ORTHO DEVELOPMENT®

Alpine® Cemented Hip Stem

SURGICAL TECHNIQUE

The following technique is a general guide for the instrumentation of the Alpine® Cemented Hip Stem. It is expected that the surgeon is already familiar with the fundamentals of hybrid and cemented Total Hip Arthroplasty (THA). Each patient represents an individual case that may require modification of the technique according to the surgeon's judgment and experience. Please refer to the Instructions for Use (IFU) for the Alpine Hip System for intended uses/ indications, device description, contraindications, precautions, warnings, and potential risks.

ALPINE CEMENTED HIP STEM DESIGNING SURGEONS:

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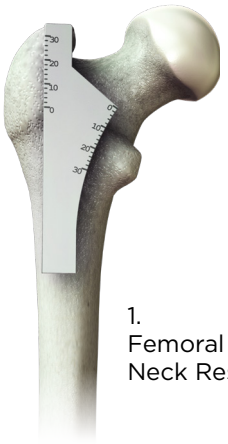
Surgical Technique Overview



1.
Femoral
Neck Resection

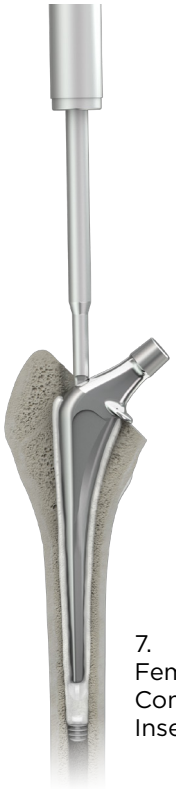
2.
Femoral
Preparation

3.
Reaming

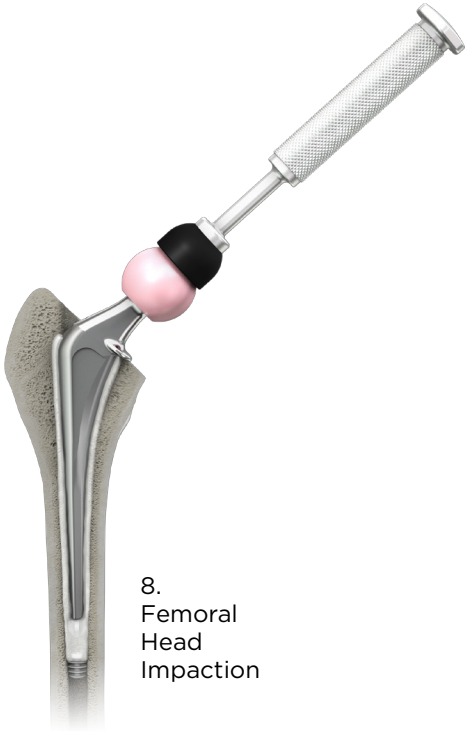
4.
Broaching

5.
Calcar
Planing

6.
Trial
Reduction



7.
Femoral
Component
Insertion



8.
Femoral
Head
Impaction

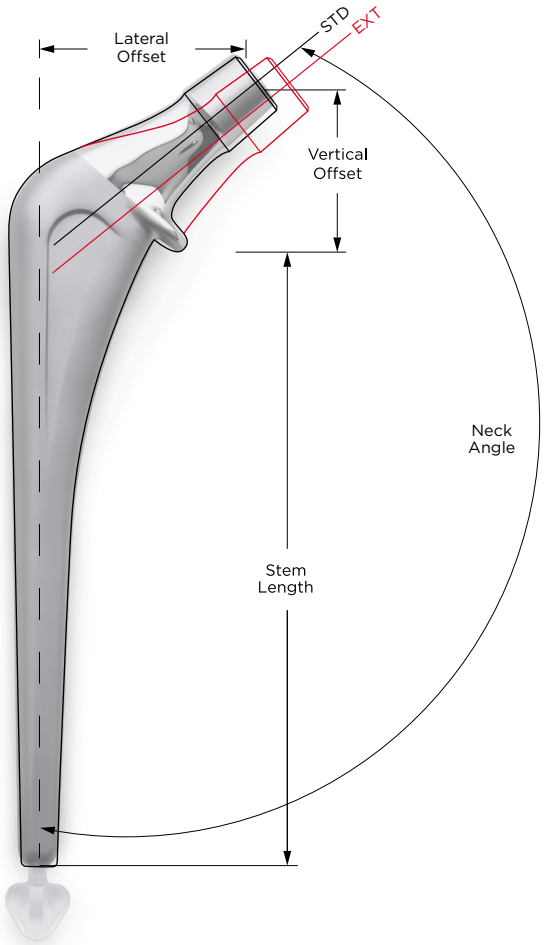
Alpine Cemented Hip Stem Overview

The Alpine Cemented Stem builds upon clinically proven cemented stem technology, and has enhancements that provide surgeons with greater intraoperative flexibility through multiple surgical approaches.

