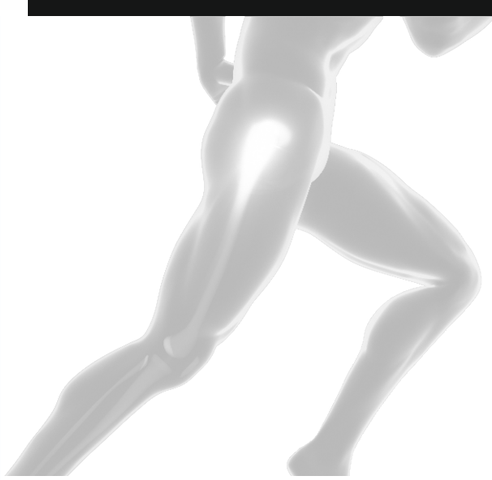
Instructions for Use

Meril

Orthopedics

LATITUD™ | Hip Replacement System



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℞ Only

⚠ **CAUTION:** FEDERAL LAW (U.S.A) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED PHYSICIAN.

1. Device name: Latitud™ Total Hip Replacement System:

Latitud™ Total Hip Replacement System consists of individually packed Modular Shell, Modular Liner, Bipolar Monoblock Shell, Modular Femoral Head, Acteabular Cemented Cup, Uncemented Femoral Stem, Cemented Femoral Stem and Proximal Coated Uncemented Femoral Stem.

2. Device Description:

A Total Hip Replacement system is composed of individually packaged components i. e. Modular Shell (Viz. Acetabular cup), Modular Liner (Viz. Acetabular Liner), Modular Femoral Head and Uncemented Femoral Stem or Cemented Femoral Stem or Proximal Coated Uncemented Femoral Stem.

A Hemi Hip Replacement system is composed of individually packaged Bipolar Monoblock Shell, Modular Femoral Head and Uncemented Femoral Stem or Cemented Femoral Stem.

2.1. Modular Shell:

Modular Shell is made from Titanium alloy- ELI (Ti6Al4V- Extra Low Interstitials (ELI) (ASTM F136/ ISO 5832-3) and is intended for press fit, uncemented fixation within prepared acetabulum. Modular Shell is available in a range of sizes. The outer surface of Modular Shell is coated with commercially pure titanium. Inner surface is designed for use with Modular Liner of matching size.

Following individually packaged accessories are used with Modular shell.

- **Bone Screw:** Bone Screw is made from Titanium alloy- ELI (ASTM F136/ISO 5832-3). Bone Screw has 6.5 mm cancellous-type threads and is available in various lengths. It is available if additional fixation of the Modular Shell is required. The Bone Screws are intended for fixation into cancellous bone only.
- **Apical Hole Occluder:** Apical Hole Occluder is made up of Titanium alloy ELI (ASTM F136/ISO 5832-3). It is designed to occlude the apical hole of the Modular Shell which mates with instrumentation during implantation.

2.2. Modular Liner:

Modular Liner is made from HXLPE (Highly Cross-Linked Ultra-High Molecular Weight Polyethylene) (ASTM F648 / ISO 5834-2). Modular Liner is available in arange of sizes and is designed for use with Modular Shell and Modular Femoral Head.

2.3. Cemented Cup:

Cemented Cup is made from Ultra High Molecular Weight Polyethylene (UHMWPE) (ASTM F 648) and highly cross linked polyethylene (HXLPE) (ASTM F2565). Cemented Cup is available in range of sizes. Cemented Cup is designed for use with Modular Femoral Head.

2.4. Bipolar Monoblock Shell:

Bipolar Monoblock Shell is an assembly of (outer) metal dome and (inner) plasticliner. The metal dome is made from stainless steel 316LVM (ASTM F139 / ISO 5832-1) and inner plastic liner is made from Ultra High Molecular Weight Polyethylene (UHMWPE) (ASTM F648 / ISO 5834-2). Bipolar Monoblock Shell is available in arange of sizes. The outer surface of Bipolar Monoblock Shell is designed to articulatedirectly with patient's acetabulum and inner plastic surface is designed to assemble with Co-Cr Modular Femoral Head.

2.5. Modular Femoral Head:

The Modular Femoral Head is available in two material (i. e. cobalt chromium (ASTMF 1537/ISO 5832-12)) and BIOLOX delta (High-purity alumina ceramic compound (ISO 6474-2)). Modular Femoral Head is available in a range of different sizes and offsets. Modular Femoral Heads have a 12/14 taper and are designed to articulate against the Modular Liners or Bipolar Monoblock Shell and also to mate with Femoral Stem.

