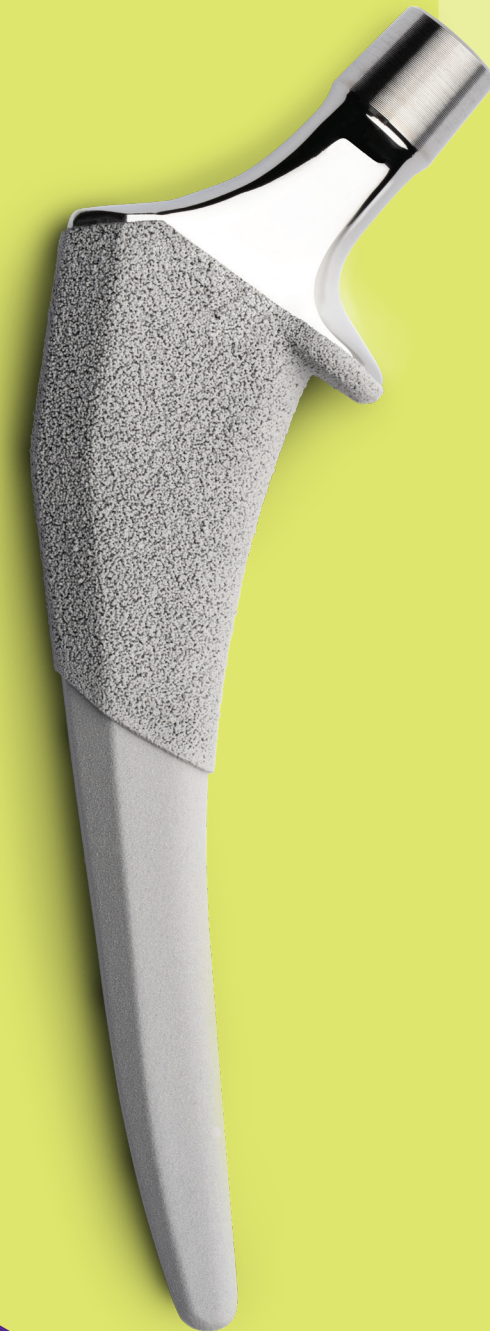




Trivicta[®] Hip Stem



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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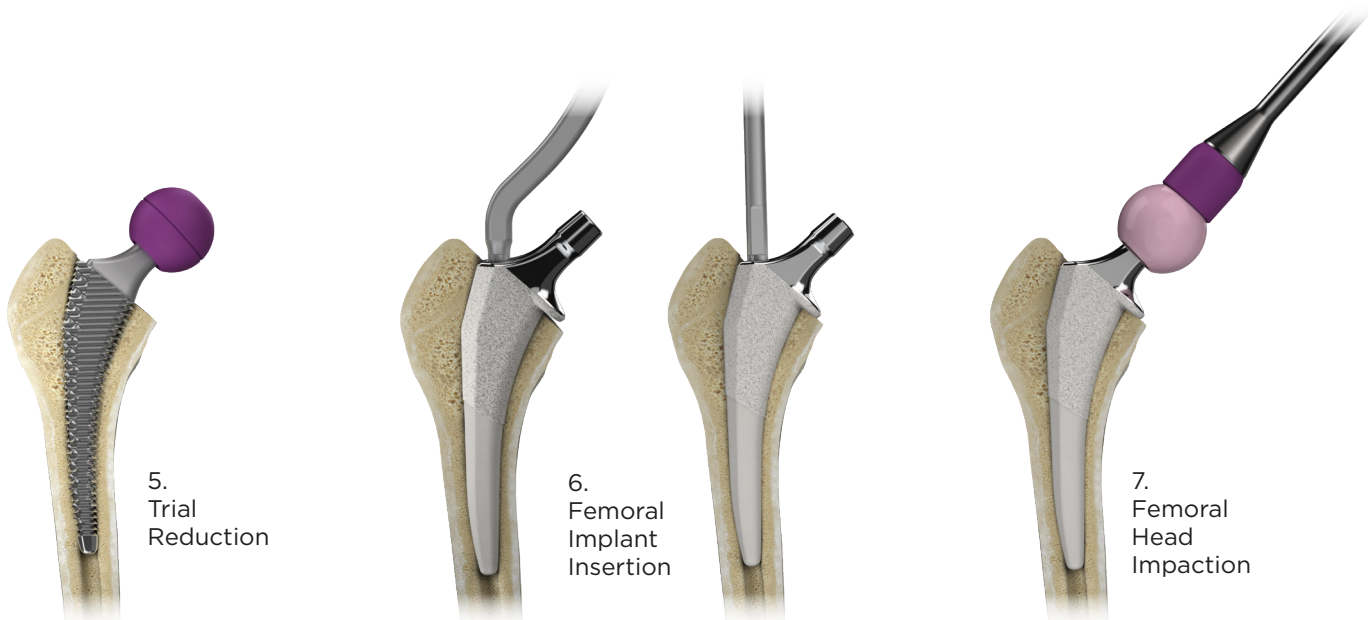
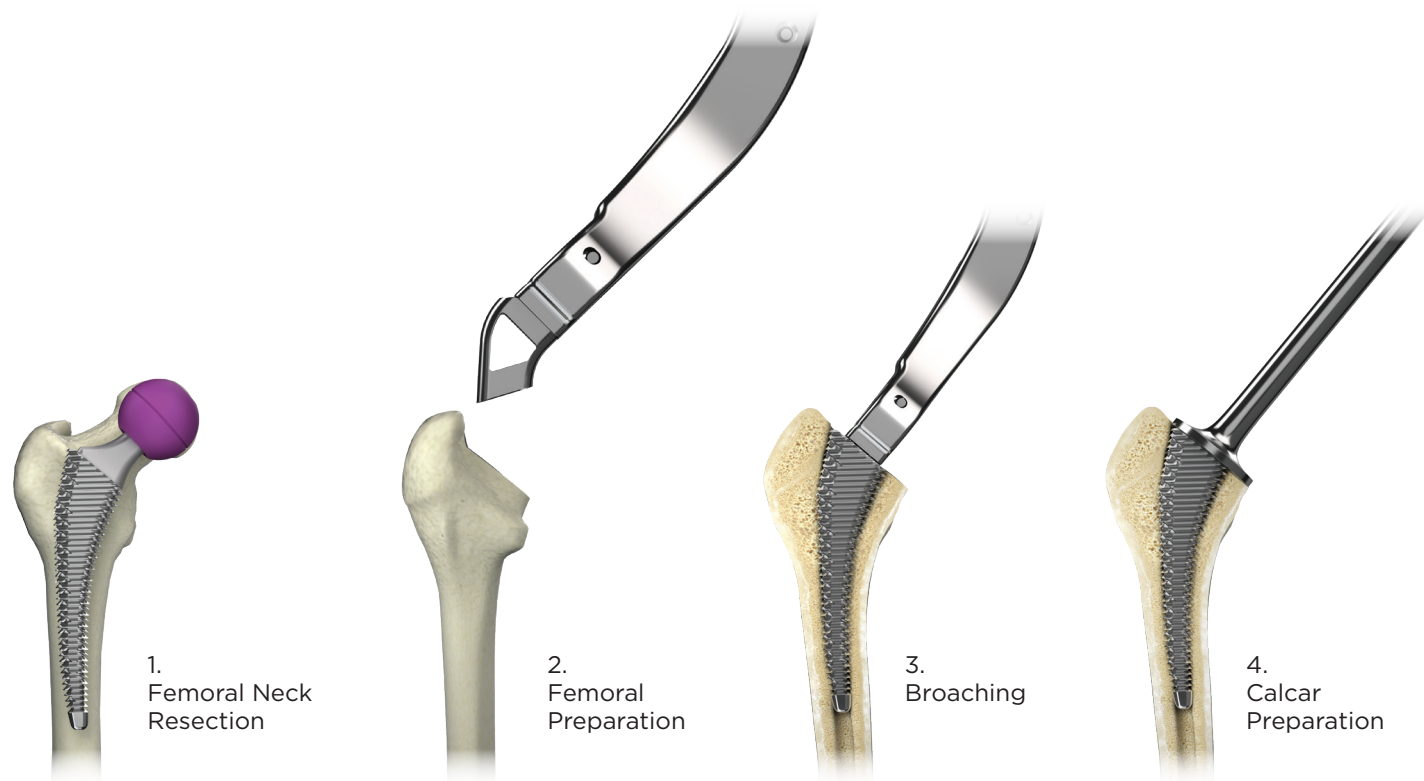
SURGICAL TECHNIQUE

The following surgical technique is a general guide for the instrumentation and implantation of the Trivicta Hip Stem. It is expected that the surgeon is familiar with the fundamentals of total hip arthroplasty (THA) and hybrid broaching techniques. 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 intended uses/indications, device description, contraindications, precautions, warnings and potential risks.



