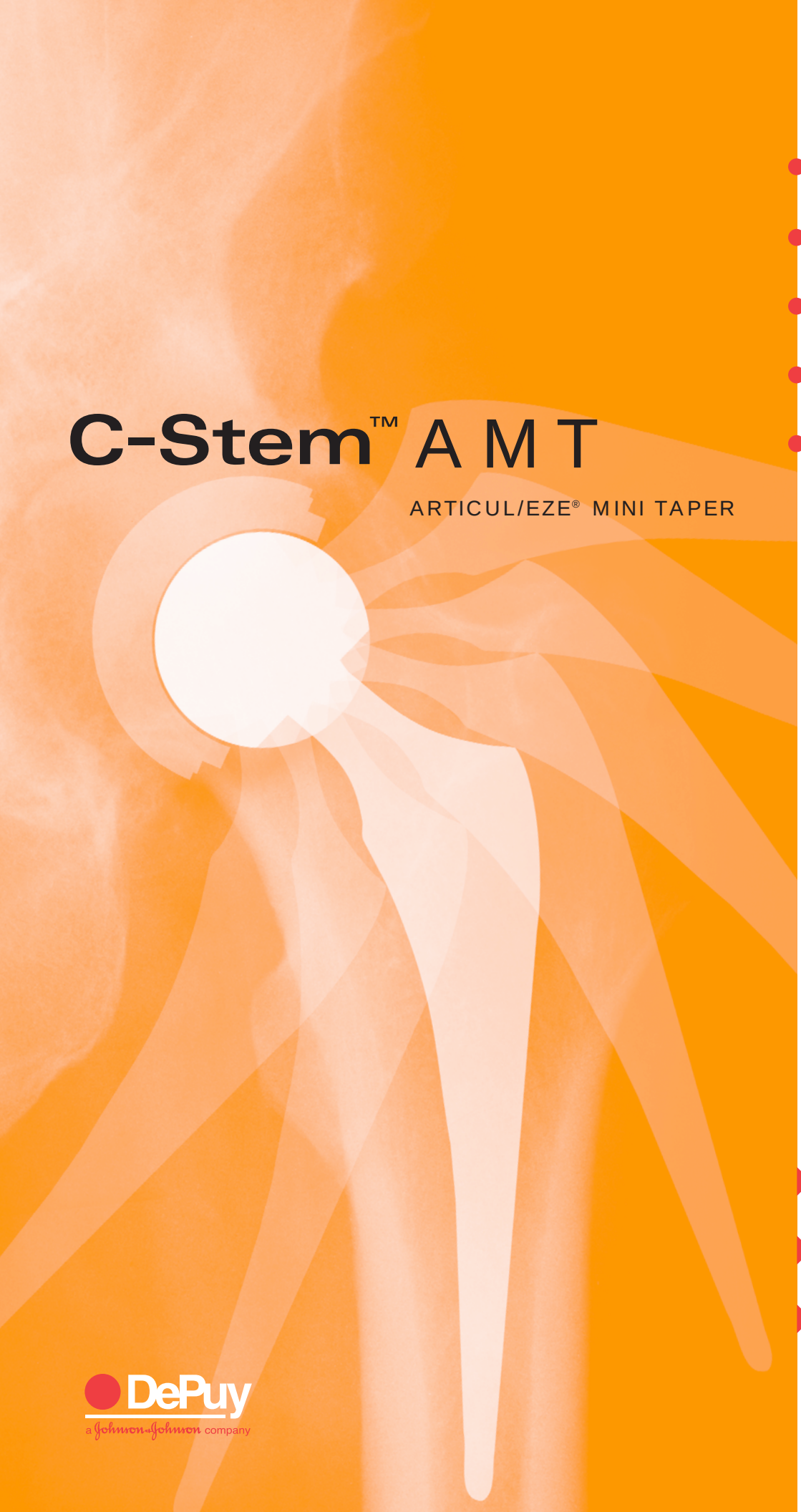
SURGICAL TECHNIQUE

C-Stem™ A M T

ARTICUL/EZE® MINI TAPER



- POSITIVE BONE REMODELING
- ENHANCED BIOMECHANICS
- CEMENT MANTLE INTEGRITY

DePuy
a Johnson & Johnson company

Charnley low-frictional torque arthroplasty remains the gold standard in cemented total hip arthroplasty with over 35 years of clinical results demonstrating reliability and durability. Nevertheless, improvements in design and technique, and in particular cementing technique, and a more sophisticated understanding of fixation philosophies within the cement mantle have been made with cemented stems.

The C-Stem™ AMT builds on the foundation of knowledge garnered from the Charnley experience. The C-Stem was originally designed along with Professor Michael Wroblewski in accordance with the taper-slip philosophy in order to favorably load the bone with radial hoop stresses. Unlike traditional double tapered stems, the C-Stem adds the unique third taper from broad lateral to narrow medial, which restricts subsidence to within the limits of cement creep, confers improved axial and torsional stability, and favorably loads the proximal medial bone. The distal void centralizer prevents distal stem support and enables engagement of the three tapers within the cement; and the polished surface minimizes shear debris generation during the taper engagement into the cement mantle.

The C-Stem AMT advances this robust intramedullary design by providing improved extramedullary options which facilitate balancing of the soft tissues and maximizing hip stability. Multiple offset options, along with the 12/14 neck taper accommodating multiple head sizes in a wide variety of neck lengths provide to the surgeon tremendous versatility in optimizing the biomechanical reconstruction of the hip.

