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

Bipolar prostheses aim to reduce erosion or wear of the acetabulum by enabling motion between the prosthetic head and the inner articulation of the bipolar cup, while also allowing for extreme ranges of motion. ModuLoc™ Cups are based on well established design principles that include anti-varus head dynamics, an integral liner design that nearly eliminates the risk of mechanical polyethylene failure and the use of contemporary state of the art materials and manufacturing technologies.

Several outcome studies\(^1\)\(^-\)\(^3\) have shown significantly superior outcomes with bipolar hemi-arthroplasty when compared with conventional internal fixation, for treatment of displaced femoral neck fractures in elderly patients.

The ModuLoc Polyethylene Bearing

ModuLoc™ Cup Liners are manufactured from GUR 1020, the internationally recognized grade of Ultra High Molecular Weight Polyethylene (UHMWPE) complying with ISO 5832-4. Carefully controlled, hygienic manufacturing conditions guarantee dimensional integrity. Validated ETO sterilisation guards against oxidation thereby eliminating oxidative degradation\(^8\) as a potential cause of liner wear.

The combination of material, processing conditions, packaging and sterilisation method are carefully chosen to create bearing conditions and wear rates meeting current international benchmarks.
Dissociation of the modular head from bipolar cups is recognized to occur when bipolar cups do not possess self-centering ability. Inappropriate liner designs, for example, UHMWPE liners with slits to enable expansion, are known to undergo mechanical failure. Further, bipolar cups with low polyethylene liner thicknesses (3-4mm) suffer from a heightened risk of early failure due to increased wear of the polyethylene.

The ModuLoc™ Bipolar Cup design respects several design principles crucial to long term performance.

Anti-Varus Head Dynamics

Featuring self-centering ability, the ModuLoc™ Cup possesses anti-varus head dynamics. The balanced load transfer enabled by this feature minimizes the probability of supero-lateral liner wear and resultant dissociation of the cup from the modular head.

Safety against mechanical failure

The polyethylene liner in the ModuLoc™ Cup is designed as an integral single piece construct, securely encased in its outer metal shell. The design does not feature slots or irregular features that could provoke early mechanical failure.

Polyethylene Liner Thickness

All ModuLoc™ Cups are designed to offer a minimum polyethylene liner thickness of 5.5mm. This enables high safety against early failure due to liner wear. Minimum liner thickness is assured through the use of 22mm heads for Cups up to 43mm diameter and 28mm heads for Cups greater than 43mm diameter.
Evaluation of Intraoperative Assembly Stresses

Adler® Modular Heads are assembled with the ModuLoc™ Bipolar Cups intraoperatively through a push-fit mechanism. FEA (Finite Element Analysis) has been used to evaluate the stresses generated in the polyethylene liner during Inner Head insertion. FEA has helped in establishing safety of the design through quantification of the residual effects in the Liner after Inner Head insertion, which are well within the limits of design safety.

Safety through in Vitro Testing

In vitro testing was carried out subsequent to the Finite Element Analysis to establish the expected clinical performance of the ModuLoc™ design. Test protocols were designed for the two main modes of mechanical failure in bipolar cups, axial pull-out and angular lever-out. ‘Worst case cup diameters’ of 39mm and 45mm that have minimum polyethylene liner thicknesses were tested†. The tests have provided evidence that the forces required to dissociate the Adler® Modular Head from the ModuLoc™ Bipolar Cup are comparable to those reported in similar testing7 carried out for various contemporary bipolar cup designs in successful clinical use.
Correct Implant Combinations

ModuLoc™ Bipolar Cups are designed to provide a minimum polyethylene liner thickness of 5.5mm to enable superior wear performance. Cups from 39mm - 43mm are used with 22.20mm Adler® Modular Heads while Cups from 45mm upwards are used with 28.00mm Adler® Modular Heads. Details on how to correctly combine these implants are illustrated below:

Trial Reduction

ModuLoc™ Trials are designed for the combination of ModuLoc™ Bipolar Cups, Adler® Modular Heads and EndoFit™ Femoral Stems. Trialling is enabled at both the Rasp insertion as well as the Stem insertion stages of the operative procedure.