2.6. Femoral Stem:

Femoral stems are available in three designs, Uncemneted Femoral Stem, Cemented Femoral Stem and Proximal Coated Uncemented Femoral Stem.

2.6.1 Uncemented Femoral Stem:

Uncemented Femoral Stem is made from Titanium alloy- ELI (ASTM F136/ISO 5832-3) and is coated with Hydroxyapatite below the resection. The Uncemented Femoral Stems are available in various sizes and 3 different neck angles. The 12/14 taper of the Uncemented Femoral Stem is designed to mate with Modular Femoral Head. Uncemented Femoral Stem is intended for press-fit, uncemented use only

2.6.2 Cemented Femoral Stems:

The Cemented Femoral Stem is made from high nitrogen stainless steel (ASTM F 15886 / ISO 5832-9). The 12/14 taper of the Cemented Femoral Stem is designed to mate with Modular Femoral Head. Cemented Femoral Stem is indicated for use cemented use only.

Following individually packaged accessories are used with Cemented femoral stem.

- **Centralizer:** The Centralizer is made from Polymethylmethacrylate (PMMA) (ASTM F451) / Ultra High Molecular Weight Polyethylene (UHMWPE) (ASTM F648). It is used during fixation of cemented stem and is available in two designs: winged and non-winged.
- **Cement Restrictor:** The Cement Restrictor is made from Polymethylmethacrylate (PMMA) (ASTM F451/ISO 8257-1) / Ultra High Molecular Weight Polyethylene (UHMWPE) (ASTM F648/ISO 5834-2). It is used to restrict bone cement in medullary cavity during surgery and is available in two sizes: Small and Medium.

2.6.3 Proximal Coated Uncemented Femoral Stem:

The Proximal Coated Uncemented Femoral Stem is made from Titanium alloy- ELI (ASTM F136/ISO 5832-3) and is coated with titanium below the resection line. The Proximal Coated Uncemented Femoral Stems are available in various sizes and 3 different neck angles. The 12/14 taper of the Proximal Coated Uncemented Femoral Stem is designed to mate with Modular Femoral Head. The Proximal CoatedUncemented Femoral Stem is indicated for press-fit, uncemented use only.

3. Indications:

The Latitud™ hip Replacement system is intended for use in total hip arthroplasty and hemi-hip arthroplasty. However BIOLOX® Delta Modular Head is not intended for use in hemi-hip arthroplasty. Total hip arthroplasty is intended to provide patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is an evidence of sufficient sound bone to fix and support the components. Hemi-hip arthroplasty is performed in patients where there is evidence of a satisfactory natural acetabulum and sufficient femoral bone to fix and support the Femoral Stem.

3.1 Total hip replacement is indicated for the following conditions:

3.1.1 Non-inflammatory degenerative joint diseases including osteoarthritis, post traumatic arthritis and a vascular necrosis

3.1.2 Rheumatoid arthritis.

3.1.3 Congenital hip dysplasia.

3.1.4 Acute traumatic fracture of the femoral head or neck.

3.1.5 Certain cases of Ankylosis.

3.1.6 Dislocation of the hip.

3.1.7 Correction of functional deformity.

3.1.8 Revision of failed joint reconstruction or treatment.

3.1.9 Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur.

Note:

- The Titanium coated Modular Acetabular Shell is intended for press-fit, uncemented use only.
- The Hydroxyapatite coated Uncemented Femoral Stem is intended for press-fit, uncemented use only.
- The Cemented Femoral stem is intended for cemented use only.
- The Modular Acetabular Liner is intended for use with Modular Acetabular Shell.
- The CoCr Modular Femoral Head is intended to articulate with Modular Acetabular Liner to mate with uncemented stem or cemented stem.
- The Biolox® delta Modular Femoral Head is intended to articulate with Modular Acetabular Liner to mate with uncemented stem or cemented stem.
- The Bone Screw and Apical Hole Occluder are intended for use with Modular Acetabular shell.
- The Centralizer and Cement Restrictor are intended for use with cemented stem only.

3.2 Hemi-hip arthroplasty is indicated in the following conditions:

3.2.1 Acute traumatic fracture of the femoral head or neck that cannot be appropriately treated with internal fixation

3.2.2 Fracture dislocation of the hip that cannot be appropriately treated with internal fixation.

3.2.3 Avascular necrosis of femoral head

3.2.4 Non-union of femoral neck fractures

3.2.5 Certain high subcapital and femoral neck fractures in the elderly

3.2.6 Degenerative arthritis involving only the femoral head in which the acetabulum does not require replacement does not require replacement.