C-Stem AMT Cemented Stem was designed in consultation with:

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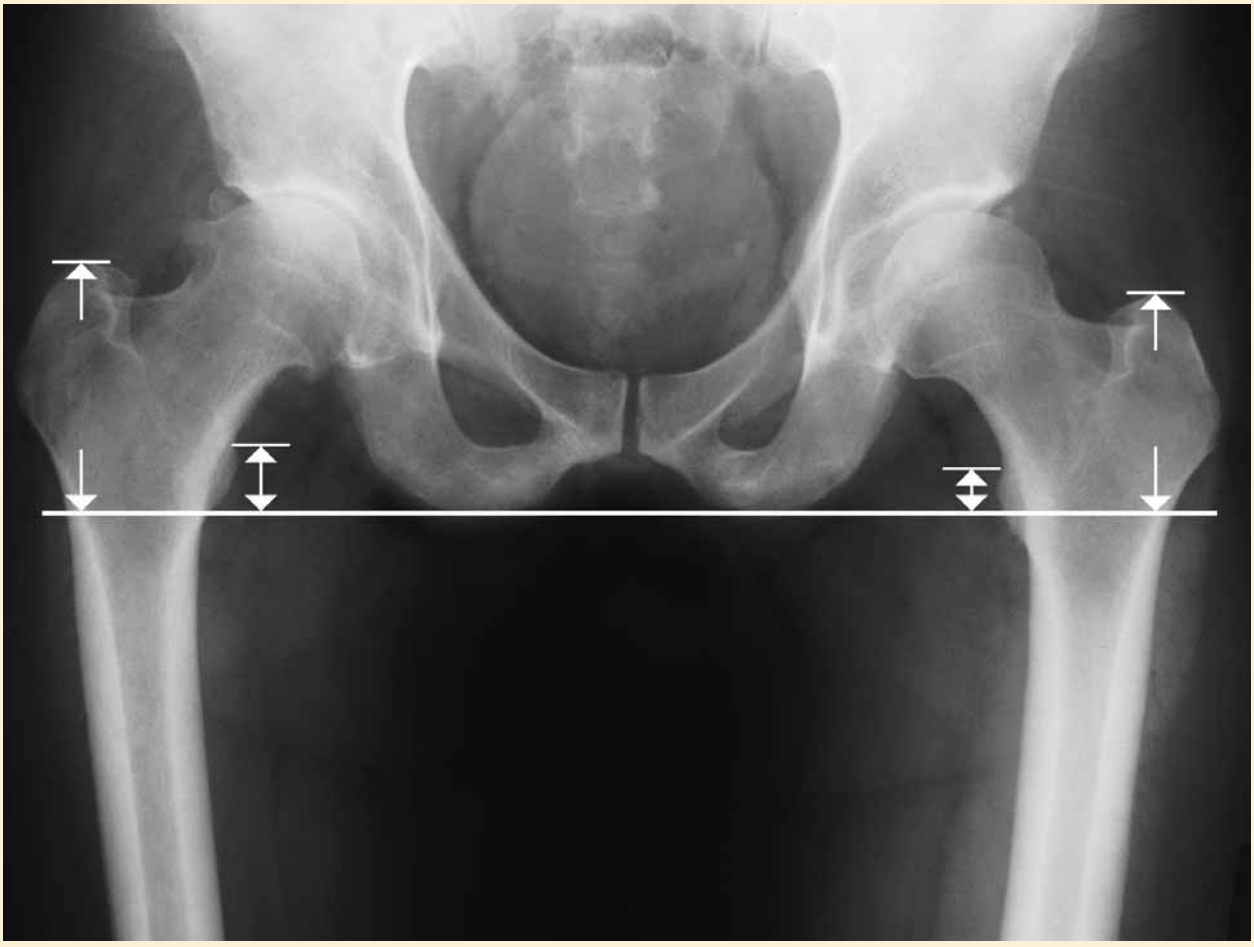
The C-Stem AMT Surgical Technique was written in consultation with Andrew I. Spitzer, MD.

Preoperative Planning Goals

Preoperative planning enables the surgeon to optimize the biomechanical reconstruction of the hip and to fully anticipate intra-operative challenges. A thorough preoperative plan requires evaluation of the patient's history, a physical examination and radiographs. From this analysis, key pieces of information emerge. First, the surgeon gleans an understanding of the preoperative impact of the degenerative process, including limb length discrepancy, bony deficiency, soft tissue imbalance, contractures and muscular weakness. Second,
the reconstructive plan can be individualized to address a specific patient's problems, including acetabular size and placement, femoral component size, position, fit and adjustment of the biomechanical properties of limb length and offset. This reconstructive plan begins with preoperative templating (Figure A).

