

TaperFill™

Surgical Technique



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Taperfill™ Hip System

System Description

The TaperFill Hip System consists of the following:

- Increased sizing options with fourteen standard sizes:
5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, and 19.
- Standard and Lateralized offset versions in each size
(Lateral offset only for size 19.)
- Delta Ceramic heads are available.
- Reduced neck geometry.
- A twelve-degree proximal taper in the porous coating section.
- Taper of the distal medial border of the prosthesis
- Single reamer.
- Broach handle attachment allowing for version control during broaching and simple removal of the broach.
- Threaded stem inserts that allows for complete control of version during implantation.

Indications

Joint replacement is indicated for patients suffering from disability due to:

- Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis of the natural femoral head
- Rheumatoid arthritis
- Correction of functional deformity
- Femoral fracture

This device may also be indicated in the salvage of previously failed surgical attempts.

The constrained acetabular component is indicated for primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability and for who all other options to constrained acetabular components have been considered. This stem is to be press-fit. This stem is intended for cementless use.

Contraindications

Joint replacement is contraindicated where there is:

- Infection or sepsis;
- insufficient bone quality which may affect the stability of the implant;
- muscular, neurological or vascular deficiencies, which compromise the affected extremity;
- Osteomyelitis;
- Rapid joint destruction or bone absorption apparent on roentgenogram;
- Pathological conditions of the acetabulum, which would prevent achieving proper range of motion, appropriate head stability, and/or a well-seated and supported smooth articulation of the head within the acetabulum;
- Alcoholism or other addictions;
- Materials sensitivity;
- Loss of ligamentous structures;
- High levels of physical activity (e.g. competitive sports, heavy physical labor);
- Materials sensitivity;
- Pregnancy
- Uncooperative patient or a patient with neuralgic disorders and incapable of following instructions
- Distant foci of infections