Key Features include:

- Progressive neck lengths for intraoperative flexibility in the majority of femoral geometries
- Simple and reproducible ream and broach technique
- Distal centralization to achieve a circumferential cement mantle
- Satin surface finish (Ra=20 micrometers)
- Oval cross-section neck to diminish impingement and improve range of motion

The Alpine Cemented Stem is available in 7 sizes with Standard and Extended neck offsets. The Stem is Forged Cobalt-Chrome Alloy, and has a 12/14 taper. It is compatible with Acetabular Components and Femoral Heads sold by Ortho Development. Please refer to the applicable Acetabular System surgical technique for more information.



1. Preoperative Planning

Preoperative planning is essential to prepare for the different situations that may arise during Total Hip Arthroplasty. The preoperative planning phase should include patient history, physical exam, and standardized radiographs. Magnification markers should be utilized to verify magnification. The A/P radiograph should be used to plan for stem size, femoral head center of rotation, and femoral offset. Once the femoral template has been positioned, measurements are taken from the proximal corner of the lesser trochanter to the neck resection level, and to the center of rotation of the prosthetic head. **In addition, the distance between the medial portion of the broach and the most medial portion of the calcar at the neck resection level must be recorded to aid with proximal stem alignment.** Such measurements should be verified during surgery.

ALPINE CEMENTED

SIZE	LENGTH	DISTAL TIP DIAMETER	NECK ANGLE	LATERAL OFFSET		VERTICAL OFFSET (STD)
				STANDARD	EXTENDED	
10	112	5.5mm	130°	35	40	28
11	114	5.5mm	130°	36	41	29
12	116	6.4mm	130°	37	43	29
13	118	7.3mm	130°	37	43	30
14	120	8.2mm	130°	38	44	31
15	125	9.0mm	130°	39	47	31
16	130	9.8mm	130°	40	48	32

Alpine stem dimensions and offsets (all dimensions are in mm)

Distal Centralizer available in 1mm increments from 8mm – 18mm

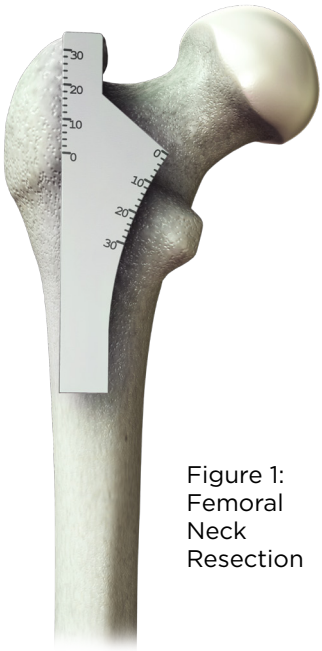


Figure 1:
Femoral
Neck
Resection

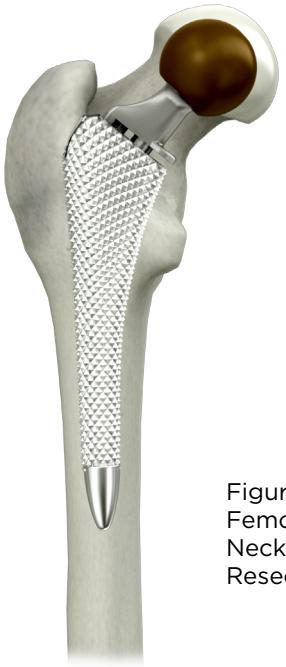


Figure 2:
Femoral
Neck
Resection

2. Surgical Exposure

Exposure is achieved through a variety of surgical approaches based upon surgeon preference and patient anatomy. Instrumentation is available to facilitate implantation through various approaches including the Director Anterior, Anterolateral, and Posterolateral approach.

