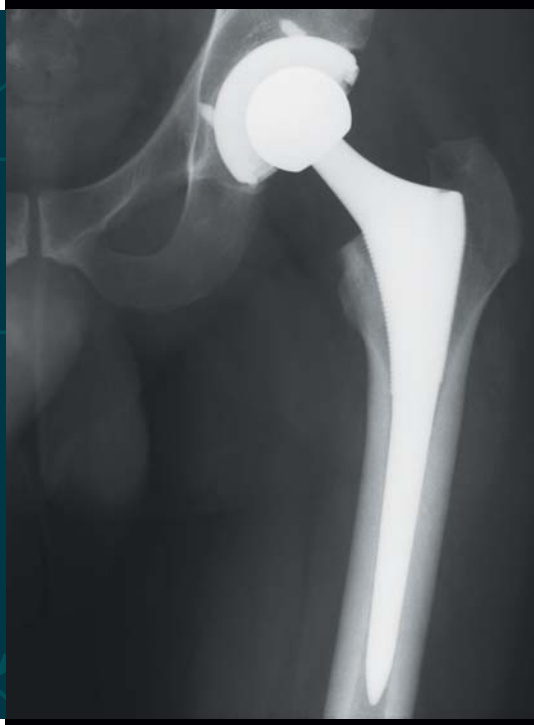
SUMMIT™
TAPERED HIP SYSTEM

SURGICAL TECHNIQUE

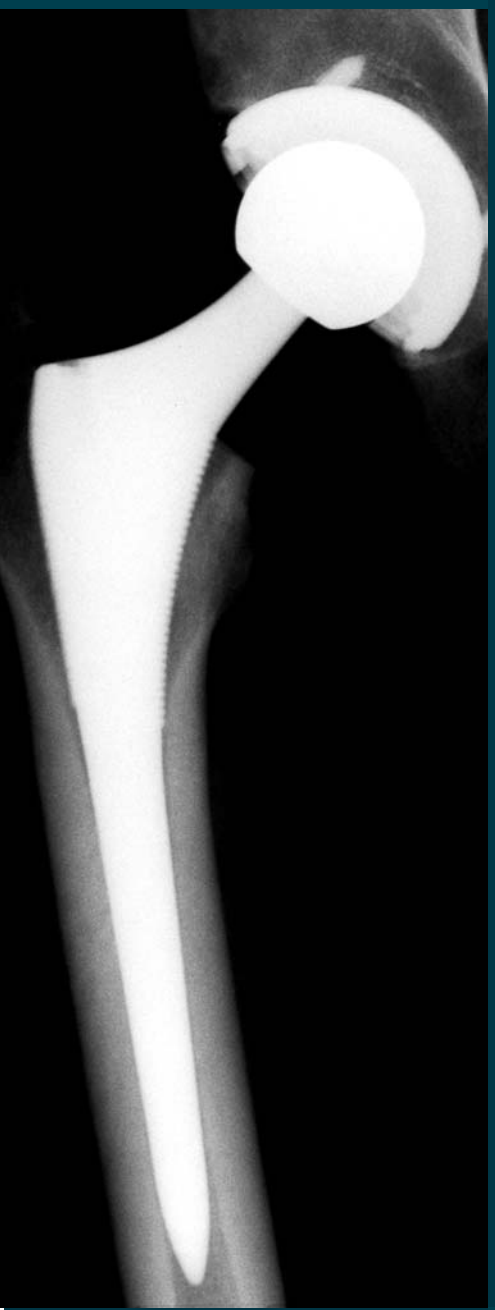
POROCOAT®
&
DUOFIX™ HA



- TAPERED PHILOSOPHY
- PROVEN FIXATION
- BIOMECHANICAL EXCELLENCE

DePuy
a Johnson & Johnson company

INTRODUCTION

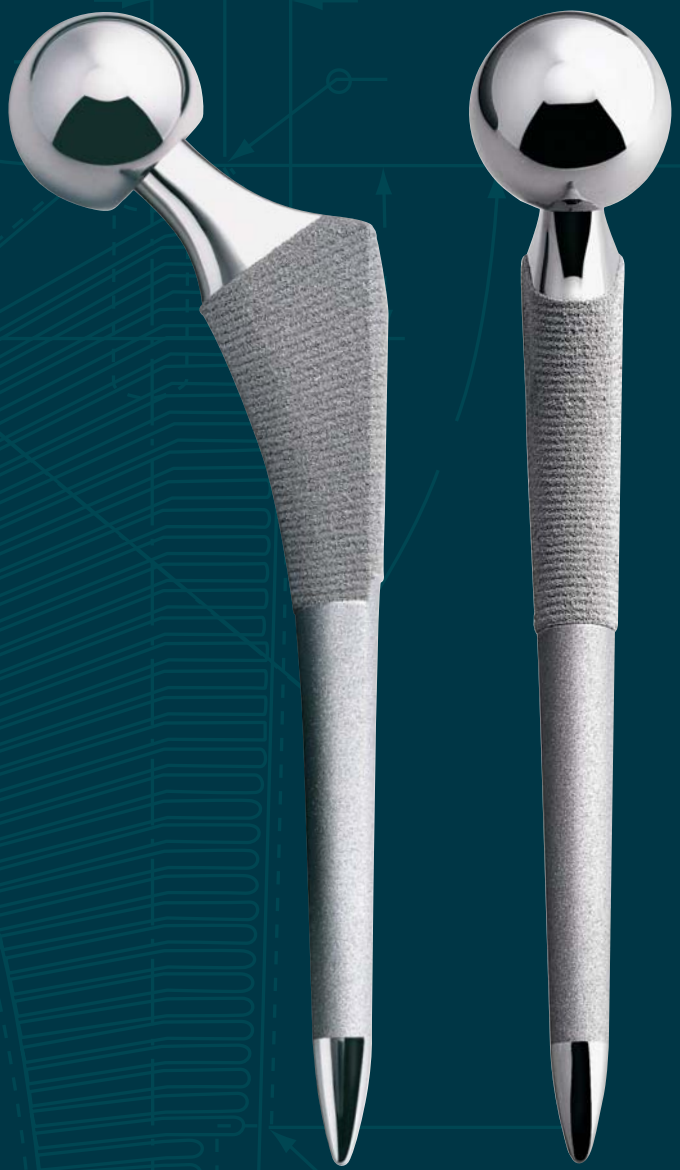


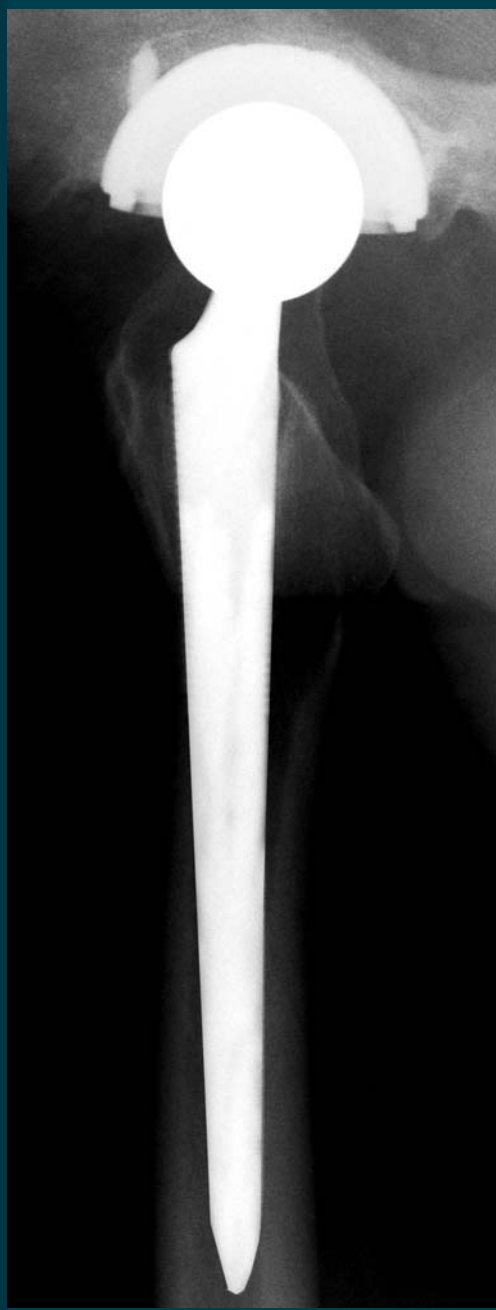
The Summit™ Tapered Hip System implants, Porocoat® and DuoFix™ hydroxyapatite (HA) stems, are cementless designs developed following the classic tapered stem philosophy. Advancements have been made to enhance fixation, provide improved fit, restore joint biomechanics and maximize range of motion.

Summit Porocoat and DuoFix HA stems are precision manufactured from high-strength forged titanium alloy and incorporate a 3-degree biplanar taper. Each stem has a medially rounded, laterally flared, proximal cross-sectional geometry that has been refined for optimal fit and fill and rotational stability. Global proportional sizing in both standard and high offset configurations ensures superior patient fit. Both stem styles incorporate DePuy's proprietary Porocoat Porous Coating over radial ZTT™ steps.* Porocoat Porous Coating has been clinically proven since 1977. ZTT steps, clinically proven since 1983, create a series of internal collars to enhance bone-implant contact, tissue ingrowth and compressive proximal femoral loading. The added benefit of radial ZTT steps is the conversion of hoop stresses to compressive loads.

* Radial ZTT patent pending.

The Summit Tapered Hip System's 130-degree neck shaft angle was refined to maintain strength while optimizing range of motion for high-performance biomechanics. The optimized Articul/eze® taper is compatible with cobalt chrome and ceramic heads of various diameters, making the Summit Tapered Hip System compatible with DePuy advanced bearing systems.





