

Surgical Technique Consensus® Hip System



INDICATIONS AND USAGE

Indications for use of the CONSENSUS^{*} HIP SYSTEM must be carefully considered with respect to the patient's entire evaluation and alternative procedures. The selection of the CONSENSUS^{*} HIP SYSTEM is based on the judgment of the surgeon as to the needs of the patient and the expected post-operative conditions. Patient selection is dependent on age, general health, available bone stock and quality, and any prior surgery or anticipated future surgery.

Indications for use of the CONSENSUS[®] HIP SYSTEM - PRIMARY HIP:

- A. Significantly impaired joints resulting from rheumatoid, osteo, and post-traumatic arthritis.
- B. Revision of failed femoral head replacement, cup arthroplasty or other hip procedures.
- C. Proximal femoral fractures.
- D. Avascular necrosis of the femoral head.
- E. Non-union of proximal femoral neck fractures.
- F. Other indications such as congenital dysplasia, arthrodesis conversion, coxa magna, coxa plana, coxa vara, coxa valga, developmental conditions, metabolic and tumorous conditions, osteomalacia, osteoporosis, pseudarthrosis conversion, and structural abnormalities.

Indications for use of the CONSENSUS® BIPOLAR or UNIPOLAR:

- A. Primary replacement of the femoral head and neck with very little if any acetabular degradation noted.
- B. Proximal femoral fractures.
- C. Avascular necrosis of the femoral head.
- D. Non-unions of proximal femoral neck fractures.
- E. Revision of failed total hip arthroplasty.
- F. Treatment of malunion or nonunion acetabular fractures.

Consensus® Hip System Surgical Technique

Table of Contents

Introduction	1
Pre-operative Planning	3
Surgical Approach	
Osteotomy	4
Femoral Preparation	
Procedure for Cemented Fixation	8
Bipolar Trials	10
Pre-assembled Bipolar Preparation	
Traditional Bipolar Preparation	11
Bipolar Disassembly	12
Final ROM and Closure	12



Introduction

The Consensus[®] Hip System was developed from well established and clinically proven design principles. With consistent application of those principles and a logical system of instrumentation, the Consensus[®] Hip System offers the surgeon a variety of implant options for a wide spectrum of patient indications.

Femoral Heads

Femoral heads are available in cobalt chrome or BIOLOX[®] *delta* ceramic. They are ultra-precision manufactured to high sphericity and surface finish to minimize wear.

Acetabular Inserts

The acetabular insert is offered in a neutral and hooded design. The hooded acetabular insert provides additional coverage to increase the stability of the reconstructed hip. Inserts are available in Ultra High Molecular Weight and Highly Cross-Linked Polyethylene.

Acetabular Shells

The Consensus[®] Acetabular Shell offers a metal backed and an all polyethylene acetabular component. Metal backed components are intended for cementless use, and can be used for cemented use at the discretion of the surgeon. All polyethylene acetabular components are intended for cemented use only. The $CS2^{TM}$ Cup is available in either a hemispherical or flared rim design. Screw holes are provided as an option for enhanced component fixation.

Note: Please refer to surgical techniques specific to Consensus[®] Acetabular Shell and $CS2^{TM}$ Cup for information on acetabular preparation.

Stems

Consensus' stems are available in forged cobalt chrome Cobalt Chrome (CoCr) provides an optimal combination of high strength, stiffness, hardness and excellent biocompatability for use in a cemented stem application.

The non-porous CoCr cemented stems (1012) feature a compound proximal wedge body, cement normalization steps, wrap around collar, grit blast proximal body and the option of a tapered or non-tapered distal stem.



1012



Figure 1a



Figure 1b



Figure 1c

Pre-operative Planning

Diligent pre-operative planning can help to predict intraoperative challenges and ensure an optimal result with the Consensus[®] Hip System. Planning begins with thorough radiographic evaluation of the affected hip joint as well as a contralateral radiographic comparison of the unaffected hip. A/P and lateral views should clearly demonstrate acetabular form, proximal metaphysis, distal diaphysis and endosteal and periosteal contours of the femoral head. The Consensus[®] Hip System offers x-ray templates to assist the surgeon in pre-operative planning. The set contains femoral templates, acetabular templates and bipolar templates. Solid lines on the templates indicate prosthesis size while dotted lines indicate cement mantle.

