

Alpine[®] Cementless Hip Stem

SURGICAL TECHNIQUE

The following technique is a general guide for the instrumentation of the Alpine® Cementless Hip Stem. It is expected that the surgeon is already familiar with the fundamentals of 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.

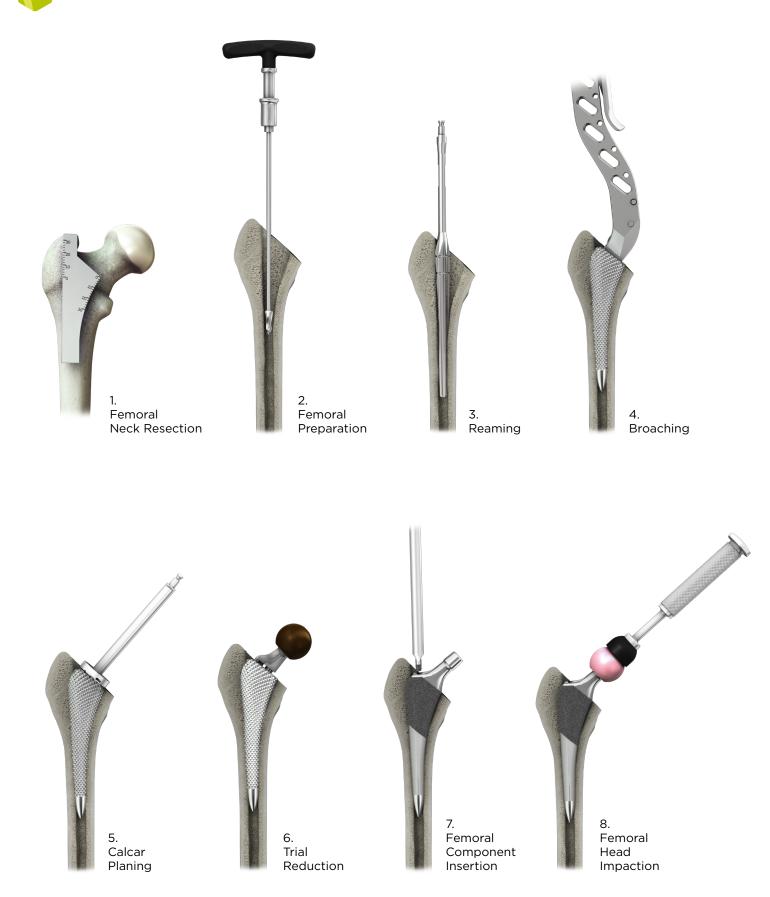
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Alpine Cementless Hip Stem Overview

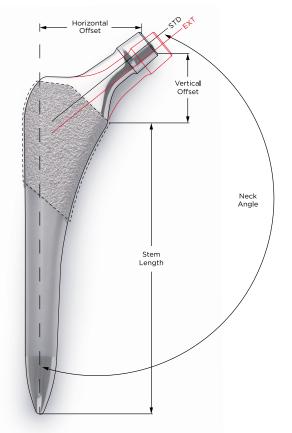
The Alpine® Cementless Hip Stem builds upon the clinically proven proximal to distal conical tapered hip stem design. The philosophy behind the design aims to improve anterior/posterior and medial/lateral fill of the proximal femur. The design allows for solid fixation of the femoral stem with resistance to anteversion and retroversion, torque and subsidence. The Alpine Cementless Hip Stem makes enhancements that provide surgeons with greater intraoperative flexibility in multiple surgical approaches.

Key Features include:

- High-strength Titanium Alloy
- Medial curve and associated calcar width for optimized proximal fit
- Progressive neck lengths for intraoperative flexibility in smaller and larger femoral geometries
- Titanium Plasma Spray coated proximal body surface for solid, long-term fixation
- Polished distal tip to mitigate distal point loading
- Minimal Ream and Broach instrumentation to simplify the surgical procedure
- Progressive 1mm distal sizing

The Alpine Cementless stem has a 12/14 taper, and is available in 12 sizes with standard and extended neck offsets. It is compatible with Acetabular compnents and Femoreal 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 measurements are made the neck resection level can be marked for verification during surgery.

