www.merillife.com

Corporate Headquarters, Vapi
Meril Healthcare Pvt. Ltd.
H1-H3, Meril Park
Survey No. 135/2/B & 174/2
Muktanand Marg, Chala
Vapi 396 191. Gujarat. India.
T: +91 260 3052 100
F: +91 260 3052 125
E: orthopedics@merillife.com

International Sales & Marketing
Meril Healthcare Pvt. Ltd.
612, B-Wing, Bonanaza
Sahar Plaza, Andheri East
Mumbai 400 059
Maharashtra. India.
T: +91 22 3935 0700
F: +91 22 4047 9717

India Sales & Marketing
Meril Healthcare Pvt. Ltd.
512, Midas, Sahar Plaza, J.B. Nagar
Andheri East, Mumbai 400 059
Maharashtra. India.
T: +91 22 4047 9797

Meril South America
DOC MED LTDA
1079 – Cep: 04077-003 - Moema
Sao Paulo, Brazil
T/F: +55 11 3624 5935/6

Meril GmbH
Bornheimer Strasse 135 – 137
D – 53119 Bonn, Germany
T/F: +49 228 7100 4000/1

Meril Tibbi Cihazlar
Imalat Ve Ticaret A.S.
6, Mimar Sinan Mah.,
Cavusbasi Cad, Ozde Sok
Aydin Eksi Is Merkezi Kat:1
Cekmekoy/Istanbul, Turkey
T: +90 53 2272 5172

OCTOBER 2015

www.merillife.com

Meril
Orthopedics

LATITUD Acetabular Cup System

Surgical technique

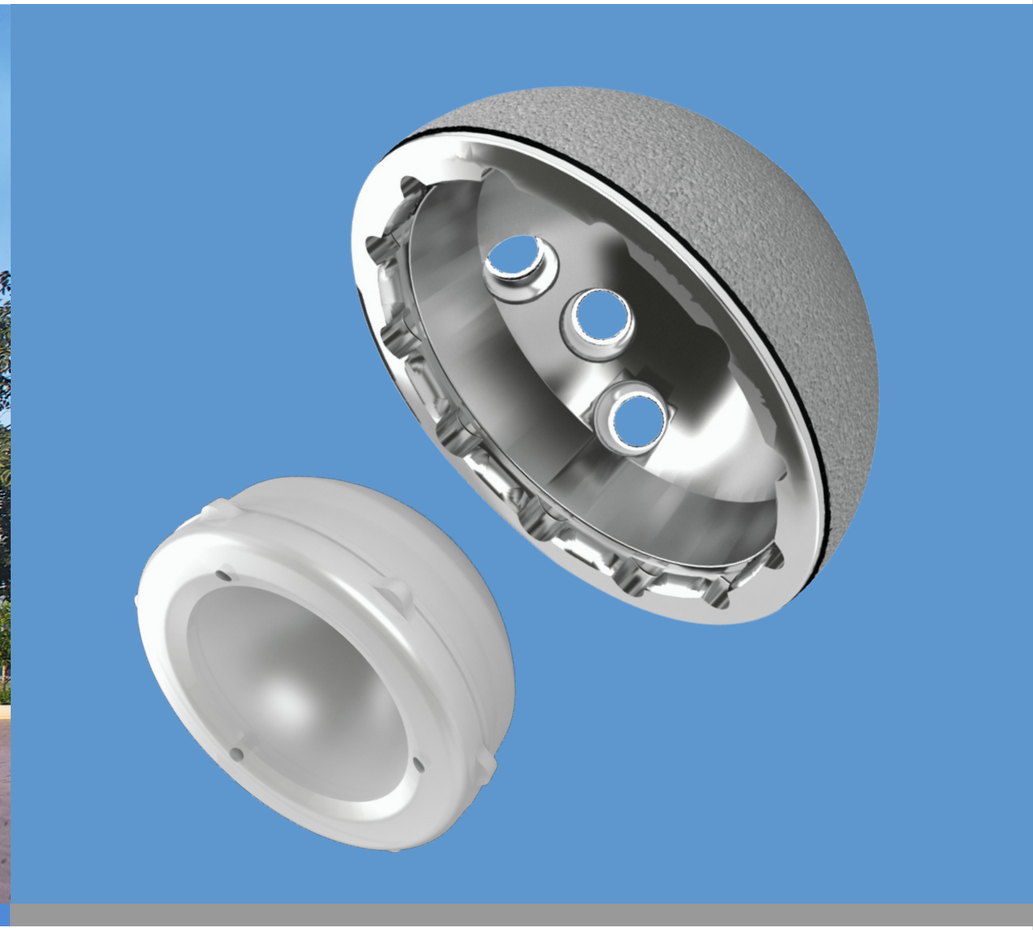
Meril
Orthopedics

Meril is a global medical device company dedicated towards design and development of novel, clinically relevant, state-of-the-art and best-in-class devices to alleviate human suffering and improve the quality of life, spanning broad operational canvas from vascular interventional devices to orthopedics, in-vitro diagnostics and endo-surgery.