3. Femoral Neck Resection

The Neck Resection Guide may be used to mark the desired neck resection level and angle (Figure 1). This may also be confirmed by using the templated resection level. The level of the neck resection that corresponds to both preoperative templating and intraoperative measurement should be marked with electrocautery. Prior to the resection of the femoral head, the Broach, Neck Trial, and Femoral Head Trial that correspond to the templated implant size can be assembled and used as a guide for femoral neck resection (Figure 2). Resect the femoral head with an oscillating saw.

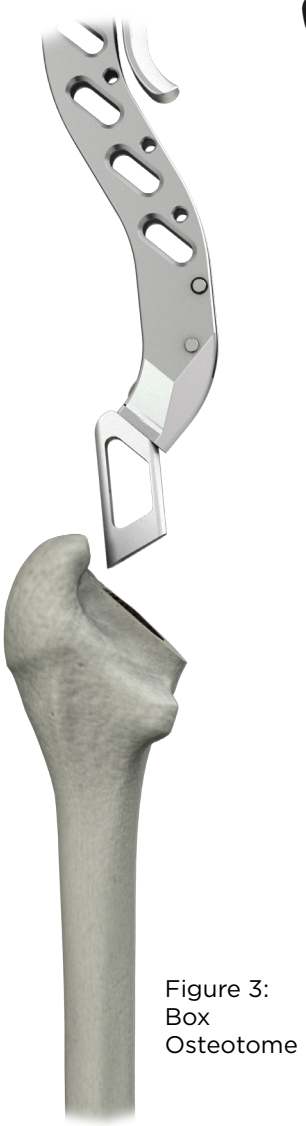


Figure 3:
Box
Osteotome

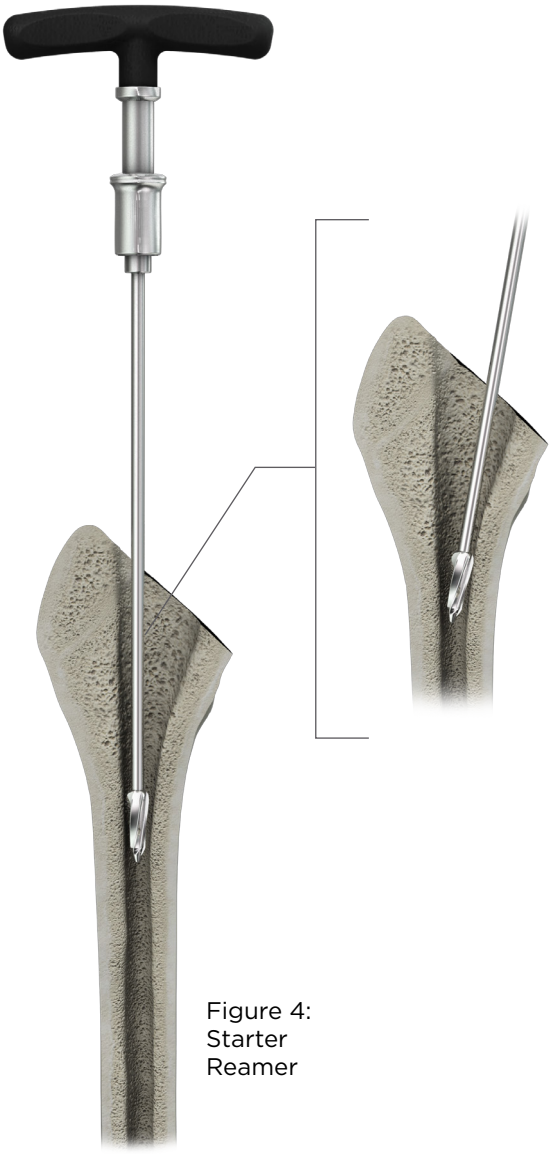


Figure 4:
Starter
Reamer

Figure 4a:
Starter
Reamer
Incorrect
Alignment

Figure 5:
Trochanteric
Reamer

4. Femoral Preparation

Use the Box Osteotome to open the femoral canal in the vicinity of the piriformis fossa to assure a homogeneous cement mantle in the sagittal plane and to establish adequate version (Figure 3). The Box Osteotome may also be used to help lateralize the position of the Starter Reamer. Connect the Starter Reamer to the T-Handle and insert it into the femur to access the femoral canal. The Starter Reamer should advance easily into the femoral canal (Figure 4). If the instrument does not easily advance into the canal, check for proper alignment, making sure to avoid placing the Starter Reamer in varus (Figure 4a). This will ensure proper alignment for the Trochanteric and subsequent Tapered Reamers.