TaperFill™ Hip Stem Sizing Charts

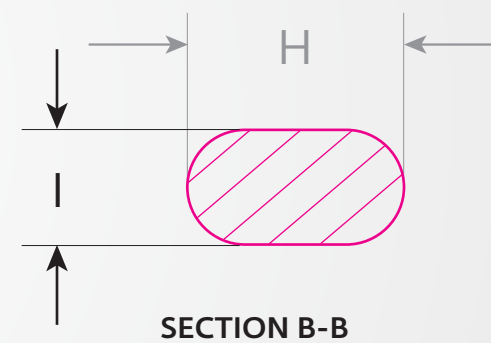
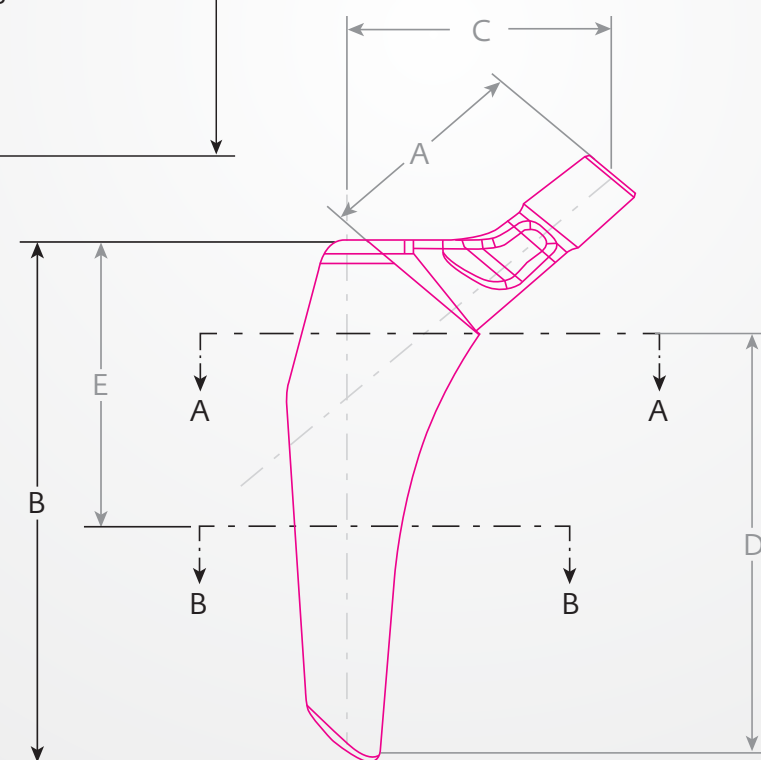
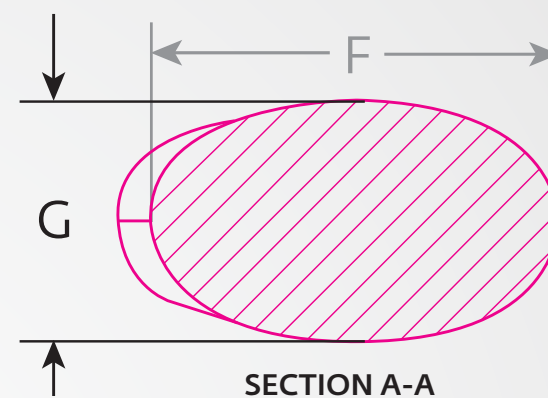
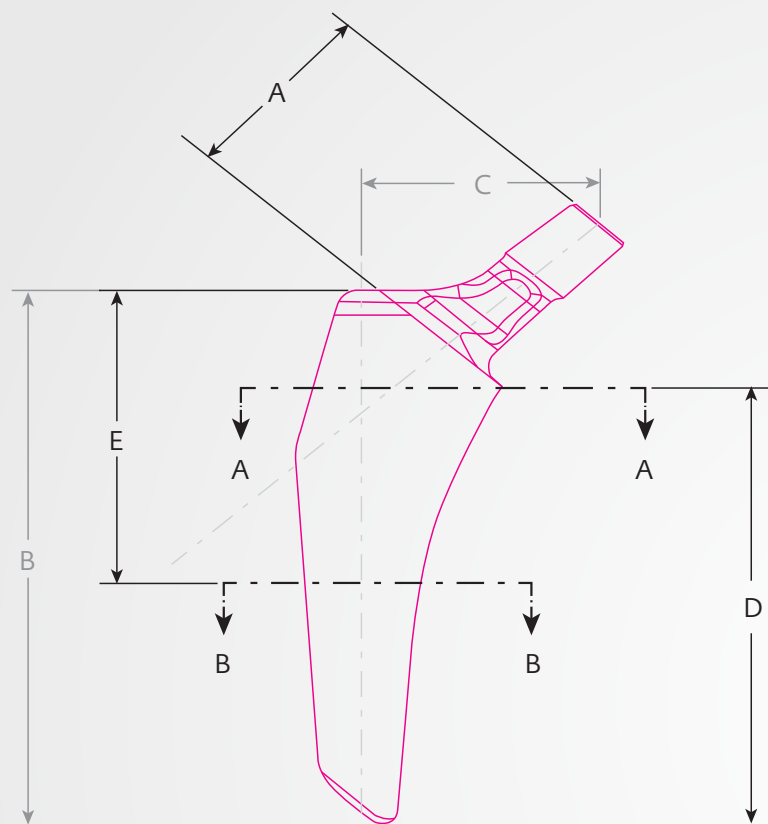
The TaperFill Hip stem is press-fit titanium, P2® coated tri-tapered design. Each stem size is available in standard and lateralized offset versions (size 19 is only available in the lateral offset option).

