide wire is inserted into the femoral canal. Flexible reamers are utilized to widen 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. A **facing reamer** is used to plane the osteotomy site so as to ensure direct contact and accurate seating of the prosthesis upon the cortices. The correct facing reamer size is selected for the chosen stem to prepare the osteotomy site for the radius on the stem at the stem/seat junction (**Figure 4**).

6496-9-208/217
Facing Reamer

GMRS Tray No: 4A

Preparation of the Femur (continued)

The chosen cemented stem trial is placed in the reamed femur to facilitate ease of insertion and appropriate cement mantle. If there is any difficulty, continue reaming until the trial fits freely in the canal, or reassess stem size. It is extremely important to verify the close apposition of the seat of the cemented stem trial to the proximal femoral cortex. Optional cement centralizers are available for the 127mm long cemented stems. The last size flexible reamer used corresponds to the diameter of the distal centralizer necessary for correct positioning of the stem tip.

Bipolar Head Sizing

A trial Centrax or UHR Bipolar femoral head prosthesis is chosen, based on the measurement taken from the femoral head that has been resected. The trial is utilized to test the "suction" fit of the head in the acetabulum. Full seating of the trial should be checked. **It is important to pull the remaining capsular structures over the attempted head reduction to try to recreate the suction fit**. The trial should however still move freely in the acetabulum.

NOTE: It is suggested that the detailed Surgical Technique for the Centrax or UHR Bipolar system be reviewed. If an acetabular component is being implanted, then the appropriate surgical technique should be reviewed.

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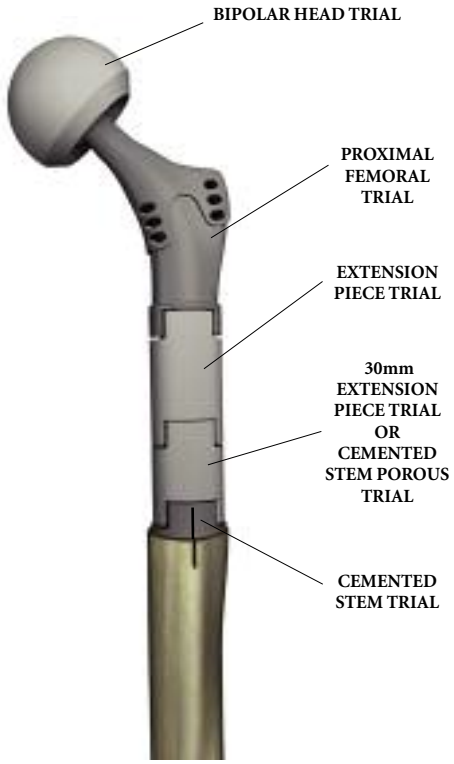

Trial Reduction

The purpose of the trial reduction is to determine the ease of insertion of the femoral prosthesis and bipolar components prior to cementing, and to determine whether the length of the prosthesis is appropriate. If the prosthesis is too long, too much tension will be placed upon the neurovascular structures. If it is too short, stability can be compromised. The parts that must be assembled to articulate the proximal femoral trial include: the **cemented stem trial**, **extension piece trial** (when needed based on resection length), **proximal femoral trial**, femoral head trial, and bipolar head trial. Place the appropriate head trial on the proximal femoral trial. The femoral heads are available in multiple neck offset options. Choose the option which re-establishes leg length and joint stability. The assembled trial prosthesis is then placed into the femoral canal. Assemble the Centrax or UHR Bipolar trial onto the appropriate head trial; then reduce into the acetabulum (**Figure 5**).

6496-1-001/002
Proximal Femoral Trial

GMRS Tray No: 1A

6496-6-030/220
Extension Piece Trial

GMRS Tray No: 1A/1B

6486-3-XXX
Cemented Stem Trial

GMRS Tray No: 4A/4B

Trial Reduction (continued)

The proper anteversion of the trial assembly can be checked against the rotational alignment marks on the cemented stem trial. These marks can be used to aid in setting the appropriate anteversion of the prosthesis. As a guide to anteversion alignment, align the rotational alignment mark on the cemented stem trial with the rotational reference mark previously made on the anterior cortex of the femur, and antevert the prosthesis 10° to 15°. The linea aspera can also be used as a guide. Construct an imaginary sagittal plane that passes directly anterior, originating from the linea aspera. If a curved stem is used during the trial evaluation, the anteverted proximal femoral trials may need to be used since the orientation of the component may be dictated by the anatomy of the femur. 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. The pulses are palpated distally. If the pulse is diminished, a shorter prosthesis is required. This will necessitate modifying the length of the prosthesis or removing additional bone from the femur. Range of motion of the hip joint is tested with the capsule pulled over the femoral head component. The prosthesis should be stable in flexion, adduction, and internal rotation. Fine-tuning of the prosthetic length can be performed with the selection of femoral head neck lengths available.