Connect the Trochanteric Reamer to the T-Handle, or to power, then lateralize in order to achieve straight access into the femoral canal. Failure to properly lateralize the femoral work may result in varus implantation of the stem. Work the cutting flutes laterally towards the greater trochanter to further lateralize and open the proximal femoral canal as needed (Figure 5). When working with the Trochanteric Reamer, use extreme caution so as not to apply excessive force to the greater trochanter thus potentially causing inadvertent fracture.

The Alpine Cemented Stem is designed to be prepared with a ream and broach technique. Broaches are specially designed with a polished bullet-shaped tip to diminish the risk of femoral perforation.

Begin sequential reaming with the Tapered Reamers, starting from the smallest Tapered Reamer size available. Each Reamer has depth measurement markings for two stem sizes (Figure 6a). It is important to pay close attention

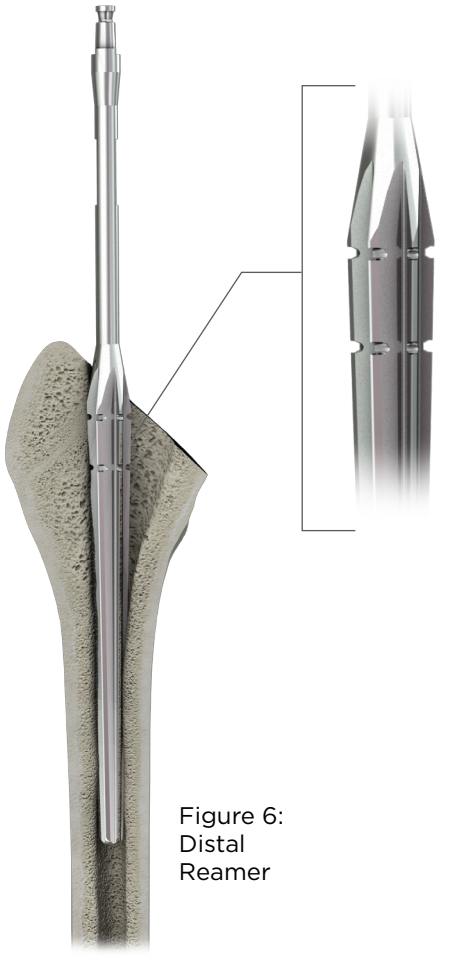


Figure 6: Distal Reamer

Figure 6a: Depth Markings

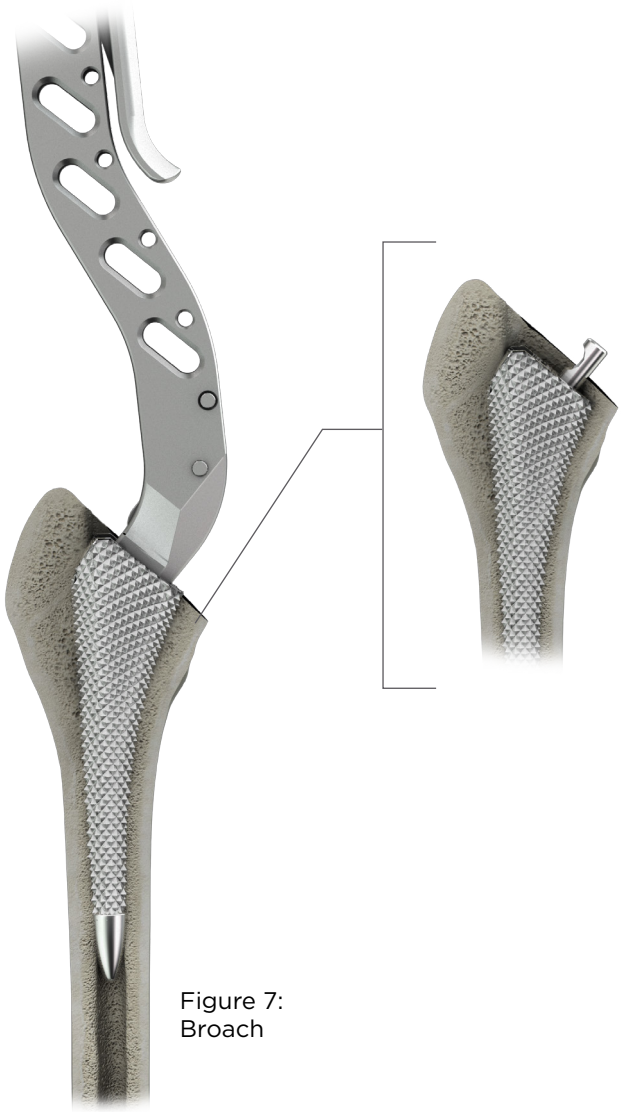


Figure 7: Broach

Figure 7a: Broach Countersunk

to the alignment of the reamer, making sure to proceed in neutral alignment (Figure 6). To help determine accurate reaming depth, the Reamer is introduced until the depth marker corresponding to the stem size is aligned with the medial neck resection level. Increase the Reamer size until adequate resistance is detected. Reaming to hard cortical bone will unnecessarily remove cancellous bone required for optimal cement interdigitation.

Broach Handles are available in Straight and Dual Offset to accommodate multiple surgical approaches. Begin broaching the proximal femur with a Broach that is 2-3 sizes smaller than the final Tapered Reamer used, and/or the preoperatively templated stem size. Advance the Broach down the medullary canal, paying close attention to version and