Standard

PART #	SIZE	A	B	C	D	E	F	G	H	I
		NECK LENGTH	STEM LENGTH	NECK OFFSET	DISTANCE TO A-A	DISTANCE TO B-B	A-A M/L	A-A A/P	B-B M/L	B-B A/P
425-96-005	5	37	104.5	38	84	51	27	15	15	9
425-96-006	6	37	106	39	86	53	28	16	15	10
425-96-007	7	37	107.5	39	87	54	28	17	16	10
425-96-008	8	37	109	40	89	56	29	17	17	11
425-96-009	9	37	111	40	90	58	30	18	17	11
425-96-010	10	37	112.5	41	92	60	31	19	18	12
425-96-011	11	37	114	41	93	61	32	20	18	12
425-96-012	12	37	115.5	42	95	63	33	20	19	12
425-96-013	13	37	117	42	96	65	34	20	20	12
425-96-014	14	37	118.5	43	98	67	35	21	21	13
425-96-015	15	37	120	43	99	69	36	22	21	13
425-96-016	16	37	121.5	44	101	70	37	22	22	13
425-96-017	17	37	123	44	102	72	38	23	23	13

Lateralized

PART #	SIZE	A	B	C	D	E	F	G	H	I
		NECK LENGTH	STEM LENGTH	NECK OFFSET	DISTANCE TO A-A	DISTANCE TO B-B	A-A M/L	A-A A/P	B-B M/L	B-B A/P
425-97-005	5	42.5	104.5	46	84	51	27	15	15	9
425-97-006	6	42.5	106	47	86	53	28	16	15	10
425-97-007	7	42.5	107.5	47	87	54	28	17	16	10
425-97-008	8	42.5	109	48	89	56	29	17	17	11
425-97-009	9	42.5	111	48	90	58	30	18	17	11
425-97-010	10	42.5	112.5	49	92	60	31	19	18	12
425-97-011	11	42.5	114	49	93	61	32	20	18	12
425-97-012	12	42.5	115.5	50	95	63	33	20	19	12
425-97-013	13	42.5	117	50	96	65	34	20	20	12
425-97-014	14	42.5	118.5	51	98	67	35	21	21	13
425-97-015	15	42.5	120	51	99	69	36	22	21	13
425-97-016	16	42.5	121.5	52	101	70	37	22	22	13
425-97-017	17	42.5	123	52	102	72	38	23	23	13
425-97-019	19	42.5	125	53	105	74	39	24	25	13



Preoperative Planning

Proper preoperative planning is done both with and without the use of templates. Proper radiographs should generally include a single A/P of the pelvis and an A/P and lateral radiograph of the hip to include the proximal one-third of the femur. A radiograph with the hip in 15 degrees of internal rotation is preferred. If proper positioning of the hip is not possible, this must be taken into consideration when templating for prosthesis size, leg length, and offset. Whenever possible, x-ray magnification calibration should be used and radiographs representing 20% magnification should be a goal.

The information obtained during the templating process is crucial to successful hip arthroplasty. Following the steps outlined below will greatly facilitate the ease of implantation and proper prosthesis choice and placement. It is important to note that templating is only a guide for prosthesis sizing and positioning.

General Architecture and Bone Quality

When assessing initial radiographs for general architecture and bone quality of the hip, pay special attention to:

- Areas of bone loss, especially in the superior weight-bearing dome of the acetabulum.
- Proximal femoral geometry, specifically the relationship between the size of the metaphyseal flare and the diameter of the femoral canal.
- Cortical thickness both proximally and distally.
- Degree of osteoporosis

Planning for Equalization of Leg Lengths

- Clinically measure the leg lengths and note any discrepancies.
- Radiographically measure any leg length discrepancy on the A/P pelvis view using the relationship between a set point on the lesser trochanter and a line drawn along the inferior borders of both pubic rami.
- Note the correlation with the clinical and radiographic measurements.

- Using the x-ray template for the neck-cutting guide, measure where a standard neck cut would be made.
- Either the level of the neck cut can be adjusted or the templated implant size may be changed to adjust the discrepancy in leg length.

Planning for Proper Offset

The availability of two offsets allows not only for restoration of proper offsets in each individual patient, but also allows increased stability of the hip in each stem size without increasing leg length.

- Draw a vertical line through the center of the femoral canal exiting proximally.
- Locate the center of the femoral head and draw a horizontal line perpendicular to the vertical line from the center of the femoral head.
- Measure the distance of the horizontal line. This is the offset.
- Compare the offset to the offset table (**page 4, column C**). Once the size is templated, compare that determination to the recommended offset to estimate final prosthesis selection.

