stryker

Orthopaedics

Cutting*Edge* Hip Instrumentation

Femoral Surgical Technique for Primary Press-Fit and Cemented Hip Implants.

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INTRODUCTION

The Stryker family of hip replacement implants enable the surgeon to match each patient with an appropriate implant using a single set of instruments.

The Cutting*Edge* Femoral Instrumentation prepares the femur for the following femoral implants: **Secur-Fit Max, Secur-Fit Plus Max, Secur-Fit HA with Collar, Omnifit HA, Omnifit EON, Omnifit HFX, Omnifit Normalized, ODC FX, and ODC Hip Stem.**

Acknowledgements

Stryker Corporation wishes to thank the following orthopaedic surgeon for his contribution in the development of the Cutting*Edge* Total Hip Instrumentation and Surgical Protocol:

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Stryker Corporation also wishes to thank the following orthopaedic surgeons for their expertise in offering surgical tips to the Cutting*Edge* Surgical Protocol:

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FEMORAL SURGICAL TECHNIQUE

Step 1: Pre-operative Planning and X-Ray Evaluation

Pre-operative planning aids in the selection of the appropriate implant style and size for the patient's hip pathology. Optimal femoral stem fit, prosthetic neck length, and neck offset/angle should be evaluated during pre-operative X-Ray analysis using provided templates. The appropriate proximal body and stem length should be assessed in the A/P view. Anatomic anomalies that could prevent the intra-operative achievement of the established pre-operative goals may also be detected through such planning. If needed, a lateral view may be taken to assess the femoral canal curvature.

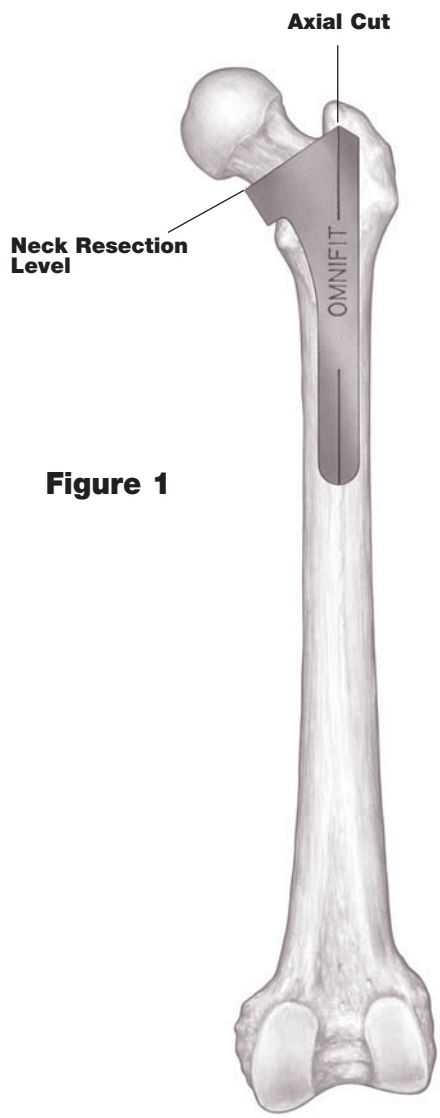


Figure 1

Step 2: Neck Resection

A proper neck resection level directly affects stem fit and placement. The resection should be made at a level determined during templating to restore proximal femoral head/neck length and offset. Using anatomic landmarks identified during templating, the Neck Resection Guide may be utilized for proper resection determination.

An initial neck resection level can be planned by making a measurement from the lesser trochanter to the Neck Resection Guide based on the pre-operative and operative analysis.

Place the Neck Resection Guide over the exposed proximal femur **(Fig. 1)**. Electrocauterization or Methylene Blue is then used to indicate the neck resection 1.0cm or 1.5cm above the lesser trochanter. This is the resection level to which all instruments should be inserted.

An oscillating or reciprocal saw is used to resect the neck along the scribe mark, taking care to align the saw blade so that it is perpendicular to the neck. Caution should also be used so as not to extend laterally into the greater trochanter. The axial resection is made at the medial border of the greater trochanter to connect it with the neck resection **(Fig. 2)**.

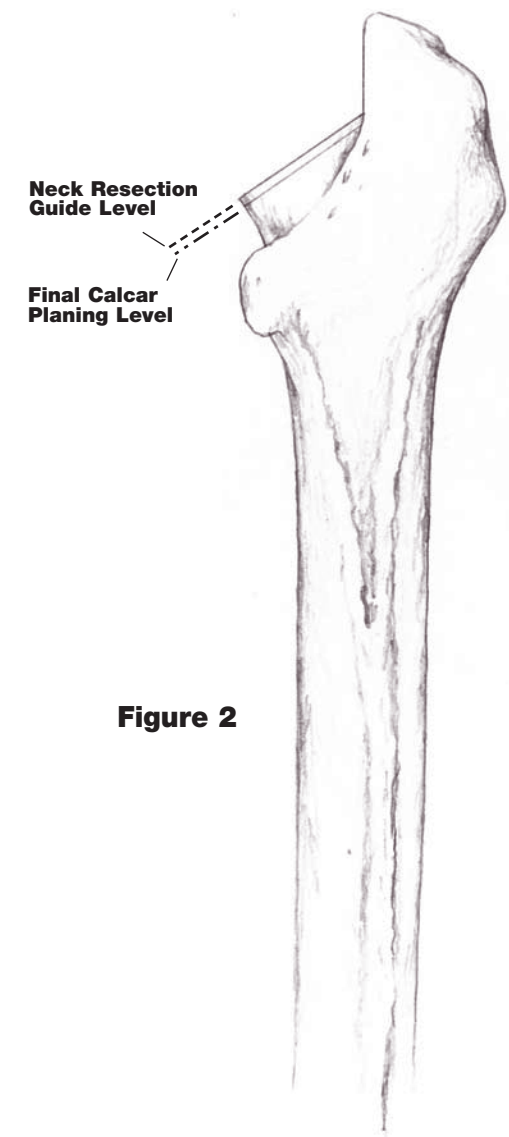


Figure 2

Step 3: Tapered Axial Reaming

Tapered axial reaming prepares the distal trochanteric/proximal diaphyseal shaft region for either a line-to-line fit with the prosthesis in a cementless application **(Fig. 3)** or provides for a cement mantle in a cemented preparation.

The Starter Reamer is used to enter the femoral canal through the trochanteric fossa. The Starter Reamer has a trocar point to facilitate entry and should be inserted to the depth of the final Broach/Tapered or Cylindrical Distal Extension assembly **(Fig. 4)**. All subsequent Tapered Axial Reamers are inserted into the canal so that the most proximal level of the cutting flutes are 1-2mm below the trochanteric fossa or at the desired femoral neck resection level. This insertion depth provides a reliable estimate of the final neck resection level.

Note: Tapered reamers for cementation will remove cancellous bone and should be minimized or avoided.