After insertion of the finalised EndoFit™ Rasp, trialling can be carried out using the combination of the Trial Rasp Adaptor (H10103.3500) and the ModuLoc Trial Heads with the ModuLoc Cup Trials, as illustrated. Final Trialling on an implanted and cemented EndoFit™ Stem can be carried out using the combination of the ModuLoc™ Trial Heads with the ModuLoc™ Cup Trials, as illustrated.
Final Implant Assembly

Final assembly of the ModuLoc™ Bipolar Cup with the Adler® Modular Head is achieved using the ModuLoc™ Bipolar Cup Press.

1. Place the ModuLoc™ Bipolar Cup Press on a flat surface. Ensure that all faces of the instrument that will come in contact with implant components are clean and dry.

2. Ensure that the threaded rod is in the “fully-open” position by unscrewing it using the in-built tommy bar. Place the selected ModuLoc™ Bipolar Cup on the base of the Press ensuring that the opening of the Cup that accepts the Inner Head faces upward as shown.

3. Place the Cup Aligner Cap over the ModuLoc Cup to prevent tilting of the Cup while the Modular Head is being inserted.

4. Place the selected Adler® Modular Head on top of the ModuLoc™ Bipolar Cup, ensuring that the tapered cone in the Head faces upwards as shown.

5. Holding the body securely, rotate the handle of the Press in a clockwise direction till the plastic insert of the Press enters the morse cone of the modular head. Support the Aligner Cap and Head as needed to enable correct alignment.

6. Continue rotating the handle clockwise to enable full insertion of the modular head into the bipolar cup. An audible expulsion of air will indicate full and correct assembly of the two components.

7. Once assembly is complete, rotate the handle of the Press counter-clockwise till the threaded rod reaches the top most position (7a). Lift off the Aligner Cap (7b). Now the Modular Head/Bipolar Cup assembly can be removed from the Press (7c) and is ready for implantation.

Check for free movement of the Modular Head in the Bipolar Cup. If the Head does not move freely, place the assembly on the Press and repeat steps 1 to 7.

Note that an improperly assembled implant could be responsible for premature implant failure.
Instrument Set

ModuLoc™ Instrumentation

ModuLoc™ Trial Head

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ModuLoc™ Bipolar Cup Trial

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ModuLoc™ Bipolar Cup Press

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ModuLoc™ Bipolar Cup Impactor

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Head Gauge Set for prosthesis

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Upper Tray, EndoFit™/ModuLoc™ Instrument Set

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Middle Tray, EndoFit™/ModuLoc™ Instrument Set

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Lower Tray, EndoFit™/ModuLoc™ Instrument Set

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EndoFit™ Instrumentation

Femoral Trial Stem Cum Rasp, EndoFit™

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Impactor for final tapping, EndoFit™

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Trial Rasp Adaptor, ModuLoc™

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Head Chisel

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Modular Rasp Handle Assembly, EndoFit™

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Stem Introducer, Assembly, EndoFit™

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Femoral Taper Reamer large, small

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Implants

Hip Replacement
General Instruments with EndoFit™/ModuLoc™
Instrument Set

Charnley Retractor
With Weights, Adler®
H0103.01

Diamond Pointed Awl
H0101.11

Head Extractor/
Judet Extractor
C0902.00

Right Angle Retractor
(Bent Hohmann), Adler®
H0103.29

Right Angle Retractor
(Bent Hohmann), Long, Adler®
H0103.37

Pin Retractor, Adler®
H0103.03

Retractor Ranawat
Pattern, Adler®
H0103.30

Modular Head
Disimpactor, Adler®
H0103.36

Retractor (Hohmann) Long
Wide Tip 22mm, Adler®
H0103.02

Intramedullary Canal gauge

Code Ø (mm)