PREOPERATIVE PLANNING

Preoperative planning enables the surgeon to prepare for the case and anticipate situations that may arise during surgery. A thorough preoperative plan incorporates elements from the patient's history, physical examination and radiographic analysis.

Preoperative Planning Goals

1. Determine preoperative leg length discrepancy
2. Assess acetabular component size and placement
3. Determine femoral component size, position and fit
4. Assess femoral offset

Radiographs

The first step in accurate templating is obtaining high-quality radiographs using a standardized protocol with known magnification. Use magnification markers attached to the patient's leg at the level of the greater trochanter to verify magnification.

The Summit Tapered Hip System templates incorporate 20 percent magnification.

Obtain an anterior/posterior (A/P) view of the pelvis with both extremities in 15 degrees of internal rotation to position the head and neck parallel to the coronal plane. A direct lateral radiograph should also be obtained and used to determine three-point femoral fixation.

Determination of Leg Length Discrepancy

To determine existing preoperative leg length, perform a clinical evaluation in conjunction with a radiographic analysis. Use both to determine intraoperative leg length management.

As an estimate of leg length discrepancy radiographically, draw a reference line through the bottom of the obturator foramina (Figure A). Measure the distance from the lesser trochanter landmark to the reference line on each side. The difference between the two is the radiographic leg length discrepancy.

The tip of the greater trochanter may be used as an alternative reference mark in conjunction with the lines through the obturator foramina.

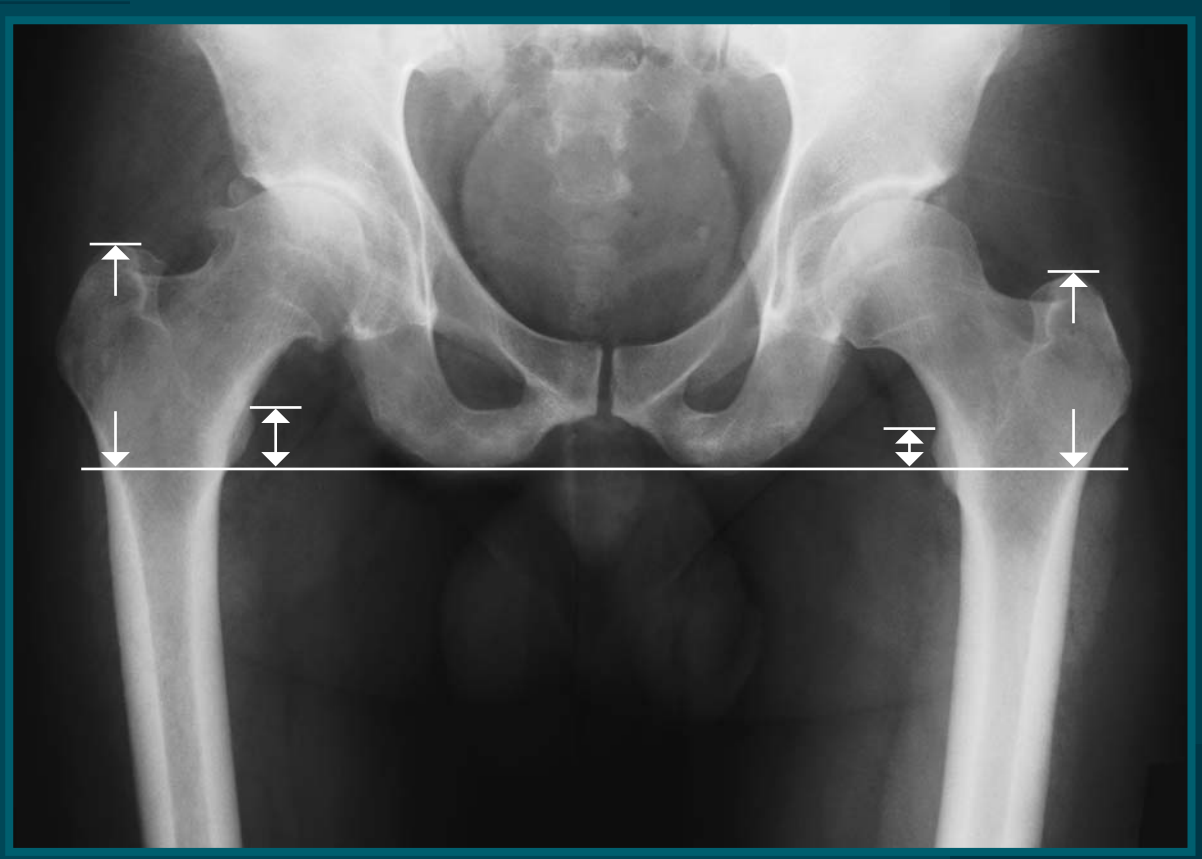


Figure A

PREOPERATIVE PLANNING cont.

Acetabular Cup Size and Position

Most sizing predictions are made on the A/P radiograph of the hip. Determine the optimal position for the acetabular component and predict the size using template overlays. The acetabular teardrop can be referenced as the inferior margin of the acetabular reconstruction.

The goal in cementless acetabular fixation is to maximize bone contact. Once this is determined, mark the intended center of rotation of the bearing surface on the A/P radiograph (Figure B).

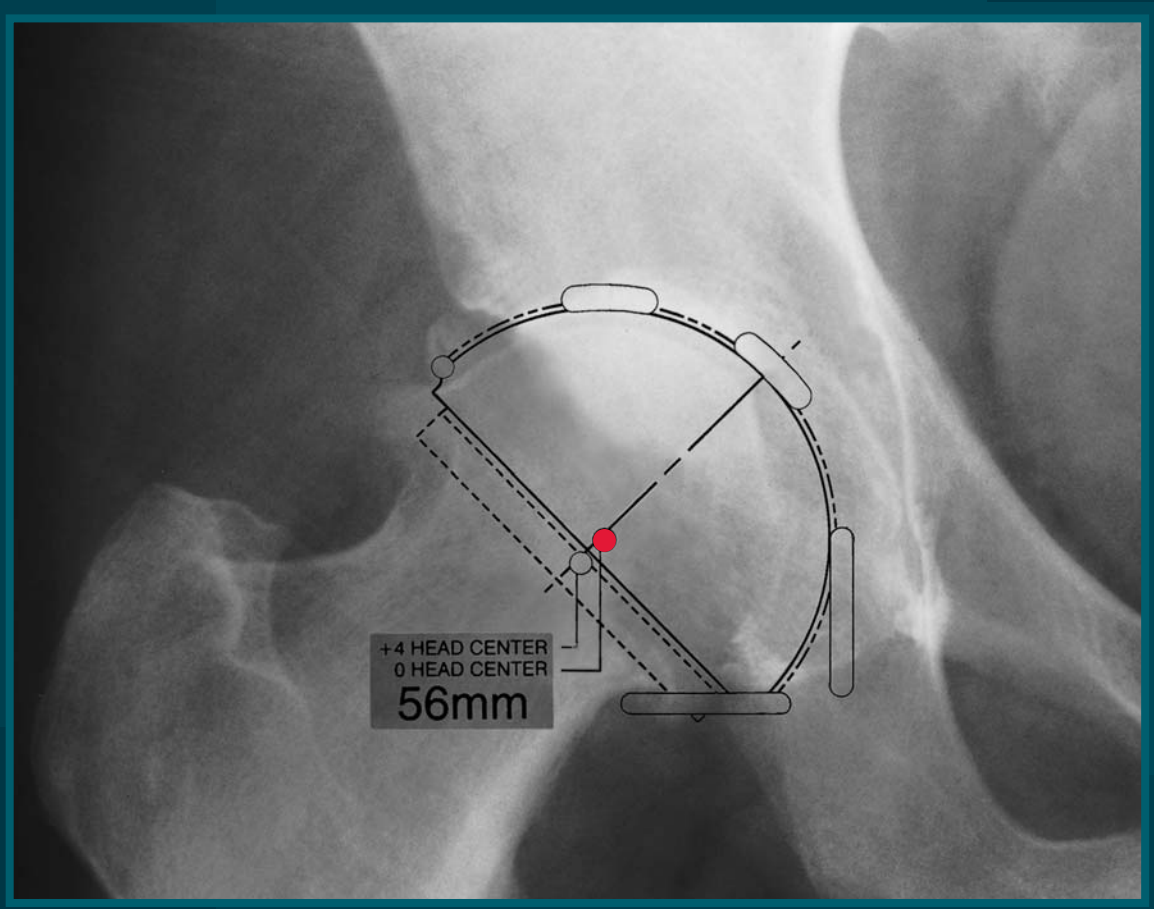


Figure B

Cementless Femoral Component Selection

Select the femoral component template size that will fit the proximal femur and equalize leg lengths. The tapered geometry of the Summit Tapered Hip System femoral component does not require distal canal fill.

The femoral template should be in line with the long axis of the femur and the neck resection line drawn at the point where the selected stem provides the desired amount of leg length.

The vertical distance between the planned center of rotation of the acetabular component and the center of rotation of the femoral head constitutes the distance the leg length will be adjusted.

The level of neck osteotomy depends on the stem size and the desired leg length, with the goal of using a non-skirted modular head to increase range of motion prior to prosthetic impingement. To help properly position the template on the lateral radiograph, estimate the distance between the tip of the greater trochanter and the lateral shoulder of the prosthesis using the A/P radiograph (Figure C).

Verify that the stem size chosen in the A/P plane also fits in the lateral plane. The lateral radiograph of a properly sized tapered implant will typically exhibit three-point fixation (Figure D).