alignment. Small changes in version of the stem may be made during broaching if desired, based on surgeon preference and as allowed by patient anatomy. The final Broach should sit with the top cutting teeth in line with the neck resection (Figure 7). If the neck resection is correct and the Broach is rotationally unstable or countersunk (Figure 7a), the next larger size Broach should be selected. Additional reaming may be necessary to accommodate the larger size Broach.

Once the rotationally stable Broach is seated at the level of the neck resection, remove the Broach Handle leaving the Broach in place.

Figure 8:
Calcar
Planar

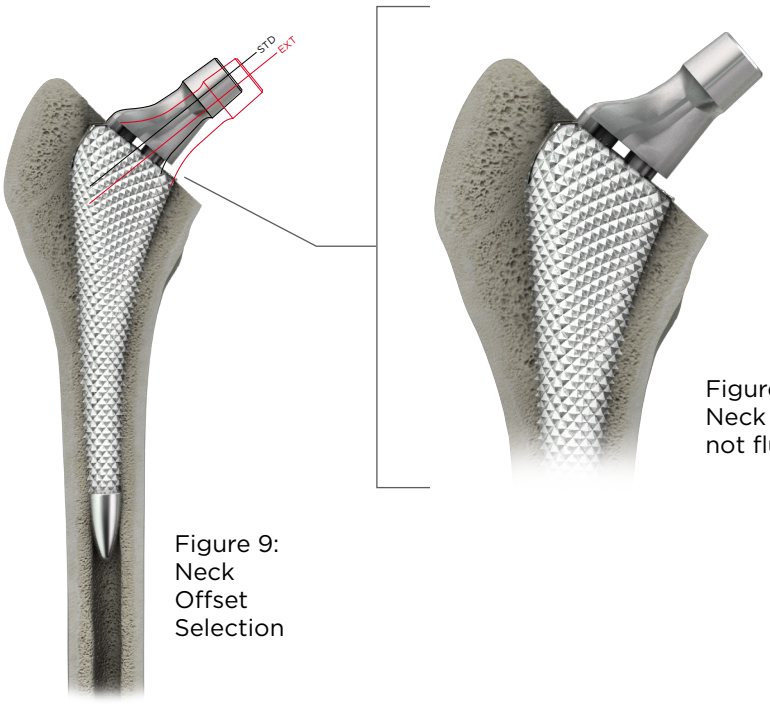


Figure 9:
Neck
Offset
Selection

Figure 9a:
Neck Trial
not flush

5. Calcar Preparation

The Alpine Cemented Stem is a collared stem, therefore, calcar planing is recommended. Place the Calcar Planar over the post of the fully seated Broach (Figure 8). To prevent the Calcar Planar from binding, engage the power prior to making contact with the bone. Advance the Calcar Planar to the level of the Broach. Preparation of the calcar will help with final implantation by allowing visualization of the final position of the Implant relative to the Broach.

6. Trial Reduction

The Alpine Hip System offers neck and head Trials to allow intraoperative assessment of motion, leg length, joint stability, and component position. The Alpine Cemented Hip Stem is available in standard and extended offsets for each stem size. The offset for the extended stem increases 5mm–8mm of direct lateralization depending on stem size (Figure 9). Build a trial construct using a Standard or Extended Neck Trial as determined by preoperative planning. The Neck Trial will not sit flush with the Broach (Figure 9a). The distance from the Neck Trial to the Broach varies by Neck Trial size grouping. Neck Trials are offered in specific size groupings based on broach size, see chart below.

