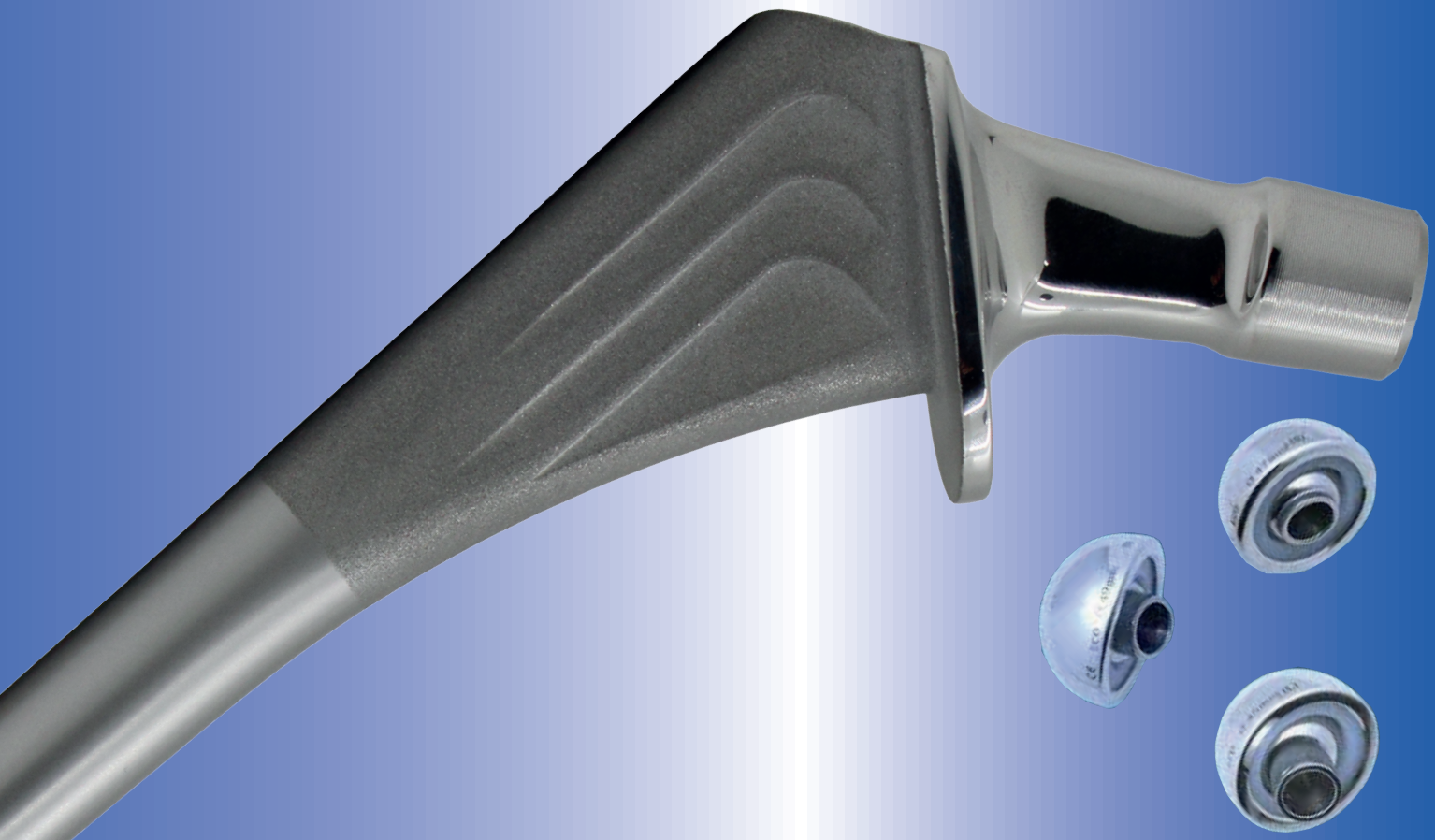

Surgical Technique

Consensus® Hip Bipolar System

Shalby Advanced Technologies, Inc.
Restoring Mobility, Improving Lives.