Prosthesis Size

- Using the template, align the centerline of the femoral stem to the center of the femoral shaft.
- Use varying sizes to template. The proper size should be in contact with the endosteal surface laterally and medially in the porous coating section of the prosthesis.
- Once a provisional size has been determined, overlay the standard and lateralized version of the same stem size and assess the relationship between the center of the femoral head on the template and the true anatomic femoral head.
- Choose the prosthesis that overlays most accurately in size and offset.
- As a check, once you determine your size by templating, compare the offset of that size with the offset, as previously measured in step three.

Surgical Technique

Surgical Approach

Surgical approach is determined by surgeon preference. The TaperFill Hip stem and instrumentation have been designed to accommodate all surgical approaches with ease. General principles of proper arthroplasty surgical approach should be followed. These include:

- Proper patient positioning.
- An incision of adequate length.
- Consistent use and placement of retractors for optimal visualization.

Femoral Neck Resection

The femoral neck cut can be made using the neck cutting guide by placing a pin in the center of the femoral head and sliding the guide over the pin (**Figure 1**). The distal part of the guide is centered over the femoral neck. Alternatively, you can place the femoral broach against the outer surface of the femur at the level determined by preoperative templating. You can then mark the osteotomy with an electrocautery. Prior to cutting, always check the level of the resection visually and in relation to the lesser trochanter for proper positioning. As a general rule, the femoral neck cut should be approximately 15mm above the lesser trochanter. After the femoral neck cut is made, the acetabular prosthesis is implanted.

Use of the Box Osteotome

Lateralization of the prosthesis is critical to proper positioning. Visualize the center of the femoral canal along the outer border and mark a vertical centerline using an electrocautery along the outer surface of the proximal femur extending proximally. Note where this line exits at your femoral neck cut. A rongeur is useful to initially remove laterally retained femoral neck. Centering the box osteotome over the vertical centerline, remove a few millimeters of proximal bone (**Figure 2**). Care must be taken to ensure proper version by placing the leg in a neutral rotation position and noting the version of the femoral neck. This allows a check for proper anteversion of the stem. Normal version is approximately 10-15 degrees of anteversion.

If the noted neck version is within this range with the leg in a neutral position, simply follow the version angle of the neck with the box osteotome and subsequent broaches. Adjust this accordingly.

Figure 1

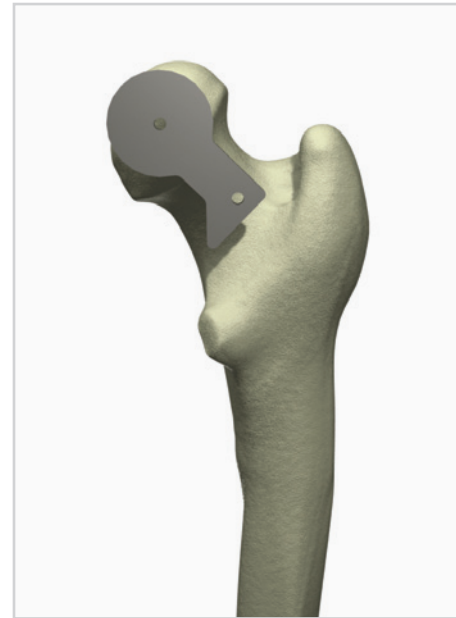
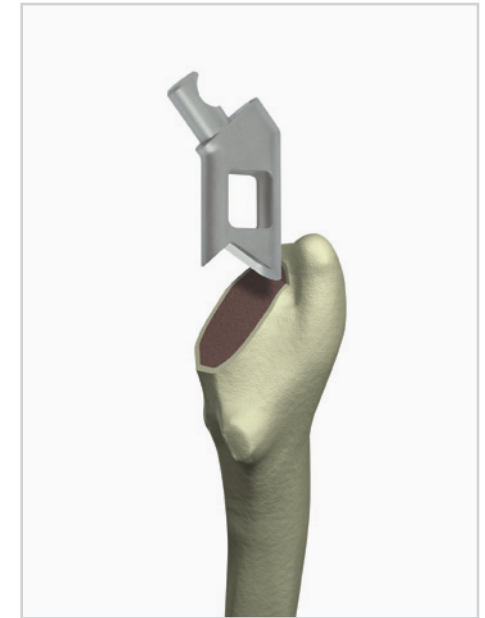


