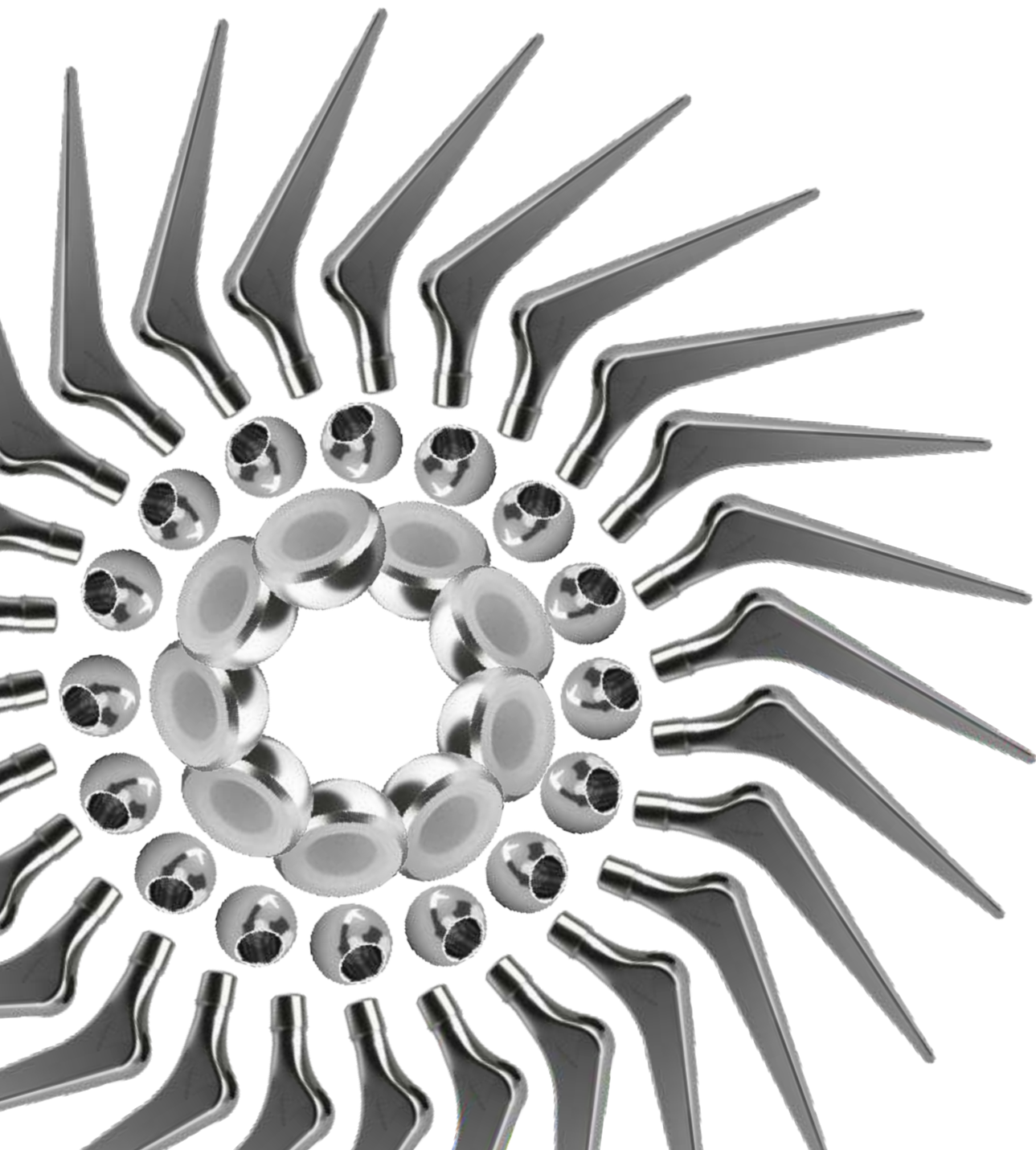


LATITUDTM | HIP SYSTEM
Freedom of Choice

Bi-Polar Cup System & Cemented Stems



Situated on 180 acres of land and built over a 300,000 sq.ft. area, Meril's ISO 13485 & cGMP certified ultra-modern manufacturing facility is constructed to satisfy the stringent needs of our cardiovascular, orthopedics, diagnostics and endo-surgery businesses, as well as our R&D endeavors.

Fully integrated manufacturing systems ensure backward integration, flawless man-material movement and complete control over processes to eliminate production errors. All manufacturing and sterilization processes are conducted in-house, in addition to the analytical and microbiological QA/QC tests required to meet the world-class production standards.