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

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Shalby Advanced Technologies, Inc.
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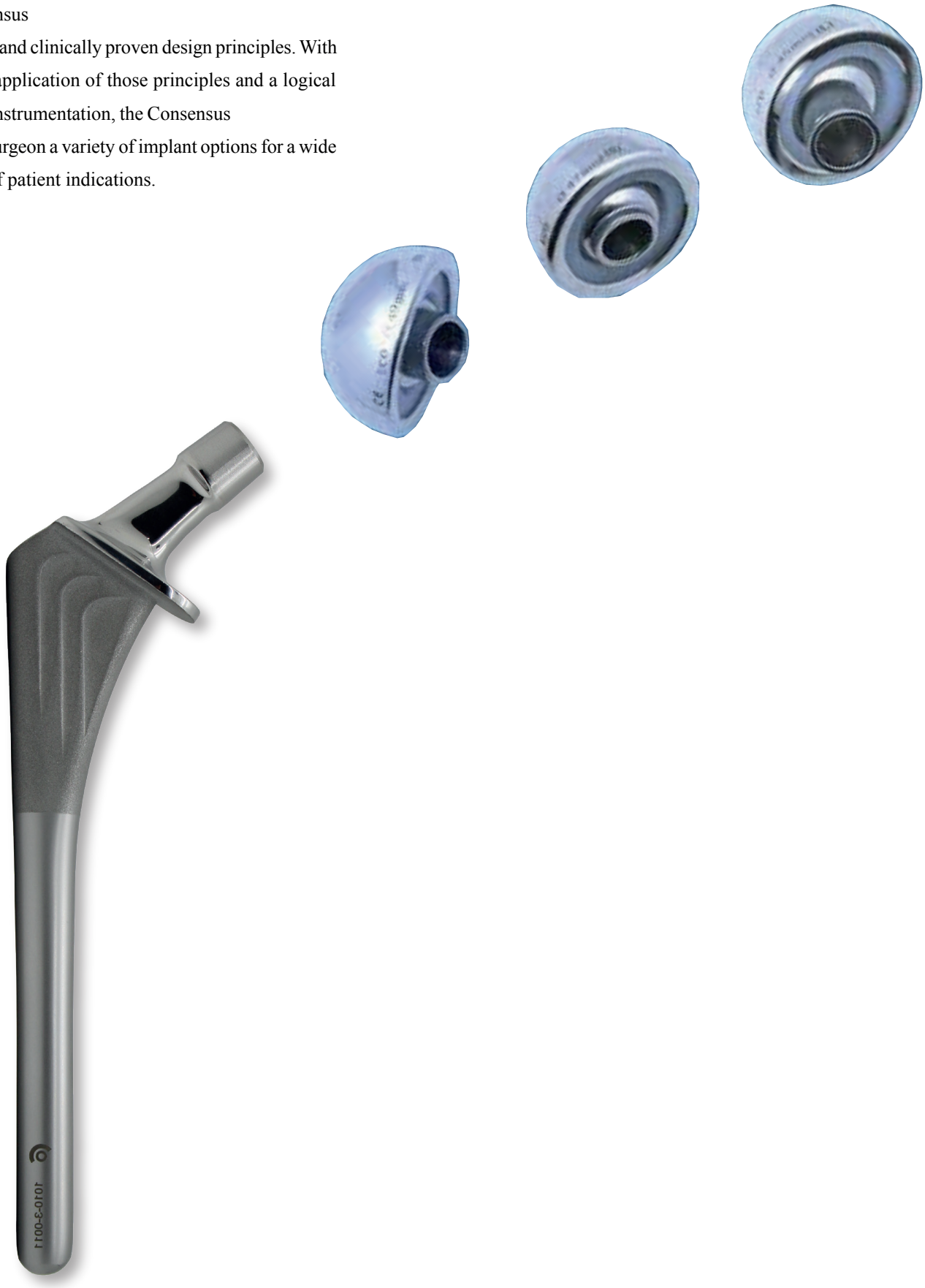
Introduction

The Consensus
established and clinically proven design principles. With consistent application of those principles and a logical system of instrumentation, the Consensus
offers the surgeon a variety of implant options for a wide spectrum of patient indications.