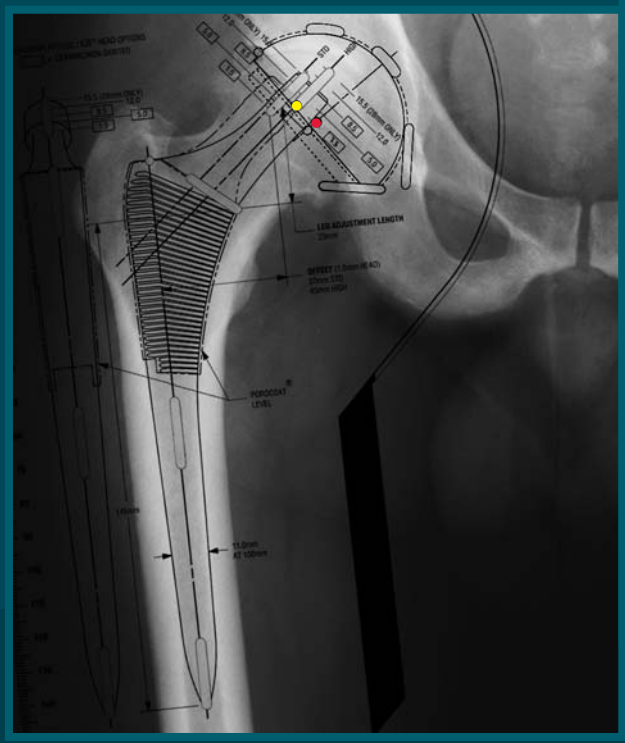


Figure C

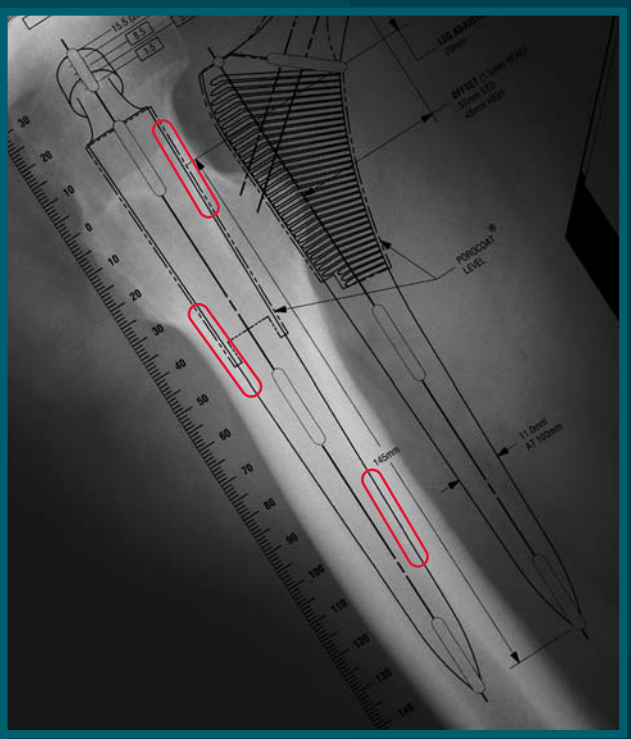


Figure D

PREOPERATIVE PLANNING cont.

Offset Requirements

The Summit Tapered Hip System cementless femoral components are available with standard and high offset options for all stem body sizes. Through templating and intraoperative trialing, determine which option restores proper offset by matching the cup's center of rotation with the desired head center of rotation (Figure E).

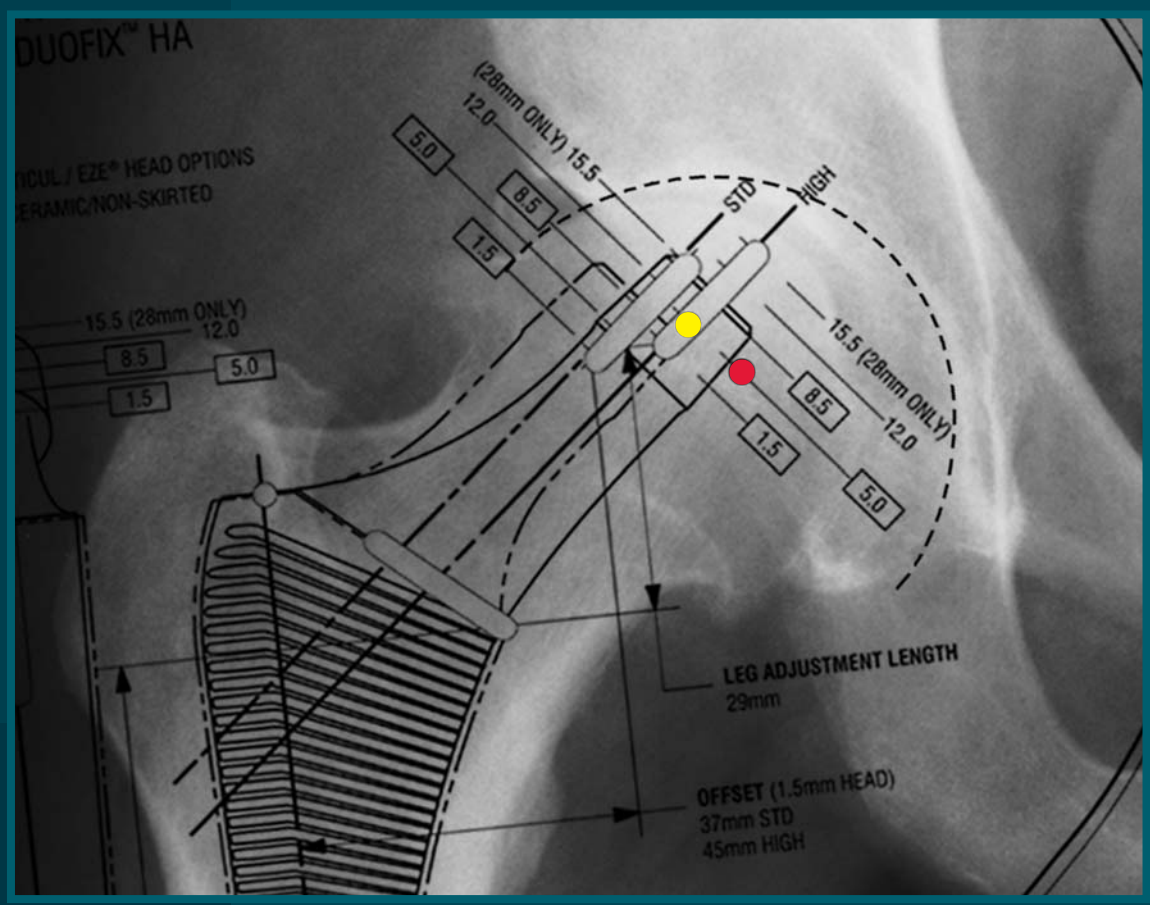


Figure E

SURGICAL TECHNIQUE

Femoral Head Resection

The Summit Tapered Hip System surgical instrumentation was developed to accommodate all surgical approaches.

Elevate the proximal femur and align the neck resection guide down 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 (Figure 1). Mark the resection line using electrocautery or methylene blue. Resect the femoral head.

If desired, make a conservative neck resection initially. The calcar planer may be used later to adjust the neck cut.

Figure 1

ACETABULAR PREPARATION

Reaming and Alignment

Make sure the acetabulum is fully exposed and remove soft tissue from the acetabular rim.

Progressively ream the acetabulum until healthy subchondral bone is reached and a hemispherical dome is achieved (Figure 2).

Using the cup impactor, place a trial cup sizer into the reamed acetabulum and assess its position and cortical bone contact.

The inferior rim of the trial cup should be level with the bottom of the teardrop. The trial cup angle of orientation should match that recorded during preoperative templating, which is normally 45 degrees of lateral opening (abduction) and 15-30 degrees of anteversion. Confirm this using the external alignment instrumentation (Figure 3).

Remove the cup impactor from the trial shell and place the desired liner trial into the cup trial.