Assembly of the Prosthesis (Cemented)

The femoral prosthesis consists of the cemented stem, extension piece (when needed based on the length of the reconstruction), the proximal femoral segment, and the femoral head. Check that the correct sizes of all components have been chosen before assembly. If necessary, it is acceptable to join two extension pieces to make up the necessary length.

When assembling a 127mm long cemented stem, the instruments used for the assembly of the prosthesis are the impaction tube, appropriate size impaction tube insert, 5-in-1 impactor and mallet.

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

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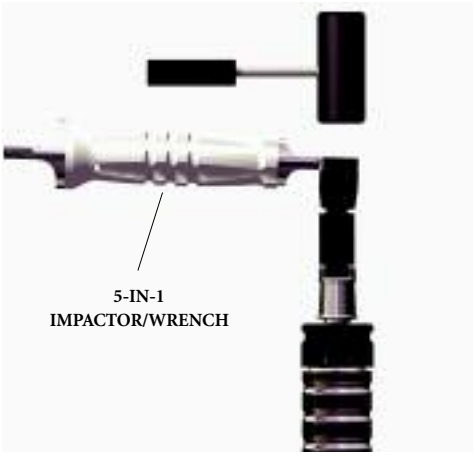

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Assembly of the Prosthesis (Cemented) (continued)

The cemented stem and extension piece are assembled first. The **impaction tube insert** corresponding to the stem diameter is assembled with the **impaction tube** base (**Figure 6**).

The cemented stem is placed into the impaction tube, and the extension piece body is mated with it (**Figure 7**). The femoral/tibial hole of the **5-in-1 impactor** is placed over the taper of the extension piece (**Figure 8**), and impacted with several swift blows of the **mallet** to lock the tapers. Next, the proximal femoral component is inserted onto the extension piece and the shoulder of the proximal femoral component is impacted by placing the 5-in-1 impactor against it and impacting with several swift blows of the mallet (**Figure 9**).

6496-9-065/066
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

5235-2-520
Mallet
GMRS Tray No: 3

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Assembly of the Prosthesis (Cemented) (continued)

When assembling a 203mm long curved cemented stem, the instruments used for the assembly of the prosthesis are the impaction tube, appropriate size impaction tube insert, **impaction support block** and mallet (optional). The proximal femoral component is inserted into the impaction block. The extension piece, if required, is then inserted into the proximal femoral component and the cemented stem is either inserted into the extension piece or proximal femoral component. The impaction tube insert corresponding to the stem diameter is assembled with the impaction tube base and inserted over the stem.

The construct can be impacted together by either sliding the impaction tube over the stem as a slap hammer (**Figure 10**) or the impaction tube can be placed flush against the seat of the stem and impacted with several swift blows of the mallet (**Figure 11**). The appropriate femoral head is then impacted onto the proximal femoral trunnion. The Centrax or UHR Bipolar is placed onto the femoral head.

6496-9-064
Impaction
Support Block

GMRS Tray No: 1A

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Implantation and Orientation of the Femoral Prosthesis

The femoral canal is thoroughly irrigated. A cement plug can be placed at the appropriate depth if the distal tip is still in the diaphysis. This depth is checked by inserting the trial femoral stem to verify 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. Surgical Simplex P bone cement is then mixed and injected into the canal to ensure complete filling of the canal. Some cement is then placed around the stem of the prosthesis.

NOTE: If a stem centralizer is not being used, plug the distal 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 stress occur in the cement and may initiate cracks in the cement at the stem tip.

The orientation of the prosthesis is critical. As a guide to appropriate anteversion, align the rotational alignment mark on the femoral stem segment with the rotational reference mark previously made on the anterior cortex of the femur, and antevert the prosthesis 10° to 15°. The linea aspera can also be used as a guide. Construct an imaginary sagittal plane that passes directly anterior, originating from the linea aspera. If implanting a curved stem with an anteverted proximal femoral component, the assembly will not need to be rotated since the anteversion is built into the proximal femoral component. The prosthesis is then inserted into the femoral canal at the proper anteversion until the stem seat is flush with the host bone at the osteotomy site (**Figure 12**). Excess cement is removed from around the prosthesis. Care is taken to prevent cement from getting into the porous-coated area on the stem. The prosthesis is firmly held in place while the cement cures.

CAUTION: The prosthesis should be slowly inserted into the canal. Rapid insertion can pressurize the canal and can lead to a fat embolism which can be fatal immediately or in the post-operative period. The anesthesiologist should be alerted and prepared for this possible event.