Stem

Consensus® stem is available in either 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

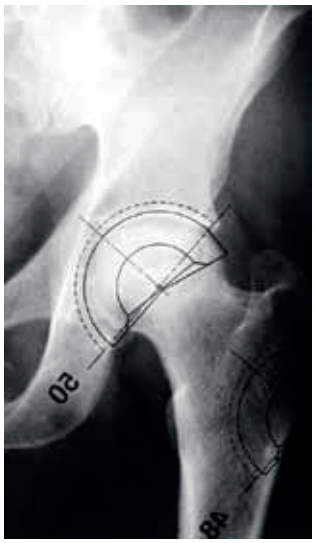


Figure 1a

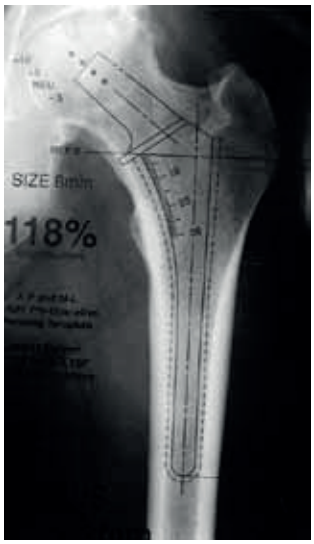


Figure 1b

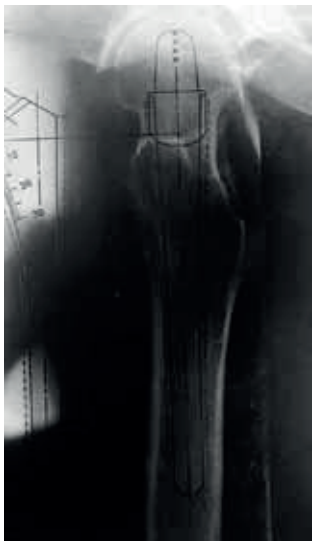


Figure 1c

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).

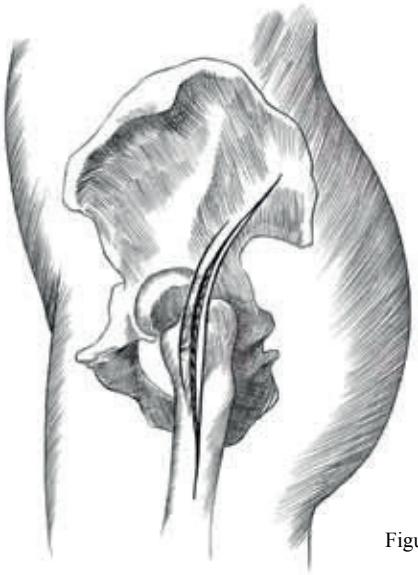


Figure 2

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.

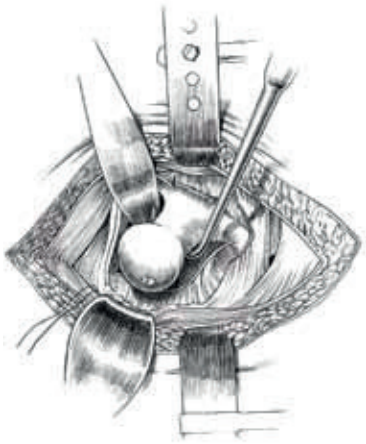


Figure 3

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.