Meril's 2,700+ personnel are a strong, experienced team comprising designers, engineers, chemists, microbiologists, regulatory affair experts, R&D scientists, clinical affairs experts, legal, finance, sales and marketing professionals with innovative capabilities. The team is continuously striving towards improving and saving lives every day by providing revolutionary solutions for diagnosis, prevention and treatment.

Meril Orthopedics | HIP SYSTEM

Meril Orthopedic, a venture of Meril in association with Maxx Ortho Inc (www.maxxmed.com), is at the helm of developing and marketing innovative Orthopedic implants. Our joint replacement technologies and wide range of products make us a valuable partner to healthcare institutions in more than 40+ countries. At Meril, we have a guiding principle that the Physician-Patient-Product interaction is of utmost importance.



Bipolar Cup System

Bipolar Cup is an alternative to total hip arthroplasty, particularly indicated in the treatment of displaced femoral neck fractures in elderly patients.

Bipolar Monoblock Cup

The Bipolar Monoblock cups is comprised of an outer Stainless steel metal dome, an inner liner of Ultra high molecular weight polyethylene. Bipolar Monoblock cups has the following basic design features: The metal dome of Bipolar Monoblock cups is fabricated from the stainless steel 316 L. It consists of an outer metal surface of stainless steel 316L designed to articulate directly in the patient acetabulum by press fit with surface roughness $Ra = 0.05 \mu m$. It has an inner ultra-high molecular weight polyethylene (UHMWPE 1050) surface which is assembled during manufacturing. Modular femoral head will articulate in liner. Surface roughness of this articulating surface is $Ra = 0.05 \mu m$ The Modular head will be assembled in bipolar cup by surgeon during implantation and intended to be used with femoral stem.

Femoral Stem System Modular femoral head

Modular head is designed to mate with 12/14 taper of femoral stem through taper-locking arrangement and to be articulated with Modular Liner.

Modular heads are manufactured from High Nitrogen Stainless Steel as per ISO 5832-9.

Available in 5 sizes ranging from diameter (\varnothing) 22 & 28mm with different offsets viz. +0.0, +3.5, -3.5, +4.0, -4.0, +7.0. Surface roughness value of outer articulating surface is $Ra = 0.05 \mu m$.

The Bipolar Monoblock shell is available in 21 different sizes ranging from 37 to 63mm. 37 to 51mm in 1mm increment and from 53 onwards in 2mm increment.

Bi-polar & Modular Head Compatibility

Sr. No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Bi-polar Cup Size	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	53	55	57	59	61	63
Modular Head	22	22	22	22	22	22	22	28	28	28	28	28	28	28	28	28	28	28	28	28	28

Surgical Steps



1 Correct positioning of the patient, on the operating table, is very important and the hip joint is exposed using a preferred surgical approach for hemiarthroplasty.



2 The femoral neck is cut 1-2cm above the lesser trochanter. (This cut can be determined by where the fracture has occurred). A trial stem can be used, if required, to help identify where the neck cut should be and a line made using a diathermy probe or skin marker.



3 The saw cut should be perpendicular to the neck and the position of the tibia should be vertical while the cut is made.



4 The femoral head is removed using the corkscrew. A light tap may help engagement and purchase into the femoral head.



5 The femoral head size can then be estimated using the femoral head template guide.



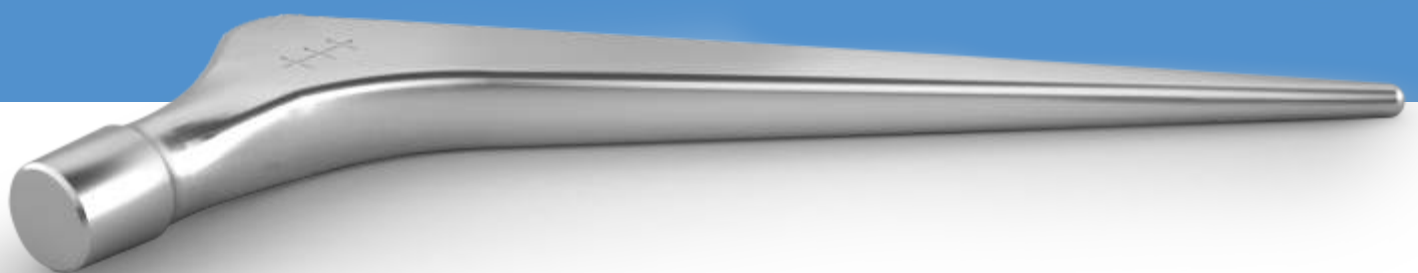
6 Sizing is confirmed using the trial heads and introducer. The Labrum is best left intact but, if necessary, can be sectioned at this point to allow the correct size head to be selected.