We share an enduring commitment to advance healthcare solutions, so more patients live longer, healthier lives. We thus have a strong commitment towards R&D and adherence to best quality standards in manufacturing, scientific communication and distribution known today.

Meril Orthopedics | HIP SYSTEM

Meril Orthopedic, a new 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.



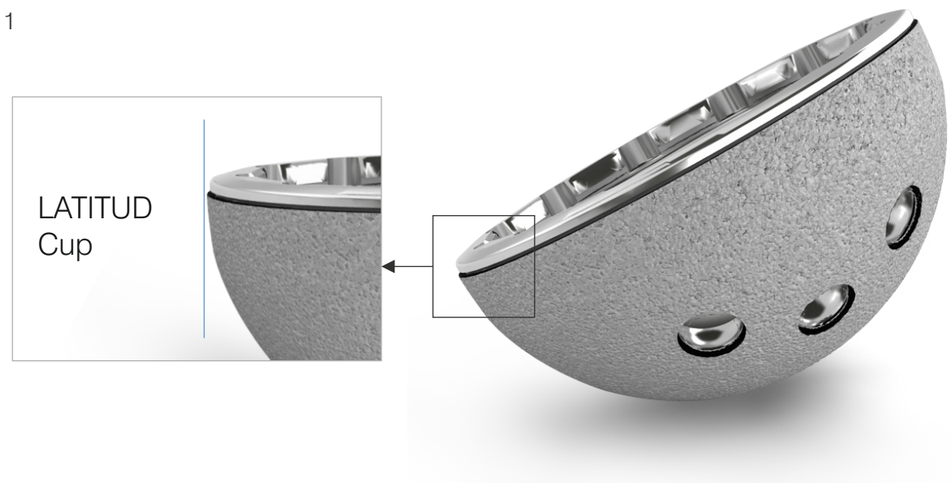
Established in 2006, Meril was launched in line with the health-care diversification plan of Bilakhia Group. Located 150kms north of Mumbai at Vapi, ensconced within the serene hill-sides of Chala town, Meril sits proud in its ultra modern manufacturing facilities.

LATITUD™ Acetabular Cup System Design Features

The Press Fit Concept

The LATITUD™ shell has been designed to be implanted into the acetabulum most tightly just below the shell equator (FIG. 1). This is obtained by over-sizing of the shell proximally, with the shell diameter in this area being 1.3mm larger in relation to the reamed cavity in the bone.

FIG. 1



On impaction of the shell into the acetabulum, the exterior shell surface has been designed to pre-stress the bone in the oversized area specifically to prevent unwanted preferential apical loading. For this reason the shell has been designed with a relatively flat base (FIG. 2).

FIG. 2

The LATITUD™ shell press fit is designed to occur just below the acetabular bone margin, and this further assists retention of the shell.

A size 52mm shell is actually 53.3mm in diameter at the equator, and 51mm at the apex. In standard bone, when implanting a 52mm shell, a 52mm reamer is used. It is possible to increase the degree of pre-loading by using a shell size larger than that pre-reamed. (e.g. a 54mm shell is implanted into a 52mm or 53mm reamed cavity).

This is important to consider in conditions such as osteoporosis, rheumatoid arthritis, and patients on steroid treatment etc.

Pre-Operative Templating

Templating for cup size is an important step in planning for THR, and X-ray overlays are available with 15% magnification.

A full AP pelvis X-ray (FIG.3), and AP and Lateral x-rays (FIG.4) of the hip taken at 1 meter distance, aid with offset and leg length management. The overlay should be placed over the AP X-ray at 45 degrees of abduction, and with the center of rotation over the acetabular anatomical centre.

Templating is especially important in dysplasia and revision hip surgery. A CT scan may be used to assess unusual conditions in the acetabular roof not always apparent on plain X-rays.

FIG. 3

FIG. 4

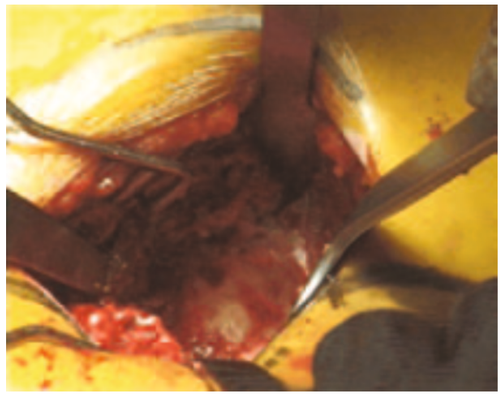
Note: Templating preoperatively is a guide only, and final component sizing and positioning needs to be assessed at surgery.