Figure 3

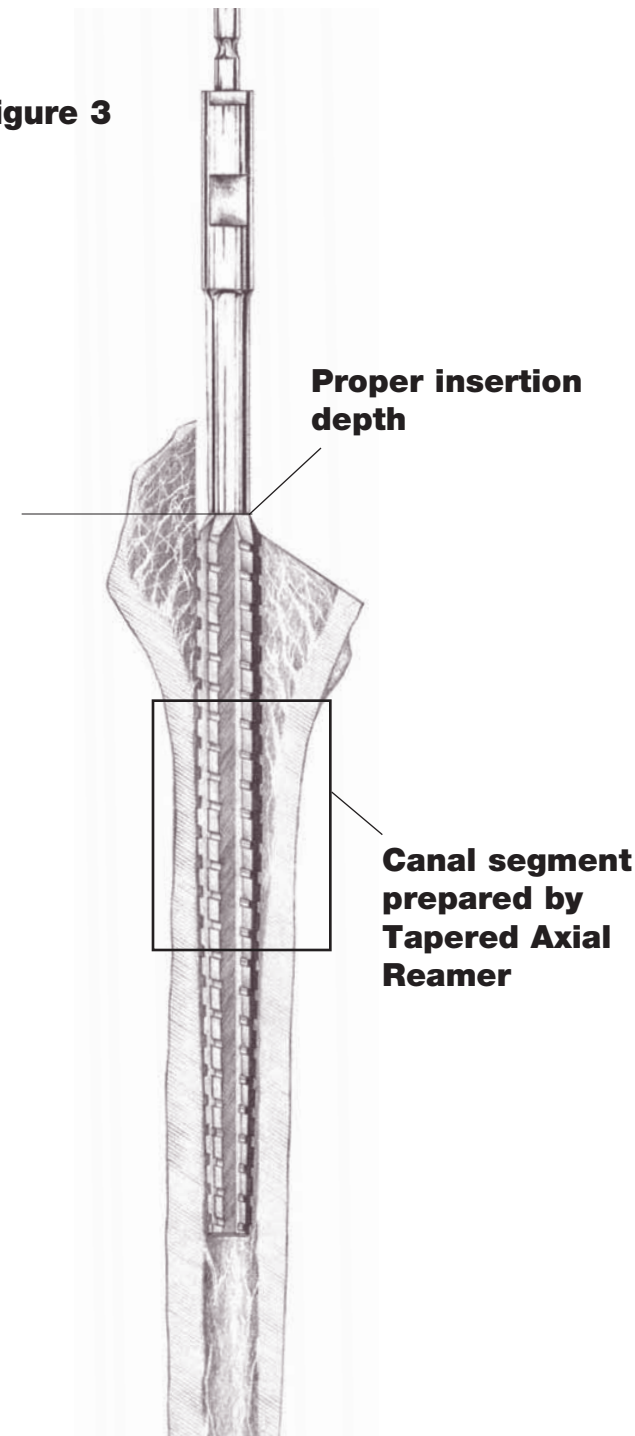
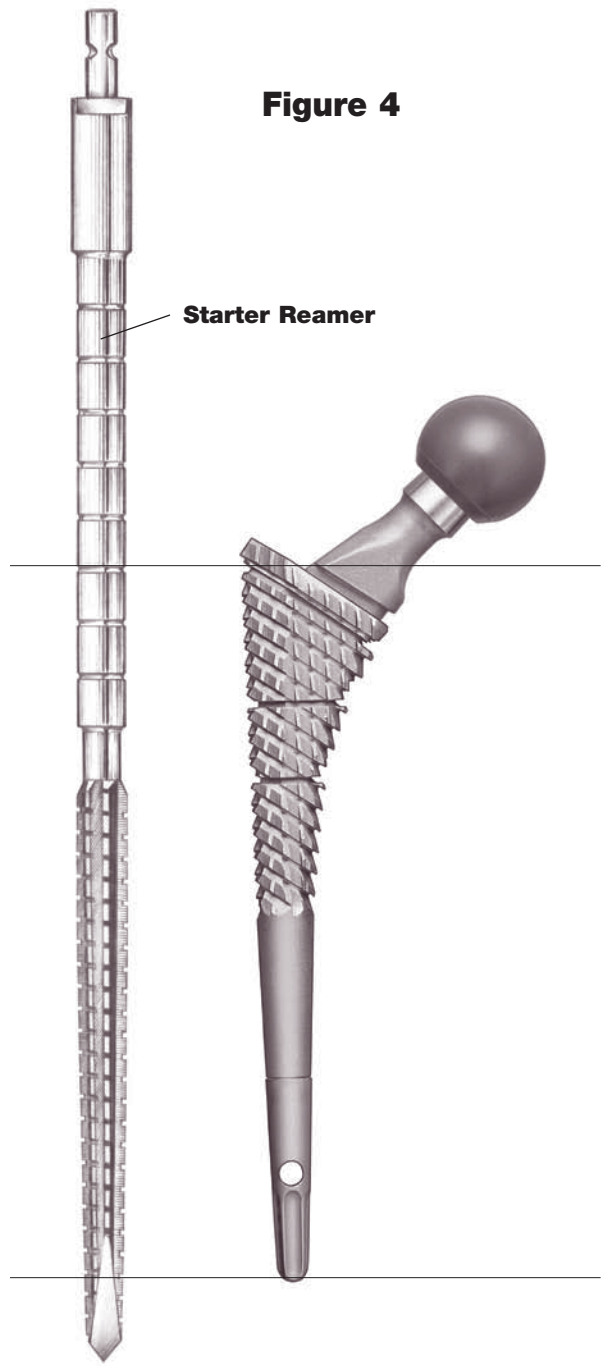


Figure 4



The Starter Reamer is introduced manually with the Quick-Release T-Handle or a low speed power tool. Place the Starter Reamer on the exposed trochanteric fossa and proceed down into the shaft along its axis to the pre-determined depth **(Fig. 5)**. For accurate stem placement, axial alignment must be maintained at all times during reaming **(Fig. 6)**. A Box Chisel or Trochanteric Reamer can be used to assist with proper axial alignment of the instrumentation. Refer to Appendix B for further procedural information regarding the Box Chisel or Trochanteric Reamers.

Note: If power equipment is used to initiate the opening, reaming should then proceed manually to prevent accidental penetration of the femoral shaft cortex.

Starting one or two sizes smaller than the templated size, ream sequentially upward in size until the last Tapered Axial Reamer inserted achieves good contact with cortical bone **(Fig. 7)**. Typically, the final Tapered Axial Reamer used matches the pre-operatively planned implant size. Occasionally, the actual stem implanted varies up or down in size from the originally templated stem size. The implanted stem size must be smaller or equal to the final Tapered Axial Reamer size used.

> *"At this point, the instruments offer a check of the pre-operative plan. The reamer should encounter cortical bone and require a fair amount of effort to completely ream to where the teeth are seated below the cut surface of the neck of the femur."*
>
> *William N. Capello, M.D.*

Note: Aggressive tapered reaming can lead to significant reduction of cancellous bone leading to premature loosening at the bone cement interface. Every effort should be made to ensure adequate cancellous bone is left for cement interdigitation.

Figure 6

Figure 7

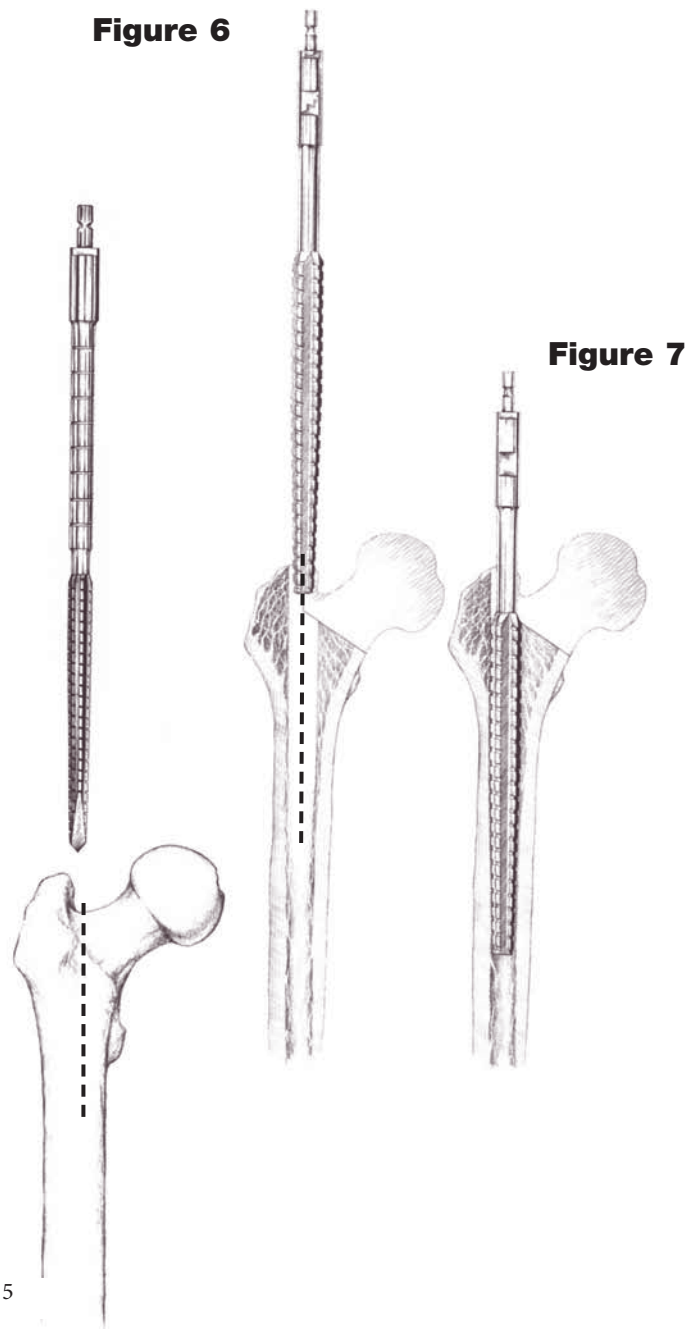


Figure 5

Step 3a: Cylindrical Axial Reaming

(For Secur-Fit Plus Max Only)

(Fig. 8)(Table 1)

Table 1

Cylindrical Reamer Sizing (for Secur-Fit Plus Max only)

	Distal Diameter (mm)	Final Cylindrical Reamer (mm)	Cylindrical Reamer Minimum Depth of Insertion (mm)
5	9	8.5 or 9.0	110
5	11	10.5 or 11.0	110
6	10	9.5 or 10.0	120
6	12	11.5 or 12.0	120
7	11	10.5 or 11.0	130
7	13	12.5 or 13.0	130
8	12	11.5 or 12.0	140
8	14	13.5 or 14.0	140
9	13	12.5 or 13.0	150
9	15	14.5 or 15.0	150
10	14	13.5 or 14.0	160
10	16	15.5 or 16.0	160
11	15	14.5 or 15.0	170
11	17	16.5 or 17.0	170
12	16	15.5 or 16.0	170
12	18	17.5 or 18.0	170
13	17	16.5 or 17.0	170
13	19	18.5 or 19.0	170
14	18	17.5 or 18.0	170
14	20	19.5 or 20.0	170

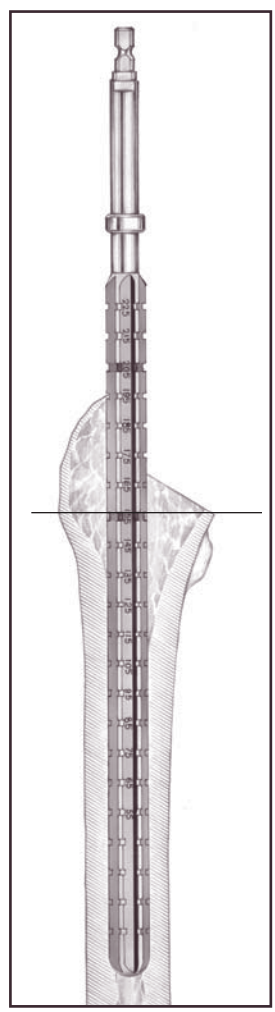


Fig. 8

Proper insertion depth

Step 4: Broaching

The Femoral Broach/Trial is used to contour the medial, anterior and posterior aspects of the proximal femur **(Fig. 9)**. Unlike reamers which cut cortical bone, broaches are primarily scraping and crushing instruments which shape proximal cancellous bone.