The appropriate size acetabular template is selected and positioned such that the anatomical and prosthetic centers of rotation coincide and the insert is properly aligned (Figure 1a). Femoral A/P and lateral templates are positioned to ascertain optimal prosthetic metaphyseal fit and diaphyseal fill (Figure 1b and 1c). The distal diameter of the selected template will indicate the final reamer diameter during the surgical procedure, provided, that intraoperative sizing information does not dictate a different reamer diameter. Sizing and positioning information should be gathered from the affected hip as well as the contralateral hip.

Bipolar templates are also provided to help the surgeon in pre-operative planning for hemiarthroplasty.

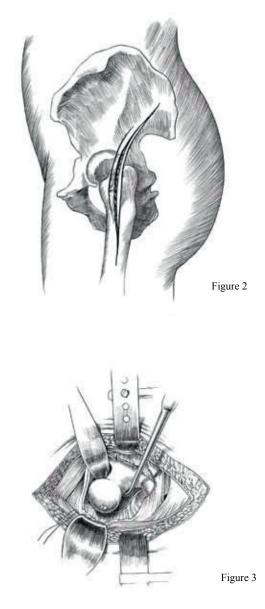
Surgical Approach

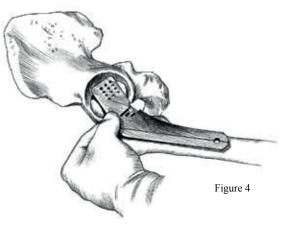
The Consensus[®] Hip System allows for performance of total hip arthroplasty through any standard approach based on the surgeon's experience and personal preference. Positioning of the patient, skin incision, soft tissue dissection, and hip dislocation should result in adequate exposure of the acetabulum and proximal femur (Figure 2 and 3).

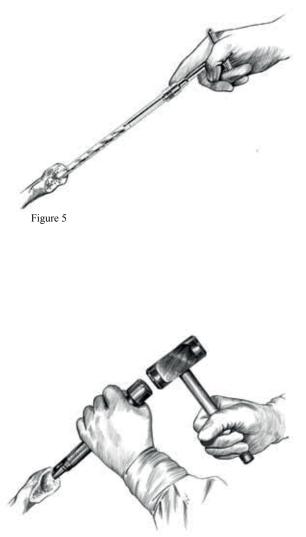
Osteotomy

Identifying the location of the femoral neck osteotomy is accomplished intraoperatively with the use of the *Femoral Neck Osteotomy Guide*. The head of the femur is exposed and the center of rotation is identified and marked with cautery. The center line of the guide is aligned corresponding to the center of the femoral shaft. The guide is then moved proximally until the cautery mark on the head of the femur is located through the offset/ stem hole that corresponds with pre-operative templating (Figure 4). While holding the guide in place, the saw or cautery can be used to mark the neck of the femur through the appropriate slot that corresponds to the pre-operative templated stem size.

Remove the guide and continue the osteotomy through the neck up to the base of the greater trochanter. Then take the saw and cut the superior neck parallel to the superior edge of the greater trochanter.







Femoral Preparation

Unless previously determined, an intraoperative decision to cement can be made at this time. *Cemented* Broaches are in the instrument set to accommodate *Broaches* are in the instrument set to accommodate a cemented fixation.

Identification of the femoral canal is accomplished once the proximal end of the femur is elevated with a retractor to properly expose the previously osteotomized neck and greater trochanter. Utilizing the *Starter Reamer* with the T-handle, put the tip parallel to the greater trochanter and slowly rotate clockwise down into the cancellous bone until the canal is identified (Figure 5).

Lateralization of the greater trochanter is accomplished using the *Box Osteotome*.

