Specification Guide

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MODULOC

Modular Bipolar Cup

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MODULOC◇ Modular Bipolar Cup

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 significantly minimises 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

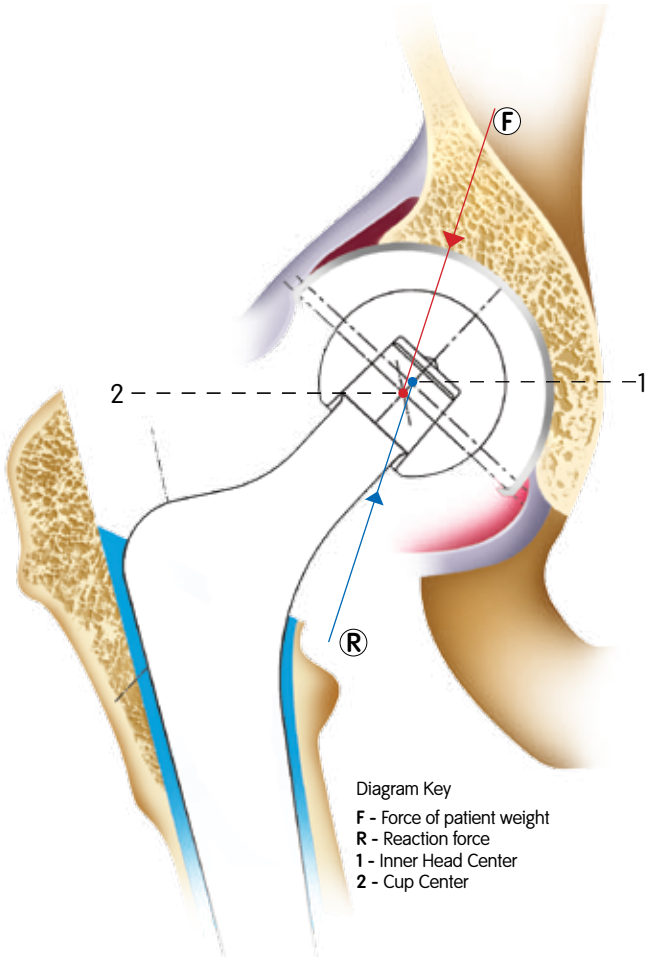
MODULOC Cup Liners are manufactured from GUR 1020, the internationally recognized grade of Ultra High Molecular Weight Polyethylene (UHMWPE) complying with ISO 5832-4. Carefully controlled, hygienic manufacturing conditions guarantee dimensional integrity. Validated ETO sterilisation guards against oxidation 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.

Philosophy and Design Rationale

Dissociation of the modular head from bipolar cups is recognized to occur when bipolar cups do not possess self-centering ability[4]. Inappropriate liner designs, for example, UHMWPE liners with slots to enable expansion, are known to undergo mechanical failure[5]. Further, bipolar cups with low polyethylene liner thicknesses (3-4mm) suffer from a heightened risk of early failure[6] 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

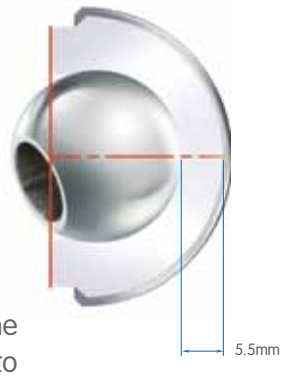
Featuring self-centering ability[4], the MODULOC Cup possesses anti-varus head dynamics. The balanced load transfer enabled by this feature minimizes the probability of supero-lateral liner wear[5] and resultant dissociation of the cup from the modular head.

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[5] that could provoke early mechanical failure.