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Inserter for Cement
Restrictor, Adler®
H0102.12

Murphy Skid
H0101.10

Inserter for Cement
Restrictor, Adler®
H0102.12

Trochanteric Elevator, Adler®
H0103.31

ModuLoc™
Bipolar Cups*

Adler®
Modular Heads,
High Nitrogen
Stainless Steel

Code Ø (mm)

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Head Extractor/
Judet Extractor
C0902.00

References


* Even Cup Sizes “made to order”. Even sizes code nos. H0306.06xx where xx = cup diameter 40,42,44,46,48,50,52,54mm). Eg. H0306.0642 = 42mm. Minimum Order Quantities apply.

† Not part of standard “Loaner” Set.
1. Correct Prosthesi s selection is extremely important: Selection of the proper size, shape and design of the prosthesi s significantly influences the potential for success of the procedure. Careful implant sealing and adequate foreign body support are required. Smallest sized patients with relatively smaller anatomical dimensions may require the use of smaller sized implants. These smaller sized implants may not be appropriate for other patients. Regardless of the endoatral state of the bone, surgeons are encouraged to use their best medical judgement to choose the proper implant size for a given patient.

2. The following factors related to patient selection can be critical to eventual success of the procedure:

a. Patient Weight: Prostheses can be severely loaded due to overweight obese patients. Such loads can lead to failure of the prosthesis. This can be a major consideration in cases where patients are small statured with small anatomical dimensions that require the use of a small sized implant.

b. Patient occupation: Activity levels by operated patients that involve substantial walking, running, lifting or other activities that can cause muscle strain can result in forces that can cause failure of the fixation, the device or both. Patient’s must be cautioned against unrealistic expectations of function and must bear in mind the fact that joint replacement prostheses do not pass the capability of restoring function to the level expected from normal healthy human bone.

c. Alcoholism, senility, mental illness: Patient’s suffering from these conditions, among others, may be led to ignore certain limitations and precautions related to having been implanted with a joint replacement implant; leading thereby to failure or other complications.

d. Foreign body sensitivity: Where sensitivity to materials is suspected, patients should be subjected to appropriate tests prior to material selection or implantation.

Special Note: Patients with renal insufficiency may be sensitive to potential metal ion release. Further, since not much is known about the transport of metal ion release across the plaques, these devices should be used with caution in women of childbearing age.

Intended Purpose, Indications
The Moduloc Bipolar Cup is designed for uncemented use in conjunction with a standard cemented or uncemented femoral replacement implant for the following:

1. Treatment of proximal femoral non-un, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.

2. Non-inflammatory degenerative joint disease including osteoarthritis, osteonecrosis, avascular necrosis and post-traumatic arthritis.

3. Rheumatoid arthritis.

4. Arthritis secondary to a variety of diseases and anomalies and correction of functional deformity such as congenital hip dysplasia or ankylosis spondylitis.

5. Revision procedures where other treatment or devices have failed.

System Description and Materials
Moduloc Bipolar Cups consist of a polyethylene liner encased in an outer metallic shell. Liner inner diameters are either 22.20mm or 28.00mm depending on the outer shell diameter. Outer and inner diameters are clearly marked on individual product labels.

Materials used in the construction of Moduloc Bipolar Cups include ultra-high molecular weight polyethylene (UHMWPE) conforming to ISO 5834-2, stainless steel conforming to ISO 5832-1, stainless steel conforming to JIS6911 and chrome-cobalt alloy conforming to ISO 5832-4.