ITEM #	DESCRIPTION
800-0201	Alpine STD Neck Trial 9-11
800-0202	Alpine STD Neck Trial 12-14
800-0203	Alpine STD Neck Trial 15-20
800-0204	Alpine EXT Neck Trial 9-11
800-0205	Alpine EXT Neck Trial 12-14
800-0206	Alpine EXT Neck Trial 15-20

Figure 10:
Trialing

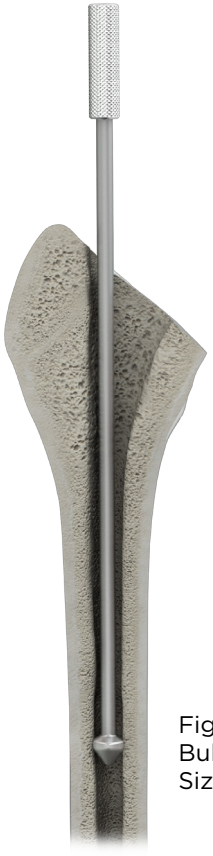


Figure 11:
Bullet
Sizer

Attach the appropriate Femoral Head Trial to the Neck Trial (Figure 10) based on planned leg length, and acetabular liner compatibility. The Neck Trial can now be attached to the Broach and the hip reduced. Perform a range of motion and stability test. If necessary, change the offset, neck length, and acetabular liner until stability of the hip is achieved and the desired leg length is reconstructed. Dislocate the hip. Remove the Head and Neck Trial, taking note of the final sizes chosen. Attach the Broach Handle to the Broach and remove it from the femur. Verify the size of the last Broach used for selection of the Alpine Cemented implant.

7. Sizing the Distal Centralizer

Distal Centralizers made from polymethylmethacrylate (PMMA) are available, and range in diameter from 8mm to 18mm, in 1mm increments. Use the Bullet Sizers to determine the size of the Distal Centralizer needed (Figure 11). The centralizer should be 1mm bigger than the last sizer that passes the canal at the level of the distal tip of the stem. The appropriate Distal Centralizer should be assembled to the stem. Verify that the Centralizer is fully seated and parallel to the long axis of the stem (not tilted or angled, which may result in difficulty advancing the stem into the cement of the femoral canal later).

8. Cement Restrictor Insertion

The use of a cement restrictor is recommended for proper cementing technique. Select an appropriately sized cement restrictor (not provided by Ortho Development). Aspirate the femoral canal before introducing the cement restrictor. The restrictor should be introduced slowly to avoid air and fat marrow embolization. At final depth of insertion, the stability of the restrictor can be assessed by applying increasing pressure to the restrictor inserter. An unstable restrictor should be replaced with a bigger one. The proximal end of the cement restrictor should be placed 1-1.5 cm distal to the Distal Centralizer. Select the final cement restrictor, and insert it into the canal.

9. Final Canal Preparation and Delivery of Cement

It is important that all debris be removed from the canal during the cleaning process. Pulsatile lavage may be used to remove loose bone debris, fat, marrow, and blood. A clean and dry intramedullary canal is a prerequisite to achieve good cement interdigitation and diminish fat embolization.

A cement gun is employed to introduce doughy cement in a retrograde technique. Keeping the tip of the nozzle embedded allows the force generated by the rising cement to slowly proceed the nozzle toward the canal opening. Continue to inject cement until the canal is filled completely. With the tip of the nozzle in the cement column, seal the proximal femoral opening with your thumb or a flexible canal sealer and pressurize the cement column.