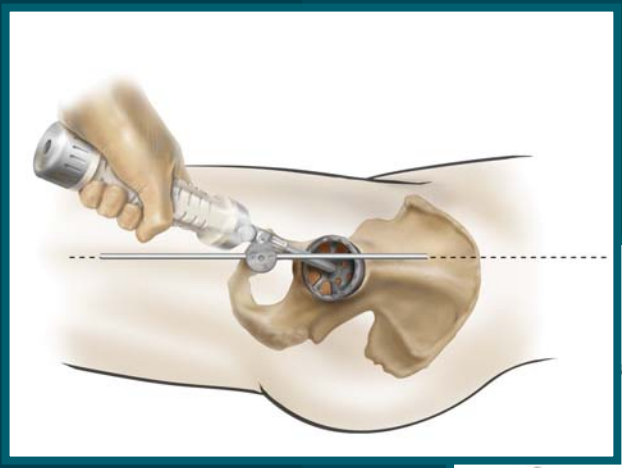


Figure 2

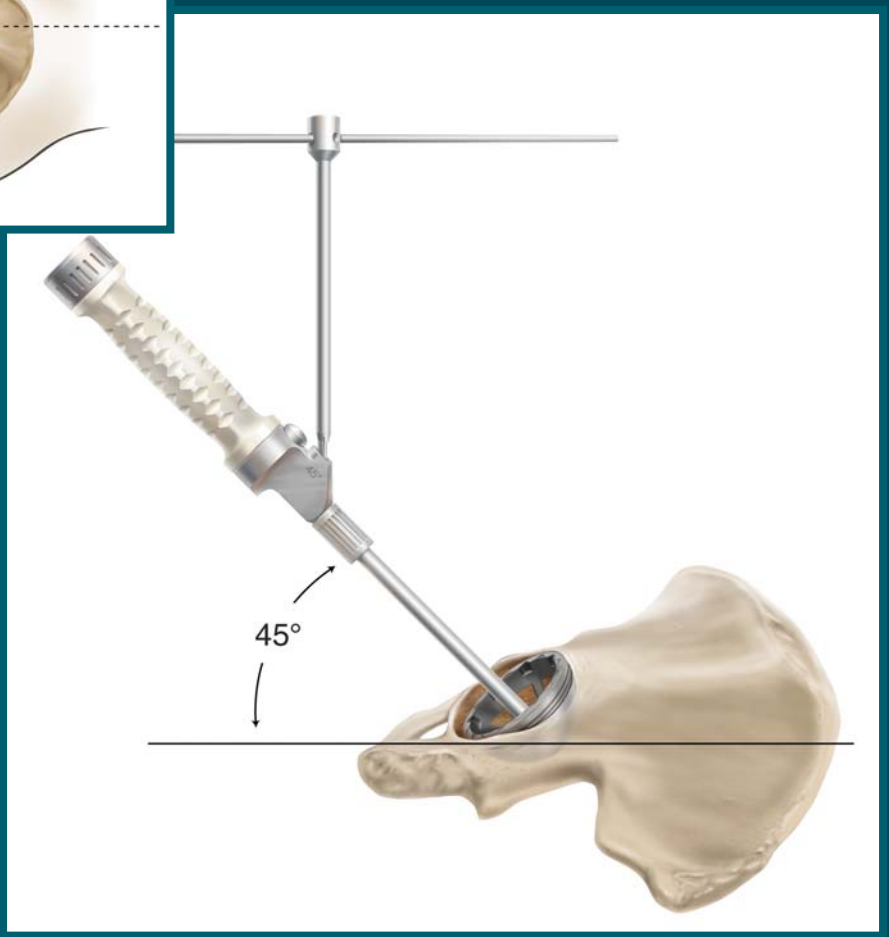


Figure 3

FEMORAL PREPARATION

Access Medullary Canal

Initiate the pilot hole opening with the stepped IM initiator. The opening should be aligned with the femoral canal.

To accomplish femoral canal alignment, place the IM initiator at the posterior margin of the neck resection, lateral near the piriformis fossa. Advance the IM initiator until sufficient circumferential clearance for the box osteotome and canal probe is achieved (Figure 4).

Use a box osteotome to enter the femoral canal at the junction of the femoral neck and the greater trochanter (Figure 5).

Figure 4

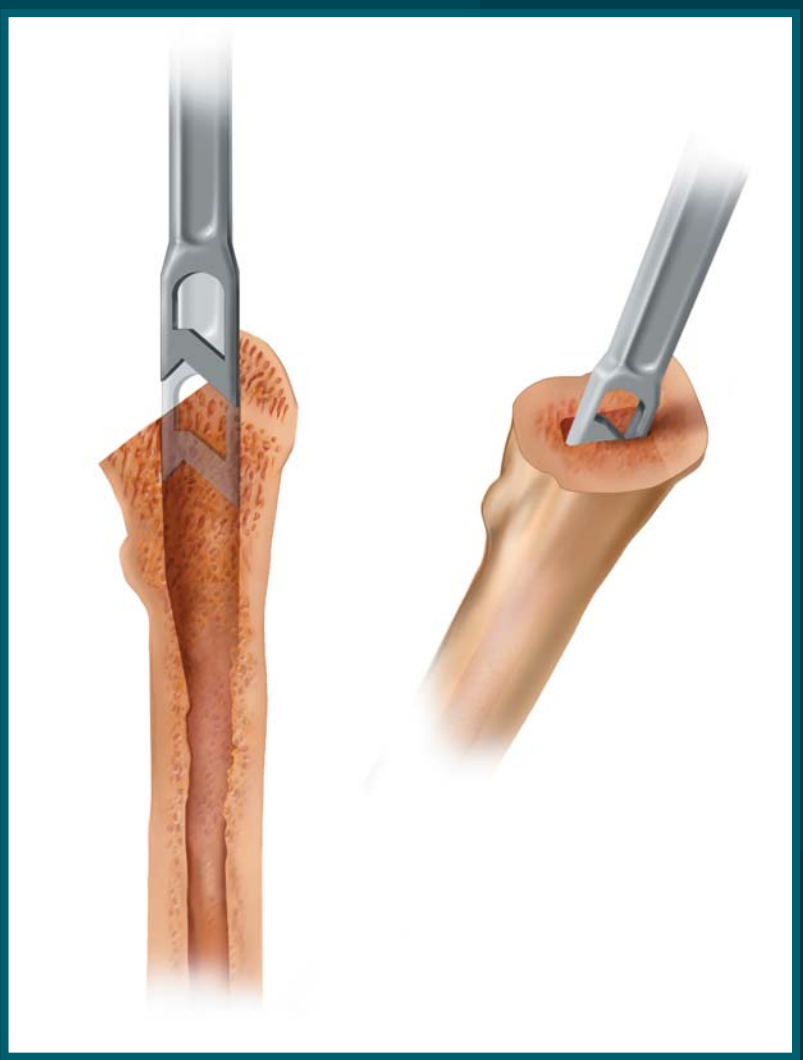


Figure 5

FEMORAL PREPARATION cont.

Medullary Canal Opening

Utilize the tapered canal probe attached to the T-handle to establish a direct pathway to the medullary canal. Advance the canal probe to where the superior margin of the cutting flutes meets the neck resection (Figure 6). The canal probe should pass easily if proper alignment has been achieved. It is important to have circumferential clearance with the canal probe to avoid reaming in a varus orientation.

Figure 6

Alignment Verification

The path established by the canal probe will dictate the route for the optional trochanteric reamer, tapered reamers and broaches. Take caution to ensure neutral alignment of the canal probe (Figure 7).

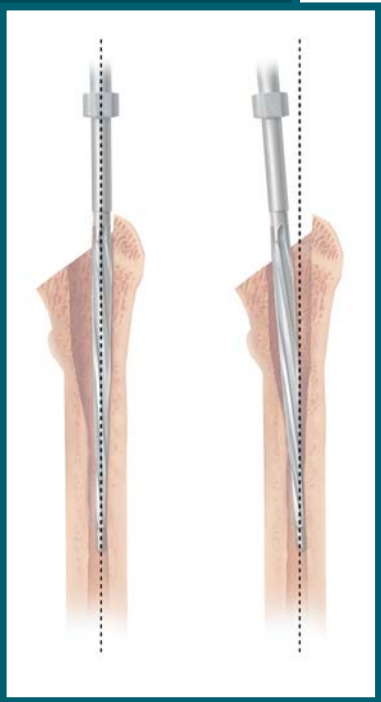


Figure 7

Optional Trochanteric Reaming

To aid neutral stem alignment, the optional trochanteric reamer may be used to lateralize the proximal entry point for the subsequent tapered reamers and 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 8).

Figure 8

TAPERED REAMING

Depth Calibration

NOTE: If a conservative neck cut is made, the neck resection may not be an accurate reference point. With a conservative neck cut, referencing the greater trochanter is recommended. **The final implant size is determined by the broach, not the reamer.**

Use tapered conical reamers to prepare the distal femur. Proper alignment of the reamer along the long axis of the femur is important to ensure correct component positioning. Sequential reaming beginning two or three sizes below the preoperatively templated size is recommended. Resistance and chatter from cortical engagement may be used as a signal to cease tapered reaming.

The Summit Tapered Hip System's tapered reamers correspond to two femoral broach and implant sizes and provide the option of referencing either the calcar or the greater trochanter. Therefore, each reamer has dual depth calibration lines for each of two stem sizes, located distally for calcar referencing and proximally for greater trochanteric referencing (Figure 9). The reamer depth reference lines for either referencing landmark are calibrated to the center of rotation of the corresponding femoral component with a 28 mm +5 Articul/eze femoral head.

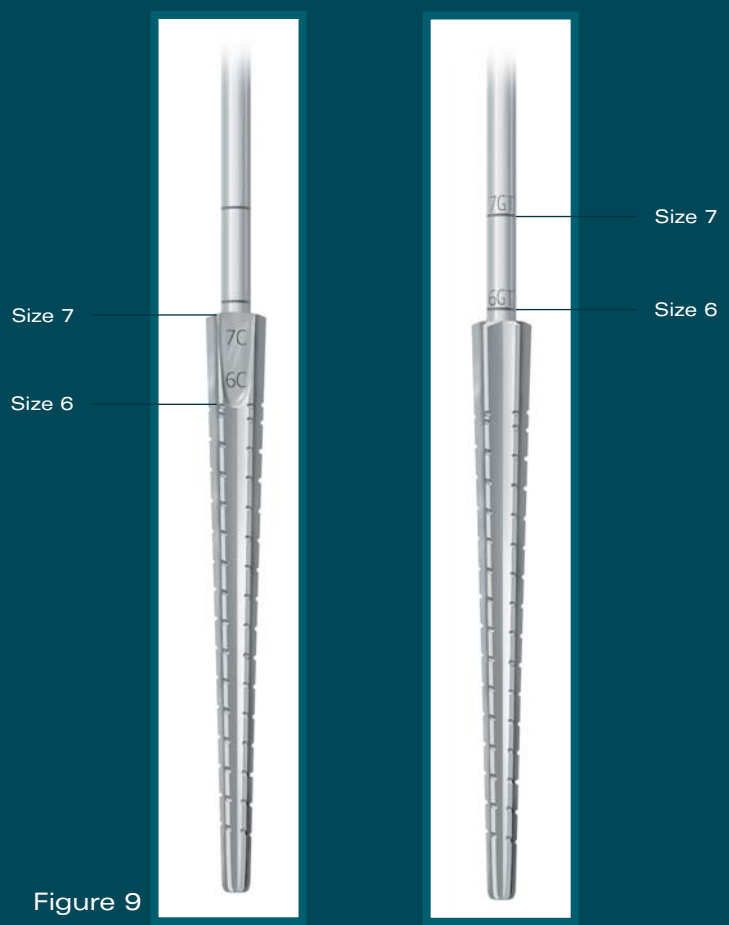


Figure 9

Size 6/7
Calcar
Reference Marks

Size 6/7
Greater Trochanter
Reference Marks

Dual Reference Options

Calcar Referencing

When referencing from the calcar, use the distal reamer depth reference lines for the desired femoral component for reamer depth gauging. The reamer depth reference line for the desired size should align with the medial neck resection at the cortical-cancellous margin of the calcar.