(Figure 6).

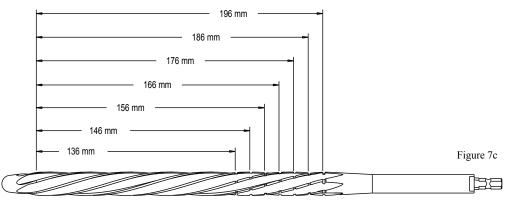
Figure 6

Broach selection for the proximal femur should be done before distal canal reaming commences in order to provide an intraoperative check on the pre-operative plan. This is accomplished by taking the templated size broach, inverting it, and placing it over the proximal femur. The stem should be centered over the canal in order to visually determine the fit of the proximal body shape to that of the proximal femur. The cemented broach is properly fit line-to-line anterior and posterior, with approximately 2mm of medial cancellous bone.

Reamer size can now be selected based on templated distal canal. Cemented broaches provide a 1.5-2mm distal and a 2mm proximal cement mantle around the implant. With that in mind, consider the distal canal size before deciding to ream to the exact size required for the broach chosen. Be sure to check the pre-operative planning with the intraoperative sizing to determine any variances. Progressive reaming of the femoral canal can now begin utilizing the self-centering bullet tip Femoral Canal Reamers in one millimeter increments. Ream up to the size engraved on the selected broach. The flat longitudinal cutting edges and self-centering features will ensure that the distal canal is properly formed to a cylinder that corresponds with the distal end of the implant. Use the depth marks of the reamer to gauge depth from the greater trochanter (Figure 7a-c).



Figure 7a



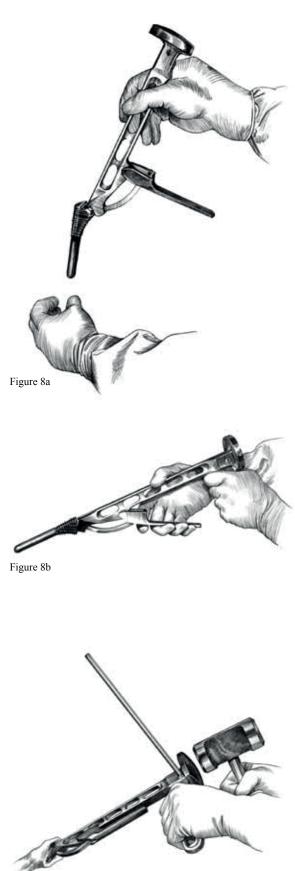


Figure 9

Broaching of the proximal femur now follows. With the lever open, secure the broach one size below the selected femoral broach to the *Femoral Broach Holder* by inserting the hook into the internal feature of the broach with the lateral side facing up (Figure 8a). Secure the broach by drawing the lever into the closed position (Figure 8b). Place the broach into the reamed canal. Then, slowly advance the broach until resistance is met.

Position the broach in 10 degrees of anteversion by placing the Anteversion Rod in the holes provided in the broach holder. The Anteversion Rod should be aligned with the flexed tibia for proper alignment. Anteversion may also be visually accommodated. Begin striking the broach holder impaction surface with a mallet. The broach should sink 2 - 3mm with each impact at first. Once the teeth of the broach engage the bone, the broach will sink only 1/2mm to 1mm with each impaction. If broaching is difficult, it is advisable to impact and remove the broach with alternating mallet blows until final seating of the broach has been achieved. This alternating "rasping" motion may help prevent intraoperative fractures of the femur while broaching. Continue impaction until the broach sits flush to 2mm below the medial calcar (Figure 9). Follow the same technique for the actual broach size selected. (NOTE: If the broach sinks easily below the medial calcar and it is felt it could be seated more than 3mm below the osteotomy, the surgeon should consider the possibility of using the next size broach).

Consideration of the distal femoral cortex thickness is important when going up another size broach since additional reaming is required. Once the broach is seated, release the lever and remove the broach holder.