CONTRAINdicATIONS:
Contraindications include, but are not limited to the following:

• Acute or chronic infections in the vicinity of the joint or of a systemic nature

• Accompanying illnesses affecting the function of the joint implant

• Systemic illnesses and metabolic disturbances

• Severe osteoporosis or osteomalacia

• Severe damage to bony structures that stands in the way of stable implantation of the implant components

• Bone tumours in the area of implant anchoring

• Bone deformities, axial mis-positioning or bony conditions that rule out implantation of an artificial joint

• Obesity and overweight patients

• Expected overlaying of the joint implant

• Drug abuse or alcoholism

• Lack of patient co-operation.

Possible Adverse Effect:
A listing of the possible adverse events, includes, but is not limited to the following:

• Early of late loosening, disassembly, bending and/or breakage of any or all of the implant components

• Foreign body (allergic) reaction to implants, corrosion products and debris including metallosis, tumour formation, staning and/or auto-immune disease

• Joint dislocations, limitations in the mobility and postoperative changes in the length of the leg and joint pain

• Venous thrombosis, pulmonary embolisms and cardiac arrest

• Nerve damage, haematomas and wound-healing impairment

• Periarticular calcification with joint pain and restricted movement

NOTE: Diabetes, at present, has not been established as a contraindication. However, because of the increased risk for complications such as wound healing, etc., the physician should carefully consider the advisability of hip replacement in the severely diabetic patient.

Warnings and Precautions:
Pre-operative
Before surgery, the surgeon must plan the operation with a view to correct selection and sizing of the implant components and their positioning in the bone. The surgeon needs to ensure that:

• All necessary implant components are available

• Highly aseptic surgical conditions are present

• The implantation instrumentation is complete and in good working order

• The implant bed is prepared using the appropriate ADLER instruments for the specific replacement procedure being performed

• All informational material concerning the range of implants, instrumentaion and surgical technique has been reviewed and is available and the surgeon and the surgical team are familiar with this information

• The rules of medical skill, the state of the art, and the contents of scholarly publications by medical authors are known and observed

• In uncertain preoperative situations, especially with implants already in place, prior relevant information has been obtained from the concerned manufacturer

Intra-operative:
The Moduloc Bipolar Cup is available with various outside diameters to suit the acetabulum being treated. The various nominal outside diameters are explicitly marked on the packaging and the implants themselves. Each Moduloc Bipolar Cup also has a specified inside diameter that corresponds to the diameter of the Adler Modular Head to be used.

The nominal inside diameter is also explicitly marked on the packaging. Always make certain that the inside diameters of the Moduloc Cups and the diameter of the Modular Head are compatible.

Moduloc Bipolar Cups have a specific technique to enable assembly of the Cup with the corresponding Adler Modular Head. This technique is clearly described in the Moduloc product literature. Ensure that the technique is correctly followed and that the assembly of the Moduloc Cup and the Adler Modular Head is fully and completely re-sterilized.

Caution: Incomplete or inadequate assembly of the Moduloc Bipolar Cup with the Adler Modular Head could lead to undesirable surgical outcomes including dislocation of the implant components, severe early wear of the polyethylene liner or dislocation.

Selection of the outside diameter of the Moduloc Bipolar Cups is accomplished using trial implants provided as part of the EndoFit/Moduloc Instrument Set.

Selection of the Adler Modular Head inside diameter of the cup being used is made using the trial implants provided in the EndoFit/Moduloc Instrument Set.

Prior to wound closure, all exposed cement and bone residue should be removed. Bone cement particles and pieces of bone that find their way into the gliding surfaces of the implant are known to cause abnormal wear that could lead to early failure and the need for revision surgery.

Note: Modular implant components made by different manufacturers may not be compatible with one another. Combining modular implant components of different manufacturers, in the absence of specific manufacturer confirmation, is not permitted.

Post-operative
The physician’s postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important:

• Detailed instructions must be given to the patient concerning the use and limitations of the implanted device.

• The patient must be warned that loosening, bending and/or breakage of the device are complications that may occur due to early or excessive weight bearing or muscular activity. The patient should be warned to avoid excessive or sudden jumps of stature.