Figure 2



Instrumentation

Guide [803-03-012]



Box Osteotome [803-00-040]



Canal Finder

A thin, sharp canal finder is then used and placed down the centerline (**Figure 3**). This should encounter minimal resistance. Pay special attention to both medial/lateral and anterior/posterior placement of the canal finder.

Tapered Reamer

The tapered reamer should be attached to power, although hand reaming is possible. Placing the reamer down the center of the canal, ream straight down the canal to the distance determined by preoperative templating. The reamer has proximal markings corresponding to the prosthesis sizes. These marking should be brought down to the level of the osteotomy (**Figure 4**).

Figure 3 (a).

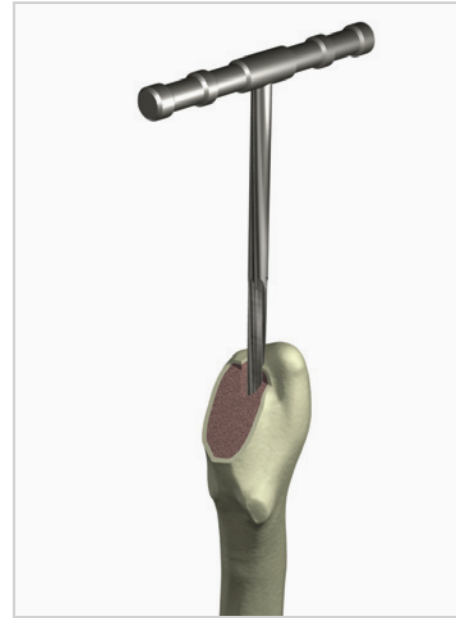


Figure 3 (b).

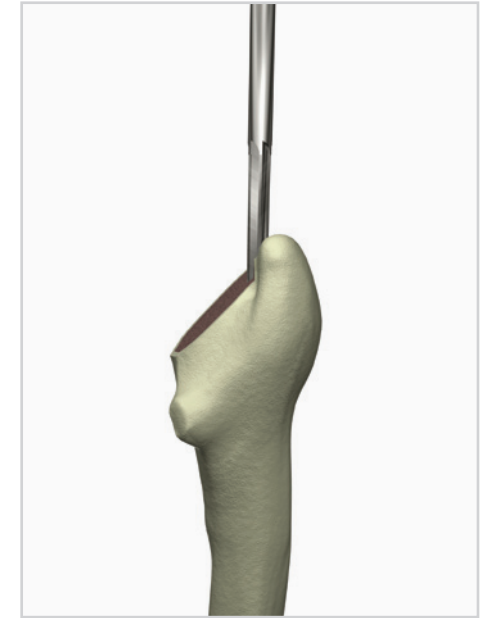


Figure 4 (a).