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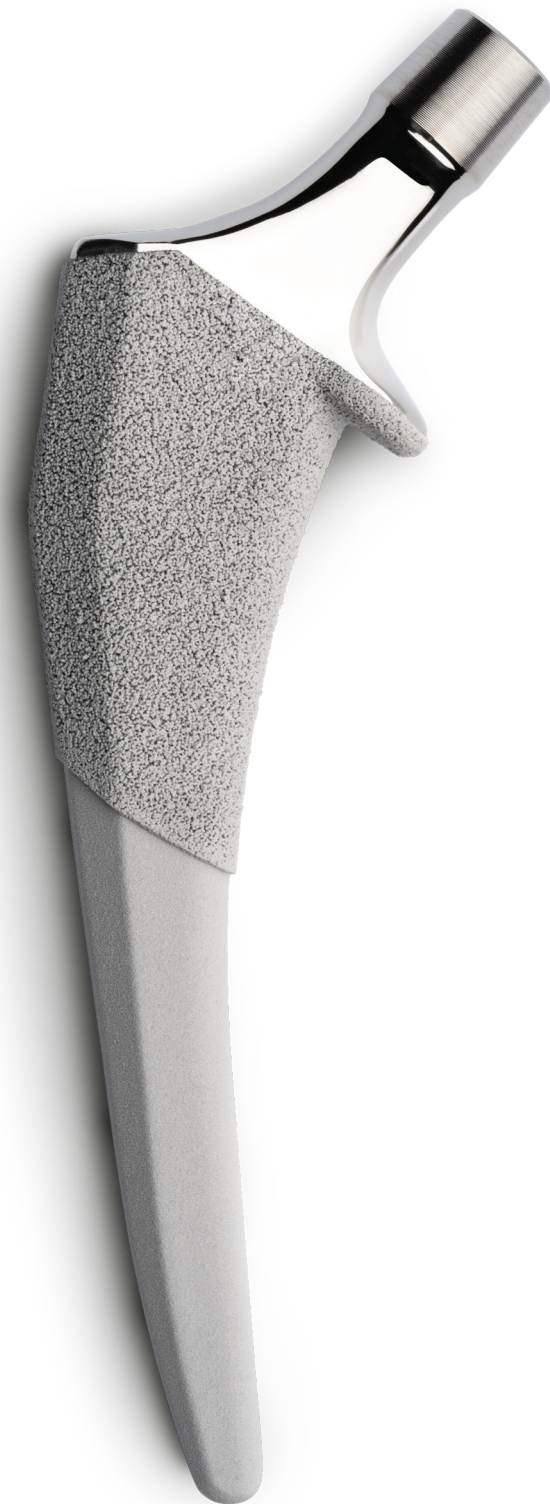


Confidence in Refinement

The Trivicta Hip Stem is developed using Ortho Development's evolutionary innovation philosophy, incorporating refinements to clinically proven stem design principles. These refinements are intended to support initial mechanical stability and long-term biological fixation while preserving bone.

Trivicta is designed to accommodate a broad range of femoral anatomies and provide intraoperative flexibility through progressive neck lengths and offset options, allowing smooth size transitions.

Instrumentation is designed to prepare the femur using a combination of controlled cancellous bone compaction and bone removal to allow consistent implant placement.



Trivicta Overview

The Trivicta Hip Stem is a cementless, triple-taper femoral component. The stem features a multi-tapered proximal body and a triple-taper cross-section that contribute to axial and rotational stability.

Trivicta uses hybrid broaching techniques and a 35µm hydroxyapatite (HA) coating applied over sintered titanium beads to support biological fixation.^{1,2} The stem has a constant 132° neck angle with progressive neck lengths. It is available in standard and extended offsets to provide smooth size transitions, allowing direct lateralization without altering leg length. Trivicta is offered in 12 standard and 11 extended neck offset sizes.

The Trivicta stem is compatible with Ortho Development's acetabular shell systems. The stem has a 12/14 taper and is compatible with CoCr Femoral Heads and BIOLOX®delta Ceramic Femoral Heads available through Ortho Development, in sizes 22 mm, 28 mm, 32 mm, 36 mm and 40 mm. Please refer to the appropriate surgical techniques for more information.