Greater Trochanter Referencing

When referencing from the tip of the greater trochanter, use the proximal reamer depth referencing lines for the desired femoral component for reamer depth gauging. The reamer depth reference line for the desired size should align with the tip of the greater trochanter (Figure 10).

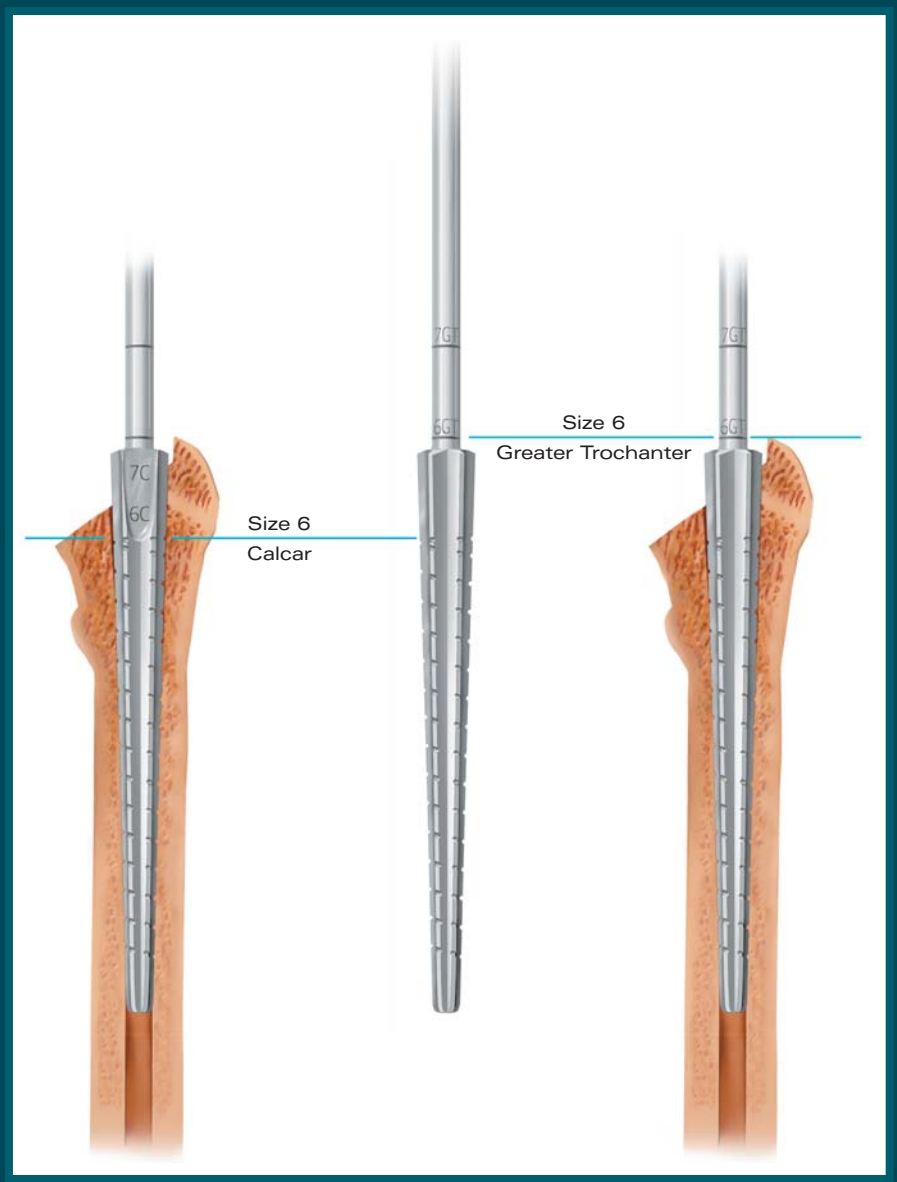


Figure 10

Calcar Referencing Size 6 | Size 6/7 Tapered Reamer | Greater Trochanter Referencing Size 6

FEMORAL BROACHING

Broaching the Femur

NOTE: The Summit instrumentation is designed to prepare the femur line-to-line. The porous-coated region of the femoral component is oversized by .375 mm per side relative to the instrumentation.

Broaching of the proximal femur should begin two to three sizes smaller than the preoperatively templated size. Attach the appropriate broach to the broach handle (Figure 11). The etched icon on the handle indicates the proper alignment of the broach to the handle. Engage the broach by pushing the broach handle lever to the upright locked position.

To ensure proper broach alignment, orient the broach laterally toward the greater trochanter. Ensure that any remaining superior lateral femoral neck remnants are cleared to avoid malalignment. There is one broach for every implant size.

Sequentially advance the broaches down the medullary canal, ensuring proper alignment and anteversion are achieved.

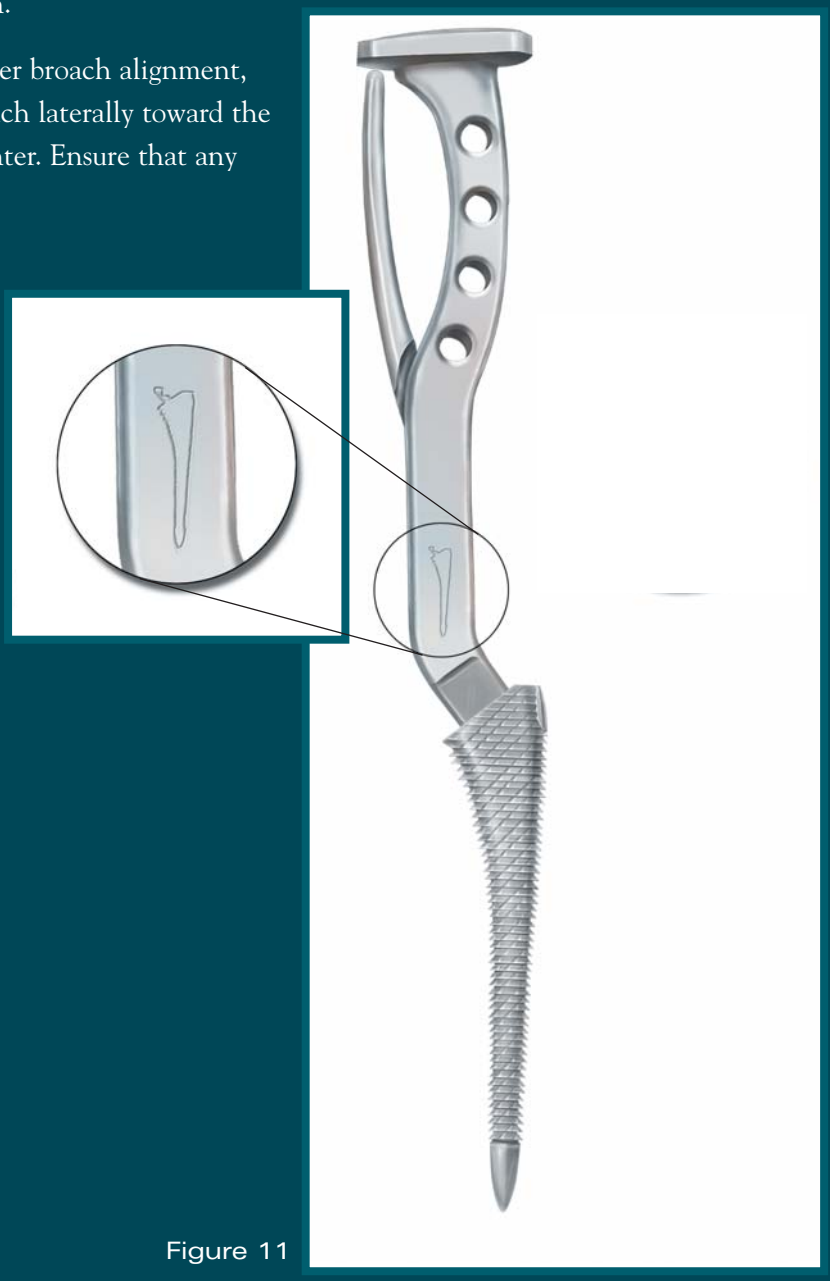


Figure 11

The final broach should fit and fill the proximal femur, with the top of the cutting teeth resting at the point of the desired neck resection. The final broach should feel rotationally stable (Figure 12).