FIGURE A *Preoperative templating*



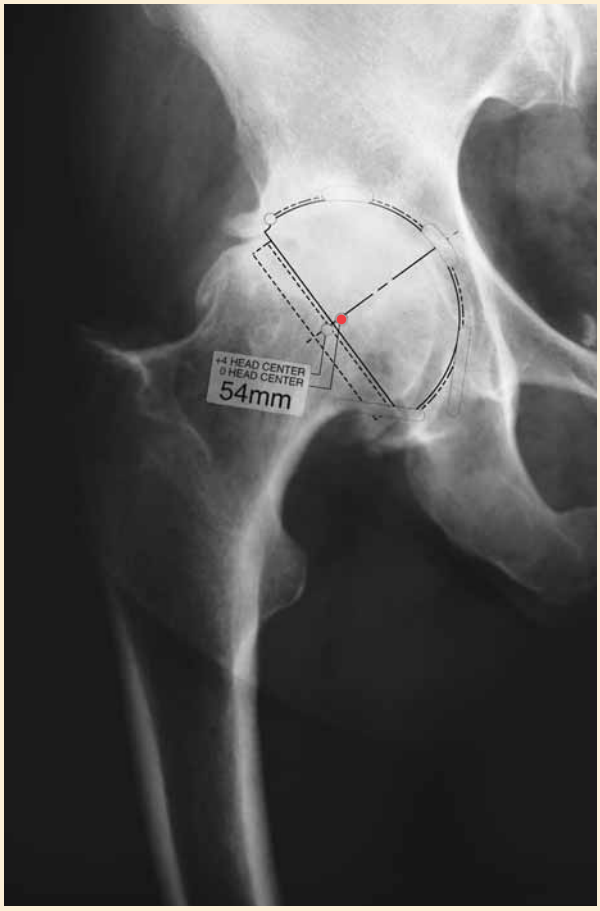
Preoperative Templating

Extensive anthropometric studies define a comprehensive range of stem sizes, neck lengths and offsets to address nearly 100% of the populations studied. Preoperative templating ensures accurate implant sizing, placement and alignment. The C-Stem AMT implant offers a complete range of templates with 20% magnification.

In order to template accurately, a high quality low anterior/posterior (A/P) view of the pelvis of known magnification with both femora internally rotated 15 degrees is necessary. This view presents the bony landmarks, such as the teardrop, of the pelvis in their correct anatomical position, and presents the femoral head and neck parallel to the coronal plane, demonstrating the native hip's maximal offset. The opposite hip on this view can also be used as a reference for planning the reconstruction. It is from this radiograph that a neck resection level that will restore limb length will be determined and the appropriate femoral stem size and offset will be chosen. A lateral view of the involved femur confirms the femoral canal diameter and reveals any abnormalities in this plane.

To begin the templating process, prepare the A/P pelvis radiograph. Mark the current center of rotation of the hip on the radiograph. Draw a line connecting the base of the ischial tuberosities. At the medial aspect of the teardrops, draw verticals to the intra-ischial line. These lines provide a grid against which to measure the impact of implant placement on the alteration of the center of rotation of the hip, limb length and offset. This is necessary to re-establish adequate soft-tissue tension of the hip abductors in order to restore hip stability.

FIGURE B *Acetabular cup template*



Acetabular Cup Size and Position

The size and position of the acetabular component should be determined first because this will often displace the hip center of rotation. In turn, the femoral neck resection level and the femoral implant offset and position chosen to re-establish appropriate soft-tissue tension will be significantly impacted as well. Mark the new center of rotation or draw the entire proposed acetabular component on the radiograph (Figure B).

Femoral Stem Size and Position

The goal of femoral stem templating is to select the femoral component size and broach envelope that will fit the proximal femur, equalize limb lengths and reproduce appropriate offset.

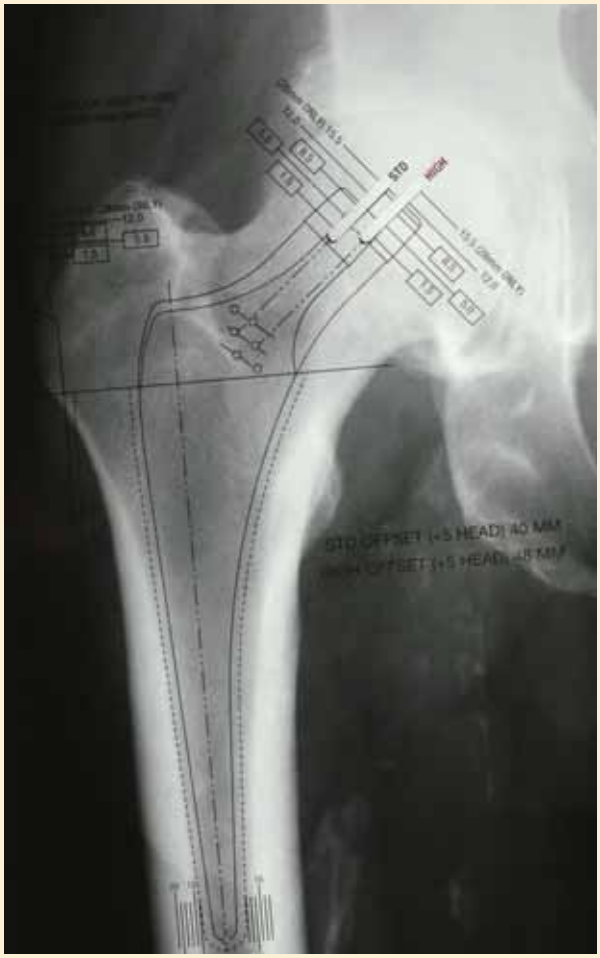
Templating Implant Size

Choose the size of the template which optimizes cement mantle to 2 to 4 mm (as referenced by the dotted lines surrounding the implant on the x-ray templates) on both the A/P and lateral radiograph of the femur.

Establishing the Neck Resection Level

With the template positioned so that its center line is aligned with the long axis of the femur, slide the template proximally or distally until the position re-creates appropriate limb length, considering the preoperative center of rotation of the hip and any alteration to it by placement of the templated acetabulum (Figure C). Ideally, the use of a skirted femoral head should be avoided. If one of the shorter femoral head centers marked on the template does not adequately re-establish appropriate offset, utilize the high offset template for the chosen femoral stem size, which moves the center of rotation medially to restore joint stability and reduce the chance of impingement without increasing limb length. Mark the x-ray through the slot to correspond with the center marking on the proximal body. This defines a “neutral” neck resection level to maintain existing leg length. Draw a line across the femoral neck at this level. Also draw a parallel line that just touches the femoral head’s superiomedial point. Measure the distance between the two lines along the femoral neck axis. Calculate the true length of this line from the known magnification of the x-ray, and set the resection level to this landmark.