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Press-fit Stems

NOTE: The GMRS Press-fit stems may not be appropriate for all resection levels. Extremely long or very short resections, where the majority of the stem length exists in the proximal or distal metaphysis, may not obtain a sufficient press-fit. The press-fit stem must be engaged in sufficient bone stock to support the device.

Preparation for the 150mm and 200mm Bowed Press-fit Stems

Preparation of the Femur

Flexible reamers are used to prepare the intramedullary canal to accept the anteriorly bowed press-fit stems. To determine the appropriate size flexible reamer, it is necessary to know the stem diameter planned for preoperatively. Select the diameter of a flexible reamer starting with a size at least one to two millimeters smaller than the templated size. Use flexible reamers that are available in 0.5mm increments only. Progressively ream under power until resistance and cortical chatter is encountered (**Figure 13**). If good cortical contact is not achieved with initial reaming, increase the reamer diameter in 0.5mm increments until cortical contact is achieved. Ream until the desired stem length depth groove aligns with the femoral resection and the axial center of the canal. Mismatch of the implant curvature with the prepared canal may prevent the prosthesis from fully seating.

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Therefore, the surgeon may choose to additionally flexible ream 1mm to 2mm greater than the diameter of the intended stem or the surgeon may choose to implant a stem 1mm to 2mm smaller than the diameter of the final flexible reamer if cortical wall thickness is of concern. However, under-reaming is recommended by 0.5mm smaller than the stem size selected for implantation to ensure a press-fit of the stem depending on bone quality and surgeon preference and/or requirements.

The stem trials can be used as a guide for selecting stem size and verifying complete seating of the implant. Note that the stem trials are 1.25mm smaller then the stem to be implanted. The implants are typically 0.25mm larger than their labeled size. Therefore, due to the recommendation of under-reaming by 0.5mm, the stem trials will only be 0.5mm smaller than the preparation or the last reamer used. (i.e. Trial engraved 15mm is actually 14mm in diameter for trialing for a 15.25mm stem in a canal reamed to 14.5mm). Once a stem diameter is determined, the appropriate size facing reamer should be used to prepare the osteotomy to ensure direct contact and accurate seating of the prosthesis upon the cortices (**Figure 14**).

Flexible reamers should always be used with a guide wire for guidance and removal in the event the reamer becomes lodged.

6496-9-208/217
Facing Reamer

GMRS Tray No: 6A

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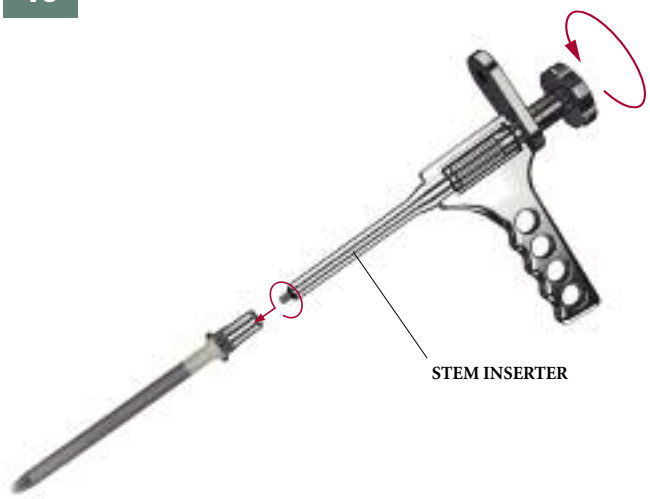
Trial Reduction

The appropriate size **bowed press-fit stem trial** should be assembled to the appropriate length extension piece trial, if required, and the proximal femoral trial. Recreation of leg length can now be verified, soft tissue tension elevated and circulation checked. The pulses are palpated distally. If the pulse is diminished, a shorter prosthesis is required. This will necessitate modifying the length of the prosthesis or removing additional bone from the femur. Range of motion of the hip joint is tested with the capsule pulled over the femoral head component. The prosthesis should be stable in flexion, adduction, and internal rotation. Fine-tuning of the prosthetic length can be performed with the selection of femoral head neck lengths available. As a guide to rotational orientation, align the rotational alignment mark on the stem trial with the rotational reference mark previously made on the anterior cortex of the femur (**Figure 15**). The linea aspera can also be used as a guide. The anteverted proximal femoral trials may need to be used since the orientation of the component may be dictated by the anatomy of the femur. 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.

16



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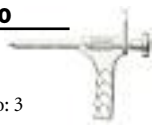
Stem Implantation

Once the appropriate size stem has been selected, the implant can be assembled to the Command **stem inserter** by threading the instrument into the end of the male taper of the implant (**Figure 16**). As the inserter is threaded into the implant it is important to align the key on the end of the inserter with the slot in the end of the male taper of the stem. The knob should be hand tightened until the instrument is fully seated within the countersink of the implant (**Figure 17**).