Polyethylene Liner Thickness

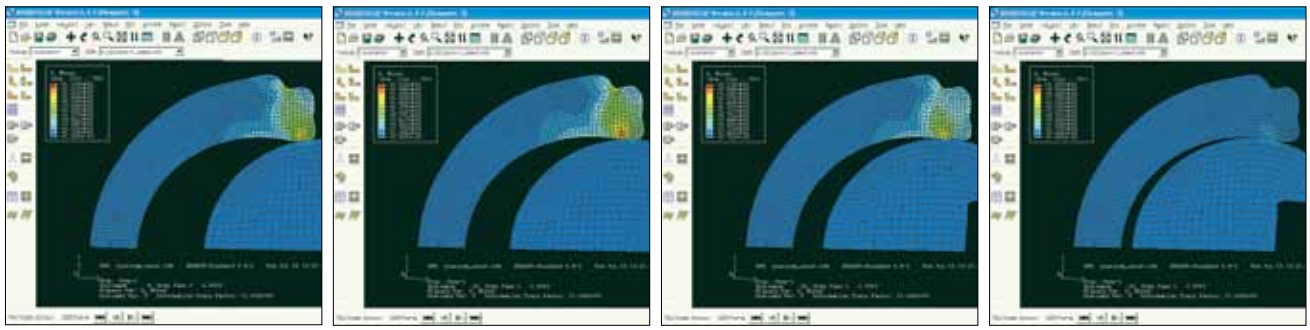
All MODULOC Cups are designed to offer a minimum polyethylene liner thickness of 5.5mm. This enables high safety against ea failure due to liner wear. Minimu liner thickness is assured through the use of 22mm heads for cups up to 43mm diameter and 28mm heads for cups greater than 43mm diameter.

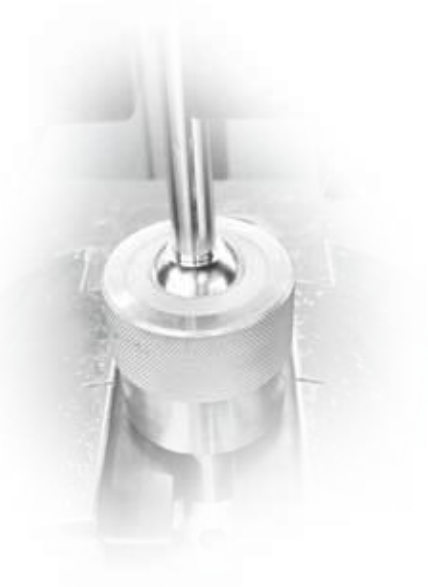


Validation

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.

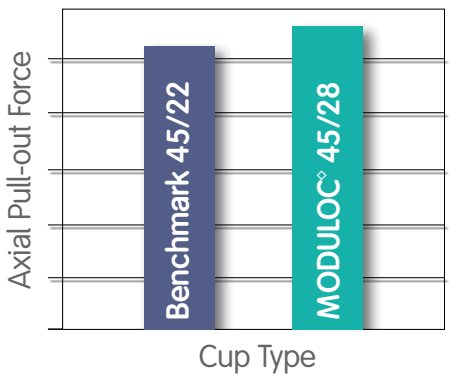




Safety through in Vitro Testing

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 polyethyelene 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 testing[7] carried out for various contemporary bipolar cup designs in successful clinical use.