FIGURE C *Femoral templating*



Femoral Head Resection

The C-Stem AMT is implantable through any standard or reduced-incision approach.
Once the femoral head is exposed, align the neck resection guide against the long axis of the femur. Determine the resection level by aligning the top of the guide with the tip of the greater trochanter or by referencing a measured resection level above the lesser trochanter, or from the superiomedial aspect of the femoral head along the axis of the femoral neck as determined above (Figure 1). Confirm the resection level with the preoperatively templated plan. Mark the resection line using electrocautery or methylene blue. Resect the femoral head. The collarless stem enables proximal and distal adjustment regardless of neck resection level; however, orientation of the cut should be perpendicular to the neck axis and not horizontal to the long axis of the femur in order to avoid impingement of the medial stem against the medial neck.

FIGURE 1 *Femoral resection guide*

Acetabular Preparation

Fully expose the acetabulum and clear soft tissue from the acetabular rim.

Progressively ream the acetabulum until healthy subchondral bone is reached and a hemispherical dome is achieved (Figure 2). Check that acetabular graters are correctly oriented: approximately
45 degrees of abduction with 15 to 30 degrees of anteversion.

Using the cup impactor, place a trial cup sizer of the same diameter, or 1 to 2 mm larger in diameter than the final reamer used, into the acetabulum and assess its position, cortical bone contact and press fit. The trial cup may be seated fully or used for sizing only.

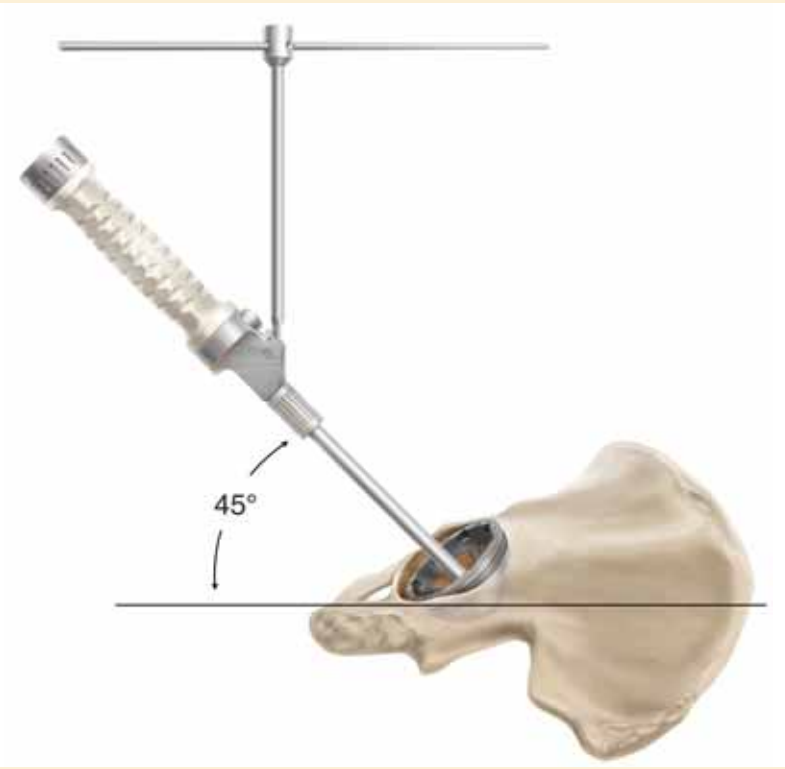
Verify the position of the cup using intraoperative landmarks and external alignment guides. Ideally, the cup should be anteverted so that its posterior border is flush with the ischium and abducted so that its inferior border is level with the teardrop. This procedure ensures correct orientation of the newly created acetabulum within the anatomic acetabulum (Figure 3).

Position the trial liner into the trial acetabular cup using a universal hex screwdriver.

For a more detailed review of acetabular preparation, please reference the *Pinnacle® Acetabular Cup System Surgical Technique*.

FIGURE 2 *Reaming the acetabular cup*

FIGURE 3 *Positioning the acetabular cup trial*



Femoral Preparation

Remove any remaining superior and lateral femoral neck and clear residual soft tissue attachments in order to fully expose the piriformis fossa. Access the femoral canal at the piriformis fossa using the IM Initiator attached to the T-Handle (Figure 4). Accurate position of the entry point is essential
to avoid implant malalignment. Centralize the initiator in line with the piriformis fossa in both the A/P and lateral projections. The piriformis fossa is an extension of the femoral canal and lies posteriorly and laterally. Placing the entry hole and subsequent broaches more anteriorly risks being driven down the anteverted femoral neck, effectively splitting the cement mantle and causing stem malalignment on the lateral view with the distal tip contacting the posterior endosteal surface. Any obstruction caused by overhanging greater trochanter or retained femoral neck should be relieved at this point to avoid problems with impingement and varus malalignment of the broaches and actual implant.

Using the box osteotome positioned laterally toward the greater trochanter, enlarge the entry point of the femoral canal to establish anteversion complementing the patient's anatomy for broach alignment. Reverse the osteotome and extend the entry point medially. Remove a wedge of cancellous bone that is the approximate size of the proximal segment of the prosthesis (Figure 5).