3.2.7 Pathology involving only the femoral head/neck and /proximal femur that can be adequately treated by hemi-hip arthroplasty

4. Contraindications:

4.1 Active local or systemic infection.

4.2 Poor bone quality or Bone stock that is inadequate for support or fixation of the components.

4.3 Loss of musculature, neuromuscular compromise or vascular deficiency in the affected limb rendering the procedure unjustified.

4.4 Any condition that may interfere with the survival of the implants such as Charcot's disease, or Paget's disease.

4.5 Skeletally immature patients.

4.6 Metabolic disorder which may impair bone formation.

4.7 Patients having sensitivity to the implant materials

4.8 For hemi-hip arthroplasty, any pathological condition of the acetabulum, such as distorted acetabuli with irregularities, protrusion acetabuli (arthrokatadysis), or migrating acetabuli, that would preclude the use of the natural acetabulum as an appropriate articular surface for the hemi-hip prosthesis.

5. Warnings and Precautions:

5.1 Improper selection, placement, positioning, alignment and fixation of the implant components may results in unusual stress conditions which may lead to failure of the components. Proper implant selection must consider design, fixation and environmental variables including: Patient weight, age, bone quality and size, activity level and preoperative level of health.

5.2 The conditions like obesity or overweight, active sports participation, high levels of patient activity, alcohol or drug addiction tend to impose severe loading on the affected extremity, thereby placing the patient at higher risk for failure of the hip replacement.

Note: WHO (World Health Organization) defines "overweight" as a BMI (Body Mass Index) greater than or equal to 25, and "obesity" as a BMI greater than or equal to 30.

5.3 The load on the implanted prosthesis will be more when small sized components are used in larger patients.

5.4 The conditions such as osteoporosis or poor bone stock, Metabolic disorders or systemic pharmacological treatments leading to progressive, deterioration of solid bone support for the implant (e.g., Diabetes mellitus, steroid therapies, immunosuppressive therapies, etc.), history of general or local infections, severe deformities leading to impaired fixation or improper positioning of the implant, tumours of the supporting bone structures, allergic reactions to implant materials (e.g., bone cement, metal, polyethylene), congenital dysplasia of the hip which may reduce the bone stock available to support the acetabular cup component in total hip replacement, tissue reactions to implant corrosion or implant wear debris, and Disabilities of other joints (i.e., knees and ankles) tend to adversely affect the fixation of hip replacement implants.

5.5 Do not use prosthetic implants and trials of other manufacturers with Latitud™ implants.

5.6 The taper size of Modular Femoral Head must be matched with taper size of Femoral Stem.

5.7 The devices are designed for single use only. Never re-implant the Hip components, even if the implants appear undamaged. Do not reuse, re process or resterilize. Reuse can potentially compromise device performance and patient safety. If component is reused, there are chances of infection, loosening or revision surgery.

5.8 Always use trial prosthesis for trial purposes. Trials should not be assembled with any components intended for permanent implantation.

5.9 Do not alter or modify implants in any way.

5.10 Mate modular components firmly to prevent dissociation.

5.11 Do not allow coated surfaces to contact cloth or other fiber releasing materials.

5.12 Protect polished bearing areas, machined taper surfaces and coated surfaces from contact with hard or abrasive surfaces.

5.13 Mental attitudes or disorders resulting in a patient's failure to adhere to the surgeon's orders may delay postoperative recovery and/or increase the risk of adverse effects including implant or implant fixation failure.

5.14 Hydroxyapatite coated implants must not be implanted with bone cement.

5.15 Cemented Femoral Stem is indicated only for use with bone cement.

5.16 Bone cement should not be used with Uncemented Femoral Stem.

5.17 Do not use if package is open or damage

5.18 Use the device before the 'Use By' date specified on the package.

5.19 Never use a metal hammer on the BIOLOX® delta Modular Head. Use only the plastic head impactor provided for this purpose.