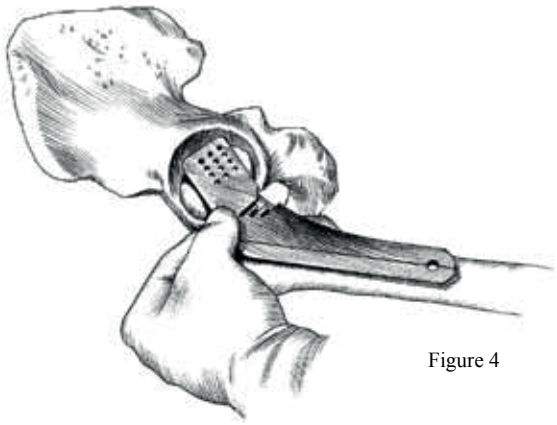


Figure 4

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 5a). This will release the locking mechanism at the distal end of the handle (Figure 5b). 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 5c). 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.

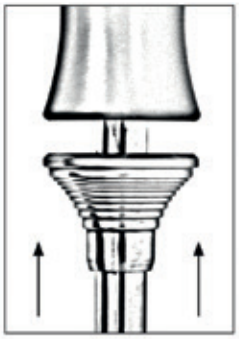


Figure 5a

Figure 5b

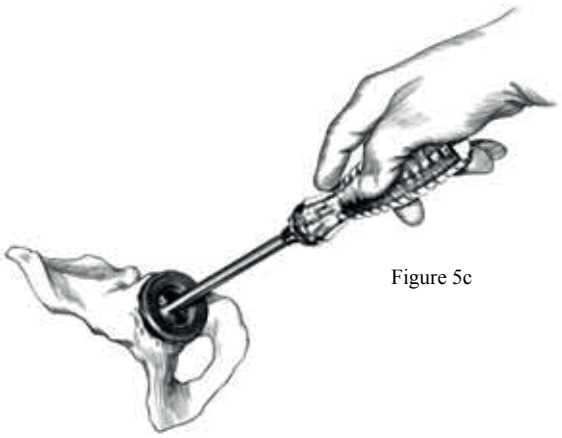


Figure 5c

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	X	NA	NA	NA	NA	NA		
	28mm		X	X	X	X	X	X	X

Figure 6

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.***

Implant assembly: Place the femoral head of the pre-assembled ***Bipolar Head Implant*** onto the stem trunnion (Figure 6). Impact the pre-assembled ***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.

Figure 7

Traditional Bipolar Preperation

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 only 28mm ID (Table 1)).

Implant assembly: Place the insert on the femoral head by levering it into place (Figure 7). 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 8a and 8b). 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.

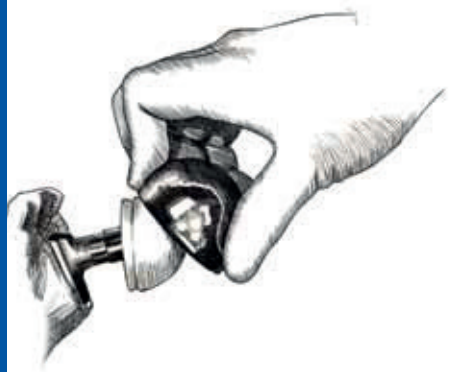


Figure 8a

Figure 8b

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 9). (NOTE: Do not hold onto the removal tool with the same hand you are using to pull the head off).

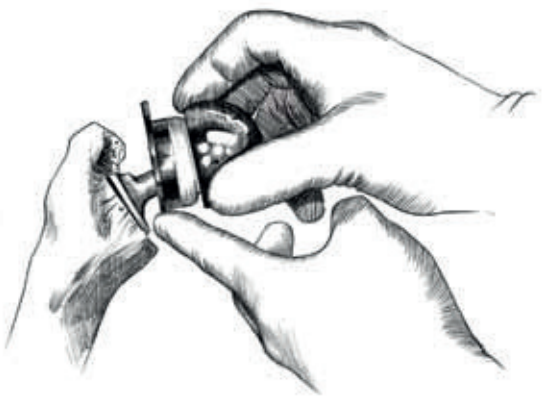


Figure 9

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.

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