Prior to use, the Tapered Distal Extension or the Cylindrical Distal Extension (Secur-Fit™ Plus Max only) and Offset Broach Handle must be assembled to the broach. Match the Tapered or Cylindrical Distal Extension to the corresponding Broach/Trial **(Table 2)**.

Thread the Tapered or Cylindrical Distal Extension onto the mating thread at the distal end of the broach. The Counter Wrench may be placed over the scalloped cut-outs or a circular rod may be placed through the cross hole in the Distal Extension to secure/remove the Distal Extension from the Femoral Broach.

Assemble the Offset Broach Handle to the broach by retracting the actuator and inserting it into the key slot in the broach **(Fig. 10)**.

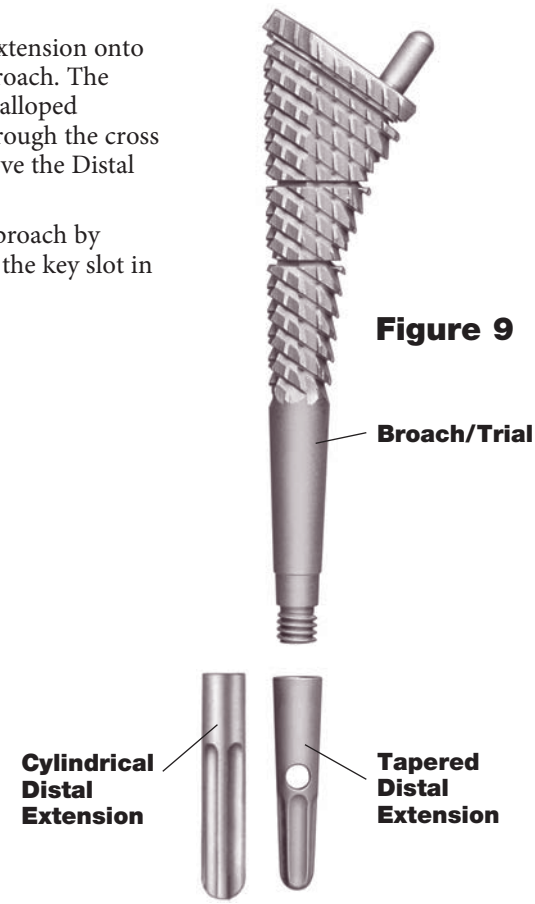


Figure 9

Figure 10

Table 2
BROACH/DISTAL EXTENSION SIZING

Cement Stem Size	Press-Fit Stem Size	Silver** Proximal Broach	Tapered Distal Extension	Cylindrical Distal Extension (Secur-Fit™ Plus Max only 6054-XXXX)
2	4	1112-0204M*	1212-0008 (8mm)*	—
3	5	1112-0305M*	1212-0008 (8mm)*	—
4	6	1112-0406M*	1212-0008 (8mm)*	—
5	7	1126-0507	1213-0507	1212-4110 (11mm) or 1212-4130 (13mm)
6	8	1126-0608	1213-0608	1212-4120 (12mm) or 1212-4140 (14mm)
7	9	1126-0709	1213-0709	1212-4130 (13mm) or 1212-4150 (15mm)
8	10	1126-0810	1213-0810	1212-4140 (14mm) or 1212-4160 (16mm)
9	11	1126-0911	1213-0911	1212-4150 (15mm) or 1212-4170 (17mm)
10	12	1126-1012	1213-1012	1212-4160 (16mm) or 1212-4180 (18mm)
11	13	1126-1113	1213-1113	1212-4170 (17mm) or 1212-4190 (19mm)
12	14	1126-1214	1213-1214	1212-4180 (18mm) or 1212-4200 (20mm)

***For press-fit stem sizes 4 thru 6, the Stryker 1112-XXXXM Broach/Trial is to be used with an 8mm Trial Distal Tip.**

****Optional gold Broaches reduce the amount of press-fit achieved with final implant and are available with Secur-Fit Max and Secur-Fit Plus Max stems only.**

Proper insertion depth of the broach in the canal is achieved when the most proximal level of the cutting teeth intersect the most proximal aspect of the anticipated final neck resection **(Fig. 11)**. The broach may be countersunk if allowance has been made for calcar planing. To prevent malalignment, it is imperative that axial alignment of the broach be maintained at all times in the canal **(Fig. 12)**.

Select and assemble a broach which is two sizes smaller than the planned implant size to the Offset Broach Handle **(Table 3)**. Broach sequentially upward in size until the broach matches that of the planned stem size and application.

Table 3

BROACH (1126-XXXX)/HANDLE SIZING

Cement Broach Size Number	2	3	4	5	6	7	8	9	10	11	12
Press-Fit Broach Size Number	4	5	6	7	8	9	10	11	12	13	14
Broach Handle	SMALL			STANDARD							

"A solid metal rod may be inserted into one of the broach handle holes to assess proper anteversion."

John Andronaco, M.D.

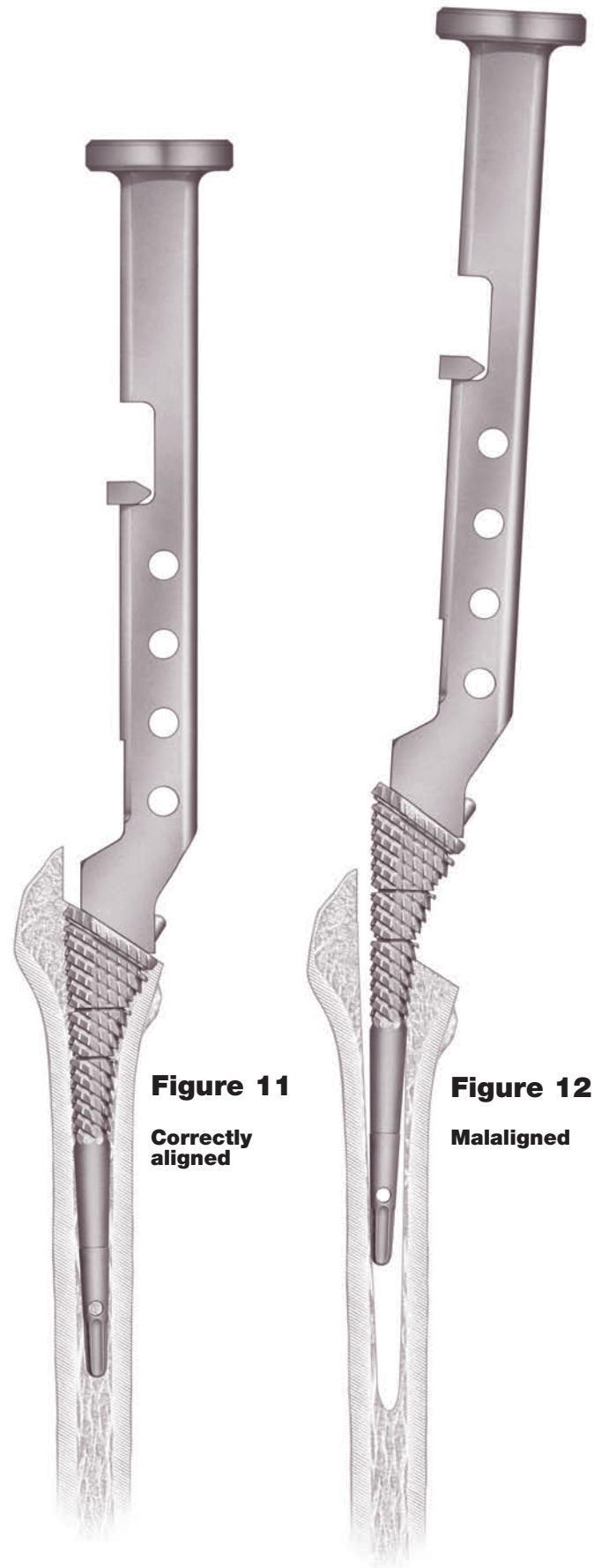


Figure 11

Correctly aligned

Figure 12

Malaligned

The final broach should seat tightly in highly densified cancellous bone **(Fig. 13A)**. The outer dimension of the broach is equivalent in size to the corresponding Stryker Omnifit® press-fit stem size, thus approximating the final stem seating level. Proper seating of the broach allows for a further evaluation of the neck resection level **(Fig. 13B)**.

Note: Secur-Fit Max Stems are 1.25mm larger than the broach (Silver) outer dimensions. For these stems, it may be necessary to slightly countersink the broach to seat the stem properly.

If a broach larger than the planned stem size is required for proper fit, the bone must be reamed with the Tapered Axial Reamers to the larger size. Failure to do so could result in a fracture of the shaft upon stem insertion.

Leave the final broach fully seated in the canal and detach the Offset Broach Handle to allow for calcar planing and trial reduction.