When using a collared stem, the proximal femur can be prepared with the **Femoral Calcar Planer**. Insert the shaft of the planer into the hole of the seated broach before rotating. Lower the planer to just above the level of the bone. Begin rotating the planer gently to engage the bone and plane the calcar until it is flat and flush with the broach (Figure 10).

Trial reduction is accomplished by mounting the appropriate *Neck Trial* and *Head Trial* on the broach (Figure 11). Trial reduction can be accomplished with a trial insert or with the final implant to assess leg length and soft tissue tension. If necessary, adjustments can be made by changing the femoral head trial.

Cemented Implant Selection

1012 - Tapered Stem

When the 1012 Tapered Stem is used, the correct stem size will be the same as that of the final fullytoothed broach. The actual stem diameter is 2mm smaller allowing for a 2mm cement mantle (1mm per side).

1010 - Cylindrical Stem

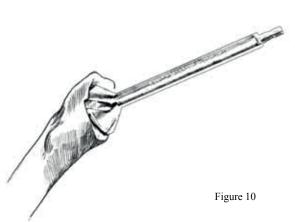
When the 1010 Cylindrical Stem is used, the correct stem size will be 2mm smaller then the final fully-toothed broach. The stem is equal to the labeled size and a 2mm smaller stem should be selected to allow for a cement mantle.

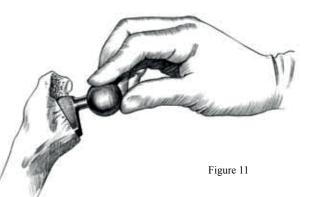
Procedure for Cemented Fixation

Femoral bone preparation after removal of the broach should be done with a pulsating lavage. The canal should be plugged at the appropriate level, dried, and suction applied to remove blood and fat from the prepared site. Introduce bone cement under pressure in its "doughy" state to ensure interdigitation with the bone.

Implant preparation simply requires the selection of the proper *Distal Centralizer* for the size of canal reamed. (NOTE: If the canal is larger than the last reamer used, *Femoral Distal Canal Gages* are included in the instrument set to properly size the distal canal for both the cement plug and distal

SHALBY ADVANCED TECHNOLOGIES, INC.





8



Figure 12

centralizer. Use the depth marks at the level of the calcar to gage distal diameter.) Secure the femoral implant to the *Femoral Stem Holder* by sliding the trunnion into the sleeve hole at the end of the handle. The divot in the top of the implant should be positioned so that the rod can be screwed down until the blunt end of the impactor rod engages the divot. Tighten the impactor rod until secure. Precoat the stem, with the *Proximal Spacer* and distal centralizer in place, using a low viscosity cement in order to initiate polymerization of the PMMA.

Implant insertion begins with the 10 degree anteversion rod in place and aligned with the calf and ankle. Begin with the stem centralized over the canal and gently push the implant with even pressure straight down the canal until resistance is felt (Figure 12). Remove all excess cement in order to visualize the medial calcar for final seating of the implant. Be sure to center the proximal stem in the canal to assure that the Proximal Spacer does not obstruct final seating. Remove all remaining cement below the collar prior to final seating. Strike the stem holder impactor head until the implant is fully seated. A solid ringing sound will be heard once the implant is at the final point of contact. Continue to remove excess cement from around the stem while holding pressure on it until the cement has cured.

Once the cement has hardened, select the correct *Head Implant* size and impact it onto the femoral stem using the *Femoral Head Impactor*. One or two solid impactions should secure it. Be sure that the stem trunnion and head are clean and dry before impacting.

Bipolar Trials

Femoral head measurement can be accomplished with a pair of calipers. Measure the head in three different areas of the circumference in order to ascertain the approximate size of the head. Remove all ligamentous structures from the acetabulum and any osteophytes that may limit range of motion.