6496-5-111/219
Bowed Press-Fit
Stem Trial
GMRS Tray
No: 6A/6B

6266-0-120
Stem Inserter
GMRS Tray No: 3



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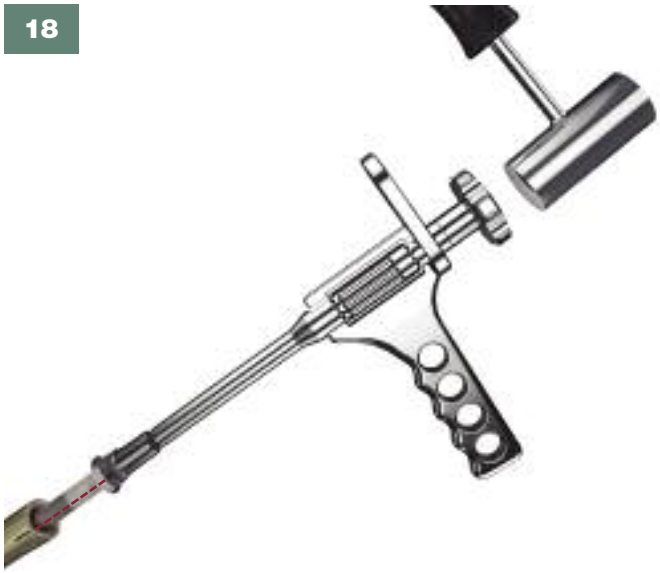

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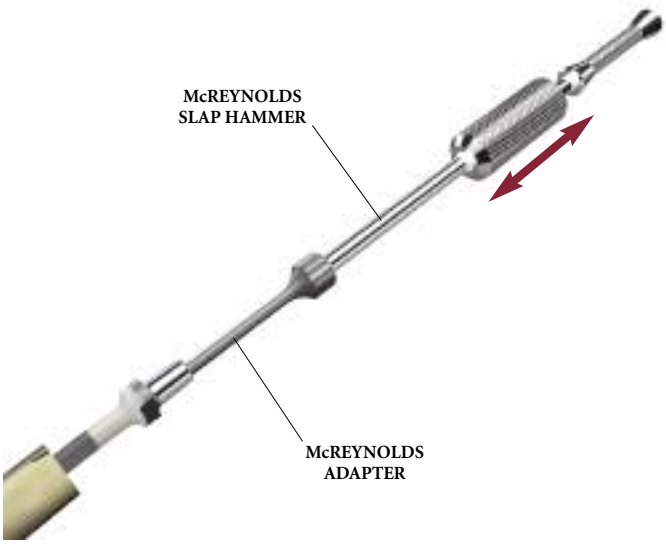

Stem Implantation (continued)

With the bow of the implant aligned in the same plane as the bow of the femur and the alignment mark of the implant in-line with the mark determined during trial reduction, the implant can be gradually impacted into the femur using the mallet (**Figure 18**). As the implant enters the femur and resistance increases, impaction may need to be halted temporarily to allow the cortices to relax. After a brief pause, impaction can be re-initiated until another segment of the stem enters the femur. Impaction may again need to be halted and the process repeated until the stem is fully seated. Orientation and rotation of the implant using the alignment mark must be monitored during the entire insertion process. The handle on the inserter can be used to guide or rotate the implant during insertion.

The progression of the press-fit stem into the canal should be monitored and should be consistent for each impact of the mallet. If the stem progression decreases significantly with each impact of the mallet, this may be an indicator that the stem is becoming lodged and may not be able to be fully seated. If too much resistance is encountered, the stem may need to be removed from the femur via impaction on the inserter or by removing the inserter and using the **McReynolds slap hammer** (**Figure 19**). The canal can then be reamed up by 0.5mm using the flexible reamers. Mismatch of the implant curvature to the femoral curvature may require repeating this process until the canal is reamed as much as 2mm larger than the stem diameter to be implanted.

NOTE: Much caution should be taken to prevent fracturing or splitting the femur. Prophylactic cabling may be required prior to impacting the stem to prevent fracture of the femur.

Proceed to **page 22** for assembly of the press-fit prosthesis.