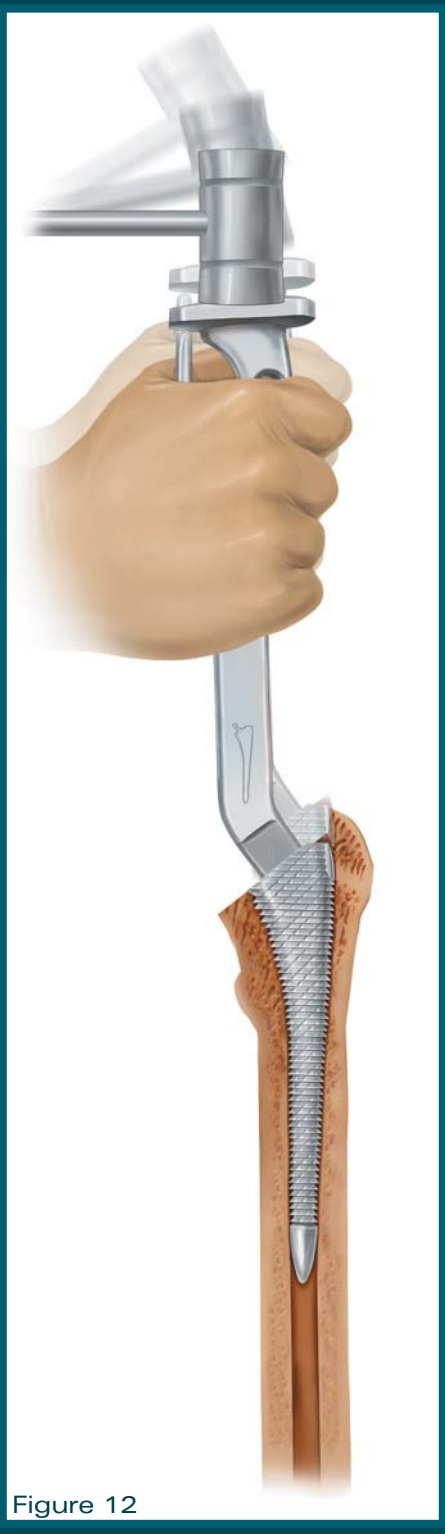


Figure 12

The broach handle is undersized to allow the broach to be countersunk. If the broach size is countersunk greater than 4 mm below the neck resection, re-evaluate the resection level (Figure 13). If the neck resection level is determined to be correct, the next larger size broach is recommended. Additional tapered reaming may also be required.

Unlock the broach handle by pulling the lever on the broach handle down. Remove the broach handle.

Figure 13

FEMORAL BROACHING cont.

Broach Extraction

Due to the self-locking nature of the 3-degree taper, broaches are occasionally difficult to remove from the femoral canal. This may occur during sequential broaching or following trial reduction. If the broach cannot be easily removed from the canal using the broach handle, it is recommended that the broach extractor be used.

To use the broach extractor, insert the tip into the slot on the lateral shoulder of the broach. Rotate the extractor 90 degrees to lock it in place. Use a mallet to extract the broach from the canal (Figure 14).

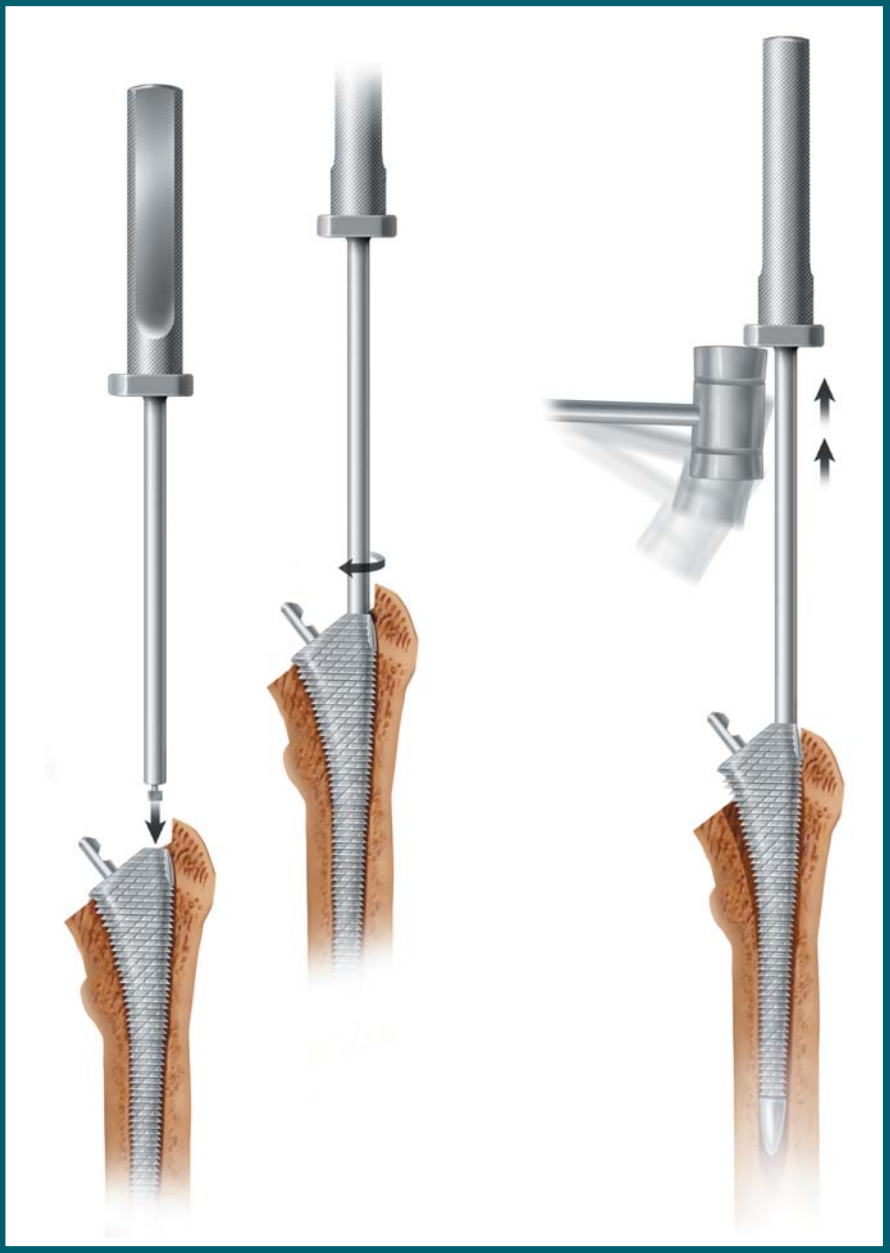


Figure 14

CALCAR PLANING

The Summit Tapered Hip System Porocoat and DuoFix HA stems are collarless designs; therefore, calcar planing is optional.

It is anticipated that the top of the Porocoat Porous Coating on the final implant will rest at the same position as the top of the cutting teeth on the broach. Calcar planing will help create a definitive landmark for stem insertion by milling a precise resection level.

Select either the small or large calcar planer and attach it to the power reamer. Place the planer over the broach stud and mill the calcar to the broach face. Make certain the planer is rotating before engaging the calcar. This will prevent the planer from binding on the calcar (Figure 15).

Figure 15

TRIAL REDUCTION

NOTE: Refer to the chart at the back of this surgical technique for detailed base offset, neck length and leg length adjustment information.

Trial neck segments and trial modular heads are available to assess proper component position, joint stability, range of motion and leg length. Standard and high offset neck segments are available for each stem size. Offset increases 6-8 mm, depending on stem size, from the standard to the high offset option without altering leg length. Perform trial reduction with a +5 Articul/eze head trial to allow for one up or down adjustment in neck length without using a skirted femoral head. With the desired neck segment and +5 modular head trial in place, perform a trial reduction and range of motion evaluation (Figure 16). With the hip in 90 degrees of flexion and 0 degrees of abduction, internal rotation should be at least 45 degrees with no tendency to dislocate. In extension, there should be full external rotation with no tendency to dislocate or impinge. Combined anteversion of the socket and femoral head should be approximately 45 degrees.

Instability can be attributed to three sources:

Soft tissue laxity can result in an unstable joint. This can be resolved by increasing modular head length or by choosing the high offset option. In extreme cases, these solutions can be employed in conjunction with trochanteric advancement.

Instability due to **component orientation** can occur. This condition can be corrected by choosing a face-changing acetabular liner and positioning it in a fashion to achieve the desired stability. If the face-changing liner fails, the acetabular shell may require repositioning.

Where instability is due to acetabular osteophytes or to trochanteric prominence, relieve these areas. Substitution of a longer modular head or selecting the high offset neck trial may be required to relieve **bony impingement.**

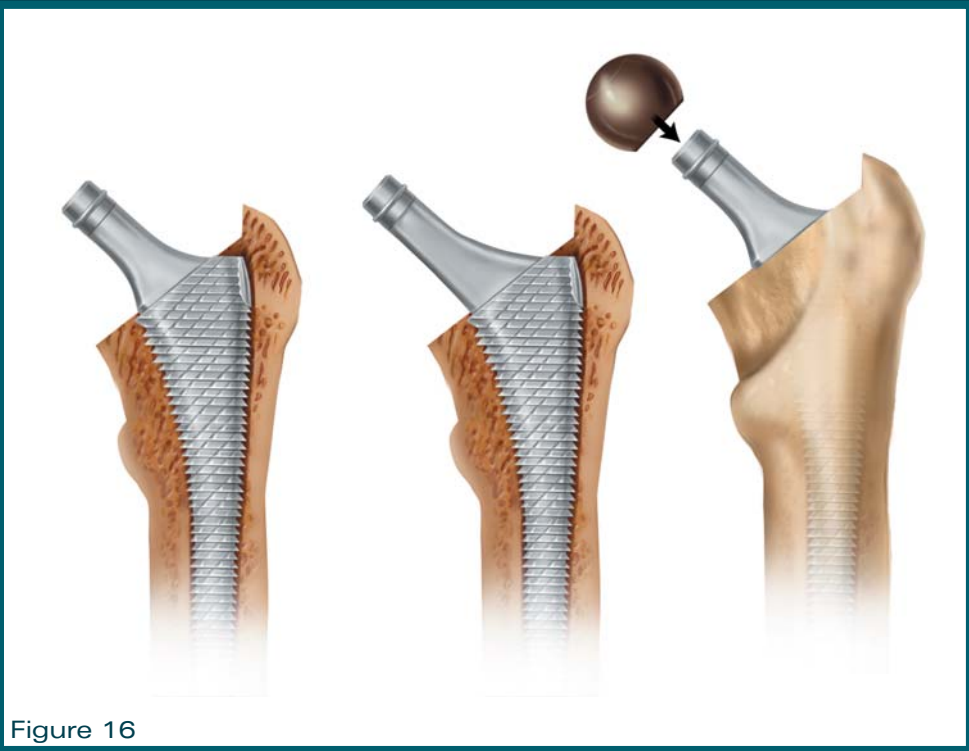


Figure 16

Standard Offset Neck Trial

High Offset Neck Trial

+5 Articul/eze Head Trial

BROACH EXTRACTION

Note the broach size and offset option of the desired components. Dislocate the hip and remove the trial head, neck segment and broach. Remove the broach by attaching the broach handle and retroimpacting (Figure 17). If the broach is difficult to remove, it is recommended that the broach extractor be employed (Refer to Figure 14).