> *"In my experience, the final centimeter of seating of that desired broach occurs with a little difficulty and a little work."*
>
> *James A. D'Antonio, M.D.*

Figure 13A

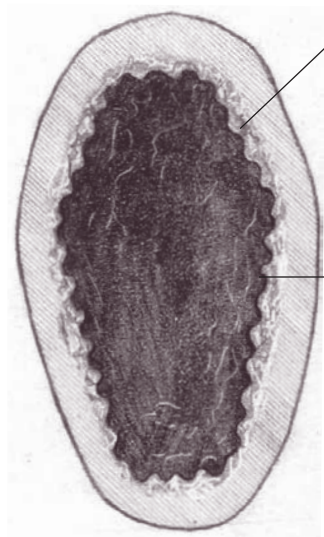
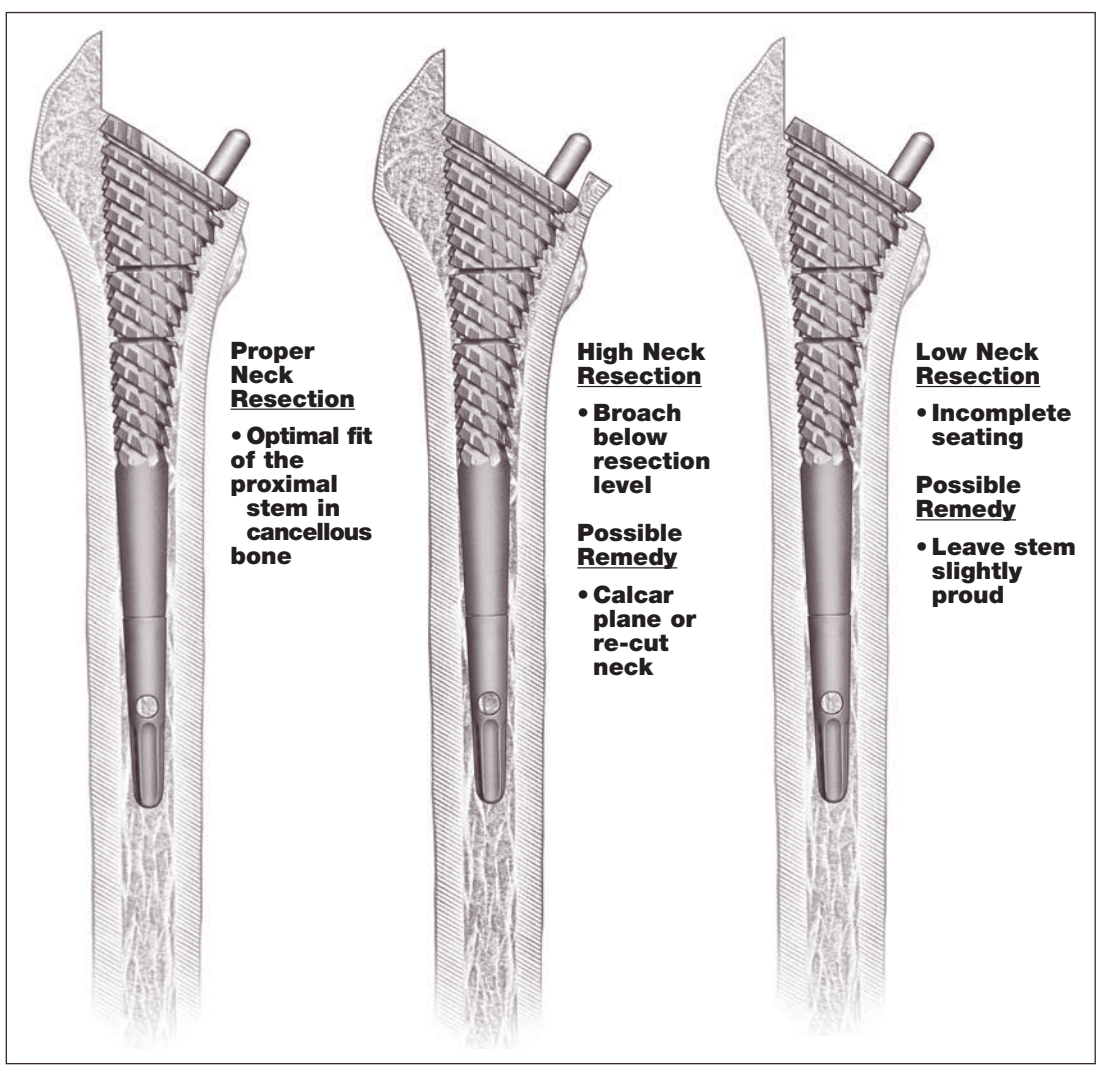


Figure 13B Broach Placement at Templated and Desired Level



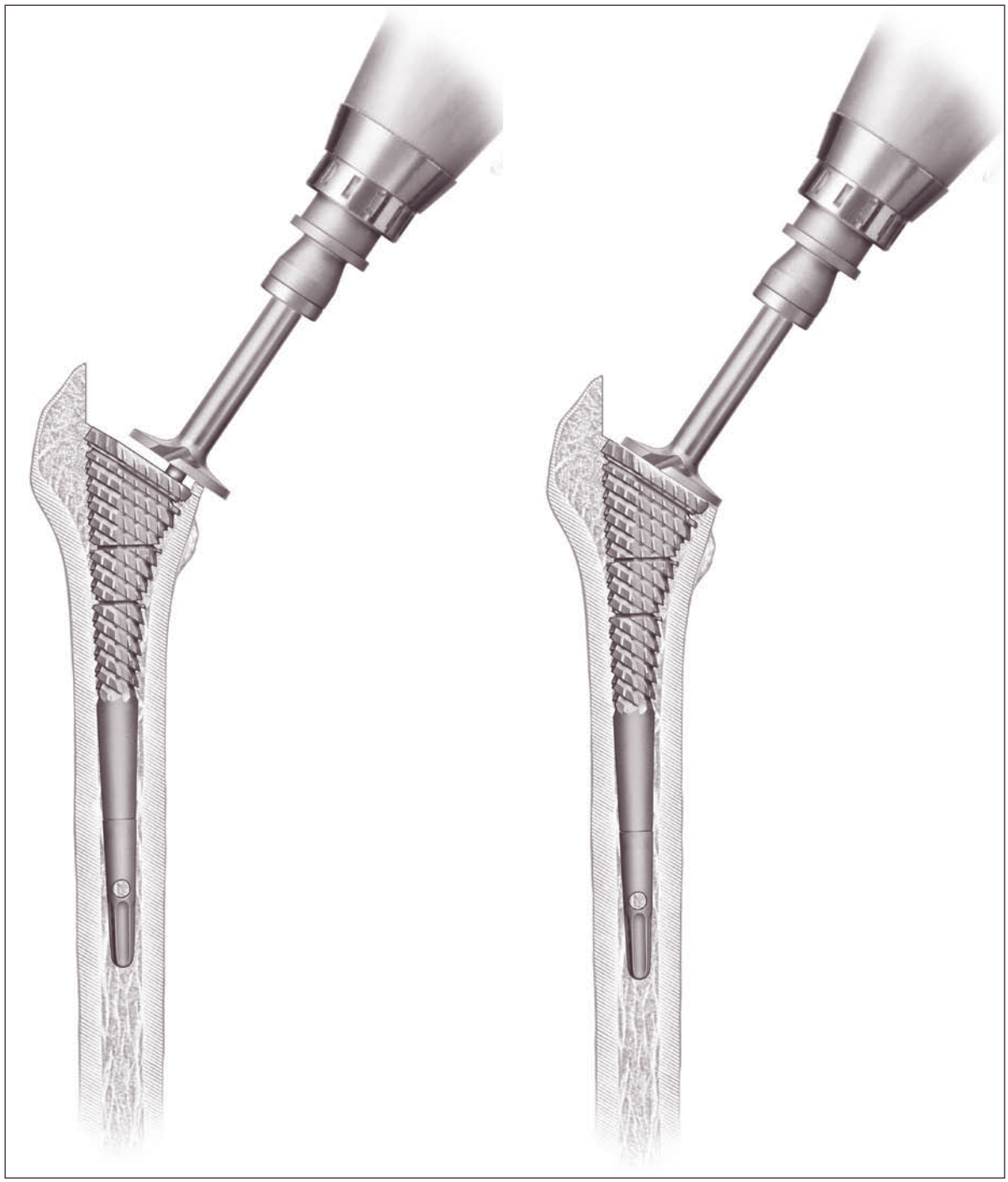
Step 4a: Optional Calcar Planing

Leaving the final Broach seated in the femoral canal **(Figure 14)**, gently guide the Calcar Planer over the Broach post (see note below) and initiate power prior to contacting the femur. Slowly advance the Calcar Planer toward the Broach to plane the femur. Planing will continue until the positive stop on the Planer contacts the Broach face.

Note: In the event that the Broach Post is seated completely below the resection plane (thus preventing engagement with the Calcar Planer), the Broach should be removed and the resection re-cut at a slightly lower level. The surgeon should then re-insert the final Broach ensuring a stable and snug fit.

Caution: Failure to operate the Calcar Planer in accordance with the instructions may result in damage to the femur.

Figure 14



Step 5: Trial Reduction

The trial assembly, which consists of the Broach/Tapered Distal Extension, Trial Neck and Trial Head, provides a thorough evaluation of hip mechanics before final components are implanted. Before the selection and implantation of the final components, modifications to the pre-operative plan in terms of neck length and/or head diameter can be made at this time.

Select a C-Taper Trial Neck which has the same base neck length as the planned implant size **(Table 4)**.