6869-1/2/3-000
McReynolds Slap Hammer

GMRS Tray No: 3

6266-0-120
McReynolds Adapter

GMRS Tray No: 3

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Preparation for the 125mm Straight Fluted Press-fit Stems

Preparation of the Femur

Designated **press-fit trial/reamers** are provided for the preparation of these stems. These trial/reamers are available in 0.5mm sizes and step in 1mm increments (i.e. 10.5, 11.5, etc.). To determine the appropriate size trial/reamer, it is necessary to know the stem diameter planned for preoperatively. Select the diameter of a trial/reamer starting with a size at least one and a half to two and a half millimeters smaller than the templated size, if possible. Insert the trial/reamer into the **reamer driver** and progressively ream under power until resistance and cortical chatter is encountered (**Figure 20**). If good cortical contact is not achieved with initial reaming, increase the reamer diameter in 1mm increments until cortical contact is achieved. These reamers/trials prepare the canal 0.75mm undersize from the stem diameter to be implanted because the implants are typically 0.25mm larger than their labeled size. The final diameter trial/reamer chosen should be inserted fully such that it also face reams the osteotomy to ensure direct contact and accurate seating of the prosthesis upon the cortices. This final diameter trial/reamer is disconnected from the power and left in the intramedullary canal as the trial stem.

Trial Reduction and Flute Preparation

The stabilization handle or a wrench can be used to rotate the trial/reamer counter-clockwise until the rotational alignment mark aligns with the mark previously made on the anterior cortex. An extension piece trial, if required, and the proximal femoral trial are then assembled onto the trial/reamer (**Figure 21**). Recreation of leg length can now be verified and circulation checked. The pulses are palpated distally. If the pulse is diminished, a shorter prosthesis is required. This will necessitate modifying the length of the prosthesis or removing additional bone from the femur. Range of motion of the hip joint is tested with the capsule pulled over the femoral head component. The prosthesis should be stable in flexion, adduction, and internal rotation. Fine-tuning of the prosthetic length can be performed with the selection of femoral head neck lengths available. 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.

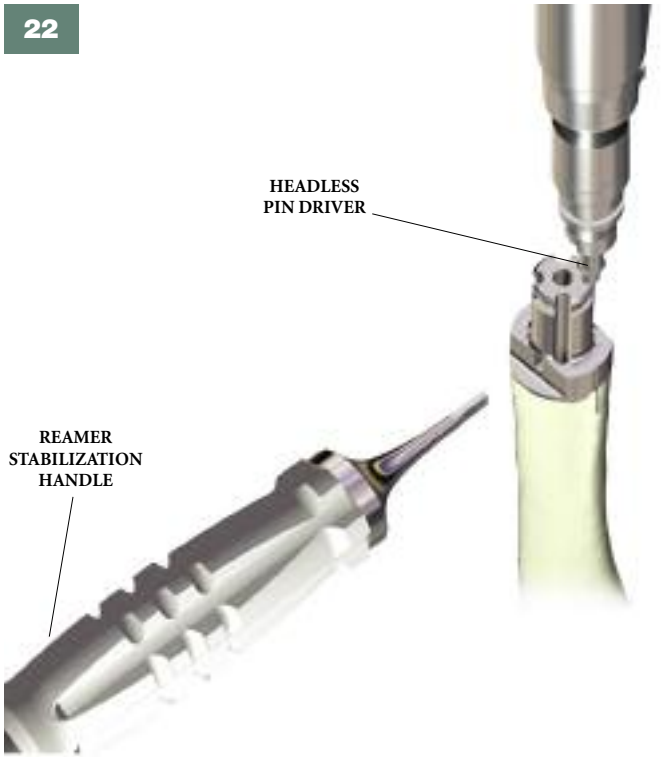
6496-9-060
Reamer Driver

GMRS Tray No: 5A

6496-9-010/017
Press-Fit Trial/Reamer

GMRS Tray No: 5A

22



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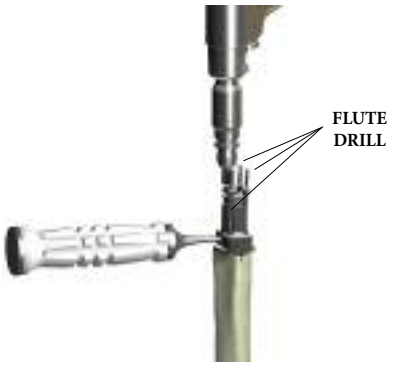

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Trial Reduction and Flute Preparation (continued)

Once the rotation is determined, the extension piece trial, if required, and proximal femoral trial are removed from the trial/reamer leaving the trial/reamer at its orientation within the canal. The **stabilization handle** is inserted through the elongated hole perpendicular to the flats of the trial/reamer and held to prevent rotation of the trial/reamer during flute preparation. While holding the stabilization handle, the **headless pin driver** is used under power to insert the first **flute drill** through any one of the holes in the trunnion of the trial/reamer (**Figure 22**). This first drill is left in place to lock the rotation of the trial/reamer.