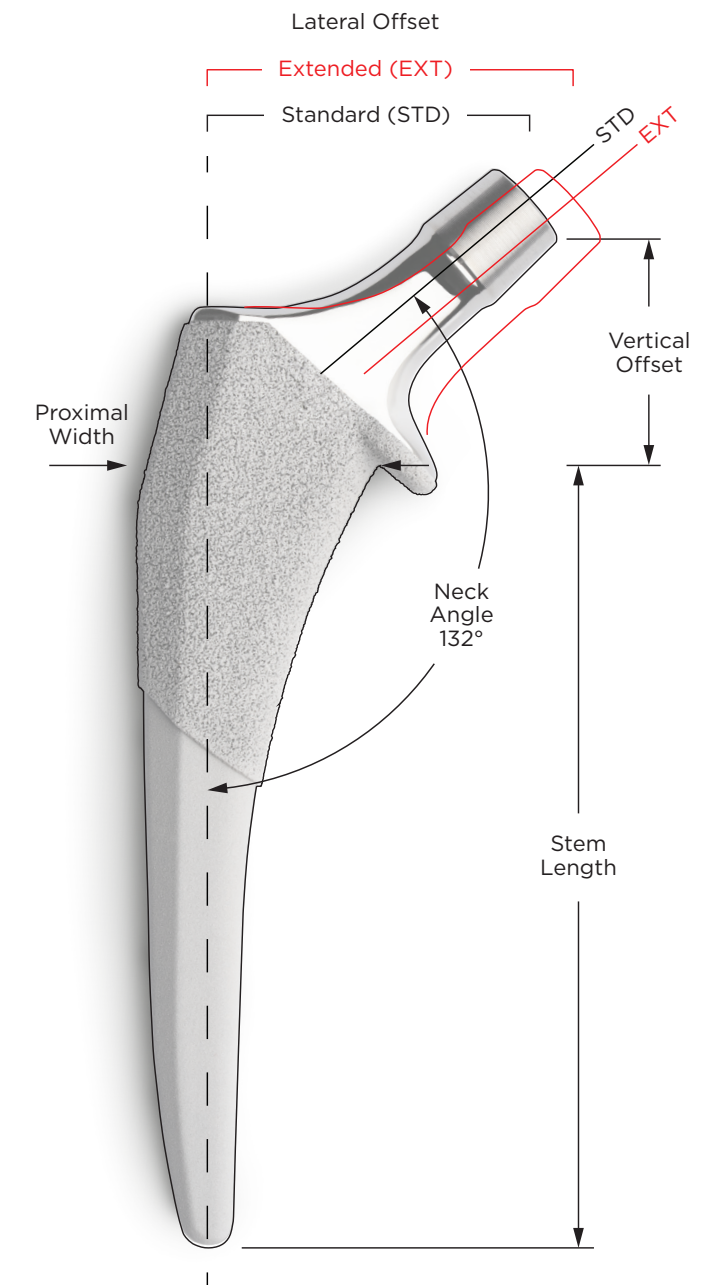


1. Preoperative Planning

Preoperative planning is essential to prepare for the range of clinical scenarios that may arise during total hip arthroplasty. The preoperative planning phase should include patient history, physical examination and standardized radiographs. Use magnification markers to verify radiographic scaling accuracy. The A/P radiograph should be used to plan stem size, femoral head center of rotation and femoral offset. Once measurements are established, the neck resection level may be marked for verification during surgery.

2. Incision

Exposure is achieved through a variety of surgical approaches based on surgeon preference and patient anatomy. Instrumentation is provided to facilitate various approaches including the Direct Anterior, Anterolateral and Posterolateral approaches.



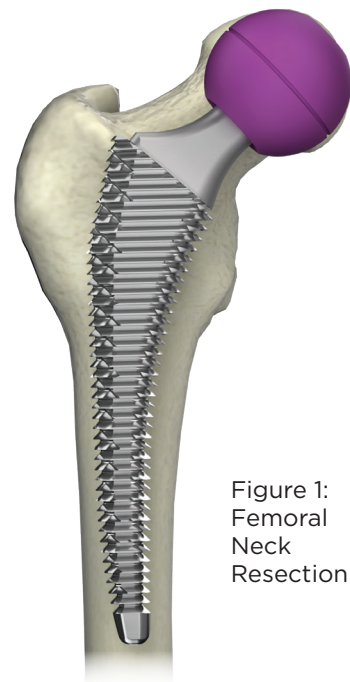


Figure 1:
Femoral
Neck
Resection

3. Femoral Neck Resection

Assemble the broach, neck trial and femoral head trial (Figure 1) that correspond to the templated implant size. Place the construct on the femur; verify the center of the rotation and the resection level of the proximal femur.

Resect the femoral head in standard fashion verifying the resection level corresponds to the templated implant size.



Figure 2:
Femoral
Preparation

4. Femoral Preparation

Use the Box Osteotome to open the femoral canal posterior and lateral to the piriformis fossa to establish appropriate version (Figures 2–4). Initiate canal entry parallel to the posterior cortex of the femur. A rongeur may be used prior to ease the insertion of the Sm Box Osteotome.

To verify the correct entry and direction of the femoral canal, the Modular Rasp Canal Finder may be utilized.