LATITUD™ Acetabular Cup System Surgical Technique Steps 1-2

STEP 1:
Acetabular Preparation

Good visualization of the acetabular margins is necessary, and this is usually obtained by removing labrum remnants (which can be quite extensive). It may be necessary to also remove a hypertrophic capsular attachment and osteophytes. Division of the transverse ligament assists with exposure. It is helpful to visualize and assess the depth of the floor of the acetabulum, with curettage of the fovea contents (FIG. 5).

FIG. 5



STEP 2:
Acetabular Reaming

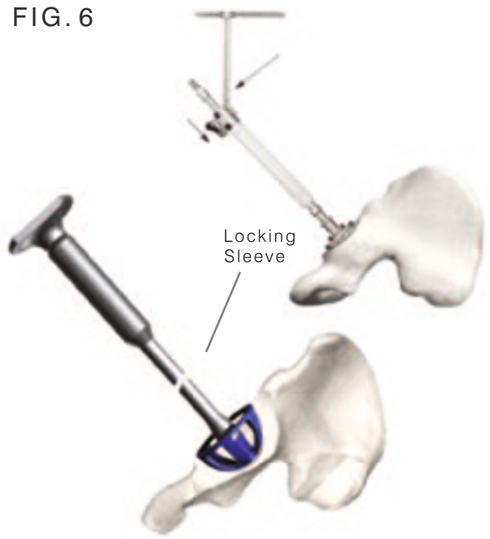
The acetabulum is accurately reamed to a hemisphere, but an endeavor should be made to preserve as much subchondral bone plate as possible.

An alignment guide is provided which can be attached to the reamer shaft (FIG. 6). The alignment guide, when orientated parallel to the long axis of the patient, will angle the reamer shaft at 45 degrees of inclination, and at an anteversion angle of 20 degrees.

Using the power tool on the "REAM" setting, it is usual to start with a reamer at least 4mm smaller than the templated size, and to use it to deepen and develop the center of the acetabulum.

The bone is then progressively reamed out usually in 2mm increments. It is important to prevent the power-tool from reaming in an excentric manner, as this may cause over sizing of the hemisphere, and poor interference fitting of the shell. Reaming is completed when all cartilage lining has been removed down to bone, and with the acetabular walls intact. Reaming to the size of the component to be implanted will provide an interference fit of 1.3mm at the equator.

FIG. 6



LATITUD™ Acetabular Cup System Surgical Technique Steps 3-5A

STEP 3: Shell Trialing

After reaming is completed, the same diameter trial shell as the last reamer used is tested in the acetabulum, and checked for bone cover and congruency, press-fit firmness and position (FIG. 7). For the straight cup impactor, ensure that the exterior shell adaptor is attached prior to the Shell trial.

Defects in the acetabulum may be grafted using cancellous bone from the last reamings, or from the femoral head. Reverse reaming with a 1mm smaller reamer than the last size used will help graft impaction of acetabular defects.

FIG. 7

STEP 4: Shell Impaction

The curved or straight cup impaction tool is screwed onto the definitive shell selected for implantation, and the alignment guide may be fitted over the shaft to assist with cup orientation. For the straight cup impactor, ensure that the exterior shell adaptor is attached prior to the definitive shell.

The screw holes need to be orientated in a cranio-dorsal position to avoid the nerves and vessels should screws be inserted.

Note: Lines placed on the shell circumference indicate the screw hole positions (FIG.9).

The shell is impacted into the acetabulum with a series of firm hammer blows using the curved or straight cup impactor, and the depth of the shell is then checked through the apex or screw holes. Once shell orientation, depth and tightness are satisfactory the impaction tool is then removed (FIG. 8).

FIG. 8

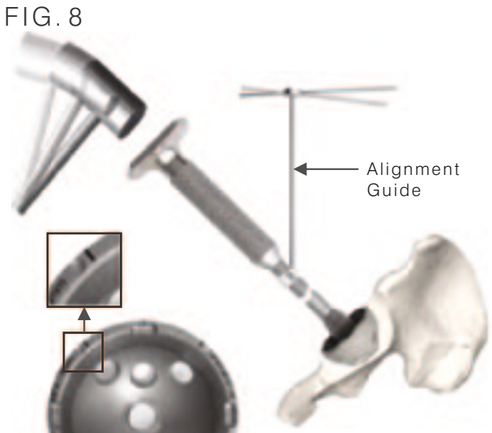


FIG. 9

STEP 5A: Screw Fixation

Increased shell fixation into the bony acetabulum is available using the screw holes provided. It is necessary to use the drill guide provided, and the guide needs to be fully inserted into the shell screw hole, to ensure that the screw head will be completely countersunk. The screw hole is drilled with a 3.2mm drill bit (FIG. 10), and in sclerotic bone the hole may need to be additionally pre-tapped with a thread cutter.