Additional flute drills are inserted into the remaining holes leaving each drill in place once it reaches its depth stop (**Figure 23**). Once all four drills have been inserted, each drill and the trial/reamer can be removed using the pin puller.

If the intramedullary canal has been reamed up using the 17.5 or 18.5mm trial/reamer, then the trial/reamer must be removed upon completion of the trial reduction and the appropriate size **drill guide** inserted and the flutes prepared using the drills and stabilization handle in the same manner mentioned above (**Figure 24**).

7650-1035
Headless Pin Driver

GMRS Tray No: 5A

6496-9-058
Flute Drill

GMRS Tray No: 5A

6496-9-047/048
Drill Guide

GMRS Tray No: 5A

6496-9-059
Reamer Stabilization Handle

GMRS Tray No: 5A

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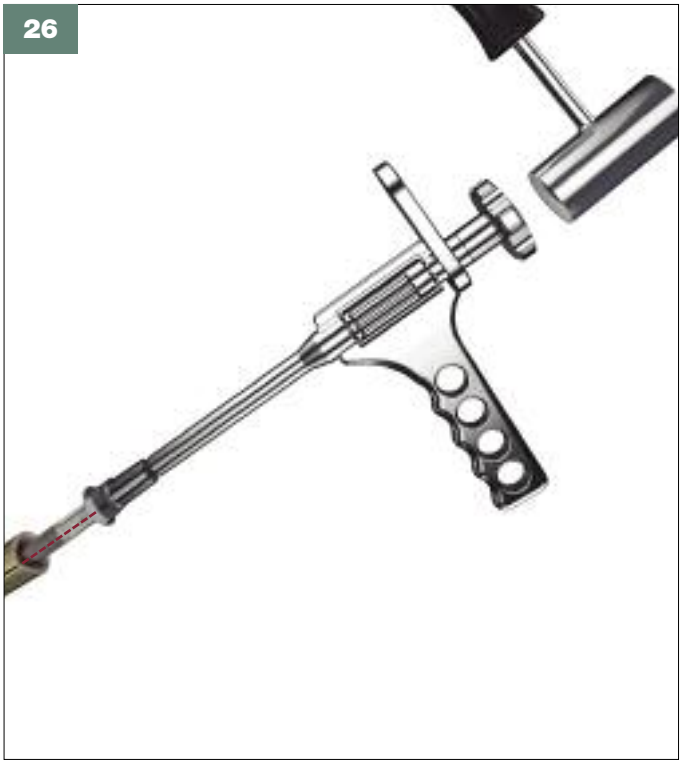

Stem Implantation

Once the appropriate size stem has been selected, the implant can be assembled to the Command stem inserter by threading the instrument into the end of the male taper of the implant (**Figure 25**). As the inserter is threaded into the implant it is important to align the key on the end of the inserter with the slot in the end of the stem. The knob should be hand tightened until the instrument is fully seated within the countersink of the implant (**inset Figure 25**).

With the alignment mark of the implant in-line with the mark determined during trial reduction and aligning the flutes with their respective preparation, the implant can be gradually impacted into the femur using a surgical mallet (**Figure 26**). As the implant enters the femur and resistance increases, impaction may need to be halted temporarily to allow the cortices to relax. After a brief pause, impaction can be re-initiated until another segment of the stem enters the femur. Impaction may again need to be halted and the process repeated until the stem is fully seated. Orientation and rotation of the implant using the alignment mark must be monitored during the entire insertion process. The handle on the inserter can be used to guide or rotate the implant during insertion.

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Stem Implantation (continued)

The progression of the press-fit stem into the canal should be monitored and should be consistent for each impact of the mallet. If the stem progression decreases significantly with each impact of the mallet, this may be an indicator that the stem is becoming lodged and may not be able to be fully seated.
If too much resistance is encountered, the stem may need to be removed from the canal via impaction on the inserter or by removing the inserter and using the McReynolds slap hammer (**Figure 27**). The canal can then be reamed up by 0.5mm using the **full size reamers** (**Figure 28**). A curette may be needed to remove any bone chips inserted into the four prepared flutes after additional reaming. Reaming up by more than 0.5mm should not be required.

NOTE: Much caution should be taken to prevent fracturing or splitting the bone. Prophylactic cabling may be required prior to impacting the stem to prevent fracture of the bone.

6496-9-111/119
Reamer

GMRS Tray No: 5B

29

30

Assembly of the Prosthesis (Press-fit)

Once the stem is fully seated, the extension piece, if required, and the appropriate proximal femoral component, neutral, left or right, can be impacted onto the implanted stem using the 5-in-1 impactor and a mallet (**Figure 29**). Each component should be impacted onto the stem sequentially; first, the extension piece, if required, and then the proximal femoral component (**Figure 30**). This will ensure a better taper lock at each taper junction rather than assembling all of the components and impacting on the end of the construct.