6. Handling Instructions for Biolox® Delta Modular Femoral Head:

Biolox® Delta Modular Femoral Head products must be handled with care. When Biolox® Delta Modular Femoral Head are taken by hand, gloves have to be used to avoid possible contamination of the product. The customer has to ensure that no damage to the Biolox® Delta Modular Femoral Head is caused by the handling. A Biolox® Delta Modular Femoral Head that is damaged any way must not be used. A Biolox® Delta Modular Femoral Head that has fallen on the floor must not be used. Contact of Biolox® Delta Modular Femoral Head with metal or with other Biolox® Delta Modular Femoral Head must be avoided under all circumstances in order to prevent possible surface contamination with metal or damages to the Biolox® Delta Modular Femoral Head. Do not use any product with a contaminated surface or other damage.

7. MR Safety Information

Latitud™ Hip Replacement Systems have not been evaluated for safety and compatibility in MR environment. It has not been tested for heating, migration in the MR environment. Surgeons should warn the patients with metallic implants of the potential risks of undergoing Magnetic Resonance Imaging (MRI) scan.

8. Adverse effect

8.1 Early or late infection

8.2 Sensitivity/Allergic reactions.

8.3 Change in position of the prosthetic component.

8.4 Loosening of the component.

8.5 Wear or fracture of the polyethylene components.

8.6 Fatigue fracture of the femoral stem.

8.7 Peripheral neuropathies, nerve damage, circulatory compromise and heterotopic bone formation.

8.8 Intraoperative perforation, fissure, or fracture of the femur, acetabulum or trochanter.

8.9 Subluxations or dislocation of the hip joints.

8.10 Lengthening or shortening of the affected extremity.

8.11 Serious complications including, but not limited to cardiovascular disorders such as thrombosis, pulmonary embolism myocardial infarction.

8.12 Haematoma and/ or delayed wound healing

8.13 Pneumonia and/ or atelectasis.

8.14 Trochanteric avulsion from excessive muscular tension, weight-bearing or inadvertent Intraoperative weakening of the trochanter.

8.15 Aggravation of problems in the ipsalateral or contralateral knee and ankle joints due to leg length discrepancy, femoral medialization and/ or muscular deficiency.

8.16 Post operative Femoral or acetabular fracture can occur due to trauma or excessive loading, particularly in the presence of poor bone stock caused by severe osteoporosis, bone defects, from previous surgery, Intraoperative reaming procedures, or bone resorption.

8.17 Bone resorption which may contribute to deterioration of fixation and eventual loosening of the implant.

8.18 Periarticular calcification or ossification which may lead to decrease in joint mobility and range of motion

8.19 Traumatic arthrodesis of the ipsalateral knee secondary to Intraoperative positioning of the extremity during surgery.

9. Information for patients and surgeon

9.1 Size Compatibility for Latitud™ Femoral components: Based on bench testing, smaller Uncemented Femoral Stems are not recommended to use with larger Modular Femoral Heads. See additional labeling for the specific Modular Femoral Heads that are contraindicated for use with these stems. Please see the implant compatibility tables in the surgical technique brochures.

9.2 Before clinical use, the surgeon must thoroughly understand all aspects of the surgical procedure, limitations of the device, instruments and implant characteristics. The Surgical technique brochure should be reviewed prior to any surgery.

9.3 Surgeon's experience and familiarity with the device and strict adherence to the indication, contraindication, precautions and warning for this product is recommended.

9.4 Periodic, long-term follow up is recommended to monitor the position and condition of the implanted prosthesis.

9.5 When the surgeon determines that hip replacement is the best medical option available and decides to use this prosthesis in a patient who has any of the above conditions or who is simply young and active, it is imperative that the patient be instructed about the strength limitations of the materials used in the device and for implant fixation, and the resultant need to substantially reduce or eliminate any of the above conditions.

9.6 The surgeon should discuss all physical and mental limitations particular to the patient and all aspect of the surgery and the prostheses with the patient before surgery. The discussion should include the limitations and possible consequence of joint replacement, and the necessity to follow the surgeon's instructions postoperatively, particularly in regard to patient activity and weight.

9.7 The patient should be released from the hospital with complete written instructions and warnings regarding exercise and therapies and any limitations on their activities.

10. How supplied:

Modular Shell, Modular Liner, Modular Femoral Head, Bipolar Monoblock Shell, Uncemented Femoral Stem, Cemented Femoral Stem, Proximal Coated Uncemented Femoral Stem, Cemented Cup, Bone Screw, Apical Hole Occluder, Centralizer and Cement Restrictor components are individually packed and supplied sterile.