Cemented Stems

Cemented stems in hip replacement surgery have been in use since the pioneering years of Sir John Charnley.

The polished dual-tapered LATITUD stem is based on the highly successful loaded taper principle with biomechanical characteristics that have been proven over more than three decades of successful clinical use.

- The fully modular system allows the surgeon to select the implants which best meet the patients clinical needs
- Versatility of the system allows for easy conversion to a total hip construct should this be required intra or post operatively
- Easy to use effective instrumentation designed to enhance clinical outcome
- Available in stem sizes, designed to ensure optimal match to patient's anatomy



Cost effective system compared to a total hip replacement

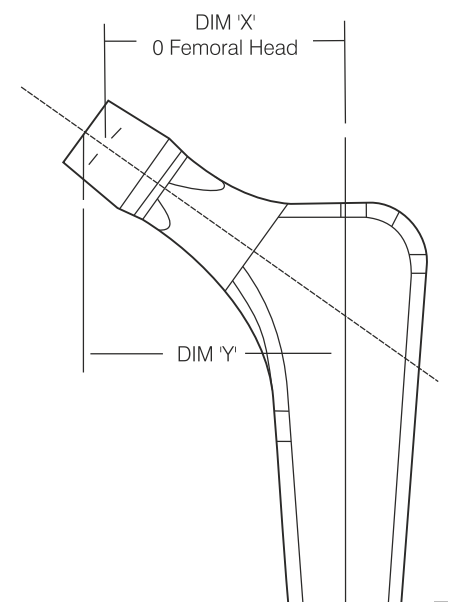
- Collarless, double tapered, polished high nitrogen stainless steel stem, designed to facilitate accurate placement of the prosthesis in the cement mantle
- Result are significantly better than would be expected with conventional hemiarthroplasty in this group of patients
- Comparable with results of Total Hip Replacement (THR) but without the risk of dislocation

Benefits

- Double taper, polished, collarless design allows the stem to load cement in compression
- Multiple offset choices replicate patient anatomy
- More sizing options allow surgeons to fit the stem to the patient
- More sizing options allow surgeons to fit broader patient populations
- Leg length and stem offset are determined independently
- Hollow centralizer protects against end bearing and provides an area for the stem to subside without disrupting the cement mantle
- Hollow centralizer aids in neutral alignment of the distal stem
- Precise control of taper angle, form and finish ensured by 100% inspection using precision measurement technology guarantee taper characteristics that minimise fretting at the bore-taper interface
- The highly polished finish allows stepwise subsidence of the stem to a stable position, with the associated micromovement producing less metal and cement debris at the stem-cement interface
- Cemented Femoral Stem neck is having a 12/14 taper trunnion for connection with Modular head

The Range, 9 sizes

Std. Stem	Size	Offset	Neck Length	Stem Length
Std. Stem	T-Loc Stem Standard Size 00	37.0	36.10	127
Std. Stem	T-Loc Stem Standard Size 01	45.0	40.56	149
Std. Stem	T-LOC Stem Standard Size 2	45.0	40.56	149
Std. Stem	T-LOC Stem Standard Size 3	45.0	40.56	149
Std. Stem	T-LOC Stem Standard Size 4	45.0	40.56	149
Narrow Stem	T-LOC Stem Narrow Size 1	38.0	38.20	149
Narrow Stem	T-LOC Stem Narrow Size 2	38.0	38.60	149
Narrow Stem	T-LOC Stem Narrow Size 3	38.0	38.60	149
Narrow Stem	T-LOC Stem Narrow Size 4	38.0	38.60	149



Surgical Steps



- 1 The proximal femur is opened using the box chisel which is positioned laterally and posteriorly so that entry is in line with the femoral intramedullary canal.



- 2 The smallest (4-8mm tapered) intramedullary reamer, which has a sharp tip, is mounted on the T-Handle, and used to expose the femoral canal. Care should be taken with this first reamer and if bone quality is poor then the 8mm intramedullary reamer should be used first, as it has a more rounded tip. Further straight reamers are used increasing in 1 mm size increments until an acceptable reaming has been achieved.



- 3 The smallest rasp (extra, extra small) is used to prepare the proximal femur. The large tommy bar should be used to control version. If the tilt of this first rasp is unsatisfactory then repeat the procedure increasing rasp size accordingly. Care should be taken to lateralise the rasps as they are inserted.



- 4 At this point, if required, the appropriate trial stem can be carefully inserted using the stem impactor.