Figure 3:
Box Osteotome
DAA Broach Sm



Figure 4:
Box Osteotome
Straight Broach Sm



Figure 5:
Chili Pepper
Broach



Figure 6:
Final Broach

If additional lateral position is required, the Chili Pepper Broach (Figure 5) can aid the lateralization of the Starter Broach.

Begin sequential broaching with the smallest Trivicta broach. Advance the broach down the medullary canal while maintaining appropriate anteversion and alignment. The final broach should sit level with the neck resection (Figure 6).

Note: It is recommended that rotational stability be checked once the broach has stopped advancing. Repeated verification of rotational stability prior to reaching the final broach size should be avoided, as it can disrupt the cancellous bone sleeve.

If the neck resection is accurate and the broach is rotationally unstable or seats below the level of the templated neck cut, proceed to use the next larger broach size. When the rotationally stable broach is seated at the level of the neck resection, remove the broach handle and leave the broach in place.

5. Calcar Preparation

The Trivicta Hip Stem is offered in a collared option. It is recommended to prepare the calcar for the collar by placing the calcar planer over the post of the fully seated broach (Figure 7). To prevent the calcar planer from binding, engage the power prior to making contact with the bone. Advance the calcar planer to the level of the broach. Preparation of the calcar will help with implantation by allowing visualization of the final position of the implant relative to the broach.



Figure 7:
Calcar
Preparation

6. Trial Reduction

The Trivicta Hip Stem offers neck and head trials to allow the surgeon to assess the range of motion, leg length, joint stability and component position. The Trivicta Stem is available in 12 standard neck sizes and 11 extended neck sizes. From the standard offset stem, the extended offset is 5 mm to 7 mm of direct lateralization, depending on the stem size. Build a trial construct using a standard or extended neck trial as determined by preoperative planning.

Based on the planned leg length and acetabular liner compatibility, attach the appropriate femoral head trial to the neck trial (Figure 8). The neck trial can now be attached to the broach and the hip reduced (Figure 9). 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 and desired leg length is achieved.

Note: If available, intraoperative fluoroscopy can be used to verify lateral offset and positioning.

Dislocate the hip and remove the head and neck trials, noting the final sizes chosen. Irrigation of the wound may be performed just prior to removing the broach, thereby protecting cancellous bone and marrow contents from removal. Attach the broach handle to the broach and remove it from the femur. Verify the size of the last broach used to select the Trivicta final implant.

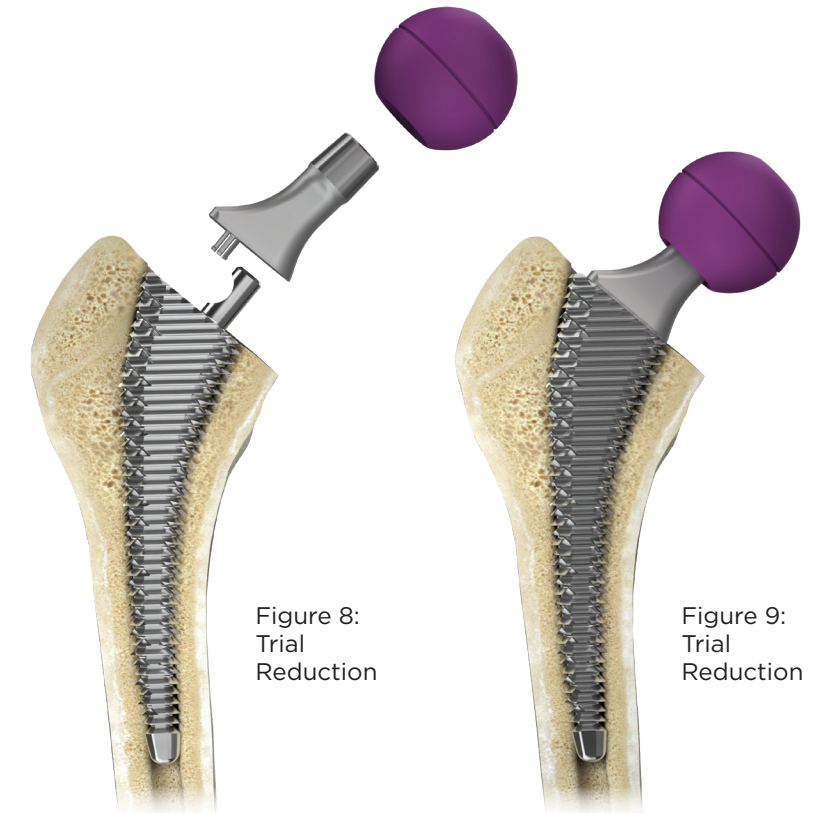


Figure 8:
Trial
Reduction

Figure 9:
Trial
Reduction

TRIVICTA DIMENSIONS (MM)