		DISTAL	NECK	VERTICAL OFFSET STD	HORIZONTAL OFFSET	
SIZE	LENGTH	DIAMETER	ANGLE		STANDARD	EXTENDED
9	100	9mm	130°	27	34	39
10	104	10mm	130°	28	35	40
11	108	11mm	130°	29	36	41
12	111	12mm	130°	29	37	43
13	115	13mm	130°	30	37	43
14	119	14mm	130°	31	38	44
15	125	15mm	130°	31	39	47
16	130	16mm	130°	32	40	48
17	136	17mm	130°	33	40	48
18	142	18mm	130°	33	41	49
19	147	19mm	130°	34	42	50
20	153	20mm	130°	35	43	51

ALPINE CEMENTLESS

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



Femoral Neck Resection

Figure 2: Femoral Preparation

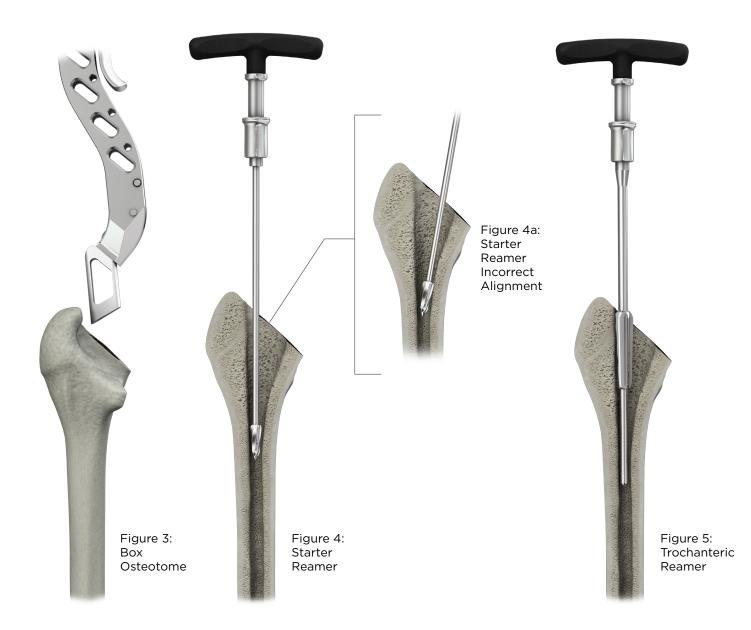
2. Incision

Exposure is achieved through a variety of methods based upon surgeon preference and patient anatomy. Instrumentation is provided to facilitate 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 (Figure 1). This may also be confirmed by using the templated resection level. The point of the femoral neck resection should be marked with electrocautery that corresponds to both preoperative templating and intraoperative measurement.

Prior to the resection of the femoral head, assemble the Broach, Neck Trial and Femoral Head Trial that corresponds to the templated implant size (Figure 2). Place the construct or the Neck Resection Guide on the femur and verify the center of rotation and the resection level of the proximal femur. Resect the femoral head with an oscillating saw.