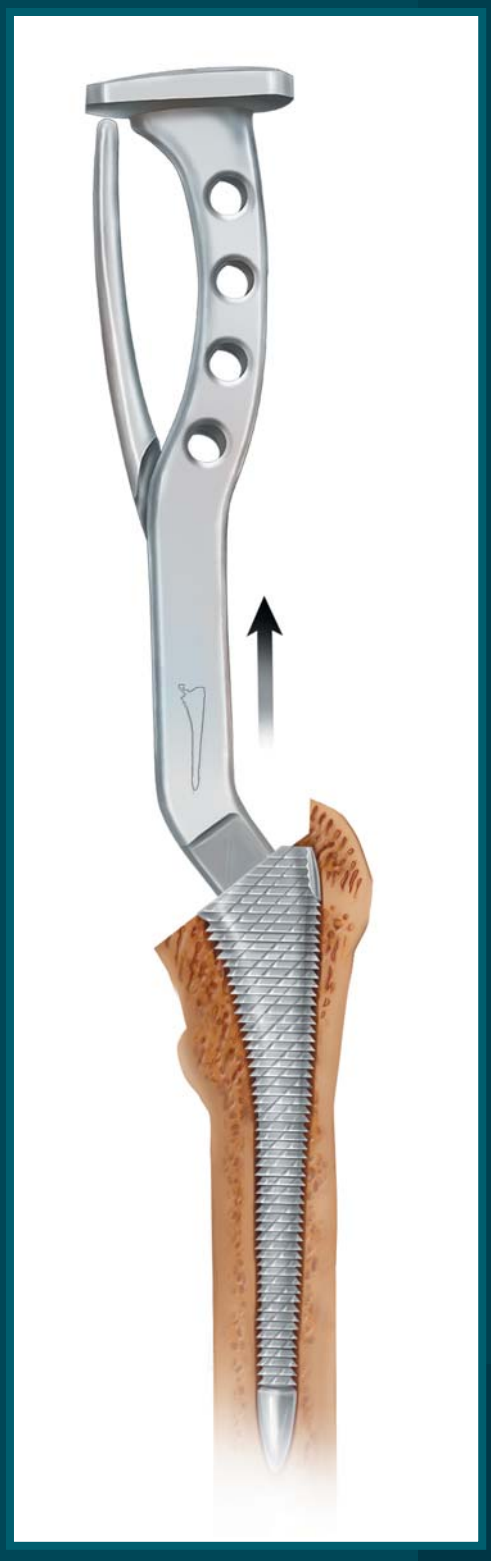


Figure 17

INSERTER SELECTION

Summit Tapered Hip System implants can be inserted with either a threaded retaining inserter or a nonthreaded inserter. Both inserters provide rotational control during stem implantation.

If the retaining inserter is chosen, verify that it is assembled with the inserter shaft threaded into the inserter handle (Figure 18). Choose the stem size that matches the final broach and thread it to the inserter.

Ensure the tines on the inserter are aligned with the recesses of the inserter platform on the top of the implant (Figure 19). Fully engage the threads of the inserter into the implant to ensure the inserter is securely attached to the implant.

Figure 18

Figure 19

ACETABULAR SHELL INSERTION

Remove the trial acetabular liner components and implant the desired acetabular shell (Figure 20). Take care to ensure cup orientation mimics the orientation of the trial component. Insert a trial liner into the shell implant.

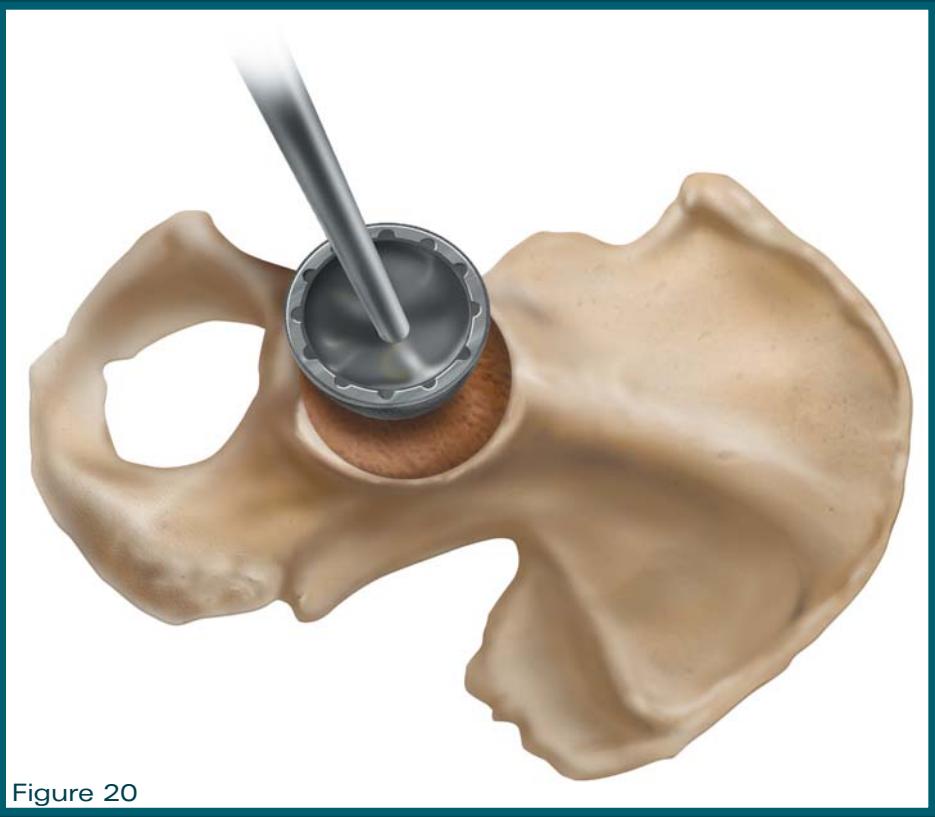


Figure 20

IMPLANT INSERTION

NOTE: When inserting the Summit DuoFix HA stem, take care to ensure the HA coating is not damaged by metal insertion instrumentation.

After the final acetabular shell is in place, introduce the hip stem to the medullary canal. Rotate the stem into its proper orientation and advance the stem into the canal using hand pressure (Figure 21). The implant should meet resistance 10-15 mm above the desired final seating position. Advance the stem into position with moderate blows from the mallet. The implant is fully seated when the top of the Porocoat Porous Coating is at the level of the top of the broach teeth and the implant is stable. If the stem stops moving with moderate mallet blows and is greater than 2 mm above the desired seating position, remove the implant and repeat the reaming and broaching steps. Excessive force should not be needed to seat the stem.

Figure 21

FINAL TRIAL REDUCTION

Perform a final trial reduction using the trial acetabular liner and trial femoral head, selecting the optimal liner and modular head for implant stability and leg length.

ACETABULAR INSERT IMPLANTATION

Following the final trial reduction, remove the trial acetabular liner and insert the appropriate acetabular liner (Figure 22).

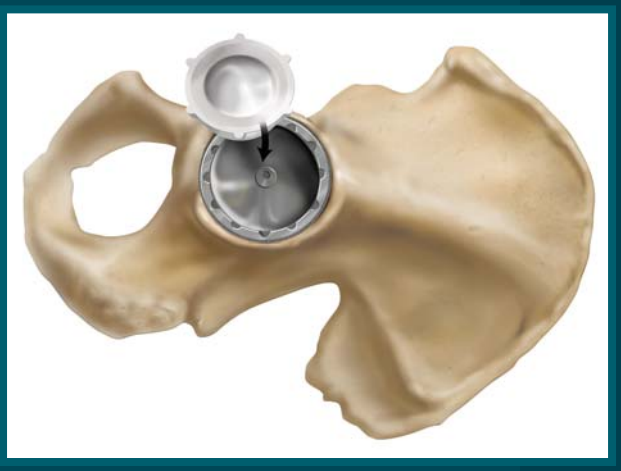


Figure 22

FEMORAL HEAD IMPLANTATION

Clean and dry the Articul/eze taper. Manually introduce the appropriate femoral head by firmly pushing and twisting the femoral head into place on the taper. Using the head impactor, engage the head with several mallet taps (Figure 23).