SIZE	LENGTH	STD NECK LENGTH	EXT NECK LENGTH	NECK ANGLE	VERTICAL OFFSET	STD HORIZONTAL OFFSET	EXT HORIZONTAL OFFSET	STD - EXT OFFSET	PROXIMAL WIDTH	PROXIMAL THICKNESS*	SHOULDER ANGLE	A/P TAPER ANGLE	M/L TAPER ANGLE	COLLAR DIAMETER	COLLAR OVERHANG
1	97	31	-	132°	27	36	-	-	25	13.6	12	3.25	3°	13	7
2	99	32	36		28	38	43	5	26	14.7	13	3.5		14	7
3	101	32	36		29	38	43	5	27	15.7	14	3.75		15	7
4	103	34	39		30	40	47	7	28	17.5	14	4		16	8
5	105	34	39		31	40	47	7	30	18.5	15	4.25		17	8
6	107	36	41		32	42	49	7	31	19.5	16	4.5		18	8
7	109	36	41		33	42	49	7	32	20.5	17	4.75		18	8
8	111	38	43		34	44	51	7	33	21.5	17	5		19	8
9	113	38	43		35	44	51	7	34	22.5	17	5.25		19	8
10	115	39	45		36	46	53	7	35	23.5	17	5.5		21	8
11	117	39	45		36	46	53	7	35	24.5	18	5.75		21	8
12	119	39	45		36	46	53	7	36	25.5	18	6		22	8