FIGURE 4 *IM initiator*

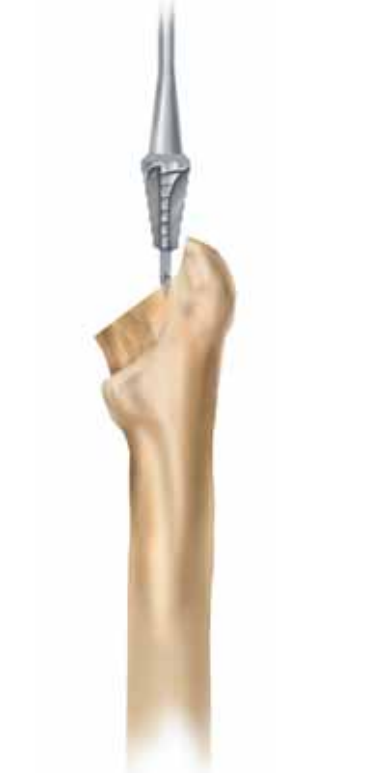


FIGURE 5 *Establishing anteversion*

Metaphyseal Preparation

To maximize the strength of the bone/cement interface, the C-Stem AMT hip system is designed as a broach-only system. Reaming is not recommended, as it removes the critical cancellous bone structure essential for cement interdigitation.

Attach the Canal Probe to the T-Handle and introduce the probe into the canal along the neutral femoral axis at the piriformis fossa. If the entry hole is positioned correctly, the probe should easily pass down the femur (Figure 6).

To aid neutral stem alignment, the optional trochanteric reamer may be used to lateralize the proximal entry point for the subsequent broaches. Attach the trochanteric reamer to the T-Handle or a power reamer and insert it into the canal. Advance the trochanteric reamer until the cutting region of the reamer is aligned with the greater trochanter. Direct the cutting region of the reamer laterally into the greater trochanter to widen the canal entry point (Figure 7).

FIGURE 6 *Canal Probe*

FIGURE 7 *Lateralizer*

Attach a broach two sizes smaller than determined during preoperative templating to the broach handle. Impact the broach down the long axis of the canal in neutral orientation. When using the posterolateral approach, incorporate 5 to 15 degrees of anteversion. To avoid varus alignment or undersizing and to create space for an adequate cement mantle adjacent to the lateral shoulder of the prosthesis, position the broach laterally toward the greater trochanter. Progressively increase the size of the broach until the final broach is seated in the femur (Figure 8).

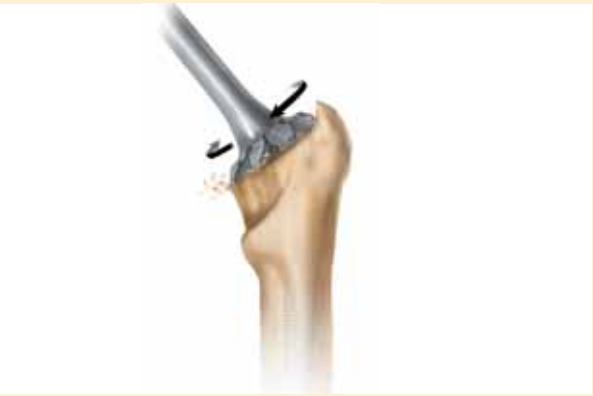
Broaching will prepare a cavity that matches the size planned during preoperative templating. The C-Stem AMT broach was designed to incorporate a circumferential 2 to 4 mm cement mantle, which includes cement interdigitation into the cancellous bone structure.

FIGURE 8 *Broaching*

Calcar Planing

Position the center hole of the planer over the broach trunnion and plane the bone until it is level with the proximal surface of the broach (Figure 9).

FIGURE 9 *Calcar planing*



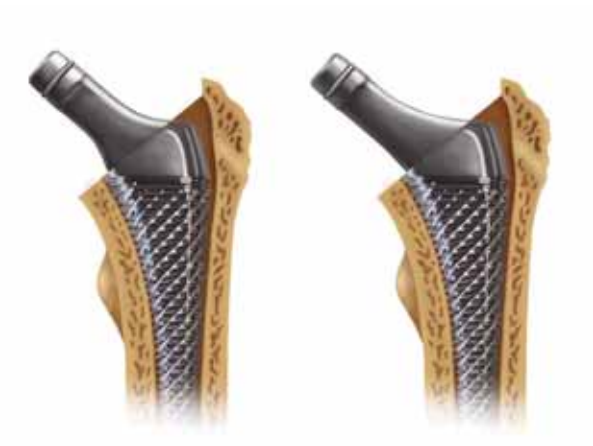
Trial Reduction

Attach the appropriate neck segment to the broach. Multiple trial heads are available to allow for proper restoration of hip biomechanics. The C-Stem AMT System offers dual offsets, which allow implant lateralization by using either a standard or high offset neck segment. If the femoral neck resection level is correct for proper leg length restoration, but there is still inadequate soft tissue abductor muscle tension, consider a high offset neck segment. This will increase the offset and the soft tissue tension without affecting leg length.

With the trials in place, evaluate range of motion, limb length and offset. Check external rotation in extension in order to assess the risk of anterior dislocation. Also perform a posterior dislocation test, bringing the hip up to 90 degrees of flexion with internal rotation. Soft-tissue tension should be tested with axial traction and direct lateral traction, both in full extension and in mid flexion. Combined anteversion of the femoral and acetabular components should approximate 45

Once adequate stability is achieved, note the neck segment (standard or high) (Figure 10) and the modular head chosen. If additional stability is required, a lateralized offset liner and/or a larger head diameter, with or without an alternative bearing surface, can be chosen. Remove the broach using the broach handle or broach extractor.