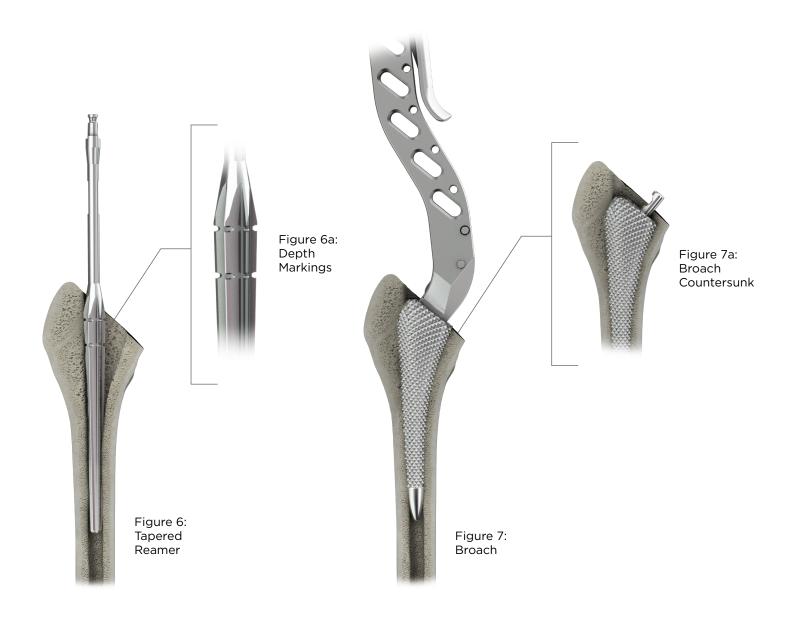


4. Femoral Preparation

Use the Box Osteotome to open the femoral canal and to establish version (Figure 3). The Box Osteotome may also be used to help lateralize the position of the Starter Broach. Connect the Starter Reamer to the T-Handle and insert it into the femur to access the femoral canal. The Starter Reamer should pass easily inside the femoral canal (Figure 4). If it does not pass easily, check for proper alignment in the femur making sure to avoid reaming in a varus orientation (Figure 4a). This will ensure proper alignment for the Trochanteric Reamer and subsequent Tapered Reamers.

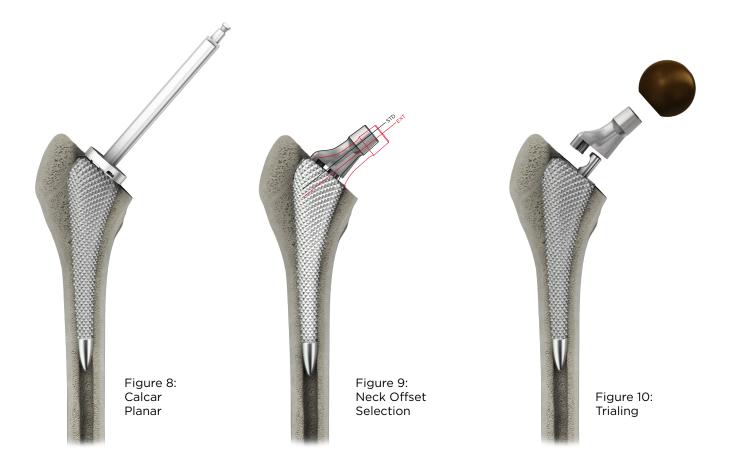
To help with alignment of the Tapered Reamers and Broaches, the Trochanteric Reamer may be used to help lateralize the entry point of the femoral canal. Connect the Trochanteric Reamer to the T-Handle or to a power tool then lateralize in order to achieve straight access into the femoral canal. Work the cutting flutes laterally towards the greater trochanter to further lateralize and open the proximal femoral canal as needed (Figure 5).

Begin sequentially reaming with the Distal Reamers, starting from the smallest Distal Reamer size available. Each Reamer has depth measurement markings for two stem sizes (Figure 6a). It is important to pay close attention to the alignment of the reamer making sure to stay in neutral alignment (Figure 6). Increase the Reamer size until the Reamer begins to engage hard cortical bone.



To help determine accurate reaming depth, the Reamer is introduced until the depth marker corresponding to the stem size is aligned with the medial resection level. Continue reaming until cortical engagement of the femur is felt.

The Alpine Hip System offers Broach Handles in straight and dual offset to accommodate multiple surgical techniques. Begin broaching the proximal femur by selecting 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 anteversion and alignment. The Alpine Cementless Stem is designed to be a proximal fit and fill stem. The final Broach should sit with the top cutting teeth in line with the neck resection (Figure 7). The final stem has proximal plasma spray which provides 0.5mm of press fit. 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.



5. Calcar Preparation

The Alpine Cementless Stem is collarless, therefore, calcar planning is optional. If desired, 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.