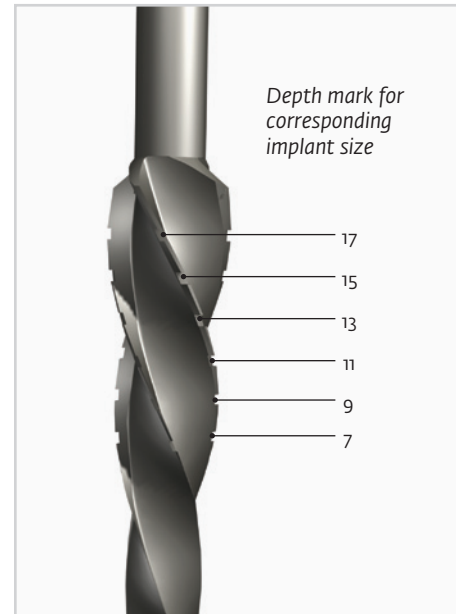
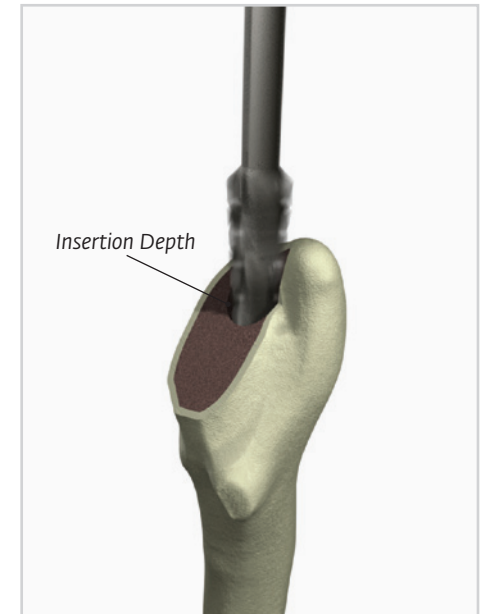


Figure 4 (b).



Instrumentation

Starter Reamer [803-00-035]



Tapered Reamer [803-03-001]



Broaching

The TaperFill System's broach handle (**Figure 5**) is designed for quick attachment and release of the broaches. Insertion of the broach into the femoral cavity is accomplished by using a mallet against the proximal strike plate. Striking the underside of the strike plate facilitates removal of the broach. Broaching is begun with the smallest available broach. As a general guideline, follow the version previously determined by the box osteotome and pay special attention to varus/valgus and anterior/posterior positioning. Pay special attention to proper lateralization of each successive broach. While the prosthesis is designed for implantation straight down the canal, the surgeon can make modifications of the positioning as needed. Successive broaching is done until the prosthesis reaches a stable position and the level of the broach teeth approximates the neck resection (**Figure 6**). Calcar reaming may be performed; however, since this is a collarless prosthesis, it is not necessary (**Figure 7**). Excessive force is not necessary to seat the broach to a stable position.

Instrumentation

Small Calcar Reamer
[803-00-032]

Large Calcar Reamer
[803-00-033]

Broach Handle
[803-03-059]



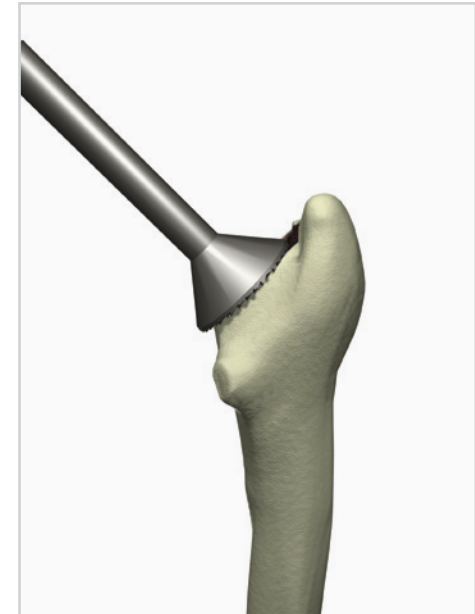
Figure 5



Figure 6



Figure 7



Trial Reduction

Once the broach reaches a position of stability, you are ready for trial reductions. The TaperFill Hip stem has two options, a standard and lateral offset (**Figure 8**). Neck trials are available in standard and lateralized versions (**Figure 9**). Either may be used on the same broach trial. Depending on your preoperative templating, place the appropriate head and neck trial on the broach (**Figure 10**). When performing trial reductions there are four important things to check:

1. Visually inspect the reduction of the head in the cup. Make sure the reduction is concentric and the appropriate amount of coverage of the femoral head is obtained.
2. Critical for the prevention of dislocation, assess appropriate tissue tension general, 1-2mm of pistoning is appropriate when pulling straight on the leg. Pulling the leg in a neutral position is important to get a true assessment of tissue tension.
3. Move the leg in a variety of positions to assess stability. The hip should be stable through a full functional range of motion. Pay special attention to particular maneuvers that lead to instability. Additionally assess the presence of anterior or posterior acetabular osteophytes that may cause the hip to sublux out of the cup.
4. Measure leg lengths at this time. If you are performing the surgery with the patient in a supine position, assessing proper leg lengths is straight forward. Patients in a lateral decubitus position present more difficulty. In those situations, your preoperative templating of the relationship of the center of the femoral head to the tip of the greater trochanter is that much more important. Depending upon your preoperative templating, you can assess your leg length status and adjust accordingly.

Figure 8

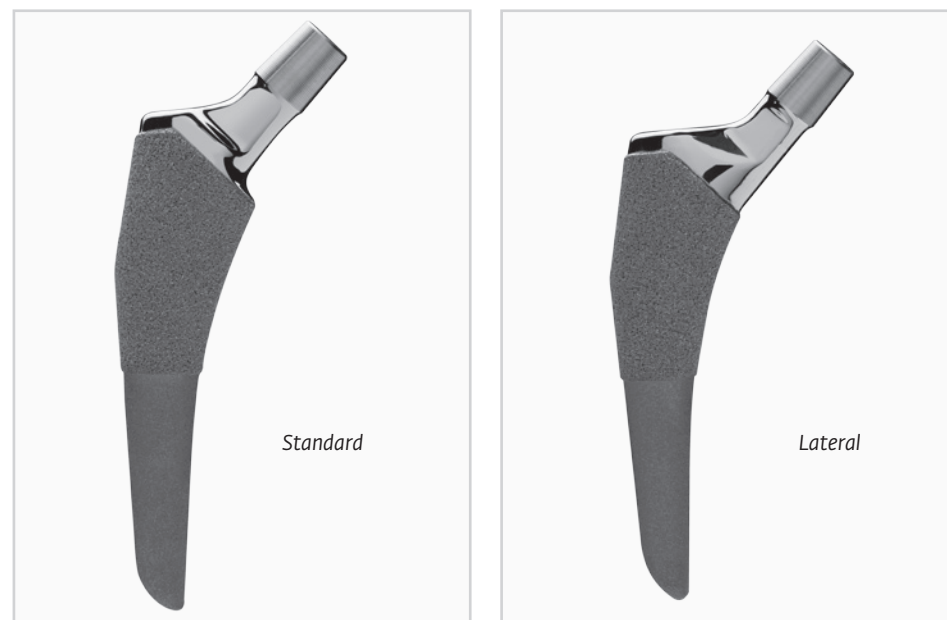


Figure 9

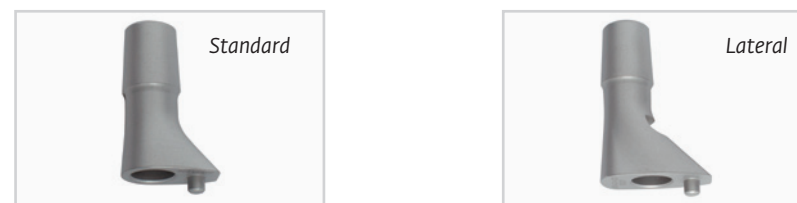
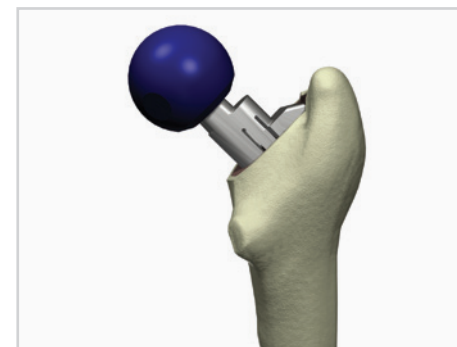


Figure 10



Instrumentation

Neck Trials
[803-21-026/027]



Head Distractor Handle
[803-03-036]



Head Distractor Small
[803-03-037]



Head Distractor Large
[803-03-038]



Final Implantation

Once the final construct is determined, final implantation of the prosthesis is performed. The TaperFill Hip stem is placed by hand into the prepared femur, and the stem inserter is then used to seat the implant. Seat the stem down the canal in the broached space (**Figure 12**). It is generally proud by one to three centimeters. Impact the prosthesis down to a stable position with a mallet. Visually confirm the prosthesis is stable on further impaction. An audible “tone change” occurs frequently when a stable position is reached. Take care not to impact the final prosthesis with too much force.