FIG. 10

LATITUD™ Acetabular Cup System Surgical Technique Steps 5B-7A

STEP 5B: Screw Fixation

Screw length is assessed with the depth gauge provided (FIG. 15), and the selected size screw firmly inserted with an articulated screwdriver (FIG. 16). A pair of screw grasping forceps assists screw insertion into the prepared hole.

It is essential to check that the screw head is completely countersunk, as otherwise it will interfere with taper locking of the liner and possible component failure.

Note: Only LATITUD™ 6.5mm screws should be used with the LATITUD™ system.

FIG. 11

STEP 6: Trial Liner Insertion

A trial liner is used to evaluate the stability, offset and leg length parameters of the implanted components. It is inserted using a hexagonal screwdriver to drive the apical screw into the implanted shell (FIG. 12). The shell may need to be repositioned if not optimal. The trial liner preferably should be left in situ until stem trialing has been completed. Once the components have been optimized the trial liner is removed with the hexagonal screwdriver.

Note: The Liner Trial should only be finger tightened when placed into either the Definitive Shell or the Trial Shell. Excessive force is not required and should not be applied.

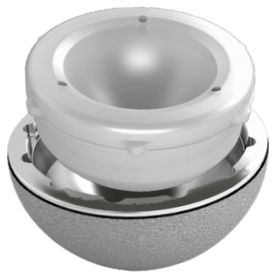
FIG. 12

STEP 7A: Liner Insertion

It is necessary to remove all soft tissue and fluid from the interior of the shell and especially the taper before inserting the definitive liner.

The polyethylene liner dome has a circumferential external taper, which needs to be inserted parallel to the cup taper in an uncompromised manner. This may best be performed by holding the liner with a “liner Holder”, and inserting it by feel to lie perfectly seated within the shell (FIG.13).

FIG. 13



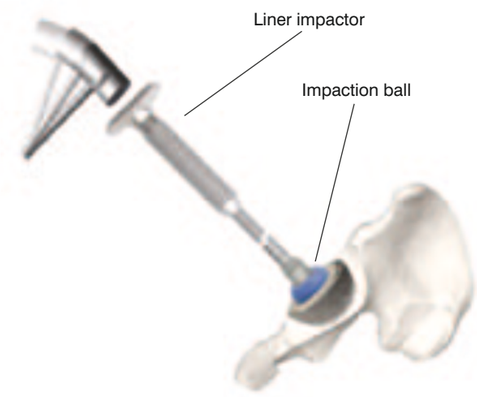
LATITUD™ Acetabular Cup System Surgical Technique Steps 7B

STEP 7B: Liner Insertion

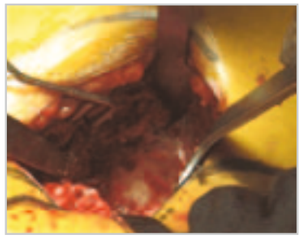
Note: Any undue angulation will prevent the liner from engaging correctly in the shell, and if forced, will damage the taper lock surfaces. Once the liner taper is engaged correctly it is locked by several firm hammer blows, applied to the correct sized plastic impaction ball on the end of an impaction handle (FIG.14).
The liner seating position is then checked to be flush with the shell. A polyethylene liner inserter is provided. Care must be taken when using this tool to ensure the external taper is accurately engaged with the shell.

Note: A polyethylene liner inserter is provided. Care must be taken when using this tool to ensure the external taper is accurately engaged with the shell.

FIG. 14



LATITUD™ Acetabular Cup System Surgical Technique Steps

STEP 1:  **ACETABULAR PREPARATION**	**STEP 2:**  **ACETABULAR REAMING**	**STEP 3:**  **SHELL TRIALING**
STEP 4:  **SHELL IMPACTION**	**STEP 5 (A–B):**  **SCREW FIXATION**	**STEP 6:**  **TRIAL LINER INSERTION**
STEP 7A:  **LINER INSERTION**	**STEP 7B:**  **LINER IMPACTION**	

Please see the package insert for the complete device description, product selection information, indication, contradictions, precautions, adverse effects, warnings, materials, sterilization and patient guidance associated with the LATITUD Acetabular Cup System.

CAUTION: THIS DEVICE IS RESTRICTED TO SALE BY OR ON THE ORDER OF A LICENSED PHYSICIAN

Instrument Set

Accetabulum Cup System