Table 4

Stem	Neck Angle		Broach Size										
	127°	132°	4	5	6	7	8	9	10	11	12	13	14
			Neck Length										
6052-XXXXS Secur-Fit Max	X				25	30	30	35	35	40	40	40	
6051-XXXXS Secur-Fit Max		X	25	25	25	30	30	35	35	40	40	40	40
6054-XXXXS Secur-Fit Max Plus	X			25	25	30	30	35	35	40	40	40	40
S2337-XXXX Secur-fit w/ Collar*		X	25	25	25	30	30	35	35	40	40	40	
6034-XXXX OmniFit Normalized w/ Collar		X	25	25	25	30	30	35	35	40	40	40	
6033-XXXX OmniFit Normalized w/o Collar		X	25	25	25	30	30	35	35	40		40	
6072-XXXX ODC FX Hip Stem*		X			25	30	30	35	35				
6017-XXXXA OmniFit HA		X	25	25	25	30	30	35	35	40	40	40	40
6076-XXXXA OmniFit HFX*	X			25	25	30	30	35	35				
6070-XXXXA OmniFit HFX*		X		25	25	30	30	35	35	40			
6073-XXXX ODC Hip Stem*		X		25	25	30	30	35	35	40			
6097-XXXX OmniFit Eon	X		25	30	30	35	35	40	40	40			
6098-XXXX OmniFit Eon		X	25	30	30	35	35	40	40	40			

*S2337, 6072, 6076, 6070, 6073 not ce marked.

*These products are NOT CE marked per the Medical Device Directive 93/42/EEC and cannot be marketed, put into service, or implanted in the European Union.

Place the C-Taper Trial Neck over the post and into the key slot in the Broach **(Fig. 15)**.

Next, select a plastic Stryker Omnifit® C-Taper Trial Head and place it onto the C-Taper Trial Neck. Refer to **Table 5** for head diameter and head offset combinations. Head offset is adjusted until leg lengths are equal. Joint stability can be checked by telescoping the leg and performing a full range of motion.

Upon confirmation of the selected components, remove the trial head and trial neck, and re-assemble the Broach Handle. Remove the broach/trial assembly with the help of the Slotted Mallet, to preserve the integrity of the established cavity. **(Fig. 16)**

*The -3mm C-Taper Trial Head is only available in 28mm O.D.

**The -5mm C-Taper Trial Head is only to be used with stems having a base neck length of 35mm and longer.

"The hip is reduced and placed through a range of motion. Full extension, with 30° of external rotation and flexion to 90° and 45° of internal rotation is necessary for stable arthroplasty."

William Capello, M.D.

"At this point, we remove the broach, irrigate the IM canal with pulsatile saline which washes away loose cancellous bone but does not eliminate the waffling effect of the firmer cancellous and cortical bone that has been cut from the inner femur."

James A. D'Antonio, M.D.

Note: If preparing for a press-fit stem, proceed directly to step 6. Otherwise, skip to step 7 (Cemented Femoral Stem Implantation).

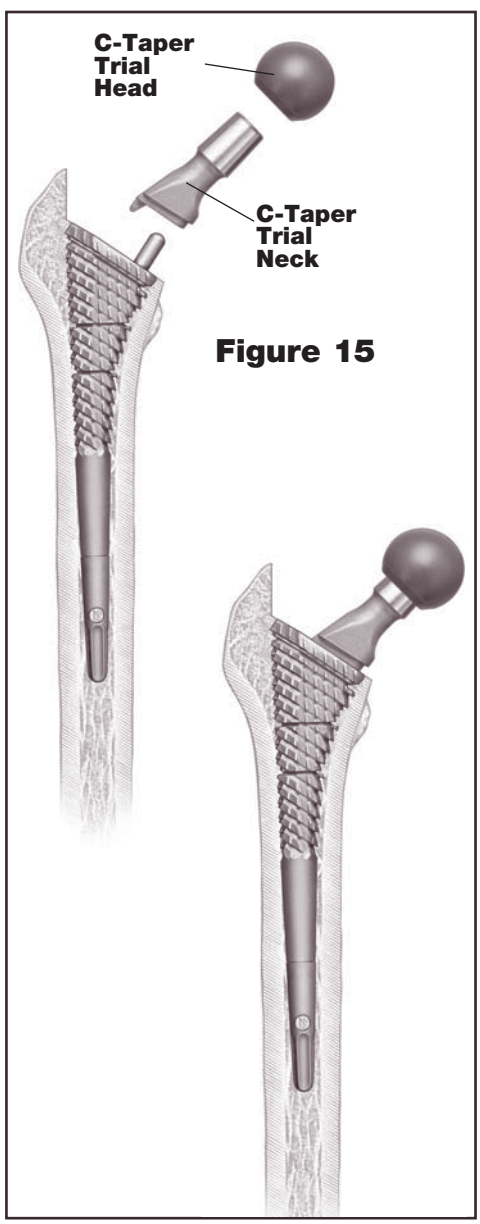


Figure 15

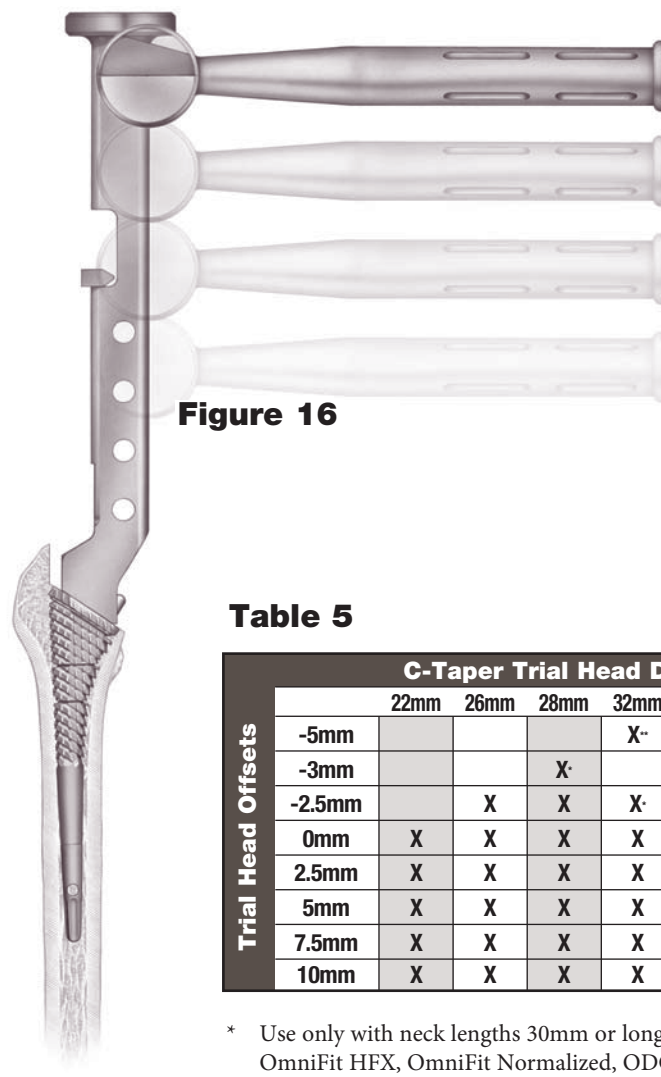


Figure 16

Table 5

Trial Head Offsets	C-Taper Trial Head Diameters						
	22mm	26mm	28mm	32mm	36mm	40mm	44mm
-5mm				X**	X**	X**	X**
-3mm			X*				
-2.5mm		X	X	X*	X*	X*	X*
0mm	X	X	X	X	X	X	X
2.5mm	X	X	X	X	X	X	X
5mm	X	X	X	X	X	X	X
7.5mm	X	X	X	X	X	X	
10mm	X	X	X	X	X	X	

* Use only with neck lengths 30mm or longer for OmniFit Eon, OmniFit HFX, OmniFit Normalized, ODC FX and ODC Hip Stem.

** Use only with neck lengths 35mm or longer for OmniFit Eon, OmniFit HFX, OmniFit Normalized, ODC FX and ODC Hip Stem.

Step 6: Press-Fit Femoral Stem Implantation

Thread the Cutting*Edge* Femoral Stem Impactor/Extractor **(Fig. 17)** into the recess on the lateral side of the proximal face of the stem. So as not to damage the threads on the stem as well as the instrument, be certain that the Cutting*Edge* Femoral Stem Impactor/Extractor is fully seated against the proximal face of the stem. A Slotted Mallet is then used to seat the stem into the canal.

Note: Should the Femoral Impactor/Extractor become difficult to remove upon implant seating, simply thread the aluminum Version Control Handle into the side of the knob and turn counter-clockwise to loosen.

"With a light mallet, progressively tap the femoral prosthesis in place until resistance is met. If that resistance is met prior to full seating, we wait 10-15 seconds and then impact the prosthesis further, and frequently find that it will seat with out great difficulty."