Reduction

Go through the same four steps outlined previously with trial head components. The proper final head is then placed and firmly impacted (Figure 13). The acetabulum is inspected for any bone or soft tissue and the hip is reduced.

Closure

Standard hip closure is then performed. Inspect the joint and the entire wound for bone and soft tissue and thoroughly irrigate. Attention to detail during the closure, with care to properly reapproximate key structures will improve joint stability and wound healing.

Aftercare

Postoperative instructions have some variability based on surgeon preference and patient factors. In general, patients are allowed full weight bearing with the TaperFill Hip stem, but are protected with a walker or Lofstrand crutches for six weeks mainly to protect the soft tissues. Physical therapy instructions are clear. The physical therapist is to only work on gait training and arthroplasty precautions. Patients are restricted from any passive range-of-motion or resistive exercises since these can stretch soft tissue repairs and capsular structures. Only active range-of-motion exercises through a limited range are recommended. The patients are walking on postoperative day one and discharged when specific parameters, set by the joint arthroplasty team, are met.

Figure 12 (a).



Figure 12 (b).

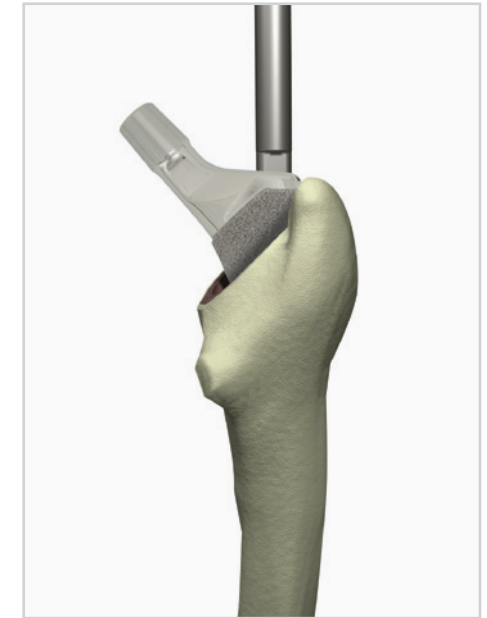
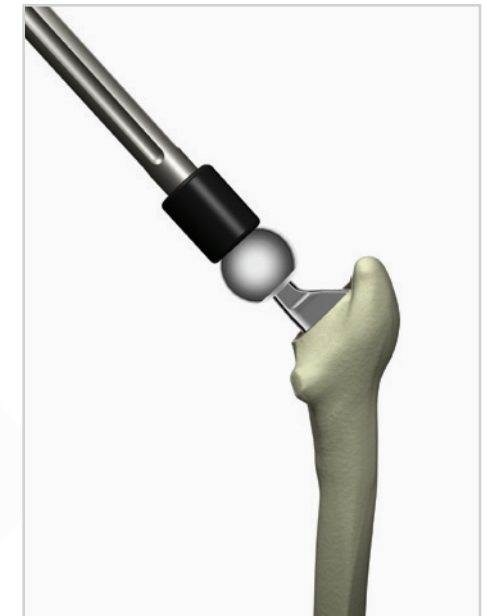


Figure 13

Instrumentation

Stem Inserter
[803-03-027]

Head Impactor
[803-03-018]





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CAUTION: Federal Law (USA)
restricts this device to sale by
or on the order of a physician.

See package insert
for a complete listing of
indications, contraindications,
warnings, and precautions.