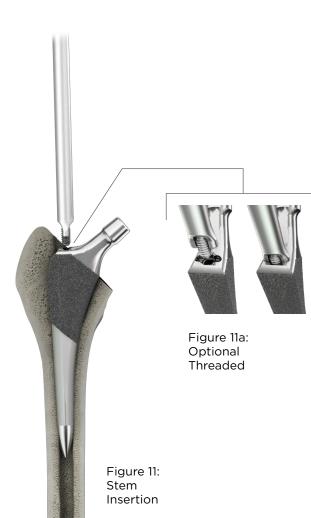
6. Trial Reduction

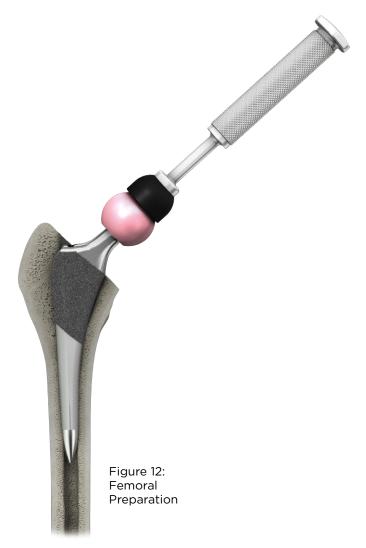
The Alpine Hip System offers Neck Trials and Head Trials to allow the surgeon to assess proper range of motion, leg length, joint stability and component position. The Alpine Cementless Hip Stem is available in a standard and extended option for each stem size. The offset for the extended stem increases 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. Neck Trials are offered in specific size groupings based on broach size, see chart.

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

Attach the appropriate Femoral Head Trial to the Neck Trial based on planned length and acetabular liner compatibility (Figure 10). The Neck Trial can now be attached to the Broach and the hip reduced. Perform a range of motion and stability assessment of the hip. If necessary, change the offset, neck length, and acetabular liner until stability of the hip is achieved and the leg length is reconstructed.

Dislocate the hip and 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 Cementless implant.





7. Femoral Component Insertion

Select the Alpine Cementless Implant that corresponds to the final Broach. Place the stem into the femoral canal by hand until it stops. Place the Inserter Shaft into the Stem and insert the implant. The system offers a threaded inner inserter shaft to engage the stem for insertion for those wanting to fix the Inserter to the final Stem. With the Implant upside down start the threads of the inner shaft into the Implant. Flip the Implant over and continue to thread into the Implant making sure the tines of the Inserter fit into the recess slots in the Implant. Continue to screw the threads into the Implant until the Inserter is secured to the Implant (Figure 11a).

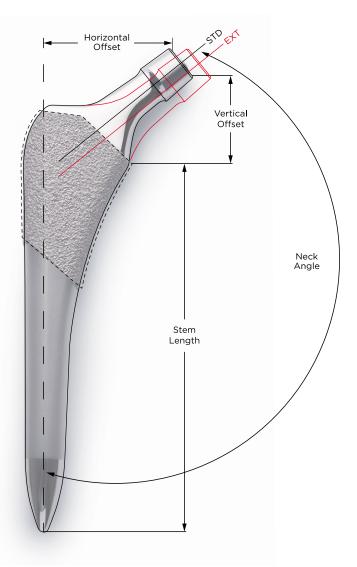
Orient the Implant to follow the path made by the Broach, and visually inspect alignment and version. Use a Mallet and the selected Stem Inserter to deliver moderate blows to advance the Implant into the final position. Fully seat the Implant by advancing it until the plasma coating meets the neck resection on the calcar and the implant is stable (Figure 11). Excessive or heavy force should not be needed to seat the Implant, and may result in a femoral fracture.

A final trial reduction may be performed before final implantation. Select the Femoral Head implant that corresponds to the last Femoral Head Trial used. Before impacting the Femoral Head make sure the Implant taper is clean and dry. Place the Femoral Head on the taper and use the Head Impactor and Mallet to seat the Femoral Head with light taps of the Mallet (Figure 12). The hip should be reduced and taken through full range of motion. After taking the hip through full range of motion and the desired result is acheived, the wound should be closed in a standard fashion.