10.1 Sterile

- Modular Shell, Modular Femoral Head, Un-cemented Femoral Stem, Cemented Femoral Stem, Proximal Coated Uncemented Femoral Stem, Biolox® Delta Modular Femoral Head, Bone Screw, Apical Hole Occluder are sterilized with Gamma radiation.
- Modular Liner, Bipolar Monoblock Shell, Cemented Cup, Centralizer and Cement Restrictor are sterilized with ethylene oxide.
- Refer to the package label for the specific sterilization method. Do not use if package is damaged.

10.2 Storage:

Storage Temperature - 15°C to 30°C

11. Size compatibility

Hip component compatibility for Modular Shell, Modular Liner, Modular Femoral Head

Hip Compatibility Table						
Shell Size (mm)	Liner Size (mm)	Modular Femoral Head Size (mm)				
40	35	22*	28			
42	37	22*	28			
44	37	22*	28			
46	40		28	32		
48	40		28	32		
50	44		28	32	36	
52	44		28	32	36	
54	44		28	32	36	
56	48		28	32	36	40
58	48		28	32	36	40
60	52			32	36	40
62	52			32	36	40
64	52			32	36	40
66	52			32	36	40
68	52			32	36	40
70	52			32	36	40

*Not available in BIOLOX® delta Modular Femoral Head

Hip component compatibility for Bipolar Monoblock Shell and CoCrMb Modular Femoral Head

Bipolar Monoblock Shell Size (mm)	CoCrMb Modular Femoral Head Size (mm)
37	22
38	22
39	22
40	22
41	22
42	22
43	22
44	28
45	28
46	28
47	28
48	28
49	28
50	28
51	28
53	28
55	28
57	28
59	28
61	28
63	28

- **Hip component compatibility for Acetabular Cemented Cup & Modular Femoral Head):**

Variants available for Acetabular Cemented cup are

1) Standard Cemented Cup With snap fit
2) Standard Cemented Cup Without snap fit
3) 10° Cemented Cup
4) 20° Cemented Cup
5) Standard low profile Cemented Cup
6) Standard Cemented Cup With snap fit & PMMA Spacer
7) Standard Cemented Cup Without snap fit & PMMA Spacer
8) 10° Cemented Cup & PMMA Spacer
9) 20° Cemented Cup & PMMA Spacer
10) Standard low profile Cemented Cup

Acetabular Cemented Cup Size (mm)	Modular Femoral Head Size (mm)				
40	22				
42	22				
44	22	28			
46		28			
48		28	32		
50		28	32		
52		28	32	36	
56		28	32	36	40
60		28	32	36	40

- **Uncemented femoral Stem** is available with Provision of 135° standard, 135° lateral, 125°Standard (coxavera) neck angle.

  135° Standard stem is available in size 0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10

  135° Lateral stem is available in size 1, 2, 3, 4, 5, 6, 7, 8, 9, 10

  125° Standard (coxavera) is available in size 1, 2, 3, 4, 5, 6, 7, 8, 9, 10

- **Cemented femoral Stem** is available with provision of standard and narrow offsets.

  Standard offset is available in size 0, 1, 2, 3, 4

  Narrow offset is available in size 1, 2, 3, 4

- **Proximal Coated Uncemented femoral Stem** is available with provision of 3 different neck angle 132o Standard, 132o Lateral, 128o Standard. Each neck angle is available in two different lengths (Full & Short) and each length is available in two different profiles (standard or distally reduced).

  Standard profile is available in size
  4,5,6,7,8,9,10,11,12,13,14,15,16,17,18,20,22,24

  Distally reduced profile is available in size
  9,10,11,12,13,14,15,16,17,18,20,22,24

12. Disclaimer of warranty and limitations of remedy to be added here:

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13. Risk of reuse:

Reuse can potentially compromise device performance and patient safety. If prosthesis is reused, there are chances of infection, loosening or revision surgery.

14. Glossary of Symbols

The symbols used in labeling are referenced in FDA recognized Standard EN ISO 15223-1:2016, "Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements"

Symbols used in labeling

Contains one unit

Keep dry

Keep away from sunlight

Use by

Consult instruction for use

Caution

STERILE EO
Sterilized using ethylene oxide

LOT
Lot number

STERILE R
Sterilized using Irradiation

REF
Reference number

Do not use if box open or damaged

Manufacturer

℞ Only
This device to sale by or on the order of a physician

Manufacturing date

For single use only do not reuse

Do not resterilize

15° C – 30° C
Temperature Limitation

Non-Pyrogenic

EC REP
Authorized representative in the European community