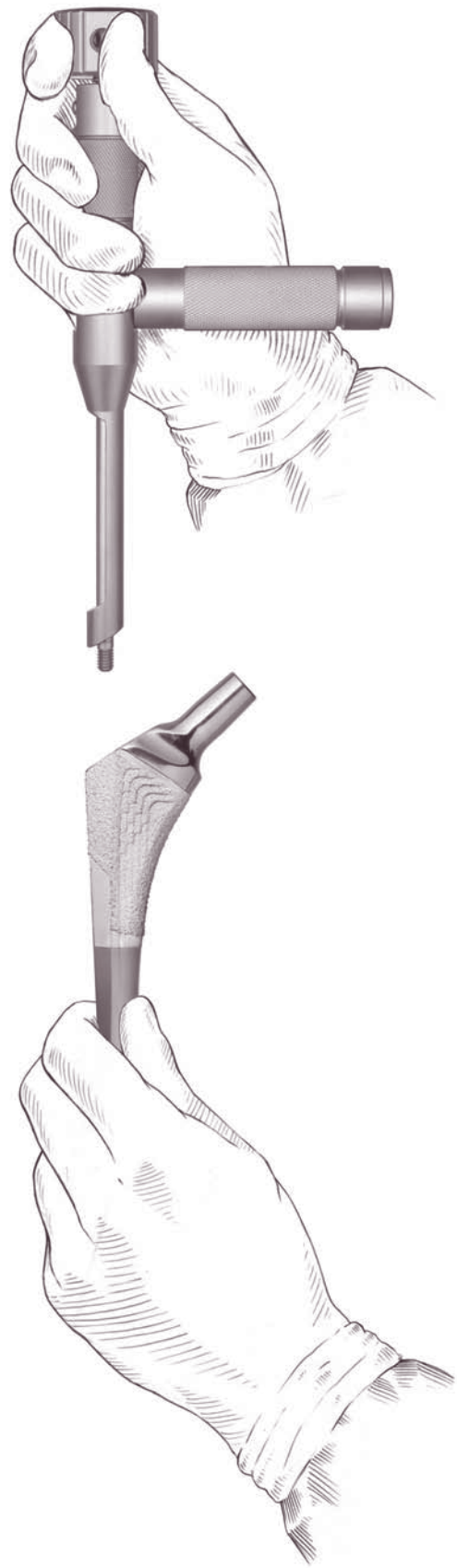
James A. D'Antonio, M.D.

"Cortical fracture may occur on final seating of the prosthesis, particularly if a harder blow is delivered as more resistance is encountered. Start with a firm enough blow that will satisfactorily advance the prosthesis and continue with that amount of force through the entire insertion. When the prosthesis stops moving, that's the time to stop the impaction."

Benjamin E. Bierbaum, M.D.

Note: Skip to Step 8 (Head Assembly).

Figure 17



Step 7: Cemented Femoral Stem Implantation

Cleaning the Canal and Cement-Plug Insertion

The established principles and methods for preparing the intermedullary canal for cementing should be meticulously applied. The practice of bristle brushing followed by pulsatile lavage provides an effective method for cleaning the canal of loose cancellous bone and trapped debris prior to Cement-Plug insertion **(Fig. 18)**. An optional Universal Cement-Plug and a sized Cement-Plug are available.

To determine the proper depth of the cement plug the selected stem is placed alongside the Cement-Plug Inserter, leaving at least 2cm between the shoulder on the threads of the instrument and the stem tip. The engraved groove closest to the medial aspect of the stem collar is used as a reference for the depth of insertion **(Fig 19)**.

When trialing for the Sized Cement-Plug, the Cement-Plug Trial must be fully threaded onto the Inserter prior to the test insertion. Proper fit is determined by the Trial which fits snugly in the canal when inserted to the reference depth or until mild resistance is encountered based on surgeon preference.

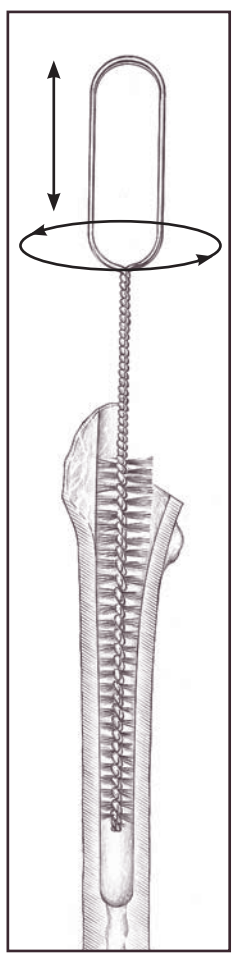
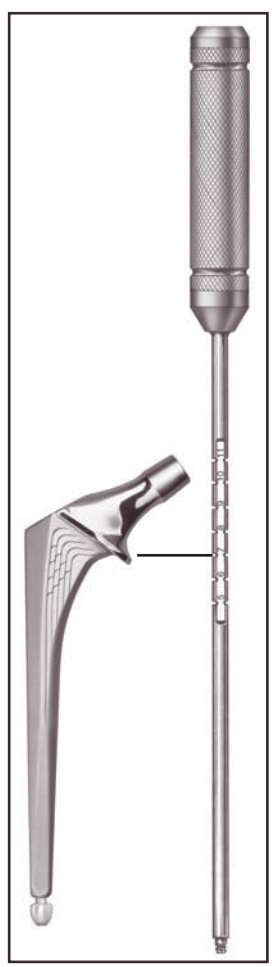


Figure 18



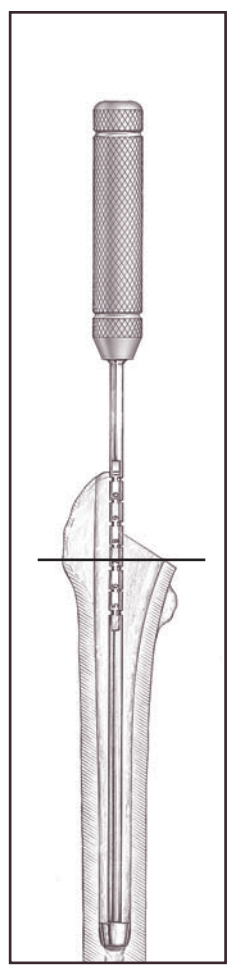


Figure 19

Distal Cement Spacer and Cemented Stem Insertion

The Distal Cement Spacer is designed to be inserted into the corresponding hole in the distal end of the cemented stem. During implant insertion, the Universal Distal Cement Spacer will assist in positioning the stem in the neutral axis of the cement-filled femoral canal **(Figure 20)**.

Caution: Do not twist the PMMA spacer in the stem as it will score and possibly fracture.

Note: If the decision has been made not to utilize the Distal Cement Spacer, then it is recommended that the distal stem hole be plugged with a small amount of unpolymerized PMMA, prior to insertion.

Note: It is recommended that the distal cement spacer be coated with unpolymerized PMMA to help prevent introduction of air and cement defects.

Note: Cylindrically reaming to the minimum size Distal Spacer is optional. However, if a larger than minimum size Distal Spacer is planned, then cylindrical reaming of the distal femoral canal may be required and should be accomplished prior to plugging the canal.

Table 6

Cement Spacer Sizing

Stem Size	Minimum Size PMMA Distal Cement Spacer	Minimum Cylindrical Axial Reamer Size To Be Used	Catalog Number
#4	8mm	8mm	1067-0008
#5	8mm	8mm	1067-0008
#6	9mm	9mm	1067-0009
#7	10mm	10mm	1067-0010
#8	11mm	11mm	1067-0011
#9	11mm	11mm	1067-0011
#10	12mm	12mm	1067-0012
#11	13mm	13mm	1067-0013

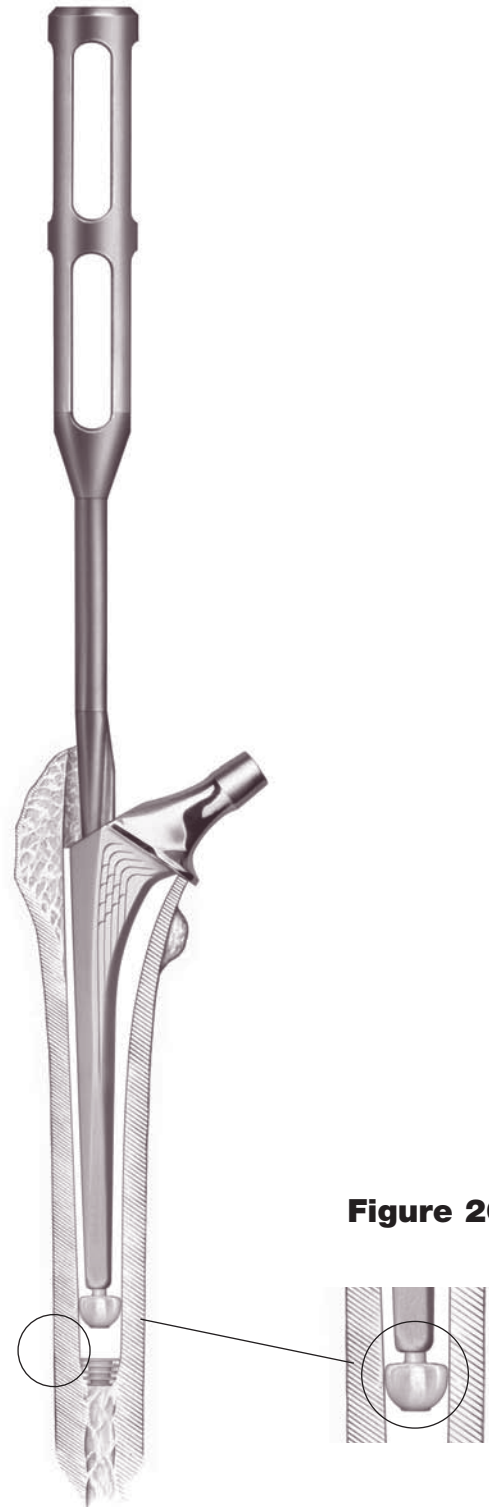


Figure 20

Note: Cylindrically reaming to the minimum size Distal Spacer is optional. However, if a larger than a minimum size Distal Spacer is planned, then cylindrical reaming of the distal femoral canal may be required and should be accomplished prior to plugging the canal.