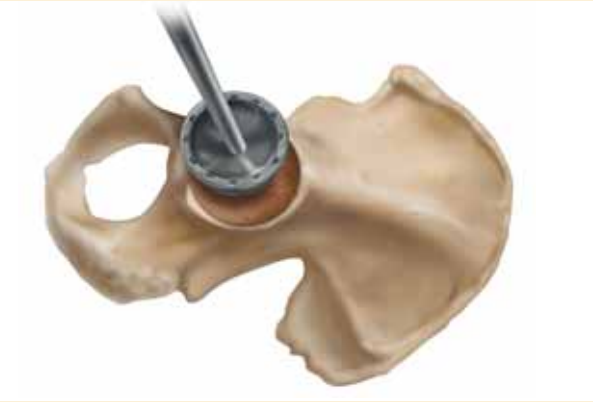
FIGURE 10 *Trial neck segments*



Completion of Acetabular Component Placement

Once trial reduction is satisfactory, remove the trial cup sizer and liner. Using the cup impactor and alignment guide (Figure 11), orient the cup in approximately 45 degrees of abduction and 15 to 30 degrees of anteversion to match the position of the trial component. The intra-operative landmarks of the teardrop and ischium may also be used to position the cup, as described above. This places the cup face parallel to the opening of the true acetabulum. Impact the cup until fully seated and stability is achieved. Place screws for additional stability if needed. Remove any large overhanging osteophytes.

FIGURE 11

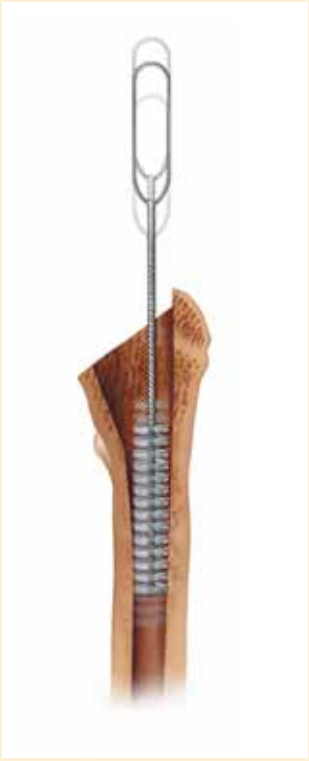


Using the polyethylene liner impactor, place the appropriately sized liner into the metal shell and tap several times with a mallet, seating it securely into the acetabular shell. Test the locking mechanism for stability.

Preparing the Canal

Brush the canal using the DePuy Femoral Prep Kit brush and remove loose cancellous bone using a curette from the DePuy Femoral Prep Kit (Figure 12).

FIGURE 12



Cement Restrictor Insertion

Size the distal femoral canal by utilizing the canal sizers. Select the appropriately sized cement restrictor and insert it into the canal (Figure 13). The sizer should achieve endosteal contact above the intended position of the restrictor, which should be approximately 2 cm below the tip of the prosthesis. Judge this depth by comparing the length of the sizer to the length of the broach.

FIGURE 13 *Cement restrictor*

Irrigating and Drying the Canal

Irrigate the canal using pulsed lavage with saline solution, ensuring that all debris is removed. Insert the DePuy Femoral Prep Kit sponge down the femoral canal to help dry and remove debris (Figure 14). The sponges may also be presoaked in an epinephrine or hydrogen peroxide solution.

FIGURE 14 *Drying the canal*

Attaching the Void Centralizer

Select the C-Stem AMT Void Centralizer that corresponds to the diameter of the femoral canal (C-Stem AMT Void Centralizers increase in 2 mm increments from 10 to 20 mm) as determined by the restrictor sizers above, and slide it over the distal tip of the stem (Figure 15).

FIGURE 15
Distal centralizer

Vacuum Mixing Bone Cement

Vacuum mixing directly impacts the mechanical properties of acrylic bone cement and the longevity of the cemented total hip reconstruction. Incorrectly mixed bone cement results in greater porosity and unmixed powder. Vacuum mixing may increase the fatigue, compression and flexural strength of bone cement by removing air pockets from the bone cement that may form during mixing. Removing these voids produces stronger cement and potentially increases the longevity of the cemented total hip reconstruction.

SmartSet® MV or SmartSet® HV Bone Cement is ideal for a cemented hip procedure. To mix, pour two batches of cement powder into the cartridge, followed by two vials of liquid monomer (Figure 16). Replace the paddle and mix head on the cartridge and rotate the handle two to three times in each direction to disperse the monomer more evenly throughout the cement powder (Figure 17). Activate the vacuum and begin mixing by fully extending the handle up and down, one time per second (Figure 18). Mix for approximately one minute from the time all the liquid monomer is added to the powder. Remove the paddle and mixing head from the cartridge and attach the nozzle. Ensure that the nozzle is tightly screwed onto the cartridge before attaching the cement gun (Figure 19).

FIGURE 16

FIGURE 17

FIGURE 18

FIGURE 19

Retrograde Fill and Pressurization

Injecting cement into the femur using a cartridge mixing system is an effective technique for achieving full interdigitation of cement into surrounding cancellous bone. It is important to note that bone cement needs to achieve the proper viscosity before it is injected into the femoral canal. Optimum cement viscosity will resist blood pressure-generated backflow of blood from the bone and avoid blood lamination within the cement mantle. Cement that is injected too early may be forced out of the pores of cancellous bone by inflowing blood, weakening the bond at the bone-cement interface.