Length measured at calcar * Measured at top shoulder

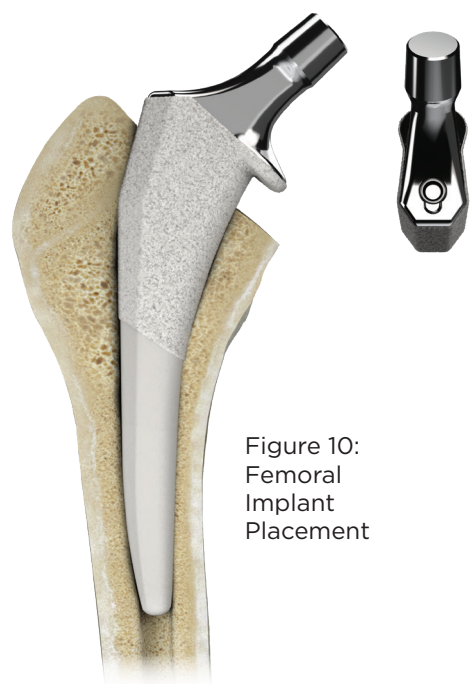


Figure 10:
Femoral
Implant
Placement

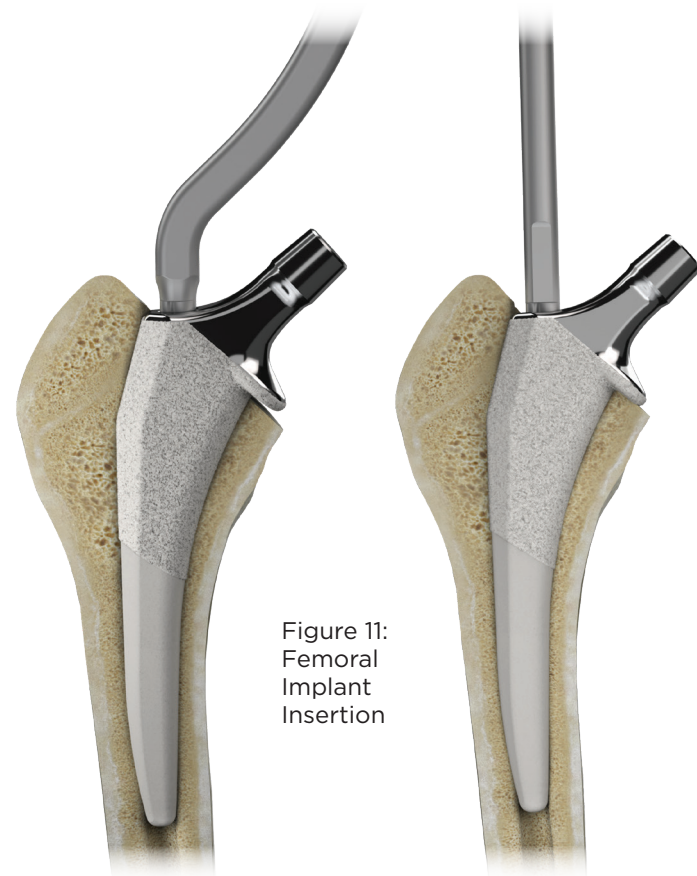


Figure 11:
Femoral
Implant
Insertion

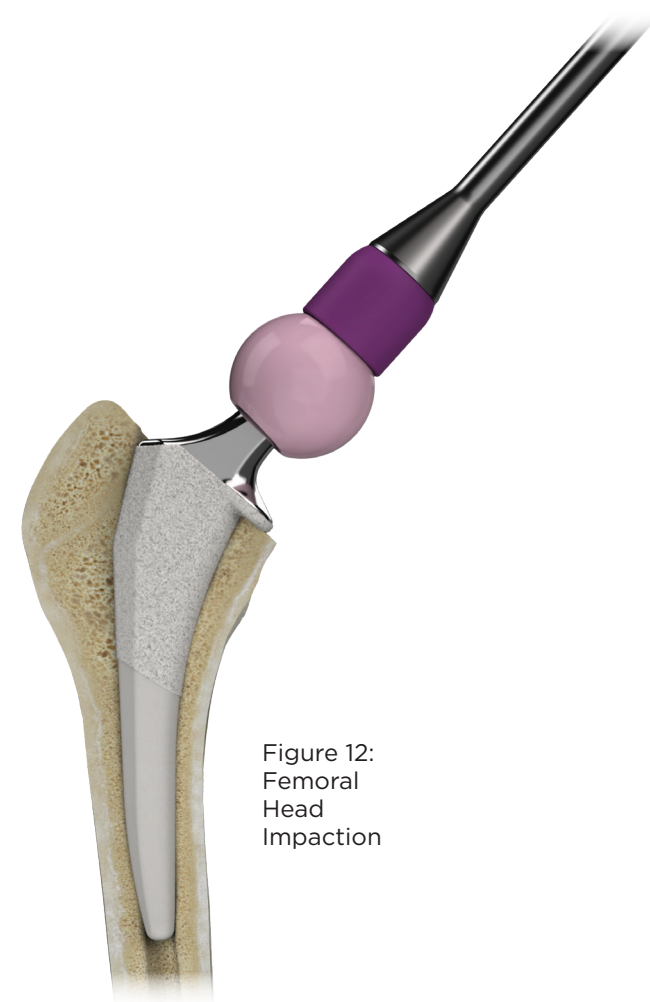


Figure 12:
Femoral
Head
Impaction

7. Femoral Component Insertion

Select the Trivicta implant that corresponds to the final broach size and place it by hand into the femoral canal until resistance is met (Figure 10). This will help position the implant in the orientation prepared by the broach. When inserting by hand, the Trivicta stem should stop 1 cm to 2 cm above the calcar resection level.

Connect the modular impactor to the selected modular stem inserter (available in Straight, Neutral, Left, Right, Bullet-Tipped and Ball-Tipped variations).

Place the shaft of the stem inserter into the implant and insert the implant into final position with controlled impaction (Figure 11). Excessive force should not be needed to seat the implant and may result in femoral fracture.

Note: In a collared stem application, the collar should sit flush onto the femoral neck resection, while maintaining full rotational and axial stability. Occasionally in patients with dense femoral bone, or Dorr Type A femurs, the distal aspect of the stem can bind in the narrow area of the femoral isthmus prior to full proximal seating. In those situations, distal reaming with a flexible reamer may be considered.

Note: A final trial reduction may be performed with the trial femoral head before final implantation.