Final Canal Preparation and Cement Delivery

The medullary canal is thoroughly lavaged and dried with a laparatomy sponge prior to cement delivery **(Fig. 21)**. A cement gun is employed to introduce doughy cement in a retrograde manner **(Fig. 22)**. The distal portion of the nozzle is broken away below the conical pressurizer and the cement is pressurized with the cement gun through the pressurizer **(Fig. 23)**.

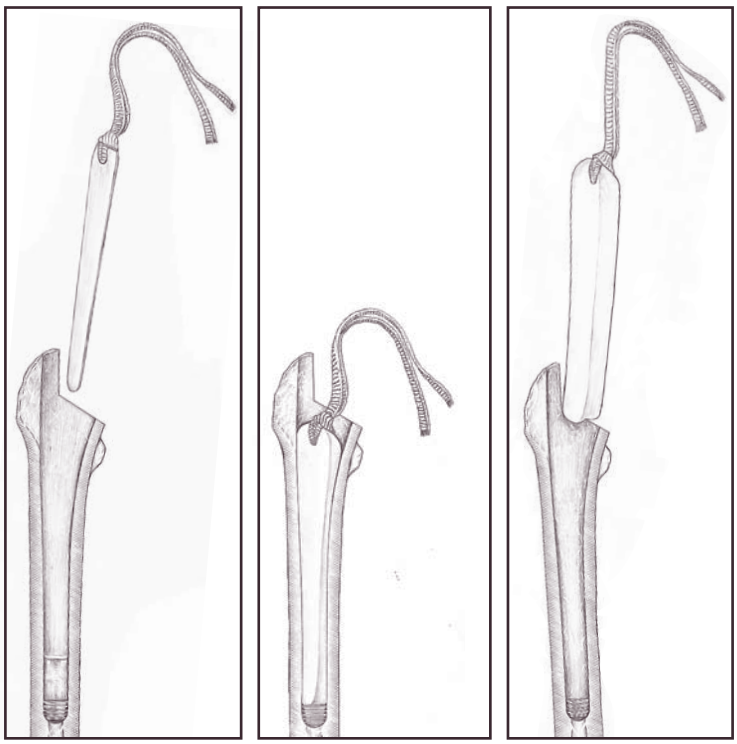


Figure 21

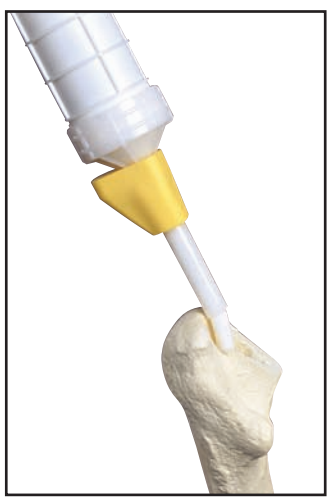
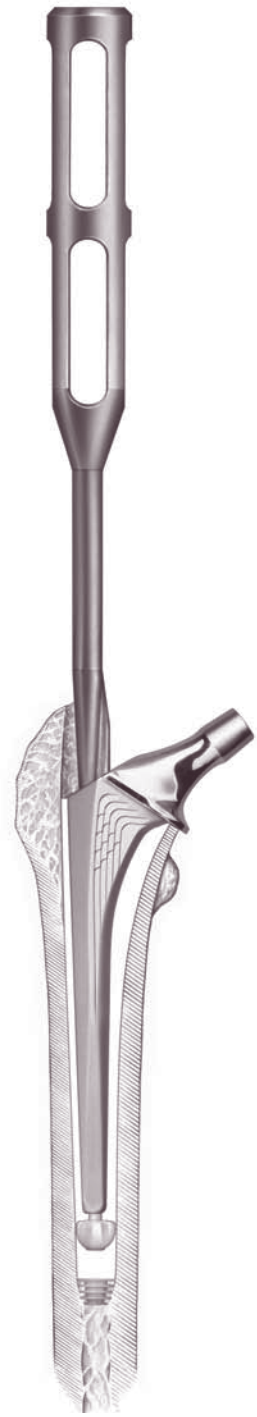


Figure 22

Figure 23

Cemented Stem Insertion

The proximal portion of the stem is coated with doughy cement to ensure that blood and fat does not come in contact with the stem. To assist in aligning and seating the stem, the OmniFit EON Stem Inserter should be used. Introduce the assembled stem into the femoral canal with an axial force while providing a laterally directed force. The goal is to introduce the stem in a neutral position with an adequate cement mantle. Remove excess cement. At final seating, the collar of the prosthesis should rest in intimate contact with the prepared neck cut.



Step 8: Head Assembly

Prior to head assembly, neck length selection may be re-evaluated using the C-Taper Trial Heads. Place the C-Taper Trial Head onto the stem neck taper and reduce the hip to ensure hip mechanics have not been altered due to implant seating.

Select the appropriate Stryker C-Taper Head and place it onto the dry trunnion of the femoral stem with a slight twist. Impact the head with two moderate blows using the Stem Head Impactor **(Fig. 24)**.

If necessary, the head can be removed utilizing the Head Dis-assembly Instrument. Refer to Appendix B for further procedural information.

Note: Cemented Stems are not compatible with Alumina ceramic heads. BIOLOX delta can be used as an alternative.

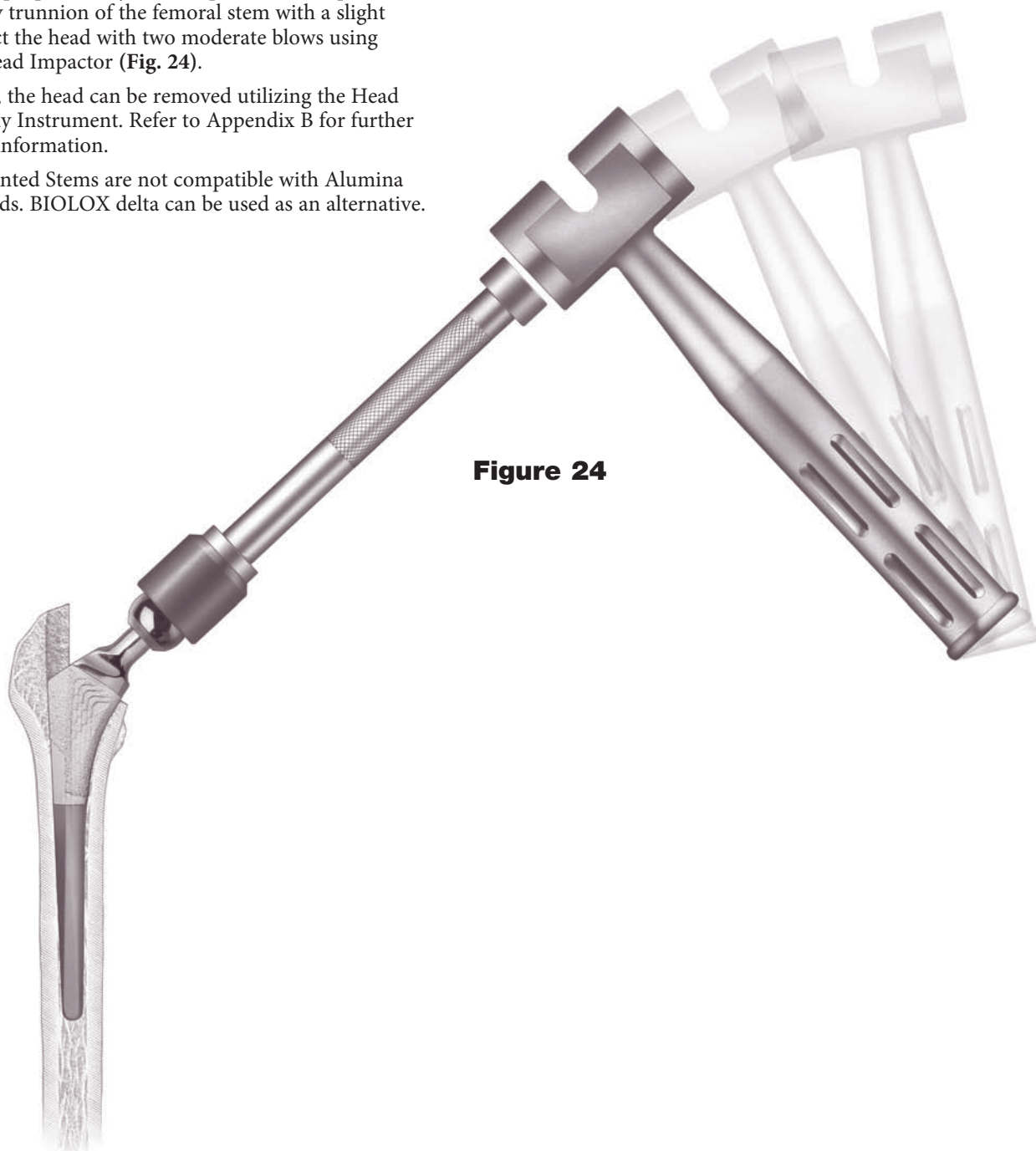


Figure 24

Step 9: Final Biomechanic Check

Relocate the femoral head into the acetabular cup and re-check the laxity and range of motion for stability. The surgical site is then closed according to surgeon preference.