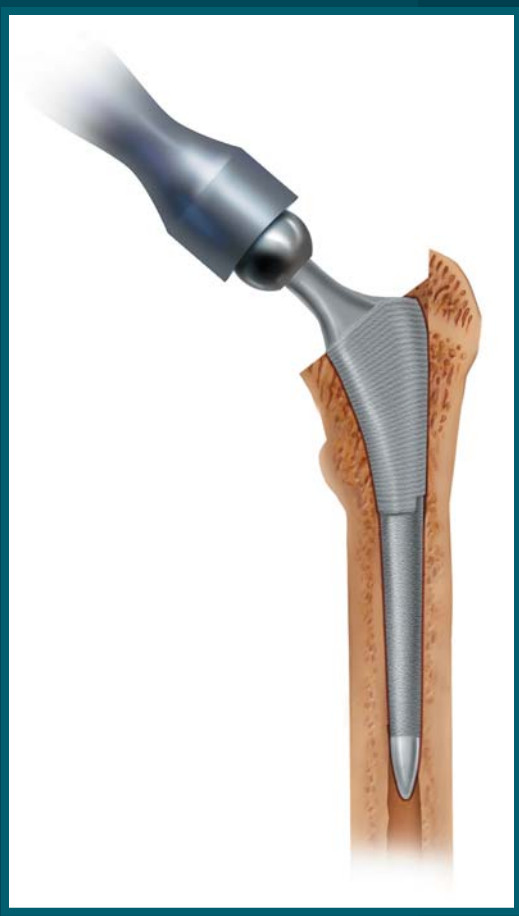
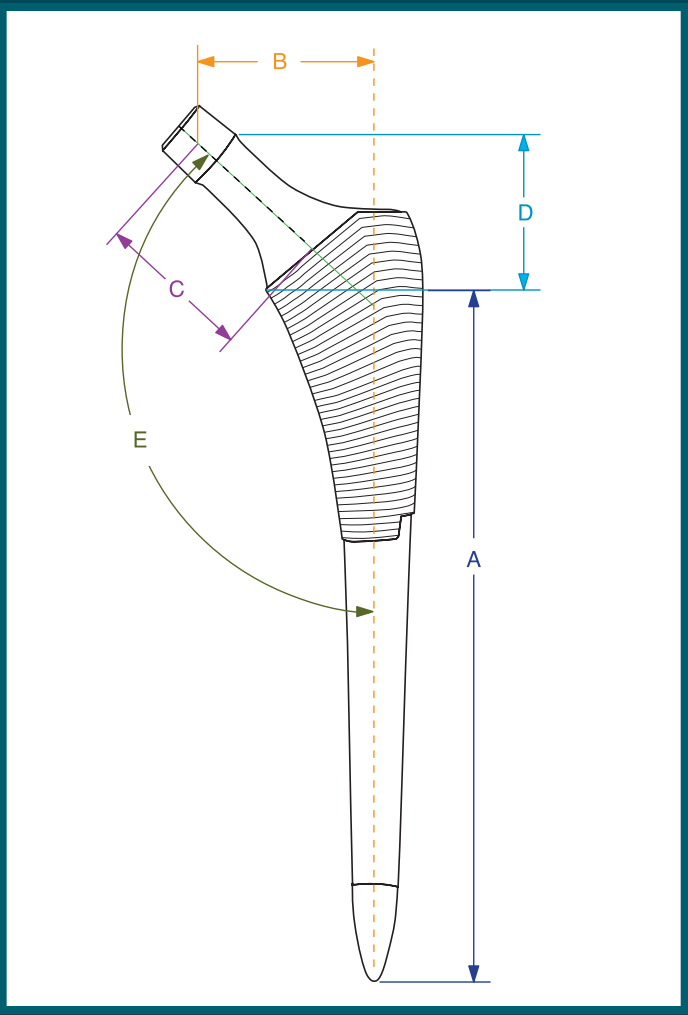


Figure 23

SUMMIT POROCOAT AND DUOFIX HA STEM SPECIFICATIONS

NOTE: All measurements are based on a 28 mm +5.0 Articul/eze head, which is the middle length of non-skirted femoral heads.



	A	B	C	D	E
Size	Stem Length	Base Offset	Neck Length	Leg Adjustment Length	Neck Angle
1 Std	125 mm	36 mm	31 mm	27 mm	130°
1 High	125 mm	42 mm	35 mm	27 mm	130°
2 Std	130 mm	38 mm	32 mm	28 mm	130°
2 High	130 mm	44 mm	36 mm	28 mm	130°
3 Std	135 mm	38 mm	32 mm	29 mm	130°
3 High	135 mm	44 mm	36 mm	29 mm	130°
4 Std	140 mm	40 mm	34 mm	30 mm	130°
4 High	140 mm	48 mm	39 mm	30 mm	130°
5 Std	145 mm	40 mm	34 mm	31 mm	130°
5 High	145 mm	48 mm	39 mm	31 mm	130°
6 Std	150 mm	42 mm	36 mm	32 mm	130°
6 High	150 mm	50 mm	41 mm	32 mm	130°
7 Std	155 mm	42 mm	36 mm	33 mm	130°
7 High	155 mm	50 mm	41 mm	33 mm	130°
8 Std	160 mm	44 mm	38 mm	34 mm	130°
8 High	160 mm	52 mm	43 mm	34 mm	130°
9 Std	165 mm	44 mm	38 mm	35 mm	130°
9 High	165 mm	52 mm	43 mm	35 mm	130°
10 Std	170 mm	46 mm	40 mm	36 mm	130°
10 High	170 mm	54 mm	45 mm	36 mm	130°

SUMMIT HIP ORDERING INFORMATION

INSTRUMENTATION

General Instrumentation

Cat. No.	Description
2570-00-000	Universal Broach Handle
2570-00-002	Broach Extractor
2570-04-100	Calcar Planer-Small
2570-04-200	Calcar Planer-Large
2570-05-000	Retaining Implant Inserter
2570-05-100	Standard Implant Inserter
2570-10-000	Case Complete
2570-01-600	Universal Neck Resection Guide
2001-42-000	T-handle
2001-80-501	IM Initiator
2001-65-000	Femoral Head Impactor
2354-10-000	Muller AWL Reamer
2611-20-000	Core 2 Instrument Case Complete
85-3927	Femoral Rasp
85-4673	Box Osteotome
2002-25-000	Anteversion Osteotome
85-3928	Broach Handle Alignment Rod

Tapered Reamer

Cat. No.	Size
2570-02-000	0/1
2570-02-100	2/3
2570-02-200	4/5
2570-02-300	6/7
2570-02-400	8/9
2570-02-500	10

Standard Neck Segment

Cat. No.	Size
2570-03-000	0/1
2570-03-100	2/3
2570-03-200	4/5
2570-03-300	6/7
2570-03-400	8/9
2570-03-500	10

High Neck Segment

Cat. No.	Size
2570-03-050	0/1
2570-03-150	2/3
2570-03-250	4/5
2570-03-350	6/7
2570-03-450	8/9
2570-03-550	10

Broach

Cat. No.	Size
2570-00-060	0
2570-00-070	1
2570-00-080	2
2570-00-090	3
2570-00-100	4
2570-00-110	5
2570-00-120	6
2570-00-135	7
2570-00-150	8
2570-00-165	9
2570-00-180	10

NOTE: All Summit Tapered Hip System femoral implants are compatible with the DePuy Articul/eze 12/14 taper femoral heads and Articul/eze "M" heads.

IMPLANTS

Summit Porocoat Stem Standard Offset

Cat. No.	Size
1570-01-070	1
1570-01-080	2
1570-01-090	3
1570-01-100	4
1570-01-110	5
1570-01-120	6
1570-01-135	7
1570-01-150	8
1570-01-165	9
1570-01-180	10

Summit Porocoat Stem High Offset

Cat. No.	Size
1570-11-070	1
1570-11-080	2
1570-11-090	3
1570-11-100	4
1570-11-110	5
1570-11-120	6
1570-11-135	7
1570-11-150	8
1570-11-165	9
1570-11-180	10

Summit DuoFix HA Stem Standard Offset

Cat. No.	Size
1570-02-070	1
1570-02-080	2
1570-02-090	3
1570-02-100	4
1570-02-110	5
1570-02-120	6
1570-02-135	7
1570-02-150	8
1570-02-165	9
1570-02-180	10

Summit DuoFix HA Stem High Offset

Cat. No.	Size
1570-12-070	1
1570-12-080	2
1570-12-090	3
1570-12-100	4
1570-12-110	5
1570-12-120	6
1570-12-135	7
1570-12-150	8
1570-12-165	9
1570-12-180	10

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 and sufficient femoral bone to seat and support the femoral stem. Hemi-hip arthroplasty is indicated in the following conditions: Acute fracture of the femoral head or neck that cannot be reduced and treated with internal fixation; fracture dislocation of the hip that cannot be appropriately reduced and treated with internal fixation; avascular necrosis of the femoral head; non-union of femoral neck fractures; certain high subcapital and femoral neck fractures in the elderly; degenerative arthritis involving only the femoral head in which the acetabulum does not require replacement; and pathology involving only the femoral head/neck and/or proximal femur that can be adequately treated by hemi-hip arthroplasty.

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. In the USA, ceramic heads are contraindicated for use with any other than UHMWPE cup or metal backed UHMWPE cup.

CAUTION: Ceramic liners are not approved for use in the United States.

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, history of infections, severe deformities leading to impaired fixation or improper positioning, tumors of the supporting bone structures, allergic reactions to materials, tissue reactions, and 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, peripheral neuropathies, tissue reaction.

For more information about the Summit Tapered Hip System, visit our web site at **www.jnjgateway.com/summithip**.

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