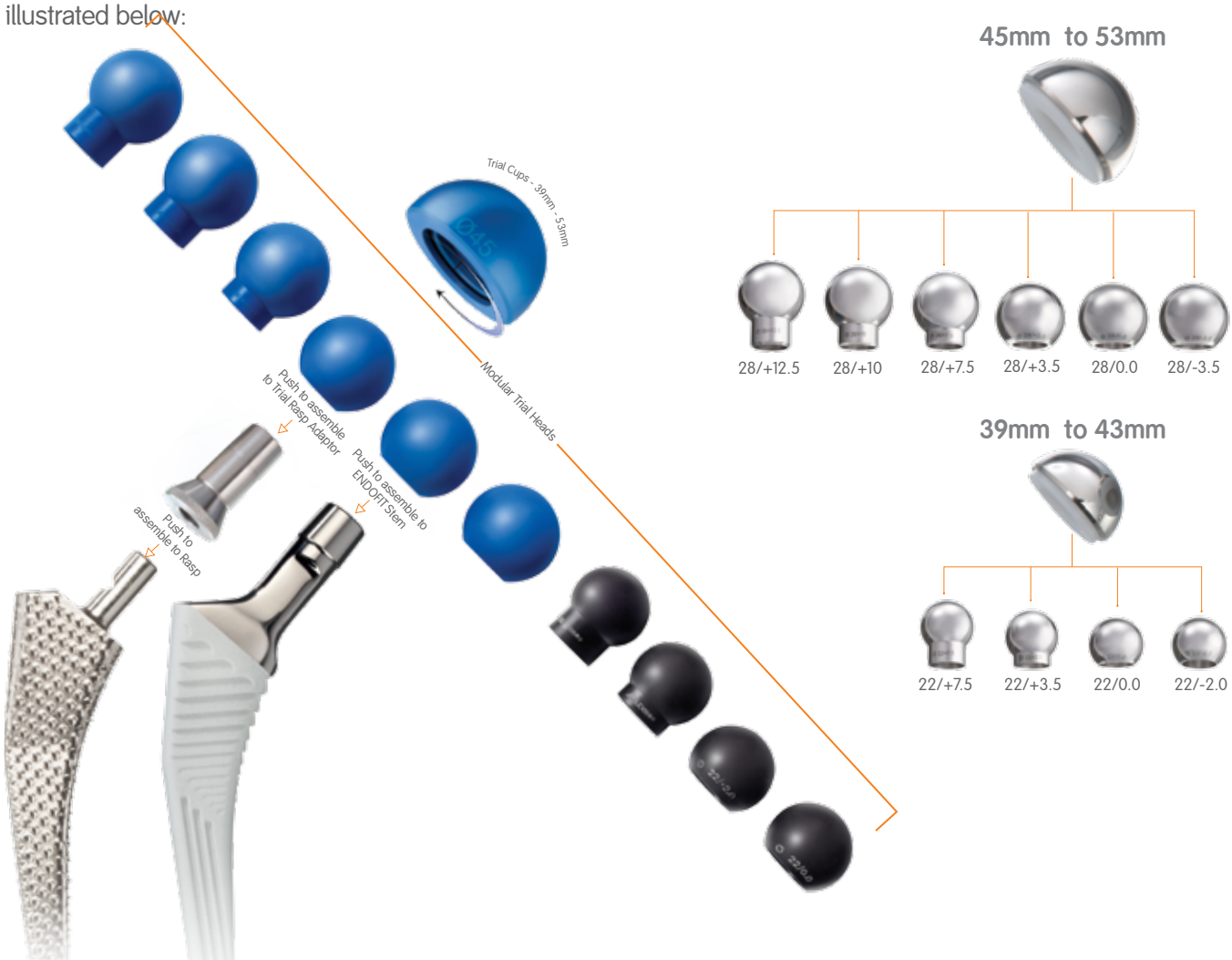
MODULOC Pullout Force Benchmarking



Modularity

Correct Implant Combinations

MODULOC® Bipolar Cups are designed to provide a minimum polyethylene liner thickness of 5.5mm to enable proper 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 Bipolar Trials are designed for the combination of MODULOC Bipolar Cups, ADLER Modular Heads and ENDOFIT® Femoral Trials* and 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* (H0103.3500) and the Modular Trial Heads* with the MODULOC Bipolar Trials, as illustrated.

Final trialling on an implanted and cemented ENDOFIT Stem can be carried out using the combination of the Modular Trial Heads* with the MODULOC Bipolar Trials, as illustrated.

* Included in the ENDOFIT Instrument Set, not shown in this catalog.

Final 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 clock wise 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.

7a

7b

7c

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.