Acetabular trial sizing is accomplished once the head size is known by selecting the corresponding *Bipolar Head Trial*. Using a thumb and forefinger, retract the collar of the *Bipolar Trial Handle* (Figure 13a). This will release the locking mechanism at the distal end of the handle (Figure 13b). Place the bipolar head trial on the distal end of the handle and release the collar, locking the head trial in place. Insert the unit into the acetabulum and assess the fit of the trial prosthesis (Figure 13c). Proper sizing has been accomplished when the trial feels like it is being sucked back into the acetabulum. The range of motion and the relationship to the acetabular rim should be checked at this time.

Trial reduction with the trial head can be performed either with the broach or implant in place. Once satisfied with the fit and range of motion, the actual implant can be assembled on the appropriately sized femoral implant head.



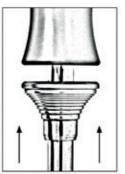


Figure 13a



Figure 13b

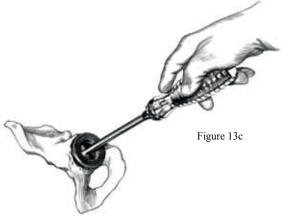


Table	1
Table	1

		Bipolar Head Size							
		38-41	42-44	45-47	48-50	51-53	54-56	57-59	60-62
Femoral Head ID	22mm	Х	NA	NA	NA	NA	NA		
	28mm		Х	Х	Х	Х	Х	Х	Х



Figure 14



Figure 15



Figure 16a



Figure 16b

Pre-assembled Bipolar Preparation

Implant selection: Pre-assembled *Bipolar Head Implants* contain the appropriate femoral head and insert completely assembled into the *Bipolar Head Implant*. (NOTE: Pre-assembled *Bipolar Head Implants* are available in a variety of offsets (except +10mm) with both 22mm and 28mm femoral heads).

Implant assembly: Place the femoral head of the pre-assembled *Bipolar Head Implant* onto the stem trunnion (Figure 14). Impact the preassembled *Bipolar Head Implant* using the *Femoral Head Impactor*. One or two solid impacts should secure it. Be sure the stem trunnion and femoral head are clean and dry before impacting.

Traditional Bipolar Preparation

Implant selection: Select the appropriate insert to match the size of the bipolar head selected. One insert fits three to four bipolar head sizes. (NOTE: Insert sizes 42 through 56 are available in 28mm ID (Table 1)).

Implant assembly: Place the insert on the femoral head by levering it into place (Figure 15). A loud snap should be heard. Then, take the selected *Bipolar Head Implant* and slide it over the insert with even pressure until the insert is flush with the bottom of the head (Figure 16a and 16b). Check to be sure the head is locked into the insert by trying to remove the head by hand. Assembly is complete and reduction of the hip can now be performed.

Bipolar Disassembly

Implant disassembly can be easily accomplished if, for any reason, the bipolar head needs to be removed. To remove the head, select the appropriate size *Bipolar Removal Tool* which corresponds with the insert size in place. Slide the removal tool over the neck of the implant with the flat face toward the femur and the cylindrical rim toward the bipolar insert and head. Slide the tool into the circumferential slot between the metal bipolar head and the plastic insert. Apply light pressure to seat the tool. Then simply twist and pull, separating the metal bipolar head from the removal tool and insert (Figure 17). (NOTE: Do not hold onto the removal tool with the same hand you are using to pull the head off).

Final ROM and Closure

Reduction of the hip should now be performed. After taking the hip through a complete range of motion, the hip can be closed in the manner in which the surgeon is accustomed.



Figure 17



USA

Shalby Advanced Technologies, Inc. 1115 Windfield Way, Suite 100, El Dorado Hills, CA 95762, Ph: +1 916 355 7100

Singapore

Shalby Global Technologies Pte. Ltd. Regus One Fullerton, 1 Fullerton Rd, #02-01, One Fullerton, Singapore- 049231 Ph: +65 88707885 /+60 125065062

India

Mars Medical Devices Ltd. Mondeal Heights, B-301 & 302, Sarkhej - Gandhinagar Highway, Ahmedabad, Gujarat-380015 Ph: +91 91671 20390







Follow us on 📢 💙 🛅 🖸