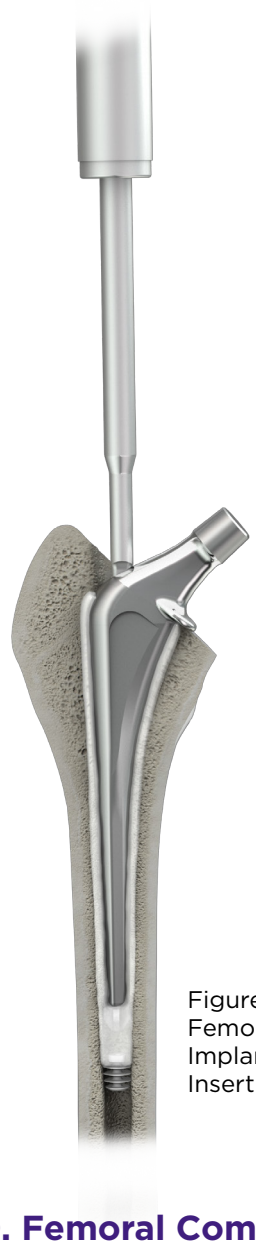


Figure 12: Femoral Implant Insertion

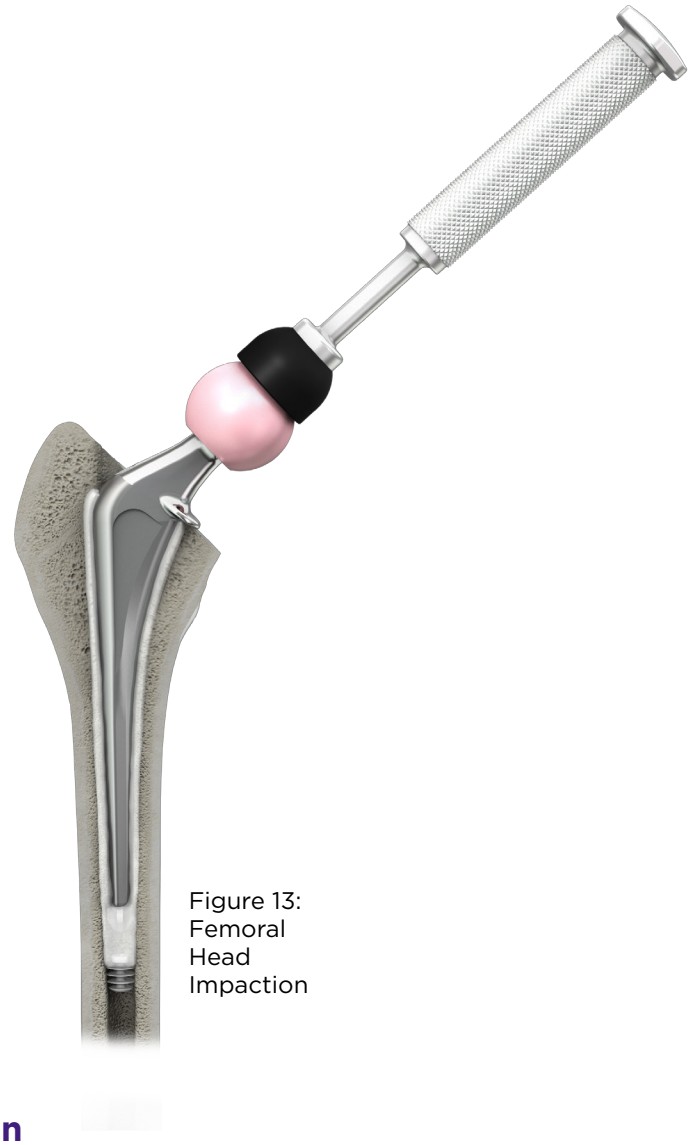


Figure 13: Femoral Head Impaction

10. Femoral Component Insertion

The Broach was designed to provide a minimum cement mantle of 2–3mm circumferentially. Open the same size implant as the last Broach used.

Orient the Implant to follow the path made by the Broach, and visually inspect alignment and version. Use the Stem Inserter to slowly advance the Implant into the cement column, while keeping the proximal femoral opening partially occluded with your thumb. To prevent cement lamination, do not change stem alignment or version during this process. Fully seat the Implant by advancing it until the collar meets the neck resection on the calcar (Figure 12). Impaction with a mallet should not be necessary. If there is resistance when seating the implant, check alignment and version of the Stem. Remove the Stem Inserter.

Allow the cement to fully cure, remove excess extruded cement as needed, plastic tools are preferred to prevent scratching the Stem.

A final trial reduction may be performed, before final head implantation, using trial heads. Select the Femoral Head implant that corresponds to the last Femoral Head Trial used. Before impacting the Femoral Head clean and dry the neck and trunnion of the stem. Place the Femoral Head onto the taper and use the Head Impactor and Mallet to seat the Femoral Head with light taps of the Mallet (Figure 13). Reduce the hip and take it through full range of motion. Once the desired result is achieved, the peri-articular soft tissue envelope should be repaired and the wound closed in a standard fashion.