• The patient must be made to understand that artificial joint replacement implants are always inferior to the function of the natural joint, and only a relative improvement of the preoperative condition can be achieved.

• The patient must be explained that an artificial joint can loosen due to overload-bearing, wear and tear, or infection. Implant loosening can necessitate a revision operation that, under some circumstances, offers no opportunity to restore joint function again.

• Following joint replacement, the patient will have to submit to regular medical follow-ups.

• The patient must appreciate that the implant cannot be subjected to undue stress through extreme loading, work, and sporting activities.

Sterility and Handling
Correct handling of the implants prior to and during surgery is decisive for the success of joint replacement.

• Implant components are individually packed in correspondingly labelled, radio-stereotised (gamma sterilisation, 25-45 Kgy) / ETO sterilised (Ethylene Oxide) protective packages

• Joint implant components should be kept in the original packaging until shortly before use; check the expiration date and verify the integrity of the sterile package before use.

• Ensure that the surfaces of the implants are not damaged under any circumstances.

• Under no circumstances may implants that have been damaged, surgically implanted or removed again be reused.

For exclusively metallic components only: If the packaging appears to be damaged, the device may be cleaned and sterilized prior to Implantation, by a user facility, in accordance with the following instructions.

CLEANING:

Use deionized, or distilled, warm (room temperature) water for soaking, cleaning and rinsing. Disassemble as appropriate. Soak coated implants for a minimum of 10 minutes. For non-coated ceramic coated implants: immerse and hand wash with a neutral pH or mild detergent. Scrub with a soft bristle brush paying close attention to holes and teeth to reach areas. If product is cannulated, insert a soft nylon brash into cannula. Rinse all components immediately and thoroughly after washing. Immediately dry product. Inspect all products prior to sterilization and storage.

STERILIZATION: (strictly applicable to exclusively metallic components only)
If sterilization of a metal component is necessary, the following parameters are recommended as they have been validated for a Sterility Assurance Level (SAL) of 10-6.

Method Cycle Temperature Exposure Time
Steam Pre-vacuum 270/121°C 10 minutes

NOTE: The adequacy of any sterilization procedure must be suitably tested. It is critical that appropriate process parameters be validated for each facility’s sterilization equipment and product/load configuration by persons who have training and expertise in sterilization processes to substantiate the process and its reliability and reproducibility.

RE-STERILIZATION:
Re-sterilization of devices supplied in sterile form carries various risks. Various components of joint replacement prostheses include UHMWPE parts that are known to carry a high risk of oxidative degradation if not packed and sterilized according to strictly applicable ISO5834-2, stainless steel conforming to ISO 5832-1, stainless steel conforming to JIS6911 and chrome-cobalt alloy conforming to ISO 5832-4.

Manufacturers shall establish and define the parameters to be validated for each facility’s sterilization equipment and product/load configuration by persons who have training and expertise in sterilization processes to substantiate the process and its reliability and reproducibility. It is critical that the aseptic processing conditions be validated for each facility’s sterilization equipment and product/load configuration by persons who have training and expertise in sterilization processes to substantiate the process and its reliability and reproducibility.

STORAGE CONDITIONS:
Store in dry place.

IMPORTANT INFORMATION ON THE Moduloc™ BIPOLAR CUP
For use by an Accredited Orthopaedic Surgeon only.
Other products from Sushrut™-Adler™

Traumatology

Mini Fixator  Locked Nailing  Reconstructive

Spine

Manufactured by
ADLER MEDIEQUIP PVT. LTD.

Exclusively marketed by
SUSHRUT SURGICALS PVT. LTD.
Sushrut House, Survey No. 288, next to MIDC Hinjewadi Phase II, At Mann, Taluka Mulshi, Pune 411 057, India. Tel: +91(0)20 66520700 Fax: +91(0)20 66520800 e-mail: info@sushrut.com Internet: www.sushrut.com