To apply the cement, place the tip of the nozzle against the cement restrictor and begin to inject cement in a retrograde fashion (Figure 20). Keep the tip of the nozzle embedded just below the surface of the advancing cement to minimize the formation of cement voids. Allow the force generated by the rising cement layer to slowly advance the nozzle superiorly toward the canal opening. Continue to inject cement until the canal is filled completely and the distal tip of the nozzle is clear of the canal.

In order to minimize the time between canal filling and pressurization and to avoid cement lamination with backflowing blood from the bone, quickly place the universal proximal pressurizer onto the cement nozzle so that it is flush with the cartridge barrel. Quickly break or cut the nozzle and place the pressurizer against the canal opening to seal the canal (Figure 21). Continuous pressure should be maintained during this period of pressurization by injecting cement using short, repeated trigger strokes.

FIGURE 20

FIGURE 21

Cemented Stem Insertion

Begin inserting the C-Stem AMT by hand (Figure 22). The inserter can be used to fully seat the prosthesis. During insertion, maintain neutral alignment in both the A/P and lateral planes. Place a thumb over the medial neck in order to maintain pressurization of the cement and prevent cement extrusion, and to assist in keeping the stem laterally in a neutral position, avoiding varus malpositioning. Steadily seat the stem in the same position that the broach previously occupied. The geometry of the C-Stem AMT will aid in an even cement mantle. Hold the stem in position by hand or with the open stem inserter until the cement has fully cured (Figure 23). Remove any excess cement which could dislodge and become a loose body in the joint.

FIGURE 22

FIGURE 23

Impacting the Femoral Head

A final trial reduction may be performed at this time, verifying the choice of neck length and head diameter.

Remove the trial head and irrigate and clean the prosthesis to ensure the taper is free of debris. Place the appropriate head onto the taper and lightly tap the head into place using the head impactor (Figure 24). Reduce the hip to carry out a final assessment of joint mechanics and stability.

FIGURE 24

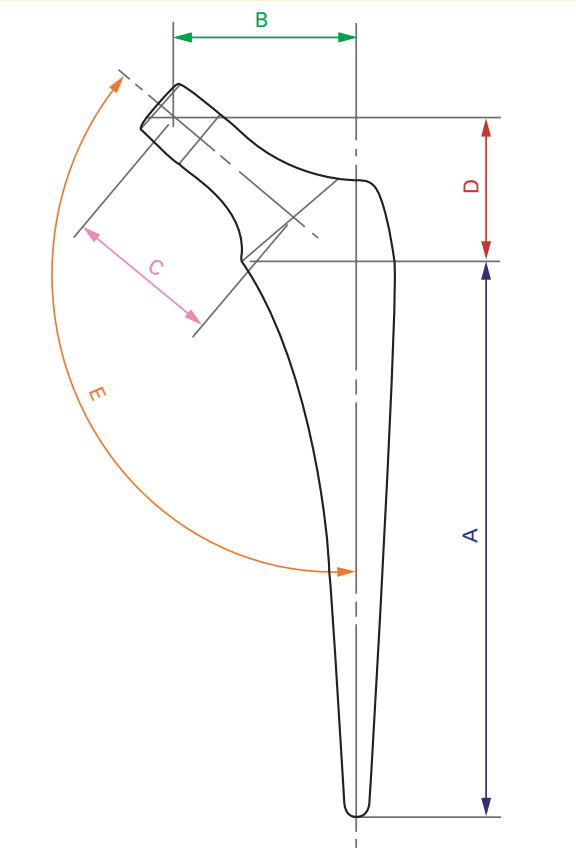
Note: Utilizing the femoral head impactor, impact the femoral head onto the stem taper with two moderate blows.

Closure

With the hip reduced, repair the piriformis tendon and the external rotators either by drilling holes in the trochanter or by using the soft tissue on the posterior trochanter. Standard closure with adequate drainage is suggested.

Postoperative Management

Encourage rapid mobilization with weight bearing to tolerance and the use of a walker or crutches for support. Provide appropriate DVT prophylaxis, along with perioperative antibiotics.



	A	B	C	D	E
Size	*Stem Length*	*Base Offset*	*Neck Length*	*Limb Adjustment Length*	*Neck Angle*
2 STD	110	38	32	28	130
2 HIGH	110	44	36	28	130
3 STD	115	38	32	30	130
3 HIGH	115	44	36	30	130
4 STD	120	40	34	32	130
4 HIGH	120	48	39	32	130
5 STD	124	40	34	33	130
5 HIGH	124	48	39	33	130
6 STD	129	42	36	35	130
6 HIGH	129	50	41	35	130
7 STD	133	42	36	36	130
7 HIGH	133	50	41	36	130
8 STD	137	44	38	38	130
8 HIGH	137	52	43	38	130

Instrument Set

Cat. No.	*Description*	*Size*
2570-00-000	Broach	
2570-00-002	Extractor	
2580-00-010	C-Stem AMT Broach	1
2580-00-011	C-Stem AMT Broach	2
2580-00-012	C-Stem AMT Broach	3
2580-00-013	C-Stem AMT Broach	4
2580-00-014	C-Stem AMT Broach	5
2580-00-015	C-Stem AMT Broach	6
2580-00-016	C-Stem AMT Broach	7
2580-00-017	C-Stem AMT Broach	8
2570-00-005	Lateralizer	
2570-01-600	Univ. Neck Resection Guide	
2580-00-056	C-Stem AMT X-Ray Templates	
2522-00-502	Stem Introducer	
2570-04-100	Calcar Planer Small	
2570-04-200	Calcar Planer Large	