Appendix B: Box Chisel and Trochanteric Reamers

The Box Chisel and Trochanteric Reamers remove bone from the proximal femur to permit true axial introduction of the femoral instrumentation.

Box Chisel

Before tapered axial reaming, position the Box Chisel as shown **(Fig. 25)**. Apply several moderate blows using the Slotted Mallet to remove the desired amount of bone. Reposition as necessary.

"It is important to be lateral with the box chisel in order to obtain true axial alignment."

John Andronaco, M.D.

Figure 25

Trochanteric Reamers

After using the Starter Tapered Axial Reamer and before the introduction of additional Tapered Axial Reamers, select and use the appropriate Trochanteric Reamer **(Table 7)**. The reamer may be introduced with the Quick-Release T-Handle or a low speed power tool. Insert the Trochanteric Reamer into the canal and bias the cutting teeth to remove the desired amount of bone **(Fig. 26 and 27)**.

Do not sink the reamer below the level of the trochanter. Performing this step can help facilitate the axial alignment of the broach so that is not pushed into varus by an overhanging trochanter. Varus positioning of the implant may result in an improperly placed or potentially undersized implant.

Table 7

Trochanteric Reamer Sizing

Templated											
Stem Size	4	5	6	7	8	9	10	11	12	13	14
Trochanteric Reamer Size	SMALL			STANDARD					LARGE		

"Take care not to sink the reamer below the level of the trochanter."

John Andronaco, M.D.

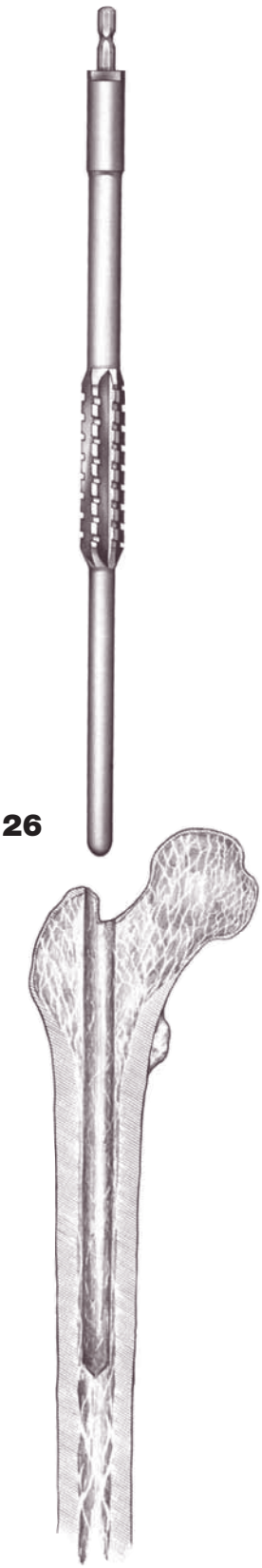


Figure 26

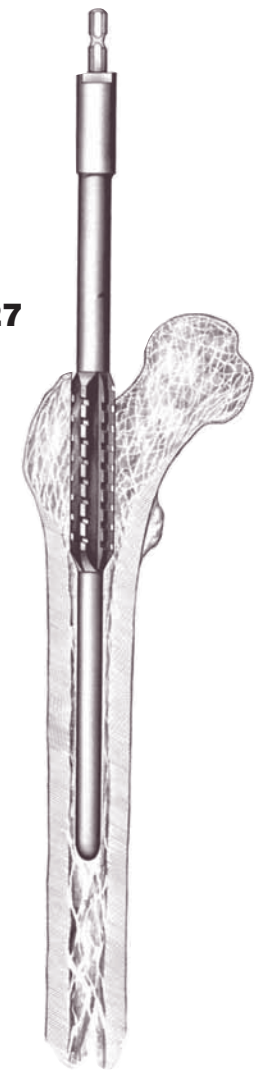


Figure 27

Post-Operative Care, Indications, Contraindications, Precautions, Warnings and Adverse Effects

The below indications are for:

- Secur-Fit Max
- Secur-Fit Plus Max

Indications

- Non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis;
- Correction of functional deformity;
- Revision procedures where other treatments or devices have failed; and,
- Treatment of non-unions, femoral neck fractures, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Contraindications

- Active infection or suspected latent infection in or about the hip joint;
- Bone stock that is inadequate for support or fixation of the prosthesis;
- Skeletal immaturity;
- Any mental or neuromuscular disorder that would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complications in post-operative care.

The below indications are for:

- Head/Neck Replacement (HNR) System

Indications

- Femoral head/neck fractures or non-unions.
- Aseptic necrosis of the femoral head.
- Osteo-, rheumatoid, and post-traumatic arthritis of the hip with minimal acetabular involvement or distortion.
- For use as a Bipolar Hip Replacement.

Other Considerations:

- Pathological conditions or age considerations which indicate a more conservative acetabular procedure and an avoidance of the use of bone cement in the acetabulum.
- Salvage of failed total hip arthroplasty.

For use as a Total Hip Replacement:

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.

Additional Indication for HOWMEDICA OSTEONICS Head/Neck Stems:

- Clinical circumstances which require an altered femoral resection level due to a proximal fracture, bone loss or calcar lysis.

Contraindications

- Any active or suspected latent infection in or about the hip joint.
- Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complications in post-operative care.
- Bone stock compromised by disease, infection or prior implantation which cannot provide adequate support and/or fixation to the prosthesis.
- Skeletal immaturity.
- HOWMEDICA OSTEONICS +10mm neck Femoral Bearing Heads are contraindicated for use with porous coated cobalt-chromium alloy femoral stems in obese or active or large patients.

Other contraindications for use as a bipolar/hemi-hip replacement include: pathological conditions of the acetabulum which would prevent achieving adequate range of motion, appropriate head stability, and/or a well-seated and supported smooth acetabular articulation of the head.

The below indications are for:

- ODC FX

Indications

For use as a Bipolar Hip Replacement:

- Femoral head/neck fractures or non-unions.
- Aseptic necrosis of the femoral head.
- Osteo-, rheumatoid, and post-traumatic arthritis of the hip with minimal acetabular involvement or distortion.
- Pathological conditions or age considerations which indicate a more conservative acetabular procedure and an avoidance of the use of bone cement in the acetabulum.
- Salvage of failed total hip arthroplasty.

Indication specific to the OSTEONICS ODC-FX HFX Hip Stems:

- Femoral neck fractures.

For use as a Total Hip Replacement:

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.

Contraindications

- Any active or suspected latent infection in or about the hip joint.
- Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complications in post-operative care.
- Bone stock compromised by disease, infection or prior implantation which cannot provide adequate support and/or fixation to the prosthesis.
- Skeletal immaturity.

Contraindications specific to the OSTEONICS ODC-FX Hip Stem:

- Patients who are heavier than 180 lbs.
- Patients who are active.
- Patients who are non-compliant with their physicians' instructions.

Other contraindications for use as a bipolar/hemi-hip replacement include: pathological conditions of the acetabulum which would prevent achieving adequate range of motion, appropriate head stability, and/or a well-seated and supported smooth acetabular articulation of the head.

The below indications are for:

- OmniFit HFX

Indications

For use as a Bipolar Hip Replacement:

- Femoral head/neck fractures or non-unions.
- Aseptic necrosis of the femoral head.
- Osteo-, rheumatoid, and post-traumatic arthritis of the hip with minimal acetabular involvement or distortion.
- Pathological conditions or age considerations which indicate a more conservative acetabular procedure and an avoidance of the use of bone cement in the acetabulum.
- Salvage of failed total hip arthroplasty.
- Femoral Neck Fracture.

For use as a Total Hip Replacement:

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, posttraumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Clinical circumstances that require an altered femoral resection level due to proximal fracture, bone loss, or calcar lysis.

Contraindications

- Any active or suspected latent infection in or about the hip joint.
- Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complications in post-operative care.
- Bone stock compromised by disease, infection or prior implantation which cannot provide adequate support and/or fixation to the prosthesis.
- Skeletal immaturity.

Other contraindications for use as a Bipolar/Hemi-Hip Replacement include: pathological conditions of the acetabulum which would prevent achieving adequate range of motion, appropriate head stability, and/or a well seated and supported smooth acetabular articulation of the head.

Warning and Precautions
See package insert for warnings, precautions, adverse effects and other essential product information.

The below indications are for:

- ODC Hip Stem
- OmniFit HA
- OmniFit Normalized
- OmniFit Eon
- Secur-Fit HA w/ Collar

Indications

For use as a Bipolar Hip Replacement:

- Femoral head/neck fractures or non-unions.
- Aseptic necrosis of the femoral head.
- Osteo-, rheumatoid, and post-traumatic arthritis of the hip with minimal acetabular involvement or distortion.
- Pathological conditions or age considerations which indicate a more conservative acetabular procedure and an avoidance of the use of bone cement in the acetabulum.
- Salvage of failed total hip arthroplasty.

For use as a Total Hip Replacement:

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.

Contraindications

- Any active or suspected latent infection in or about the hip joint.
- Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complications in post-operative care.
- Bone stock compromised by disease, infection or prior implantation which cannot provide adequate support and/or fixation to the prosthesis.
- Skeletal immaturity.

Other contraindications for use as a Bipolar/Hemi-Hip Replacement include: pathological conditions of the acetabulum which would prevent achieving adequate range of motion, appropriate head stability, and/or a well seated and supported smooth acetabular articulation of the head.

Notes

Notes

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