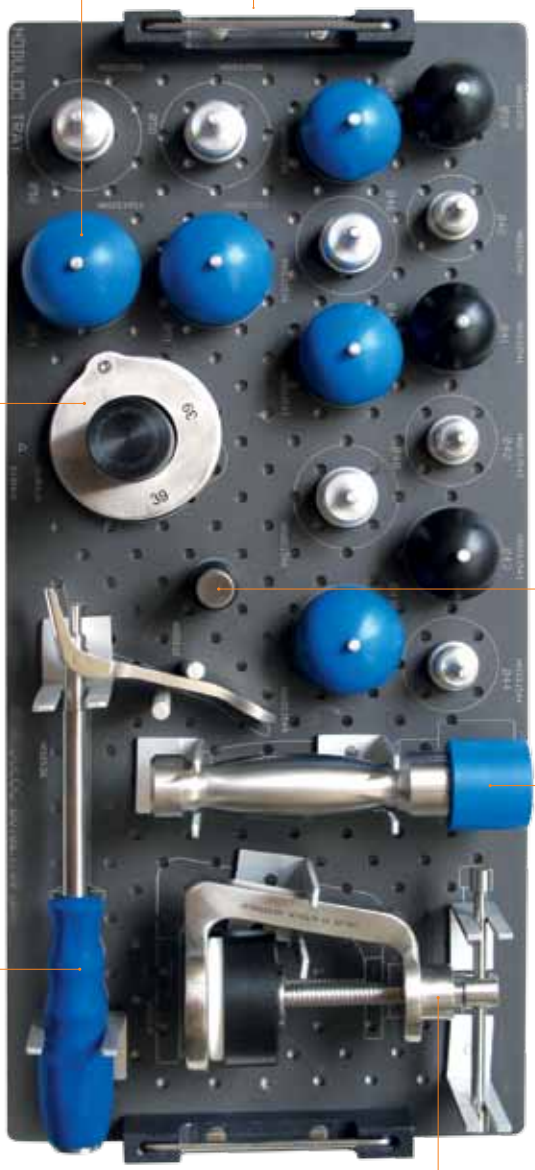
MODULOC◇ Instrumentation

Aluminium Case, 2-Part,
600 X 275 X 95,
ADLER◇

D0101.2107

Tray - MODULOC
Instrument Set

D0102.1709



MODULOC
Bipolar Trial, QuickLock

Code	Ø
H0103.1539	39
H0103.1541	41
H0103.1543	43
H0103.1545	45
H0103.1547	47
H0103.1549	49
H0103.1551	51
H0103.1553	53

MODULOC
Trial Head
Disimpactor

H0103.12

Head Gauge Set
for prosthesis

C1304.10

MODULOC
Bipolar Cup Impactor

H0102.15

Modular Head
Disimpactor, ADLER

H0103.36

MODULOC
Bipolar Cup Press

H0103.10

Illustrations not to scale.

General Hip Instrumentation

Aluminium Case, 2-Part,
600 X 275 X 95,
ADLER®

D0101.2103

Pin Retractor, ADLER

H0103.03

Tray 1 - General
Hip Instrument Set

D0102.1705

Tray 2 - General
Hip Instrument Set

D0102.1706

Charnley Retractor With
Weights, ADLER

H0103.01

Retractor
(Hohmann)
Long Wide Tip
22mm, ADLER

H0103.02

Diamond
Pointed Awl

H0101.11

Box Chisel

H0101.08

Head Extractor/
Judet Extractor

C0902.00

Right Angle
Retractor
(Bent Hohmann),
Long, ADLER

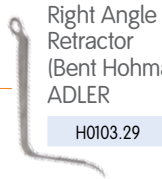
H0103.37

Femoral Taper Reamer
large, small

Large	Small
H0101.09	H0101.091

Trochanteric
Elevator, ADLER

H0103.31



Right Angle
Retractor
(Bent Hohmann),
ADLER

H0103.29

Inserter for Cement
Restrictor, ADLER

H0102.12

Murphy Skid

H0101.10

Retractor Ranawat
Pattern, ADLER

H0103.30

Illustrations not to scale.

Implants

MODULOC® Bipolar Cups

39/22	41/22	43/22	45/28	47/28	49/28	51/28	53/28
H0306.0639	H0306.0641	H0306.0643	H0306.0645	H0306.0647	H0306.0649	H0306.0651	H0306.0653

ADLER® Modular Heads, High Nitrogen Stainless Steel

22/+7.5	22/+3.5	22/0.0	22/-2.0
H0407.2275	H0407.2235	H0407.2200	H0407.2120

28/+12.5	28/+10	28/+7.5	28/+3.5	28/0.0	28/-3.5
H0407.2925	H0407.2900	H0407.2875	H0407.2835	H0407.2800	H0407.2735

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3. R. G Wetherell, B.L Hinves. The Hastings Bipolar Hemiarthroplasty for subcapital fractures of the femoral neck – A 10 year prospective study. JBJS 1990; 72-B: 788-93.
4. Krein S. W and Chao E.Y.S. Biomechanics of Bipolar Hip Endoprosthesis. J. Orthop. Res. 1984; 2:356.
5. John E. Herzenberg, John M. Harrelson, Donald C. Campbell, Paul F. Lachiewicz. Fractures of the polyethylene bearing insert in Bateman Bipolar Hip Prosthesis. CORR Mar. 1988; 228.
6. Thomas F. Calton, Thomas K. Fehring, William L. Griffin, Thomas H. McCoy. Failure of the Polyethylene after Bipolar Hemiarthroplasty of the Hip. A Report of Five Cases. J Bone Joint Surg Am. 1998; 80:420-3.
7. Frederick J. Kummer, William L. Jaffe, Kazuho Iesaka, Fausto Perez. Bipolar Head Design – Inner Bearing Range of Motion and Dissociation. Bulletin of the Hospital for Joint Diseases 2005; Vol. 63.
8. Elena Maria Brach del Prever, Alessandro Bistolfi, Pierangiola Bracco, Luigi Costa. UHMWPE for arthroplasty: past or future? J Orthopaed Traumatol. 2009; 10:1-8.