5 The chosen trial head is screwed onto the trial prosthesis and a reduction attempted. If the reduction is not possible or is regarded as too tight, remove the trial prosthesis. The neck should be resected further to permit deeper seating of the stem. Seat the rasp again and repeat the trialing process until the reduction is stable.



6 The trial stem can be removed with the use of the trial stem extractor. Care must be taken to tap out of the femur in a neutral position to prevent possible damage to the femur.



7 At this point a suitable size of cement restrictor or plug is chosen, depending on the size of the final intramedullary reamer used and screwed onto the introducer. The depth of insert is determined by placing the cement plug introducer alongside the trial/prosthesis. The plug is aligned 1-2cm beyond the distal tip of the trial/prosthesis and a measurement taken from the markings on the introducer handle. The lateral shoulder of the trial/prosthesis is a good reference point.



8 The plug is then inserted into the femoral canal at a depth of 1-2cm beyond the distal tip of the prosthesis. To remove the introducer handle turn anti-clockwise to unscrew from the plug. Do not remove the introducer handle until the plug is seated correctly at the pre-measured depth.



9 The preferred cementing technique is now used. Modern techniques recommend the use of a cement plug, lavage, drying of the femoral canal and retrograde filling with a cement gun.

Surgical Steps



- 10** Making sure the tibia is vertical, the definitive femoral stem should be inserted in neutral alignment, to ensure a continuous circumferential cement mantle, using the stem impactor and inserted to the depth determined by the trial prosthesis. The depth of the stem should be determined by the height of the centre of rotation of the femoral head on the contralateral side. If the same size rasp, trial and definitive stem are used than a cement mantle of approx. 1-2mm will be obtained. Should a thicker cement mantle be required, then a smaller size of prosthesis than the size of the last rasp used, should be selected.



- 11** Before Mating the Bipolar or mono-polar, physiological femoral head ensure that the cement is fully cured and set.



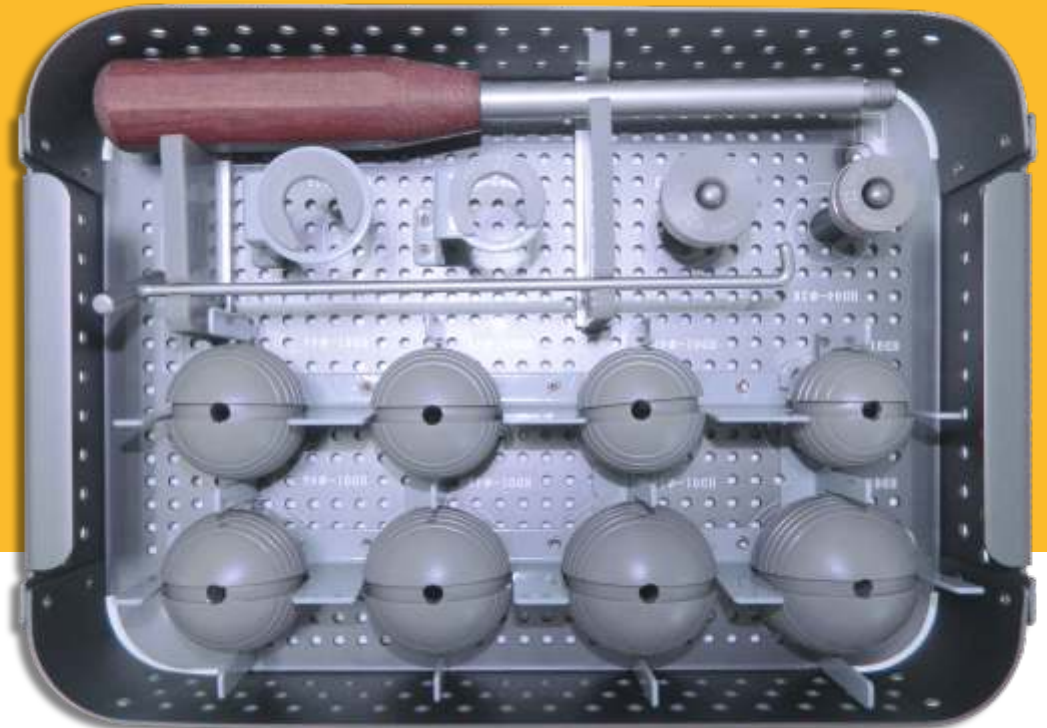
- 12** The implant head (either bi-polar or mono-polar, physiological) is fitted onto the stem and impacted using the femoral head impactor. A light tap is required to engage the taper.



- 13** Finally the joint is reduced, and the wound is closed.

Instrument Set

1. Bipolar Cup System
2. Cemented Stem



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