Core 2 Instrument Set

Cat. No.	*Description*
85-3927	Femoral Rasp
53-0360	S-ROM T-Handle, Hudson
2001-65-000	Femoral Head Impactor
2001-80-501	IM Initiator
2002-31-000	Anteversion Osteotome, Small
2354-10-000	Canal Finder
2530-81-000	Articul/eze Trial Head 28 + 1.5
2530-82-000	Articul/eze Trial Head 28 + 5
2530-83-000	Articul/eze Trial Head 28 + 8.5
2530-84-000	Articul/eze Trial Head 28 + 12
2530-85-000	Articul/eze Trial Head 28 + 15.5
2611-20-000	Core Case #2 Tray

C-Stem AMT Instruments

STANDARD NECK SEGMENT

Cat. No.	*Size*
2570-03-100	2/3
2570-03-200	4/5
2570-03-300	6/7
2570-03-400	8/9

HIGH NECK SEGMENT

Cat. No.	*Size*
2570-03-150	2/3
2570-03-250	4/5
2570-03-350	6/7
2570-03-450	8/9

C-Stem AMT Implants

STANDARD OFFSET

Cat. No.	*Size*
1570-04-085	2
1570-04-090	3
1570-04-100	4
1570-04-110	5
1570-04-120	6
1570-04-135	7
1570-04-150	8

HIGH OFFSET

Cat. No.	*Size*
1570-14-085	2
1570-14-090	3
1570-14-100	4
1570-14-110	5
1570-14-120	6
1570-14-135	7
1570-14-150	8

C-Stem AMT Void Centralizers

Cat. No.	*Size*
9612-10-500	10
9612-12-500	12
9612-14-500	14
9612-16-500	16
9612-18-500	18
9612-20-500	20

Bone Cement

Cat. No.	*Description*
3102-020	SmartSet MV 20g
3102-040	SmartSet MV 40g
3102-080	SmartSet MV 80g
3092-040	SmartSet HV 40g
5450-35-500	SmartSet GHV
5450-50-500	SmartSet GMV

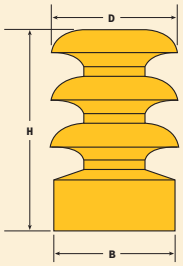
Mixing Systems

Cat. No.	*Description*
5401-98-000	SmartMix Tower
83-1615	SmartMix Cemvac
5401-80-000	SmartMix Bowl

BIOSTOP G

Cat. No.	*Description*
5463-00-500	Complete Instrument Set
5463-08-000	Cement Restrictor, 8mm
5463-10-000	Cement Restrictor, 10mm
5463-12-000	Cement Restrictor, 12mm
5463-14-000	Cement Restrictor, 14mm
5463-16-000	Cement Restrictor, 16mm
5463-18-000	Cement Restrictor, 18mm
5463-20-000	Cement Restrictor, 20mm
5463-28-500	Restrictor Trial, 8mm
5463-30-500	Restrictor Trial, 10mm
5463-32-500	Restrictor Trial, 12mm
5463-34-500	Restrictor Trial, 14mm
5463-36-500	Restrictor Trial, 16mm
5463-38-500	Restrictor Trial, 18mm
5463-40-500	Restrictor Trial, 20mm
5463-48-500	Restrictor Holder, 8mm
5463-50-500	Restrictor Holder, 10-12mm
5463-54-500	Restrictor Holder, 14-16mm
5463-58-500	Restrictor Holder, 18-20mm
5463-60-500	Inserter T-Handle
5463-62-500	Sterilization Case

SIZE	DIAMETER (D mm)	BASE (B mm)	HEIGHT (H mm)
8	10	8	15
10	12	10	18
12	14	12	21
14	16	14	24
16	18	16	27
18	20	18	30
20	22	20	33



ESSENTIAL PRODUCT INFORMATION

Total Hip Prostheses, Self-Centering™ Hip Prostheses and Hemi-Hip Prostheses

Important This Essential Product Information sheet does not include all of the information necessary for selection and use of a device. Please see full labeling for all necessary information.

Indications Total Hip Arthroplasty (THA) is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. THA is indicated for a severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis or congenital hip dysplasia; avascular necrosis of the femoral head; acute traumatic fracture of the femoral head or neck; failed previous hip surgery; and certain cases of ankylosis. Hemi-hip arthroplasty is indicated in these conditions where there is evidence of a satisfactory natural acetabulum.

Contraindications THA and hemi-hip arthroplasty are contraindicated in cases of: active local or systemic infection; loss of musculature, neuromuscular compromise or vascular deficiency in the affected limb, rendering the procedure unjustifiable; poor bone quality; Charcot's or Paget's disease; for hemi-hip arthroplasty – pathological conditions of the acetabulum that preclude the use of the natural acetabulum as an appropriate articular surface. Ceramic heads are contraindicated in revision surgery when the femoral stem is not being replaced or for use with any other than a polyethylene or metal-backed polyethylene cup.

Warnings and Precautions Ceramic coated femoral stem prostheses are indicated for uncemented press fit fixation. CAUTION: DO NOT USE BONE CEMENT FOR FIXATION OF A CERAMIC COATED PROSTHESIS. Components labeled for "Cemented Use Only" are to be implanted only with bone cement. The following conditions tend to adversely affect hip replacement implants: excessive patient weight, high levels of patient activity, likelihood of falls, poor bone stock, metabolic disorders, disabilities of other joints.

Adverse Events The following are the most frequent adverse events after hip arthroplasty: change in position of the components, loosening of components, fracture of components, dislocation, infection, tissue reaction.

The C-Stem AMT is intended for cemented use only.

For more information about DePuy products, visit our web site at **www.jnjgateway.com** or **www.depuyorthopaedics.com**.

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