OPTION: The entire implant construct including the press-fit stem can be assembled on the back table using the impaction support block. The Command stem inserter can be assembled into the proximal shoulder of the proximal femoral component (**Figure 31**). The assembly can then be impacted into the femur as a construct.

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GMRS Proximal Femoral
Surgical Protocol

Appendices

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APPENDIX I

Taper Disassembly

Should it be necessary to disengage an assembled taper joint, a **taper separator** is provided. The taper separator utilizes the mechanical advantage of a wedge(s) and lever arm to overcome the locking forces of the tapers and separator 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 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 35**). 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 36**). The chisel is inserted anteriorly at the location to be separated and impacted with a mallet until separation is achieved.

NOTE: 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.

6496-9-054/055/056
Taper Separator

GMRS Tray 3

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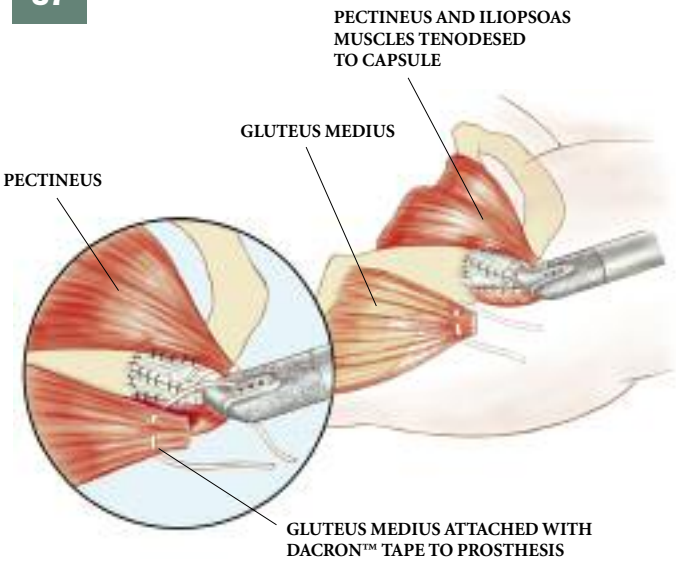

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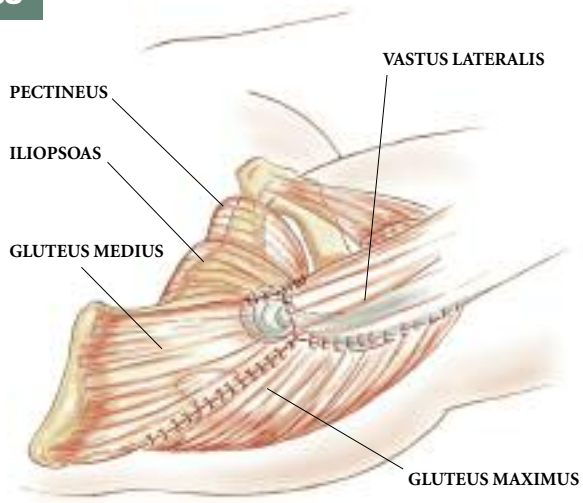

APPENDIX II

Reconstruction of Hip Capsule and Abductor Mechanisim

Once the permanent prosthesis is in place, the remaining hip capsule and abductors are reconstructed to ensure a stable prosthesis. The hip capsule is then sutured together. A 3mm Dacron™ tape is wrapped around the inferior portion of the capsule, forming a noose around the femoral neck. This is to provide immediate stability. The capsule can be reinforced by rotating the external rotator muscles proximally, and suturing them to the repaired capsule. The remaining psoas muscle can be rotated anteriorly to close and reinforce the capsular repair (**Figure 37**).

Reconstruction of Abductor Mechanisim

If the entire bone has been resected, including the greater trochanter, the remaining abductors maybe brought down to the holes in the proximal femur with 3mm tape. The vastus lateralis can now be rotated proximally to overlie the abductor muscle fixation. Soft-tissue closure of the vastus lateralis to the abductor muscles is performed. The remaining muscles are sutured to the vastus lateralis anteriorly and the hamstrings posteriorly (**Figure 38**).