8. Alpine Cementless Hip Stem

ALPINE CEMENTLESS IMPLANT KIT 700-0000-02

ITEM #	DESCRIPTION
700-0009	Alpine Cementless Stem 9 STD
700-0010	Alpine Cementless Stem 10 STD
700-0011	Alpine Cementless Stem 11 STD
700-0012	Alpine Cementless Stem 12 STD
700-0013	Alpine Cementless Stem 13 STD
700-0014	Alpine Cementless Stem 14 STD
700-0015	Alpine Cementless Stem 15 STD
700-0016	Alpine Cementless Stem 16 STD
700-0017	Alpine Cementless Stem 17 STD
700-0018	Alpine Cementless Stem 18 STD
700-0019	Alpine Cementless Stem 19 STD
700-0020	Alpine Cementless Stem 20 STD
700-1009	Alpine Cementless Stem 9 EXT
700-1010	Alpine Cementless Stem 10 EXT
700-1011	Alpine Cementless Stem 11 EXT
700-1012	Alpine Cementless Stem 12 EXT
700-1013	Alpine Cementless Stem 13 EXT
700-1014	Alpine Cementless Stem 14 EXT
700-1015	Alpine Cementless Stem 15 EXT
700-1016	Alpine Cementless Stem 16 EXT
700-1017	Alpine Cementless Stem 17 EXT
700-1018	Alpine Cementless Stem 18 EXT
700-1019	Alpine Cementless Stem 19 EXT
700-1020	Alpine Cementless Stem 20 EXT



Femoral Head Implants

BIOLOX DELTA FEMORAL HEADS

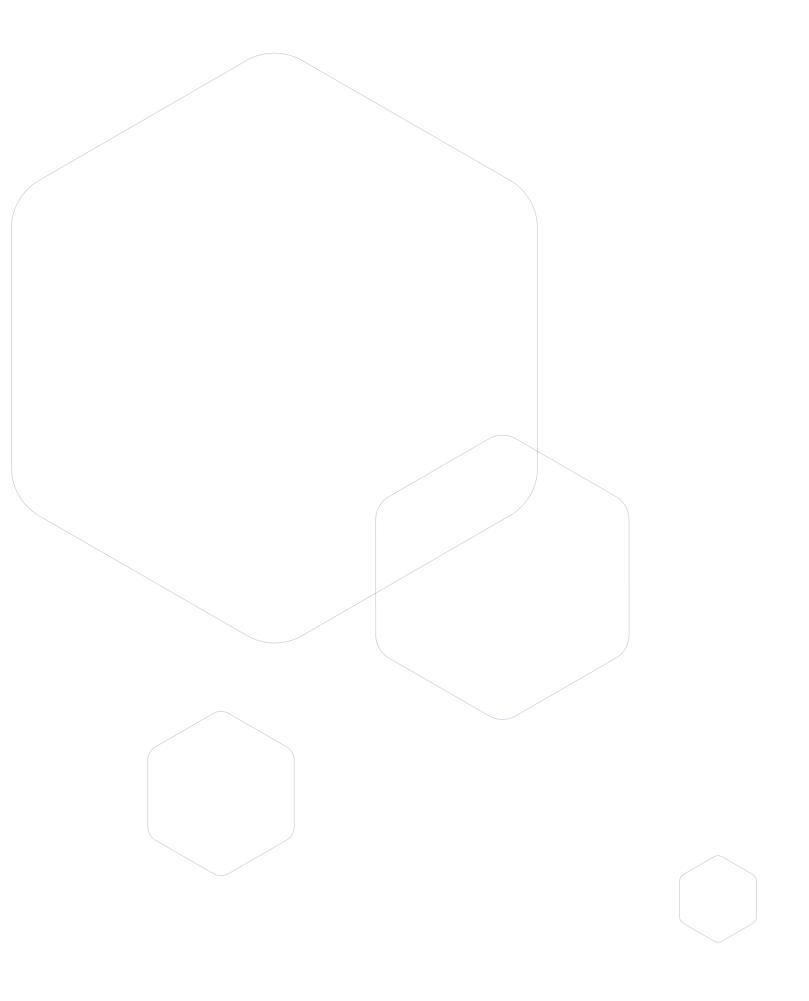
ITEM#	DESCRIPTION
136-2800	Delta Femoral Head 28mm +0
136-2813	Delta Femoral Head 28mm +3
136-2830	Delta Femoral Head 28mm -3
136-3200	Delta Femoral Head 32mm +0
136-3213	Delta Femoral Head 32mm +3
136-3216	Delta Femoral Head 32mm +6
136-3230	Delta Femoral Head 32mm -3
136-3260	Delta Femoral Head 32mm -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

TEM#	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

COCR FEMORAL HEADS











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.



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