Illustrations not to scale.

Important information on the MODULOC◇ Bipolar cup

For use by an Accredited Orthopaedic Surgeon only

DEVICE DESCRIPTION - General Information

The advancement of partial and total hip replacement has provided surgeons with the means of restoring mobility, reducing pain and correcting deformity in many patients. While the implants used are largely successful in achieving these goals, it must be recognized that implants are manufactured using metals, plastic and ceramic materials. Thus, no hip replacement system should be expected to withstand activity levels and loads as normal healthy human bone. Hip replacement implants would not therefore be as strong, durable or reliable as a natural human hip joint.

Operating surgeons should be aware of the following aspects related to the use of partial/total joint replacement prostheses:

1. Correct Prosthesis selection is extremely important: Selection of the proper size, shape and design of the prosthesis significantly influences the potential for success of the procedure. Careful implant seating and adequate bony support are required. Small statured 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 endosteal area 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 overloads 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 or activity:** Activities 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 possess 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 necessary 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 placenta, 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-union, 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 ankylosing 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 IS:6911 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
- Bony deformities, axial mal-positioning or bony conditions that rule out implantation of an artificial joint
- Obesity and overweight patients
- Expected overloading of the joint implant
- Drug abuse or alcoholism
- Lack of patient co-operation.

Possible Adverse Effects

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, staining and/or auto-immune disease
- Joint dislocations, limited flexibility, postoperative changes in the length of the leg and joint pain
- Primary and secondary infection
- Venous thromboses, 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 infection, slow 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, instrumentation 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 ADLER Modular Heads are compatible.

MODULOC Bipolar Cups have a specified technique to enable assembly of the Cup with the corresponding ADLER Modular Head. The 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 achieved.

Caution: Incomplete or inadequate assembly of the MODULOC Bipolar Cup with the ADLER Modular Head could lead to undesirable surgical outcomes including dissociation 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 neck length as well as the EndoFit femoral stem is performed with the aid of trial implants provided in the EndoFit/MODULOC Instrument Set.

Prior to wound closure, all exposed bone 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 falls or sudden jolts of any nature.
- 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 overloading, 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, radiosterilised (gamma sterilisation, 25 kGy min.) / 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 soiled products for a minimum of 10 minute. For non-ceramic coated components: immerse and hand wash with a neutral pH or mild detergent. Scrub with a soft bristle brush paying dose attention to threads and hard to reach areas. If product is cannulated, insert a soft nylon brush 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°F(132°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 prosthesis include UHMWPE parts that are known to carry a high risk of oxidative degradation if not packed and sterilized according to closely controlled and monitored conditions. Small imperfections caused on the surfaces of metallic joint replacement components are known to increase the risk of fatigue failure. Such imperfections could be caused by improper handling by untrained staff. In consideration of the above re-sterilization of joint replacement prosthesis components by user facilities is prohibited.

STORAGE CONDITIONS:

Store in dry place.

Important Information

The surgeon bears responsibility for the proper performance of surgical joint replacement and must have mastered the recognised surgical techniques both in theory and in practice. The manufacturer shall not be responsible for complications due to inaccurate diagnosis, selection of implants and surgical technique, limitations of treatment methods or lack of asepsis.

Following mobility and muscle training, special emphasis should be placed on patient information during the postoperative phase. When bone cement or bone structures that transmit forces are damaged, loosening of the components, bone or implant fractures, and other grave complications cannot be ruled out. To recognise such sources of failure as early on as possible, the condition of the artificial joint must be checked periodically through suitable measures.

Additional special information about individual joint replacement systems can be obtained from ADLER Mediquip Pvt. Ltd. or from ADLER customer service at the address on the product package or through email to ***info@adlermediequip.com***

DMNXI.2013.311a

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