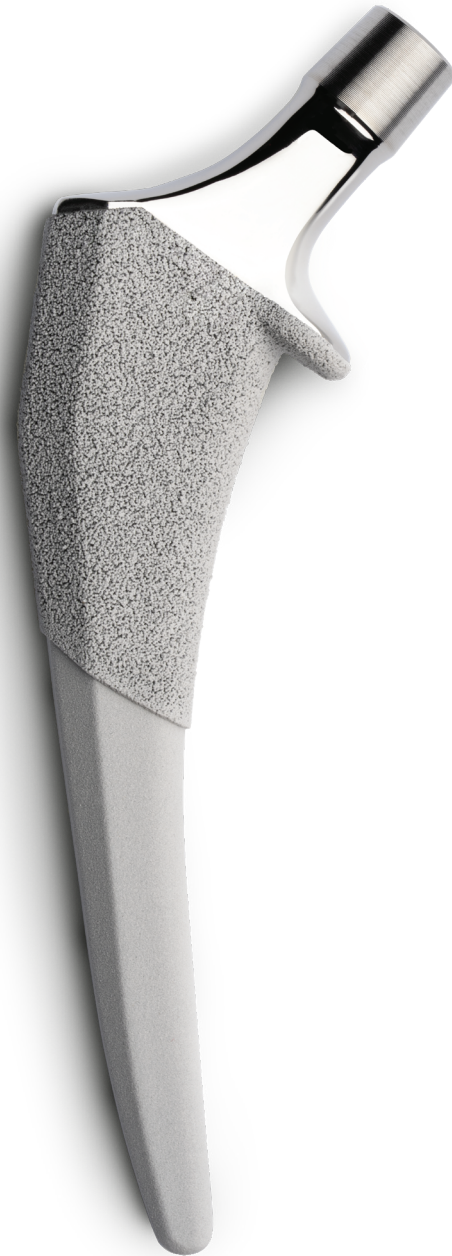
Select the femoral head implant that corresponds to the last femoral head trialed. Before impacting the femoral head implant, make sure the implant taper is clean and dry. Place the femoral head onto the stem trunnion. Connect the modular femoral head impactor to the modular impactor and seat the femoral head with light taps of the mallet (Figure 12). Reduce the hip and take it through full range of motion. After taking the hip through full range of motion, and the desired result is achieved, close the wound in a standard fashion.

1 Vidalain JP. Twenty-year results of the cementless Corail stem. *Int Orthop* 2011;35:189-94.

2 Vidalain JP (2011) 25-year ARTRO Results: A Special Vintage from the Old World. In: Vidalain JP et al; The CORAIL Hip System: A Practical Approach Based on 25 Years of Experience. Springer; pg 94-101.

TRIVICTA COLLARED STD EXT. KIT: 513-1000-02

ITEM NUMBER	DESCRIPTION
513-0201	Trivicta, Collared STD Size 1
513-0202	Trivicta, Collared STD Size 2
513-0203	Trivicta, Collared STD Size 3
513-0204	Trivicta, Collared STD Size 4
513-0205	Trivicta, Collared STD Size 5
513-0206	Trivicta, Collared STD Size 6
513-0207	Trivicta, Collared STD Size 7
513-0208	Trivicta, Collared STD Size 8
513-0209	Trivicta, Collared STD Size 9
513-0210	Trivicta, Collared STD Size 10
513-0211	Trivicta, Collared STD Size 11
513-0212	Trivicta, Collared STD Size 12
513-1202	Trivicta, Collared EXT Size 2
513-1203	Trivicta, Collared EXT Size 3
513-1204	Trivicta, Collared EXT Size 4
513-1205	Trivicta, Collared EXT Size 5
513-1206	Trivicta, Collared EXT Size 6
513-1207	Trivicta, Collared EXT Size 7
513-1208	Trivicta, Collared EXT Size 8
513-1209	Trivicta, Collared EXT Size 9
513-1210	Trivicta, Collared EXT Size 10
513-1211	Trivicta, Collared EXT Size 11
513-1212	Trivicta, Collared EXT Size 12



Femoral Head Implants

BILOX'DELTA FEMORAL HEADS 28MM-36MM KIT: 136-2000-02

BILOX'DELTA FEMORAL HEADS 40MM KIT: 136-4000-02:

ITEM NUMBER	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 KIT: 138-1000-02:

ITEM NUMBER	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 +0
138-4003	CoCr Femoral Head 40mm +3
138-4006	CoCr Femoral Head 40mm +6
138-4009	CoCr Femoral Head 40mm +9
138-4030	CoCr Femoral Head 40mm -3
138-4060	CoCr Femoral Head 40mm -6



Trivicta Hip Stem Instrument Trays

613-9000 TRIVICTA BASIC TRAY

NUMBER	ITEM NUMBER	DESCRIPTION	QTY
1	201-0018	Femoral Head Extractor	1
2	610-1000	Straight Modular Impact Handle	2
3	610-1010	Modular Rasp Canal Finder	1
4	610-1013	Modular Femoral Head Impactor	1
5	610-1019	Femoral Head Impactor	1
6	610-1100	Modular T-Handle Hudson	1
7	613-1001	Trivicta, Straight Stem Inserter	1
8	613-1002	Trivicta, Neutral Stem Inserter	1
9	613-1005	Trivicta, Ball-Tip Stem Inserter	1
10	800-0001	Diamond Calcar Planer	1
11	613-1004	Trivicta, Left Stem Inserter*	1
12	613-1003	Trivicta, Right Stem Inserter*	1
13	613-1006	Trivicta, Bullet-Tip Stem Inserter**	1

* Included as part of special order only

** Replaces #9 (Trivicta, Ball-Tip Stem Inserter) when ordered