GMRS Proximal Femoral
Surgical Protocol

Implant Listing and
Resection Length Overview Chart

Implant Listing

Description	Style	Neutral	15° Anteverted Left	15° Anteverted Right
Proximal Femoral Component	Standard	6495-1-001	6495-1-101	6495-1-201
Proximal Femoral Component	Trochanteric	6495-1-002	6495-1-102	6495-1-202

Description	Length	Cat. Number
Extension Piece	30mm	6495-6-030
Extension Piece	40mm	6495-6-040
Extension Piece	50mm	6495-6-050
Extension Piece	60mm	6495-6-060
Extension Piece	70mm	6495-6-070
Extension Piece	80mm	6495-6-080
Extension Piece	100mm	6495-6-100
Extension Piece	120mm	6495-6-120
Extension Piece	140mm	6495-6-140
Extension Piece	160mm	6495-6-160
Extension Piece	180mm	6495-6-180
Extension Piece	200mm	6495-6-200
Extension Piece	220mm	6495-6-220

Description	Diameter	Straight Stem		Bowed Stem		Long Bowed Stem	
		with porous coated body section	without porous coated body section	with porous coated body section	without porous coated body section	with porous coated body section	without porous coated body section
Cemented Stem	11mm	6485-3-011	6485-3-111	6485-3-711	6485-3-811	6485-3-311	6485-3-611
Cemented Stem	13mm	6485-3-013	6485-3-113	6485-3-713	6485-3-813	6485-3-313	6485-3-613
Cemented Stem	15mm	6485-3-015	6485-3-115	6485-3-715	6485-3-815	6485-3-315	6485-3-615
Cemented Stem	17mm	6485-3-017	6485-3-117	6485-3-717	6485-3-817	6485-3-317	6485-3-617

Description	Diameter	Straight Fluted 125mm Length	Bowed 150mm Length	Long Bowed 200mm Length
Press-fit Stem	11mm	6495-5-011	6495-5-211	6495-5-111
Press-fit Stem	12mm	6495-5-012	6495-5-212	6495-5-112
Press-fit Stem	13mm	6495-5-013	6495-5-213	6495-5-113
Press-fit Stem	14mm	6495-5-014	6495-5-214	6495-5-114
Press-fit Stem	15mm	6495-5-015	6495-5-215	6495-5-115
Press-fit Stem	16mm	6495-5-016	6495-5-216	6495-5-116
Press-fit Stem	17mm	6495-5-017	6495-5-217	6495-5-117
Press-fit Stem	18mm	6495-5-018	6495-5-218	6495-5-118
Press-fit Stem	19mm	6495-5-019	6495-5-219	6495-5-119

Proximal Femur Resection Lengths					
Proximal Femoral Replacement Length with Neutral (zero offset) Head = 70mm					
Cemented Stem without Porous Coated Body Section or Press-fit Stem (11mm Replacement Length)					
	Femoral Head				
Extension Piece Length	Head Offset > -4 Lateral Offset > 31	Neutral (0) 34	+4 37	+8 40	+12 42
None	78mm	81mm	84mm	87mm	89mm
30mm	108mm	111mm	114mm	117mm	119mm
40mm	118mm	121mm	124mm	127mm	129mm
50mm	128mm	131mm	134mm	137mm	139mm
60mm	138mm	141mm	144mm	147mm	149mm
70mm	148mm	151mm	154mm	157mm	159mm
80mm	158mm	161mm	164mm	167mm	169mm
100mm	178mm	181mm	184mm	187mm	189mm
120mm	198mm	201mm	204mm	207mm	209mm
140mm	218mm	221mm	224mm	227mm	229mm
160mm	238mm	241mm	244mm	247mm	249mm
180mm	258mm	261mm	264mm	267mm	269mm
200mm	278mm	281mm	284mm	287mm	289mm
220mm	298mm	301mm	304mm	307mm	309mm

Proximal Femur Resection Lengths					
Proximal Femoral Replacement Length with Neutral (zero offset) Head = 70mm					
Cemented Stem with Porous Coated Body Section (40mm Replacement Length)					
	Femoral Head				
Extension Piece Length	Head Offset > -4 Lateral Offset > 31	Neutral (0) 34	+4 37	+8 40	+12 42
None	107mm	110mm	113mm	116mm	118mm
30mm	137mm	140mm	143mm	146mm	148mm
40mm	147mm	150mm	153mm	156mm	158mm
50mm	157mm	160mm	163mm	166mm	168mm
60mm	167mm	170mm	173mm	176mm	178mm
70mm	177mm	180mm	183mm	186mm	188mm
80mm	187mm	190mm	193mm	196mm	198mm
100mm	207mm	210mm	213mm	216mm	218mm
120mm	227mm	230mm	233mm	236mm	238mm
140mm	247mm	250mm	253mm	256mm	258mm
160mm	267mm	270mm	273mm	276mm	278mm
180mm	287mm	290mm	293mm	296mm	298mm
200mm	307mm	310mm	313mm	316mm	318mm
220mm	327mm	330mm	333mm	336mm	338mm

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