11. Alpine Cemented Hip Stem

ALPINE CEMENTED IMPLANT KIT

ITEM #	DESCRIPTION
700-0210A	Alpine Cemented Stem 10 STD
700-0211A	Alpine Cemented Stem 11 STD
700-0212A	Alpine Cemented Stem 12 STD
700-0213A	Alpine Cemented Stem 13 STD
700-0214A	Alpine Cemented Stem 14 STD
700-0215A	Alpine Cemented Stem 15 STD
700-0216A	Alpine Cemented Stem 16 STD
700-1210A	Alpine Cemented Stem 10 EXT
700-1211A	Alpine Cemented Stem 11 EXT
700-1212A	Alpine Cemented Stem 12 EXT
700-1213A	Alpine Cemented Stem 13 EXT
700-1214A	Alpine Cemented Stem 14 EXT
700-1215A	Alpine Cemented Stem 15 EXT
700-1216A	Alpine Cemented Stem 16 EXT
700-0308	Alpine Distal Centralizer 8mm
700-0309	Alpine Distal Centralizer 9mm
700-0310	Alpine Distal Centralizer 10mm
700-0311	Alpine Distal Centralizer 11mm
700-0312	Alpine Distal Centralizer 12mm
700-0313	Alpine Distal Centralizer 13mm
700-0314	Alpine Distal Centralizer 14mm
700-0315	Alpine Distal Centralizer 15mm
700-0316	Alpine Distal Centralizer 16mm
700-0317	Alpine Distal Centralizer 17mm
700-0318	Alpine Distal Centralizer 18mm

Femoral Head Implants

BIOLOX®DELTA FEMORAL HEADS

ITEM#	DESCRIPTION
136-2800	Delta Femoral Head 28mm +0
136-2813	Delta Femoral Head 28mm +3
136-2830	Delta Femoral Head 28mm -3
136-3200	Delta Femoral Head 32mm +0
136-3213	Delta Femoral Head 32mm +3
136-3216	Delta Femoral Head 32mm +6
136-3230	Delta Femoral Head 32mm -3
136-3260	Delta Femoral Head 32mm -6
136-3600	Delta Femoral Head 36mm +0
136-3613	Delta Femoral Head 36mm +3
136-3616	Delta Femoral Head 36mm +6
136-3630	Delta Femoral Head 36mm -3
136-3660	Delta Femoral Head 36mm -6
136-4000	Delta Femoral Head 40mm +0
136-4013	Delta Femoral Head 40mm +3
136-4016	Delta Femoral Head 40mm +6
136-4019	Delta Femoral Head 40mm +9
136-4030	Delta Femoral Head 40mm -3
136-4060	Delta Femoral Head 40mm -6

COCR FEMORAL HEADS

ITEM#	DESCRIPTION
138-2800	CoCr Femoral Head 28mm +0
138-2803	CoCr Femoral Head 28mm +3
138-2806	CoCr Femoral Head 28mm +6
138-2809	CoCr Femoral Head 28mm +9
138-2830	CoCr Femoral Head 28mm -3
138-2860	CoCr Femoral Head 28mm -6
138-3200	CoCr Femoral Head 32mm +0
138-3203	CoCr Femoral Head 32mm +3
138-3206	CoCr Femoral Head 32mm +6
138-3209	CoCr Femoral Head 32mm +9
138-3230	CoCr Femoral Head 32mm -3
138-3260	CoCr Femoral Head 32mm -6
138-3600	CoCr Femoral Head 36mm +0
138-3603	CoCr Femoral Head 36mm +3
138-3606	CoCr Femoral Head 36mm +6
138-3609	CoCr Femoral Head 36mm +9
138-3630	CoCr Femoral Head 36mm -3
138-3660	CoCr Femoral Head 36mm -6
138-4000	CoCr Femoral Head 40mm +0mm
138-4003	CoCr Femoral Head 40mm +3mm
138-4006	CoCr Femoral Head 40mm +6mm
138-4009	CoCr Femoral Head 40mm +9mm
138-4030	CoCr Femoral Head 40mm -3mm
138-4060	CoCr Femoral Head 40mm -6mm

Ortho Development® Corporation designs, manufactures, and distributes orthopedic implants and related surgical instrumentation—with a specialty focus on hip and knee joint replacement, trauma fracture repair and spinal fixation. ODEV was founded in 1994 and is located at the base of the Wasatch Mountains in the Salt Lake City suburb of Draper, Utah. The company has established distribution throughout the United States and Japan, along with other select international markets.

ORTHO DEVELOPMENT®

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